Department of Energy
Carlsbad Area Office
P. O. Box 3090
Carlsbad, New Mexico 88221

ENTERED

November 3, 1999

Mr. John Kieling
Hazardous and Radioactive Materials Bureau
State of New Mexico Environment Department
2044 Galisteo Street
P. O. Box 26110
Santa Fe, New Mexico 87502-6110

Subject: REVIEW COMMENTS ON NEW MEXICO ENVIRONMENT DEPARTMENT POSITION PAPER & GUIDANCE PAPERS

Dear Mr. Kieling:

The U. S. Department of Energy/Carlsbad Area Office (DOE/CAO) is providing technical review comments on the draft risk assessment position paper and the guidance papers developed by the New Mexico Environment Department (NMED). Attachment 1 contains comments to the NMED position paper, *Guidance for Assessing Ecological Risks Posed by Chemicals: Screening-Level Ecological Risk Assessment.* Attachment 2 contains comments on the five NMED risk assessment guidance papers.

The DOE/CAO is please to provide these comments in response to the NMED request. If you have any questions regarding these attachments, please call me at telephone number (505) 234-7495 or call Ms. Linda Frank-Supka, WID at telephone number (505) 234-8816.

Sincerely,

Cynthia Zvonar

Cynthia A. Zvonar
Environmental Programs Manager

Attachments

cc w/ attachments:
L. Frank-Supka, WID

cc w/o attachments:
I. Triay, CAO
G. Basabilvazo, CAO

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Attachment 1

Comments on "Guidance for Assessing Ecological Risks Posed by Chemicals: Screening-Level Ecological Risk Assessment"

General Comments

- Following the guidance in the position paper for any SWMU/AOC containing constituent concentrations greater than background, will likely result in calculated risks greater than the target risk quotient. This result will be obtained, because the guidance opts for the most conservative assumption for each analysis step. Can you define, in general terms, the relationship between this complex screening level assessment and a site-specific risk assessment?

- There is limited information in this paper to explain what makes the data presented in the position paper adequate to address risk. Can you expand the discussion to describe the adequacy of the approach, and the degree of conservatism in the results?

- NMED is suggesting that very labor-intensive surveys be performed for habitats and inventories for terrestrial receptors. EPA guidance allows for a screening level assessment in which a site visit determines the habitat types, the layout and topography, any water bodies, evidence of potential contamination, land uses, vegetation species, and any observation of animal species or signs of species. The level of investigation suggested by NMED appears to be more appropriate for a site-specific risk assessment.

- Could you provide a specific example using this guidance?

- A list of acronyms included in the paper would be helpful.

- Is the position paper designed to address individual or group-wide risk? Please clarify in the guidance.

Specific Comments

- Phase I: Scoping Assessment. The premise of the Phase I assessment is that an ecological risk assessment is necessary. There is little discussion of planning activities and development of management goals. These activities should be included in Phase I. An additional aspect of the scoping assessment should be consideration of whether a risk assessment is the best option for supporting risk management decisions. In some cases, a risk assessment may add little value to the decision process, because management alternatives may be available to completely circumvent the need for a risk assessment. In other cases, the need for a risk assessment may be investigated through a simpler process or ecological model. In addition, the scoping assessment should direct the identification of key ecological resources as determined by a risk management team and the risk management goals for the site.

- Page 6. The guidance states that site characterization must be sufficient to define the nature and extent of contamination. It would be helpful if the guidance included a definition of acceptable characterization and a standard reference, or as a minimum include a few examples.

- Page 10, Section 1.4. The guidance states that all possible exposure pathways for each type of receptor should be considered, then those pathways that do not exist should be eliminated. Inhalation of airborne contaminants is listed as a potential exposure pathway. This pathway is not routinely considered in ecological risk assessments. Is NMED going to provide the toxicity research for this pathway?

- Page 11. The guidance states that to remove a site from further consideration, based on a lack of receptors, it is necessary to demonstrate that the contamination is inaccessible to wildlife and that this inaccessibility will be maintained in the future. Does this statement imply that paving is an acceptable corrective measure?

- Page 12, Table 1. The footnote indicates that if 5 percent or more of a receptor's total exposure dose comes from an exposure route, then that exposure route is important. Given the level of conservatism in the screening analysis process, how does NMED wish analysts to define or estimate the percent exposure dose from each exposure route?

- Page 15, Section 2.2. NMED suggests that prior to performing a screening level ecological risk assessment the "site sampling investigation must be sufficient to delineate the nature and extent of contamination". It would be helpful if NMED to provide some guidance as to what constitutes an adequate delineation and provide some actual examples.

- Page 19. EPA's Step 1 process uses ecoscreening values equivalent to a no observed adverse effect level (NOAEL) to determine if maximum site concentrations pose a potential risk, prior to performing a detailed assessment. Could NMED incorporate the same concepts in their guidance for the initial evaluation, or define their own list of NOAEL concentration values? In addition, could NMED include the EPA Region V Ecological Data Quality Levels (EDQLs) in the paper? Do the EDQLs represent a sufficient scientific basis for use to screen out constituents from the analysis? Can the Oak Ridge National Laboratory Screening Benchmark concentrations be used as additional or alternative screening levels?

- Page 23. Some clarification regarding detection levels would be helpful.

- Page 23. What frequency of detection limits are acceptable? In the example, a 5 percent frequency of detection limit would yield a different answer for 19 samples.

- Page 36, Section 2.4. At least portions of this discussion belong in the initial planning. Development of management goals for example should be completed prior to undertaking the ecoscreen.

- Page 41. Solving the equation on this page for both equal and exclusive diets and selecting the most conservative answer is highly conservative. If the researcher determines that a particular food item constitutes less than 5 % of the total diet, that food item can be eliminated from the ecoscreen. Similarly, if the researcher can delineate the intake for other food items, the screen should take that information into account, or at least make a more reasonable assumption than that all of the food items are contaminated. Can you clarify this approach?

- Page 42, Section 3.1.2. In this paragraph, NMED's instructions are to assume that 100 percent of the ingested food items and ingested media come from the contaminated area. For a species with a large home range or for very small SWMUs, this assumption is highly conservative and unrealistic. Would NMED allow a more reasonable assumption to be made for this step?

- Page 43. Please explain the sentence "For inorganic compounds for which laboratory or empirical data are unavailable, values can be calculated from the arithmetic mean of other inorganic compounds." It is unclear what data are to be used to calculate the mean.

- Section 3.1.2 Assess Exposure to Class-specific Guild Measurement Receptors (pages 41 through 59). The calculations contained in this subsection (and later pages) are very in depth for a screening level assessment. For a screening level assessment it would be more prudent to look at only the primary intake mechanisms, such as ingestion of soil or the primary prey species, rather than complete this level of analysis. Would NMED consider using a simpler approach?

- Section 3.1.2. EPA recommends using bioaccumulation factors (BAFs) alone for an ecoscreen. Why does NMED also consider bioconcentration factors (BCFs) and food chain multipliers (FCMs) in an ecoscreen?

- Page 47, Section 3.2.2.4.1. Can NMED provide an estimate for the degree of uncertainty contained in an analysis that uses recommended aquatic values for fish for Food Chain Multipliers in a terrestrial ecoscreen?

- Page 64, Section 4.2. This equation is unclear. Please provide units and mathematical traceability to the equations and results presented in earlier sections (i.e., for TRVs and EELs).

- Page 68, Third Decision Point. Why does NMED use a hazard quotient of 0.3 for sites with more than one compound? EPA is using a value of 1. If there are multiple chemicals, which exert their toxic effects on different organs, can a HQ of 1 be used for each organ? Alternatively, because the hazard quotient will be calculated for each constituent of potential concern, why not just add up the calculated quotients and compare the sum to 1?

- Appendix F. It would be helpful if NMED would repeat the headings on each table.

Attachment 2

Comments On New Mexico Environment Department Guidance Papers

Use of Tolerance Intervals for Determining Inorganic Background Concentrations

The position paper on the use of tolerance intervals is useful; however, based on this paper the NMED appears reluctant to approve the use of the upper bound of the tolerance intervals (UTLs). UTLs may provide the best statistically based estimate of background concentrations for some data sets, and NMED should encourage the use of UTLs and similar statistical tools to estimate background concentrations.

This paper could be expanded to discuss the use of prediction limits. Prediction limits are calculated and used in a similar fashion to tolerance limits and can be used to estimate background analyte concentrations.

The paper indicates that outliers must be evaluated. Methods for identifying outliers in data sets that are normally or lognormally distributed should be suggested or references that NMED feels are appropriate should be provided. NMED should add the words "to the extent possible" to the end of the second sentence of Item 2. More importantly, the position paper should identify an approach for identifying outliers in data sets that are not normally or lognormally distributed. Similarly, methods acceptable to NMED for identification of population distributions should be identified.

Item 4 on page 2 indicates that an adequate data set contains greater than 20 values. For many sites, this number may be unrealistic given the small scope of the environmental investigations. If NMED believes that the number of required background samples is a function of the size of the contaminated area, can NMED define this relationship quantitatively?

Item 6 on page 2 identifies statistical descriptors for each data set. Depending on the data set's distribution, inclusion of each listed descriptor may not be appropriate. NMED should consider adding the words "if appropriate" to the first sentence.

Determination of Extent of Contamination

It would be helpful if NMED expanded on its interpretation of adequate determination of extent. Because it will be practically impossible to delineate the dimensions of a source area/volume with no inaccuracy, some guidance from NMED is needed to make this position paper useable. For example, an adequate delineation of source area may be an estimate that is accurate to within a factor of two, or within plus or minus 50 percent. Similarly for source volume, acceptance criteria would make this position paper more useful in planning investigations or evaluating the results of an investigation.

Although provisions are included in this proposed policy for a variance, this proposal may lead to excessive sampling and analysis costs for areas that have relatively straightforward source/transport issues. For some inorganic constituents at small sites, limited sampling and physical dimensions of the area/volume of release will be adequate to make risk-based decisions. CAO requests that NMED consider adding language to the position paper to (1) specifically define what information is needed to constitute an adequate delineation of spatial extent, an (2) define the conditions and process that would lead to granting of a variance.

Allowance for statistical aberrations should be added to the list of factors that may affect the determination of the extent of contamination. Random chance and the form of the underlying distribution are likely to account for the appearance of constituents that exceed background.

Background concentrations of organic compounds are eliminated from consideration. Anthropogenic sources of organic chemicals have resulted in detectable concentrations of organochlorine pesticides, polynuclear aromatic hydrocarbons and other organic constituents in urban areas that may be unrelated to solid waste management unit activities. Accordingly HRMB should accept background levels of organic constituents on a case by case basis.

Defining the nature and extent of contamination through a comparison to background values may not be justified at some sites. Constituents present at higher than background concentrations may exhibit a low human health or ecological risk. Accordingly "level of health or ecological risk exhibited by a constituent" should be added to the bulleted list of factors that may affect the determination of the extent of contamination.

Application of Inorganic Background Values in the Risk Assessment Process.

A more appropriate title for this paper would be "The Application of Inorganic Background Values in Selecting Chemicals of Potential Concern."

Background concentrations of organic compounds are eliminated from consideration in this paper. Anthropogenic sources of organic chemicals have resulted in detectable concentrations of organochlorine pesticides, polynuclear aromatic hydrocarbons and other organic constituents in urban areas that may be unrelated to solid waste management unit activities. Accordingly HRMB should accept background levels of organic constituents on a case by case basis

The position paper briefly touches on the issue of risk due to background levels of constituents. An additional statement could be added to indicate that risk associated with background levels of constituents would not be a cause for corrective action.

Assessing Human Health Risks Posed by Chemicals: Screening-Level Risk Assessment.

The primary difference between NMED's paper and current EPA guidance is the degree of conservatism in NMED's screening step. This process is almost certain to select most constituents detected at the site for a more comprehensive risk assessment.

The goal of the screening risk step is to focus future detailed risk evaluation processes on a few chemicals that may present risk. The level of effort described in NMED's screening step is not all that dissimilar from a baseline risk assessment.

The introduction discusses that not all pathways or ecological concerns are considered in this paper. It does not make clear whether all of these additional concerns must be addressed in the screening risk assessment. For example, is NMED requiring that soil concentrations protective of groundwater be calculated? In addition, the paper does not discuss the preferred guidance documents for lead, PCBs, PAHs, Dioxins, and Furans.

The introduction and the objective seem to be contradictory. Is this document developing procedures for performing a screening level risk assessment or is it simply a methodology for calculating media specific screening levels?

A useful addition to this position paper would be a tabulation of toxicity and carcinogenic screening levels for soil and water. Such tabulation could serve as an efficient guide to assess potential hazardous levels of analytes detected in environmental samples. NMED could eliminate a lot of confusion and standardize this process by developing a standard table such as the Region 3 Risk-based Screening Levels. Facilities could use the table to compare their constituent concentrations to for a quick, consistent, and inexpensive screen. Screening values could be developed for a number of chemicals (like the Region 3 list) using the conservative exposure assumptions and pathways presented in this paper.

If this document is to present methodology for developing a screening level risk assessment there should be a discussion regarding planning.

On Page 6, Section 3.a, change the reference to Section 1.2 to read Section 1.b.

The conceptual site model is important to understand what pathways and exposure routes may exist, but calculating screening level numbers for bioaccumulation in beef, milk, etc. seems to be too complex for a screening-level risk assessment.

Page 7 of this paper proposes a non-carcinogenic effects hazard quotient of 1 for exposure to one COPC and 0.1 for exposure to more than one COPC. NMED should cite the technical guidance supporting this approach. In addition, given the level of conservatism in a screening evaluation, the addition of another safety factor of 10 to the hazard quotient seems to be overly conservative. A non-carcinogenic hazard index of 0.1 should only be appropriate for those constituents that elicit their effect on the same target organ or system. Is there a scientific basis for the safety factor of 10? EPA guidance for human health risk assessment is that if the hazard quotient exceeds unity, there may be concern for potential non-cancer effects (RAGS, 1989). EPA assumes a cumulative effect and adds potential hazard quotients from each chemical to derive a Hazard Index that is again compared to 1.0, rather than comparing each index to 0.1.

Page 16. The 1997 Exposure Factors Handbook (EFH) recommends 5,800 cm^2 for adult skin surface area for contact with soil in an outdoor exposure scenario. Has NMED reviewed the new EFH, and is NMED planning to revise any of their exposure assumptions based on the EFH?

Dermal Adherence (DA) is addressed in the EFH with average DA between 0.09 and 0.1 reported in 5 different groundskeeper scenarios. The EFH presents DA dependent on soil types and activity.

Page 18, Step 3 : Hazard Quotients are usually applied to non-carcinogenic chemicals. This procedure of evaluating which constituents exceed their screening level should probably be called something besides HQ.

Appendix B

There are several exposure parameters listed in these tables that have different values in the exposure factors handbook. For example:

The inhalation rate for an adult (averaged male and female) is reported as 13.25 m^3/day for long term exposures (ie., a resident) in the EFH.

The inhalation rate for a child 1-12 years old is reported as 8.7 m^3/day in the EFH.

Body weight for the average adult has been revised in the 1997 EFH to 71.8 kg.

Occupational duration in the EFH is 6.6 years; NMED is using 25 years for an industrial scenario. Perhaps values of 7 and 14, average and maximum, respectively could be used?

Risk-Based Remediation of Polychlorinated Biphenyls at RCRA Corrective Action Sites.

Page one, third paragraph, indicates that the risk associated with transport of PCBs from contaminated soil/sediments to groundwater should be evaluated. Please provide references or guidance for acceptable approaches for conducting this evaluation.

Table 2 provides an estimate for costs associated with the analysis of PCB congeners. Currently, relatively few laboratories are accepting samples for analysis of PCB congeners and the quoted costs are up to 50 percent greater than the maximum $1,000 quoted in Table 2.

Risk Based Decision Process Strategy.

CAO welcomes NMED's consideration of the Region 6 Risk Management Strategy. By focusing corrective actions on a results-oriented rather than an administrative-oriented process, significant cost savings can be realized. DOE looks forward to reviewing the draft of this strategy for New Mexico.