Comment Responsiveness Summary
Proposed Revisions to 18 AAC 75
October 2, 2015

In June 2015 the Alaska Department of Environmental Conservation (DEC) proposed revisions to 18 AAC 75 pertaining to how risk is calculated and risk assessments are performed at contaminated sites. The revisions were released for a 45-day public comment period on June 10, 2015. The comment period was extended from July 27, 2015 to August 11, 2015, based on stakeholder request.

Comments were received from Pam Miller, Alaska Community Action on Toxics; Chip Hilarides, Flint Hills Resources Alaska and their consultant, Arcadis; Robert Shirley, U.S. Department of Defense; Lawrence Acomb, Geosphere, Inc.; Bradley Platt, U.S. Department of Transportation Federal Aviation Administration; John Spielman and Luamarie Faverty, Ahtna Engineering Services, LLC; Ralph Hulbert, AlaskChem Engineering, and Anonymous.

The responsiveness summary arranges similar comments into the categories below and summarizes or shortens some of the comments to their key points. Revisions have been made to address 13 of the comments received on the Risk Assessment Procedures Manual, and the adopted-by-reference date of the document is updated.

- General Comments
- Cost of Complying with Regulations
- 18 AAC 75.325(h)Removal reference to 40 CFR 300.430 that provides for a cancer risk standard between 1 in 10,000 and 1 in 1,000,000
- 18 AAC 75.340(f) Risk Assessment Procedures Manual 2015 updated and adopted by reference.

General Comments

1. Comments:

- What prompted this proposed change?
- ADEC has made changes without explaining its basis for the proposed changes, offering a rationale for the proposed changes, or citing to established authority in support of the proposed changes. Alaska Statute 44.62.190(d) states that: "Along with a notice [of proposed action], the state agency shall include the reason for the proposed action ..." The proposal does not meet this requirement.

Response:

There are two primary reasons for the proposed changes – the first reason was the need to update our risk assessment process. The current version of the department's *Risk Assessment Procedures Manual* (RAPM) was last adopted into regulation in 2000; the science and methods have improved in the last fifteen years and the document is outdated. The proposed 2015 RAPM provides an updated process for conducting risk assessments that incorporates the latest science and toxicity information available for the process and the chemical compounds regulated by the department, as well as current risk assessment practices in general. The second reason is related to the current wording in 18 AAC 75.325(h) that allows the department to consider carcinogenic risk standards consistent with 40 CFR 300.430. That risk range, 1×10^{-4} to 1×10^{-6}, allows for an option to consider a less stringent risk standard than the department's carcinogenic risk standard of 1×10^{-5}. This provision has never been invoked since 1999 when it was adopted. Removing that wording from our regulations removes a potential question as to whether state cleanup standards are applicable and relevant or appropriate requirements under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and ensures a consistent risk standard at all sites. Additionally, we want to clarify that it does not change the state's ability to consider or to approve remedies that include appropriate engineering and institutional controls to achieve the 1×10^{-5} risk standard.

2. Comment: What justification is there for the proposed change?

Response: Consistent application of site cleanup rules that are protective of human health and the environment is our overarching objective. The important work of assessing risk requires the department to employ methods reflecting the most current state of the art and science. The 2000 version of the RAPM and subsequent draft versions have served their purpose to develop meaningful, protective risk assessment data to support site cleanups. However, adopting the updated RAPM in these proposed amendments offers the regulated community the best methodology and science with which to complete this work. Use of the revised RAPM with its updated hierarchy of toxicological sources is important for the department to effectively regulate the investigation and cleanup of emerging and other new contaminants.

Finally, as previously pointed out, removing the reference at 18 AAC 75.325 (h) regarding the 40 CFR 300.430 risk range ensures consistent, protective regulatory oversight for contaminated site work in Alaska.

3. Comment: We are concerned as to how DEC will go about ensuring alternative cleanup levels are protective of transport to other media. For example, permafrost deserts in the Arctic vs. Ketchikan rainy environments beg for different approaches and likely are associated with different concerns. If the evaluation can be done qualitatively in some circumstances it would be good. Quantitative modeling to estimate potential intermedia transfer can be both expensive and highly uncertain. We suggest general guidance be included that discusses such evaluations should be site-specific and may be qualitative or quantitative depending on site conditions and the nature of the chemicals.

Response: ADEC's "Fate and Transport Modeling Guidance" gives general guidance on site-specific evaluation and addresses the concerns raised by the commenter. The document is cited on page 19 of the proposed RAPM. Qualitative analysis that includes consideration of site-specific climate and other factors would necessarily occur during the conceptual site modeling phase or be discussed in an uncertainty assessment. This step is used to determine whether a specific exposure pathway at a given site is complete or not for the contaminants present. For example, and related to "intermedia transfer," if compounds are present but are not volatile, the vapor intrusion pathway would be considered incomplete. When a pathway is complete, data is required to ensure any remaining residual contamination is protective from migrating to a more sensitive pathway.

4. Comment: There is not enough discussion of the changes and there are no examples of the changes to understand how the proposed changes will work. I think it is critical to work out and document the purpose and objective of each portion of the regulations and to have example scenarios that meet and don't meet the objective before the regulation is adopted.

Response: Comment noted. The proposed changes were described in the public notice and also in the summaries discussing the changes between previous versions of the *Risk Assessment Procedures Manual* (RAPM) and the revised version. In the future, we may consider providing example scenarios for portions of the regulations; however, commenters are encouraged to ask questions during the comment period and we will make every effort to aggregate and post responses to our frequently asked questions webpage.

5. Comment: There is not an assessment of the impact of the proposed regulation changes.

Response: The department's assessment of the impact of these two regulation changes determined that the impact on the regulated community is negligible. The removal of the reference to the federal risk range language does not impact the state's flexibility to approve cleanups that incorporate engineering and

institutional controls in order to meet the risk standard. The adoption of updated procedures for conducting risk assessments incorporates updated science, clarifies and updates the steps in a risk assessment already in use and considered best practice, and formalizes these things by adopting by reference.

6. Comment: I think it would benefit everyone (ADEC, RPs, consultants, and the public) to have input from environmental professionals outside ADEC, in a working group format, while ADEC is developing the revisions to the regulations and guidance documents (i.e. prior to the public comment period).

Response: Comment noted. In the course of its interactions with the regulated community, whether in conjunction with its regulatory oversight responsibilities or during other official events, the department makes every effort to understand and take into account the needs and expectations of the regulated community while simultaneously ensuring adherence to Alaska statutes and regulations. In considering future revisions, the department may reach out to affected parties through a pre-rulemaking scoping process.

7. Comment: Proposed changes to the Alaska regulations and RAPM will further reduce flexibility, prolong the risk assessment process, delay cleanup of contaminated sites, and increase costs to the public and the regulated community. We encourage ADEC to explicitly acknowledge its statutory and regulatory responsibility and provide the public with its specific views and thorough analysis of the costs and associated impacts of the proposed changes.

Response: Comment noted. We acknowledge our statutory responsibility under AS 44.62.190(d) to estimate based on a good faith effort, the annual aggregated costs to private persons, state agencies and the municipalities of proposed regulations. We carried out a good faith effort to estimate these costs for this regulatory package. Typically, state agencies, municipalities, and other local government entities do not conduct risk assessments for their sites and only a very small number of private entities conduct risk assessments, so the number of entities impacted by this package is small. The majority of changes to the *Risk Assessment Procedures Manual* clarify and formalize many steps in the risk assessment process which previously had been unclear. The result is a shorter manual with a clearer, more transparent process that should in fact reduce the costs associated with conducting risk assessments, rather than increase the cost.

8. Comment: The most significant conclusion drawn from my review is that the proposed regulation package should not be adopted. This is the third set of proposed changes to the contaminated site regulations in the last year. I am concerned that responsible parties, environmental professionals, and the public will lose track of the regulation change packages and not provide comments when there are significant issues that affect them (i.e. multiple regulation change packages, closely spaced in time will tend to suppress comments). Also I am concerned that by going through multiple, incremental changes to the regulations, there may be cumulative effects which do not become clear until after several regulation changes have been made. I think it would be better to have fewer regulation change packages and make the packages a more complete update of the regulations.

Response: Comment noted. ADEC has considered a consolidated set of revisions, but determined that a single large package of extensive changes would be cumbersome and overwhelming for the public and affected stakeholders to be able to both review and meaningfully provide comments. We work diligently in the drafting of these proposed revisions to analyze the impacts on other aspects of the regulations which are not proposed for amendment. As always, however, we appreciate the public's review and comment on potential unanticipated effects of proposed changes.

9. Comment: We are struggling with the process that the State is using for changes to their regulations and guidance documents. Staff spends a considerable amount of their time from April to October in the field and is not available to respond in a timely and effective matter to the public notice process during this period. This system of small, iterative changes to the regulations and policy documents during the peak of the Alaska field season creates the appearance that the state is attempting to minimize the comments they receive. We believe that the regulatory and responsible party communities would be better served if future guidance and regulatory changes were developed through a working group of professionals (consultants, responsible parties, and regulators).

Response: Comment noted. ADEC respects the concern about timing of public comment periods with the field season. In the case of this package, the public comment period was extended from 45 to 60 days to allow additional time to comment. Concerning the issuance of multiple smaller proposed amendments to regulations, it is not our intent to minimize public comment, but rather to minimize the impact on stakeholders seeking to comment so they are not overwhelmed. ADEC has determined that a single large package of extensive changes would be cumbersome and overwhelming for the public and affected stakeholders to provide comments.

10. Comment: It appears that the *Risk Assessment Procedures Manual* (RAPM) was finalized on February 16, 2015. The FAA missed the opportunity to comment on the proposed changes to the RAPM. However, there appears to be some serious issues with the procedures outlined in the current RAPM being adopted by reference in 18 AAC 75. The FAA recommends that the RAPM not be adopted by reference in its current version dated February 16, 2015. The document needs considerable work to address how it is to be applied.

Response: Guidance documents and procedures documents such as the RAPM are not issued for public review unless they are adopted by reference in regulation; therefore FAA has not missed a previous opportunity to comment on the February 16, 2015 RAPM, because it was not released to the public for review until the comment period for these proposed regulation changes was initiated.

11. Comment: : Have reviewed the proposed changes to the ADEC site cleanup regulations and risk assessment procedures manual (RAPM) and discussed with my colleagues and DO NOT SUPPORT ADOPTION OF THE PROPOSED CHANGES.

Response: Comment noted. However, the current version of the RAPM adopted in regulation in 2000 is now very outdated. The draft 2011 version currently in use is consistent with the February 16, 2015 version we are proposing for adoption, but with additional updates to be current with standard risk assessment practices. However, without more specific details from the commenter(s) as to why the changes are not supported, we are unable to further address their concerns.

12. Comment: I urge you and our legislators to reject these proposed changes. Perversely, they will cause more public harm than good. Instead, I request a less biased defensible approach to assessing both risks (harm) resulting from contamination and our mitigation attempts.

The contaminated sites program (CSP) writes their regulations (for legislative approval) and the myriad supporting cleanup guidance, for which the *Risk Assessment Procedures Manual* (RAPM) provides the foundation. All have intended conservative biases at each step, from concept through cleanup. However, the CSP has provided no guidance for those pesky "unless" clauses about safety, feasibility, environmental harm, or potentially greater threats to human life or health that inevitably result from our best intentioned efforts to mitigate contamination.

In essence, the statutes require a holistic (probabilistic) health based solution while the regulations and RAPM use multiple primarily deterministic step-by-step procedures without final accounting of good vs. harm. Any erroneous deterministic value or step can lead to ludicrous results.

These proposed regulation changes again assure us "latest science and toxicity information" will be used. However, the RAPM uses the same toxicity hierarchy as previous drafts. The CSP has apparently not reviewed the myriad sources of existing cleanup limits to see if they might be similar to the PG (propylene glycol) fiasco, or even referenced the toxicity data source for each chemical.

13. Response: Comments noted. The proposed regulations replace the outdated 2000 version of the department's RAPM with a revised version that incorporates updated scientific references and procedures already in use and considered standard best practices by responsible parties and risk assessment consultants. Many of these best practices were incorporated in the draft 2011 version of the RAPM, which is currently in use, but never formally adopted by reference; it thus raised questions of what was required. Updating and adopting the reference removes that question and the perceived need for responsible parties to review procedures in both the regulatory (2000) and draft (2011) documents.

The toxicity hierarchy referenced by the commenter is generally unchanged, but the sources referenced within the hierarchy change are updated continually as the science improves. ADEC refers to this hierarchy in selecting toxicity factors and developing cleanup criteria. The toxicity data used to calculate cleanup criteria for chemicals under Method Two can be found in our 2008 Cleanup Levels Guidance and the sources for these toxicity data are available upon request.

14. Comment: The "Additional Regulations Notice Information" that accompanies the Notice of Proposed Changes in the Regulations provides that the origins of the proposed action are staff of state agency, and federal government. What federal government agency or branch is the origin of this proposed action?

Response: EPA raised concern that citing the risk range in 40 CFR 300.430 within the Site Cleanup Rules, may raise questions over whether cleanup levels adopted in the rules should be considered Applicable or Relevant and Appropriate Requirements (ARARs) on cleanups conducted under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA). This concern, along with a goal to ensure consistency, prompted the proposed change.

Cost of Complying with Regulations
15. Comment: ADEC's proposed changes to the regulations and RAPM appear to have been made without consideration of costs, which will be significant for regulated parties and for [commenter] specifically. Response costs associated with the remediation of contaminated sites can be significant and delay associated with the remediation process serves only to increase such costs. **Response:** ADEC concurs that it has a statutory responsibility under AS 44.62.190(d) to estimate, based on a good faith effort, the annual aggregated costs to private persons, state agencies and the municipalities of proposed regulations. We complied with this requirement and reported the results in the "Additional Regulations Notice" posted with the public notice on Alaska Online Public Notices. Our good faith effort to estimate these costs for this regulatory package found no increased costs for state agencies or municipalities because they do not typically perform risk assessments for their sites. Only a very small number of private entities conduct risk assessments, so the number in this category impacted by the proposed changes is very small. For these entities, the majority of changes to the RAPM clarify and formalize many steps in the existing risk assessment process that previously had been unclear. The result is a shorter manual with a clearer, more transparent set of steps that are expected to reduce, rather than increase, the costs associated with conducting a risk assessment principally by eliminating delays that would otherwise result from an uncertain and ambiguous risk assessment process. Commenters are always welcome to provide the department relevant cost specific data for consideration during the public comment period.
16. Comment: Does the ADEC have a summary of proposed changes comparing the 2015 RAPM document with the 2000 RAPM document, and is there a redline-strikeout version of the 2015 RAPM? **Response:** ADEC posted a side-by-side summary of the changes from the 2000 version to the 2015 version of the RAPM in response to this comment during the public comment period. ADEC determined that a redline-strikeout version of the 2000 RAPM with 2015 changes would be unreadable because the changes were so extensive.
17. Comment: Imposing mandatory requirements on risk assessments undermines the use of the best science by essentially freezing science at a point in time, rather than offering guidance that would encourage risk assessors to make use of the best science as it evolves over time. Under ADEC's proposed approach, scientific advances will inevitably give rise to resubmissions and clarifications, further complicating and delaying the agency's review. ADEC's proposed new approach will reduce flexibility, prolong the risk assessment process, delay cleanup of contaminated sites, and increase costs to the public and the regulated community. Instead, we encourage ADEC to continue allowing-as the U.S. Environmental Protection Agency ("EPA") and other states do-risk assessors to use alternative methods and approaches tailored to site-specific conditions. **Response:** ADEC respectfully disagrees. The clearer and more directed approach outlined in the 2015 RAPM will reduce time and costs to the responsible party by eliminating ambiguity and uncertainty in the steps of the risk assessment process.

18 AAC 75.325(h)
Removal reference to 40 CFR 300.430 that provides for a cancer risk standard between 1 in 10,000 and 1 in 1,000,000

18. Comments:

- ADEC offers no support for its proposed change. The adoption of a single cancer risk threshold removes the flexibility for addressing different site-specific cleanup strategies and creates inconsistency in addressing cleanup at federal lead sites.

- The proposed revision is not consistent with the NCP and conflicts with ADEC's statutory authority under AS 46.09.020 to develop guidelines for the containment and cleanup of a hazardous substance that are consistent with the national contingency plan revised and republished under 42 U.S.C. 9605.

- The CSP's cleanup limits are largely based on EPA derived toxicities and fate and effect models. EPA recognizes the large uncertainties and uses a variable cancer risk of 10-4 to 10-6; the CSP should not limit its options, especially when collateral risks caused by compliance are high.

Response: Language deleted at 18 AAC 75.325(h) removes the reference to 40 CFR 300.430 which allows for a cancer risk standard between 1 in 10,000 and 1 in 1,000,000 to be considered on a site-specific basis at a contaminated site during a formal risk assessment. Although this provision has not been invoked since 1999 when it was adopted, reference to the federal rule created a question for EPA at federal-lead cleanups as to whether our state cleanup standards were more stringent than federal standards and thus whether they were applicable and relevant or appropriate requirements (ARARs). Removal of the reference to the federal rule removes this concern, but does not remove the state's flexibility to approve cleanup levels or remedies that include engineering or institutional controls to achieve the risk standard. In these cases, institutional and engineering controls are incorporated into the remedy to limit exposures and ensure that the default risk standard of 1 in 100,000 is maintained. This approach is not inconsistent with the National Contingency Plan. Alaska's 1×10^{-5} risk level resides squarely in the middle of the NCP risk range of 1×10^{-4} to 1×10^{-6}. Nor is it inconsistent with our statutory authority. The regulatory citation only pertains to alternative cleanup levels proposed following completion of a human health risk assessment and not alternative risk standards.

DEC does not assert that under the proposed rules sites with contaminants that pose a carcinogenic risk greater than 1×10^{-5}, based on individual contaminants or cumulative risk, would necessarily trigger a response action under CERCLA. Triggers for CERCLA response actions are defined in federal law and guidance. However, if no action is required under CERCLA and contaminants at a site do not meet state requirements, DEC may request further response under the state law.

19. Comment: What are the implications of this for cleanup standards at contaminated sites?

Response: The risk standard of 1:100,000 is consistent with cleanup values in the regulation tables and also establishing alternative cleanup values. The risk range in the NCP, 1×10^{-4} to 1×10^{-6}, allows an option to consider a less stringent risk standard than the department's carcinogenic risk standard of 1×10^{-5}. There is no implication for contaminated sites since the 1:100,000 standard has been and continues to be used. The state continues to have flexibility to approve alternative cleanup levels and remedies that include institutional and engineering controls to meet the risk standards.

20. Comment: How is the risk calculated to be 1:100,000 as an "acceptable" risk?

Response: An "acceptable" risk level (or range) of a contaminant, is defined by law in the National Contingency Plan (NCP) (40 CFR 430(e)(1)(i)(A)(2). The Environmental Protection Agency uses the standard to make cleanup decisions at Superfund sites. This is a risk level (or range) that people can be exposed to, including sensitive populations, without health problems. For carcinogens, the acceptable risk range in the NCP is between 1 x 10-4 (1 in 10,000) and 1 x 10-6 (1 in 1,000,000). The state's 1 x 10^{-5} cancer risk standard falls within the range established by the NCP and is therefore acceptable as defined in law.

21. Comment: Why should the risk standard be 1:100,000 compared with 1:1,000,000?

Response: During a major revision of contaminated site regulations completed in 1999, the department specifically established a carcinogenic risk standard for contaminated sites work of 1:100,000 that was consistent with another recently established standard within the department that had undergone a very thorough public review prior to its adoption. In consideration of adopting a 1:100,000 risk standard for contaminated sites work, the department's goal was to establish a measure of human health protection with a sufficiently strong carcinogenic risk level acceptable to the regulated community.

22. Comment: How can the public be assured that this standard is protective of human health?

Response: The standard is just one piece of the protective measures that account for the development of cleanup levels that safeguard human health. There are other factors built into the cleanup value used to ensure protectiveness including using reasonable maximum exposure and uncertainty factors associated with the toxicity study. The Alaska Department of Health and Social Services can also perform a health assessment when there are health-related concerns from the public.

23. Comment: What is the accompanying "non-cancer" risk standard?

Response: The department's non-cancer risk standard is a Hazard Index (HI) of one (1). The HI is a summation of separate Hazard Quotients (HQ) for individual chemical compounds that may be encountered at a contaminated site. The non-cancer risk, or HI, cannot exceed 1.

24. Comment: If promulgated, this rule will confuse the regulated community conducting cleanup of released hazardous substances under the federal CERCLA statutory authority and using the Applicable or Relevant and Appropriate Requirements (ARAR) process. Does the ADEC assert that under the revised rule an excess cancer risk standard of 1 in 100,000 (1 x 10 -5) would trigger the necessity to take cleanup action? Also, is ADEC asserting that cleanup is required if cumulative cancer risk exceeds 1 x 10 -5 when there are multiple contaminants and/or pathways?

Response: No, under CERCLA the NCP and associated guidance are used to determine whether a response action is necessary. However, if no response is required under CERCLA and oil or hazardous substance contamination at a site does not meet the state requirements, DEC may require additional response under state law.

25. Comment: Alaska Statute AS 46.04.070 [Scope of Regulations] specifies, that the department shall adopt regulations that are necessary to carry out the purposes of this chapter [Chapter 4. Oil and Hazardous Substances Pollution Control] and that do not conflict with and are not preempted by federal law or regulations. How does the ADEC commissioner determine that this proposed rule does not conflict with the federal NCP given our prior comments?

Response: The removal of the reference to 40 CFR 300.430 does not conflict with the federal NCP because: 1)the adopted risk standard falls within the NCP acceptable risk range of 1 x 10^{-4} to 1 x 10^{-6}; and 2) it does not remove the state's flexibility to approve cleanup levels or remedies that may achieve a different risk standard. In these cases, institutional and engineering controls are incorporated with the remedy to limit exposures and ensure that the default risk standard of 1 in 100,000 is achieved.

18 AAC 75.340(f) RISK ASSESSMENT PROCEDURES MANUAL

26. Comment: I would like to know and see references to support your statement that: "The proposed 2015 RAPM provides an updated process for conducting risk assessments that incorporates the latest science and toxicity information available for the process and the chemical compounds regulated by the department." What "latest" scientific and toxicity information that you have used? Does this include the latest information on endocrine and epigenetic effects of chemicals at low dose exposures?

Response: ADEC appreciates that scientific and toxicity information is continually evolving. The updates to the risk assessment procedures are mainly associated with updates to the science on exposure. New assessment procedures are included to more accurately and comprehensively capture exposure risks to children as well as adults, and mutagenic effects of certain compounds. Exposure parameters used to quantify the amount of chemical intake now reflects current science and current characteristics of the human population. References are cited throughout the document and listed in the references section of the document (Section 5.0). The department itself does not perform toxicity assessment due to the large amounts of resources involved. Instead, we rely upon a hierarchy of toxicity sources. The 2000 toxicity hierarchy previously cited is outdated as some of those sources have changed or are no longer valid (for example, HEAST). The proposed updated hierarchy (see section 3.3.1) consists of (1) EPA's Integrated Risk Information System; (2) EPA's Provisional Peer Reviewed Toxicity Values; and (3) other resources as needed and as approved by ADEC on a case-by-case basis. Any information, where available, on endocrine disruption and epigenetic effects of chemicals would be captured within those toxicity assessments performed on the individual chemicals.

27. Comment: ADEC states that it is proposing changes to the RAPM in the interest of expediting its review and minimizing revision and resubmittal of risk assessment documents. The proposed changes will have the opposite effect.

Response: In the absence of specific impacts/examples from the commenter, ADEC respectfully disagrees. Because of greater clarity, specificity, and defined expectations upfront in the updated procedures, the back-and-forth of reviews and revisions will be minimized. The outcome will be a faster turnaround of reviews for the majority of risk assessments.

28. Comment: ADEC universally replaces "should" with "must," including changes to quotations from EPA guidance documents that properly contain the word "should." the global change of the word "should" to "must" has altered text that ADEC has quoted from other sources. For example, language quoted from an EPA document discussing contaminant distribution and exposure considerations has been inappropriately altered. If the change was intentional, then ADEC should provide a thorough explanation of the basis for the proposed change.

Response: The RAPM is adopted in regulation and unlike the EPA guidance document, is not a recommendation. The word "must" is used to convey when a particular step or approach is required; this

helps to ensure better consistency from site to site. Deviating from these requirements prolongs the risk assessment process, which increases cost and results in the risk assessment not being approved.

29. Comment: ADEC should make a number of edits for consistency, including use of acronyms such as ADEC/DEC and COPEC/ECOPC, and updating references consistently.

Response: Comment noted and respective changes have been made to the RAPM where appropriate.

30. Comment: ADEC uses the term "conservative" in the proposed RAPM without further explanation which creates ambiguity and is misleading. ADEC should make its intent clear by providing a thorough explanation of this term and should provide a rational justification for uniformly requiring "high-end" values in all instances.

Response: The department believes in order to ensure protection of human health, safety, or welfare, or of the environment, conservative assumptions are required to protect high end users and address uncertainties. Being predictive doesn't necessarily equate to being protective. The use of reasonable maximum exposure (RME) for a conservative exposure scenario ensures higher end users are addressed. Language from the 2000 RAPM on RME will be retained in the 2015 RAPM for clarity.

31. Comment: ADEC has added language to the proposed 2015 RAPM that was not in either the 2000 RAPM or the 2011 Draft RAPM, which gives it the option to "reject" a risk assessment rather than engaging in comment resolution and revision.

Response: Comment resolution is still incorporated into the process as stated in the paragraph and is preferred. Currently, if a resolution is not achieved, then the risk assessment is not approved. At an impasse in comment resolution there has to be a clear regulatory decision on the report. The regulatory ability to reject a risk assessment is consistent with ADEC's authority to reject other reports and work plans.

32. Comment: ADEC should clarify in the RAPM whether the ADHSS/ATSDR consultation and evaluation of the pathway is mandatory in all cases or only when the subsistence food pathway has been identified.

Response: The public can request a health assessment for a contaminated site, thus it is not specifically mandated. However when the subsistence food pathway is considered complete, ADHSS/ATSDR are considered more knowledgeable in the field and consultation with them is highly recommended for the appropriate evaluation of the subsistence food pathway as noted in section 3.2.2.3. The process would likely occur during an initial scoping meeting with ADHSS/ATSDR and they would ultimately decide if their involvement is required. We added language to the RAPM to clarify this.

33. Comment: In the discussion of Bioaccumulation in Wild Foods, ADEC states that chemicals are bioaccumulative if the bioconcentration factor ("BCF") is 1,000 or higher. The proposed RAPM adds the log K0w > 3.5 criterion. ADEC should provide a reference and its rationale for using this value. This criterion is more stringent than the other criterion, a measured BCF of 1,000 and, therefore, is not scientifically appropriate.

Response: The discussion of bioaccumulation in wild foods in the RAPM is consistent with Appendix C in ADEC's Policy Guidance on Developing a Conceptual Site Model. The BCF standard presented is cited from EPA August 2004b, Persistent, Bioaccumulative, and Toxic (PBT) Profiler, Office of Pollution Prevention and Toxics, http://www.pbtprofiler.net/. The more stringent requirement of a log Kow greater than 3.5 (when a BCF is not available) is due to the high degree of variability associated with determining log Kow values. The reference is EPA, February 2000, Appendix to Bioaccumulation Testing and Interpretation for the Purpose of Sediment Quality Assessment Status and Needs, Office of Water, Washington D.C., EPA-823-R-00-002. Both citations were inserted into the text and additional language on defining the term bioaccumulation has been added.

34. Comment: Section 4.3.4 Bioaccumulation and Field Tissue Residue Studies: ADEC has eliminated language from the 2011 Draft RAPM to make this more relevant to ecological assessment. The most critical issue is that the biota samples taken represent what people are eating. The most appropriate season to take samples would be the season that is typically used for hunting and harvesting. The new language simply refers to what "predators are eating." ADEC should provide a thorough explanation for the proposed change.

Response: The section 4.3.4 referenced by the commenter only deals with ecological risk, although there is discussion in this section about evaluating specific tissue that is most likely to be consumed for subsistence. Development of Alaska specific exposure scenarios for wild foods is addressed in section 3.2.2.3 of the RAPM. Separating the discussion about human health risk from consumption of wild foods clarifies the distinction between these two risk assessment processes.

35. Comment: The 2015 proposed RAPM appears to continue to state an ADEC preference for deterministic risk assessments over probabilistic risk assessments…. ADEC should make clear that it allows and promotes the use of probabilistic risk assessments in circumstances where there are sufficient data.

Response: It is stated in the first paragraph, "ADEC will also consider the use of probabilistic risk assessment techniques for human health and ecological risk assessments." The most recent guidance on probabilistic risk assessments from EPA is also referenced: "Risk Assessment Forum White Paper: Probabilistic Risk Assessment Methods and Case Studies (EPA, 2014)." Additional language "Where there are sufficient data" was added to the sentence above.

36. Comment: "Initial screening for all sites must be against residential chronic exposure scenarios with the most updated toxicity value". The meaning of "most updated" is unclear. ADEC should make clear that the risk assessor should use the best scientifically appropriate value whether or not it is the most updated value.

Response: The draft risk assessment relies upon the ADEC table values and regional screening levels (RSLs) for screening. The proposed change to using the RSL for screening ensures consistency between the risk characterization and screening process since the RSLs are updated more frequently than the ADEC tables. The purpose of the referenced sentence is to capture any updates to toxicity values with the tier approach. To clarify the process "most updated toxicity value" was replaced with "toxicity hierarchy from section 3.3." The

approach is consistent with other states and EPA derivative 9285.7-53 for human health toxicity values in superfund risk assessments to ensure a scientifically appropriate value.

37. Comment: Re: "Exposure Point Concentration" -- the groundwater exposure point concentration ("EPC") must be based on the maximum detected concentration in groundwater and that it is not appropriate to average concentrations over an aquifer. --- Requiring the use of the maximum detected groundwater concentration illustrates how the proposed RAPM unnecessarily compounds conservatism. Accordingly, ADEC should not depart from EPA guidance for the development of groundwater EPCs.

Response: The requirement ensures 18 AAC 75.380(c)(2) is met in regulation, where the maximum concentration is required for groundwater.

38. Comment: "Data Reduction and Field Duplicate Samples," ADEC has proposed the use of the highest detected value or results from a confirmatory method where more than one result is reported from multiple analytical methods. The more reasonable way to address duplicates and multiple analytical results is to average the results, which is the practice required in many states.

Response: ADEC disagrees, since the 95% UCL is still calculated in the process provided the data is sufficient. Taking the higher of two samples ensures reasonable maximum exposure (RME), since a duplicate sample is considered to be identical to the parent sample. Many states also require higher of the two duplicates. For example, see a 2014 guidance from State of CT**:**
http://www.ct.gov/deep/lib/deep/site_clean_up/remediation_regulations/95ucl_guidance.pdf
Using the average of the two samples is not representative of the 95% UCL to protect high end users.

39. Comment: Section 3.3 -- Toxicity Assessment: ADEC states that the "preparation of a toxicity assessment relies primarily on existing toxicity information and does not usually involve development of toxicity values or dose-response relationships." ADEC should specifically state that the derivation of de novo toxicity values is encouraged when necessary to address emerging contaminants or to improve the scientific robustness of risk assessments.

Response: ADEC doesn't have the resources to develop toxicity values and must rely upon experts in the field to derive values that are robust. The toxicity hierarchy utilizes the resources of other agencies that devote their time specifically to addressing the issue and have robust practices in place. This practice is used by the EPA Superfund Program and other states for selecting toxicity values, and when necessary, deriving appropriate values for site-specific risk assessment activities.

40. Comment: In the discussion of "Contaminants in Breast Milk," the proposed 2015 RAPM states: "Infant consumption of contaminated breast milk shall be considered a potential exposure pathway on a chemical- and site specific basis," but provides no guidance as to the circumstances under which this pathway should be considered. Further, explain why ADEC has struck the following statement from the 2011 Draft RAPM: "If contaminant exposure resulting in breast milk concentrations poses less risk to the infant than that to the mother, this pathway may be eliminated from further quantitative risk assessment." The deleted language should be reinserted.

Response: The exposure pathways are captured in the conceptual site model (CSM). Guidance on assessing potential exposure pathways is provided in the department's CSM guidance. The sentence was removed because less risk to the infant compared to the mother doesn't necessarily equate to regulatory risk standards being met for the infant. The approach is consistent with the EPA policy for risk characterization which

provides principles for fully, openly, and clearly characterizing risks. The information would potentially be used in the consideration of risk management and communication to the public.

41. Comment: Section 3.3.1 -- Toxicity Hierarchy: ADEC has changed the discussion of toxicity hierarchy significantly from the 2000 RAPM and the 2011 Draft RAPM by, for example, removing references to the cancer classifications and derivations of reference doses, and to the fact that chemicals may have multiple health-based toxicity criteria. ADEC appears to rigidly rely on the hierarchy published in EPA's 2003 OSWER Directive (9285.7-53). However, it is not consistent with the Directive, because ADEC fails to include the Directive's explanatory language which urges "use [of] the best science available on which to base risk assessments" and the consideration of "additional scientific information" when brought to the attention of EPA. ADEC should include the Directive's language recognizing the necessity for the exercise of scientific judgment on a case-by-case basis when applying the hierarchy.

Response: The 2000 toxicity hierarchy is outdated and cited from EPA's Risk Assessment Guidance for Superfund (RAGS) Volume I, Part A, Human Health Evaluation Manual. The updated toxicity hierarchy in the 2011 draft RAPM is an update that is consistent to Section 7.4 of RAGs Part A from the EPA Superfund program directive 9285.7-53. ADEC does cite the directive, but does not see a need to include the OSWER Directive language specifically referenced by the commenter.

42. Comment: In the section on toxicity hierarchy, ADEC fails to offer rationale for why it is rejecting the routine use of toxicity values from CalEPA NJDEP, ATSDR and other sources unless ADEC approves them based on the five criteria listed in the proposed RAPM. Further, case-by-case approval for every toxicity factor that is not Tier 1 or 2 is burdensome. This new policy will increase costs and create delays. ADEC should provide the public with its views and analysis of the costs and associated impacts of this proposed change as required by law.

Response: See responses under Costs of Complying with Regulations. Further, the DEC is not rejecting these sources and will consider them contingent upon the five criteria being met. Toxicity sources other than Tier 1 or Tier 2 are the exception rather than the norm. Additional costs and delays as a result of DEC's review are not anticipated because the process is more clearly defined than in the past. Approval of Tier 3 sources from routine sources mentioned above (CalEPA NJDEP and ATSDR) are expedited as is currently the practice with the 2011 draft RAPM.

43. Comment: EPA's PPRTVs are interim values derived by EPA contractors that are subject to limited peer review and no public review. PPRTVs receive internal review by two U.S. EPA scientists and external peer review by scientific experts who are contracted by EPA, but they do not receive review by other EPA programs or other federal agencies. More importantly, as noted above, the public has no opportunity to comment on the transparency of the assessment, the adherence to publicly available methodology with the current best scientific information and practices, or the consideration, or lack thereof, of higher quality studies.

Response: EPA PPRTVs are widely accepted toxicity sources both in industry, other states, and by federal agencies and will continue to be Tier 2 sources in ADEC's Toxicity Hierarchy.

44. Comment: ADEC states that for compounds with an "insufficient toxicity database," EPA or the National Toxicology Program may be approached for consideration of future testing. This approach will produce significant delays in completing a risk assessment, because it takes several years for either agency to agree to take on new compounds for future testing and then upwards of five years to conduct the actual toxicity studies and evaluate the results. Once data are produced from the studies, it takes another year or two

to finalize risk assessments based on the studies. This leaves communities and parties responsible for the cleanup of a site in uncertainty for years and creates significant costs that ADEC has not addressed here.

Response: Compounds with an insufficient toxicity database are the exception rather than the rule for contaminated sites where risk assessments are being performed. The vast majority of Alaska stakeholders and responsible parties will not be affected as described in the example provided by the commenter.

45. Comment: ADEC fails to define in Section 3.3.1 what constitutes an "insufficient toxicity database." Without this much needed clarity, there may be significant delays while ADEC puts the risk assessment on hold pending the design, execution and evaluation of new toxicity studies.

Response: An insufficient toxicity database would be determined on a case-by-case basis, for example, when the chemical is not listed in the proposed updated toxicity hierarchy, or routinely mentioned tier 3 sources, as well as in consultation with experts in the field, including EPA. Again, the occurrence of chemicals for which an insufficient toxicity database is available is rare.

46. Comment: When describing development of toxicity values in consultation with the Superfund Technical Support Center, the current document continues to use an outdated name for the National Center for Environmental Assessment office in Cincinnati (ECAO is no longer in use).

Response: The Superfund Technical Support Center name "National Center for Environmental Assessment office in Cincinnati (ECAO)" has been updated to the National Center for Environmental Assessment (NCEA).The RAPM was updated to reflect the name change.

47. Comment: The 2015 proposed RAPM states that groundwater screening levels should be used for screening surface water data in instances where ingestion of surface water is a pathway of concern. The RAPM should instead state that groundwater screening levels are not appropriate unless the surface water is consumed as potable drinking water. Moreover, ADEC should allow risk assessors to derive surface water screening levels using an appropriate ingestion amount that is less than 2.5 liters per day when there are concerns about incidental ingestion of surface water during recreational use scenarios.

Response: The screening process is consistent with other media where conservative residential values are used to determine chemicals of potential concern (COPC). A baseline risk assessment requires both current and future scenarios. There could be the potential for the surface water to be utilized as a drinking water source in the future. By performing the initial screening, these COPC are captured. During the risk characterization process, risk assessors would then be able to develop appropriate consumption rates based on the current site specific information for recreational or other use scenarios if applicable for the site. No change was made to the RAPM.

48. Comment: Section 3.1.4 - The proposed RAPM indicates that risk based screening levels, used to identify compounds of potential concern, should be derived from the EPA RSL tables (rather than from Tables B1 and C), because the EPA tables are updated twice a year. When are the screening criteria and toxicity values for the risk assessment locked in?

Response: The current practice is to typically "lock in" values at the time of the report writing, however every risk assessment can be different due to the complexity of the site. The determination would be discussed in the scoping meeting and incorporated into the work plan with agreement between ADEC and the responsible party. This is the current practice for compounds not listed in the ADEC tables.

49. Comment: In Section 3.2.2.2, ADEC requires that intake variables for a given pathway be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure ("RME") for the pathway. According to EPA, however, risk assessors should approach the estimation of the RME by identifying the most sensitive exposure parameters and using the maximum or near maximum values for one or a few of these and averages for the remaining values in deriving the RME. (EPA. 1992. Guidance on Risk Characterization for Risk Managers and Risk Assessors). ADEC should provide a thorough explanation for its approach.

Response: The prior EPA default exposure values were issued in 1991 as OSWER Directive 9285.6-03 and are consistent with the draft 2011 RAPM table. New data became available in September 2011, when EPA's National Center for Environmental Assessment, Office of Research and Development (ORD/NCEA) issued a substantive update to its exposure assessment recommendations, Exposure Factors Handbook – 2011 Edition (EFH 2011). The updated exposure factors are protective of the reasonable maximum exposure (RME), consistent with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended and the National Oil and Hazardous Substances Pollution Contingency Plan (NCP). The values presented in the table represent a mix of high-end and mid-range values. For example, 70 year life span, body weight and surface area all represent a 50th percentile, while the adult and child drinking water ingestion rates represent 90th percentile values.

50. Comment: In Table 1 (Summary of Default Exposure Factors), the "combined" exposure duration value of 26 years (20 years adult + 6 years child) appears to be in error. If the total residence duration is assumed to be 20 years based on EPA's updated default exposure parameters, then the total exposure period is 20 years, not 26 years. It should be the same for an adult and a child becoming an adult. The correct value for the combined receptor should be 20 years (14 years adult+ 6 years child).

Response: The table values are correct please see Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors at http://www.epa.gov/oswer/riskassessment/pdf/superfund-hh-exposure/OSWER-Directive-9200-1-120-ExposureFactors.pdf
Resident Exposure Duration adult (yr): Previous Default Value = 24; proposed = 20
Resident Exposure Duration child (yr): Previous Default Value = 6; proposed = 6
Resident Exposure Duration (combine adult and child) (yr): Previous Default Value = 30; proposed =26

51. Comment: In Table 1, default exposure factors, the exposure factors used to derive the promulgated Method 2 soil standards and groundwater standards are based on different exposure parameters than those described in the proposed RAPM. ADEC should provide its rationale for this change and explain how the RAPM-proposed exposure parameters do or do not impact those already codified for the Method 2 standards.

Response: The process for proposing alternative cleanup levels through a risk assessment under Method Four is designed to be rigorous and to incorporate the latest science. Default values under Method Two are generally conservative but may not always reflect the latest science. These values for Method Two cleanup criteria are proposed for amendment and currently out for public comment.

52. Comment: Table 1 Summary of Default Exposure Factors:

When the exposure factors are updated, the reasonableness of the RME values should be re-evaluated (e.g. are residents wearing shorts and short sleeved shirts really exposed to soil for 270 days, or nine months, per year in southcentral and interior Alaska?).

Response: The exposure frequency for the different climate zones is adjusted for snow cover during the winter months. The values are designed to be conservative.

53. Comment: Section 3.2 -- Exposure Assessment: ADEC now describes the default exposure scenario as "unrestricted residential land use" rather than simply "land use." ADEC should make its intent clear by providing a thorough explanation for the basis for the proposed change. In addition, ADEC further states that "prior approval with appropriate justification is required from ADEC to exclude a residential land use scenario along with the consent of each landowner who is affected." It is unclear whether ADEC expects that the risk assessor will be responsible for obtaining these consents from affected landowners as part of the risk assessment process and whether such a requirement is a precondition of securing ADEC's approval of a proposed risk assessment. If so, the injection of legal process into a risk assessment procedures manual is inappropriate.

Response: Evaluation of the residential scenario is required for all HHRAs regardless of current or proposed future exposure scenarios considered for the site. In order to deviate from the requirement, prior approval with appropriate justification is required from ADEC to exclude a residential land use scenario along with the consent of each landowner who is affected. This requirement is located in regulation and cited in the RAPM. Please see 18 AAC 75.340 (f)(2).

54. Comment: At page 15, ADEC states that "site-specific application of quantitative bioavailability adjustments in risk assessments is not recommended" and that a default value of 100% should be used. ADEC offers no support or rationale for adopting this default value, and it is contrary to published values for bioavailability of compounds. By favoring the use of the 100% default value, ADEC limits the tools available to risk assessors to perform a site-specific application as intended. ADEC should allow the use of in vivo or in vitro methods to derive site-specific bioavailability adjustment factors for organics upon submission of a robust work plan.

Response: ADEC has amended the RAPM to incorporate the default standard from arsenic at 60% in risk assessment, but retain 100% bioavailability for other chemicals. It has been the experience of ADEC that these tests are not standard, can be inconclusive, time consuming, and expensive. In addition, there is a level of uncertainty associated with any future changes to bioavailability.

55. Comment: Section 3.3.2 -- Exposure Route Toxicity Values: ADEC defines "oral slope factors" as toxicity factors for "evaluating the probability of an individual developing cancer from oral exposure to contaminant levels over a lifetime." EPA defines oral slope factors differently and stresses the upper-bound nature of the factor and its application to populations, not individuals. ADEC provides no justification for departing from EPA's approach.

Response: The sentence is simply referring to how the slope factor is applied and is consistent with definition provided in Chapter 7 Toxicity assessment from EPA Risk Assessment Guidance for Superfund (RAGs), “the slope factor is used to estimate an upper-bound probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.” The RAPM is geared toward the application for use in risk assessments as opposed to a detailed discussion on toxicity development, which would make the document too cumbersome. However, for consistency with RAGs “estimate an upper-bound probability” will be inserted into the sentence.

56. Comment: ADEC states that slope factors can be derived from drinking water unit risks, if needed. ADEC should remove this statement because one should not derive a slope factor from a unit risk without knowing the basis for the derivation of the slope factor in the first place.

Response: ADEC agrees with the commenter and has removed the statement from the RAPM.

57. Comment: ADEC states: "compounds that do not exceed ADEC-approved background concentrations are eliminated from risk characterization but may be retained for discussion in the uncertainty section if they exceed risk-based screening levels" ADEC should provide a rationale for this change so that risk assessors can better understand its intent.

Response: There is no change from the 2011 draft document as the statement is made on page 17, "Hence, although naturally occurring compounds may be excluded from the baseline risk assessment, at some sites the risk from naturally occurring background compounds may be included in the baseline risk assessment, presented separately from the site-related risks, at the option of the ADEC." The approach is consistent with the EPA Policy for Risk Characterization which provides principles for fully, openly, and clearly characterizing risks. The information is used in the consideration of risk management and communication as noted in the cited EPA document on background.

58. Comment: Section 3.3.3 -- Relative Potency Factors for cPAHs: ADEC is requiring that mixtures of PAHs be evaluated using a draft EPA carcinogenic potency scaling approach that is much debated and has not been adopted for use by any regulatory framework. Adopting EPA's draft RPF approach as regulation will cause lower soil cleanup levels for PAHs, resulting in more sites requiring response actions due to PAHs (even sites not now thought of as "PAH sites") and will increase analytical costs due to a longer list of PAHs requiring chemical analysis, even before EPA approved analytical methods have been developed and validated. Furthermore, closed sites in Alaska may be re-opened as a result of ADEC adopting EPA's draft RPFs. ADEC should provide the public with its views and analysis of the costs and associated impacts of this proposed change as required by law.

Response: Since the method 2 cleanup and RSL screening values still incorporate the RPF from, "Provisional Guidance for Quantitative Risk Assessment of Polycyclic Aromatic Hydrocarbons (EPA/600/R-93/089, July 1993)," for consistency with the cleanup and screening approach, the RAPM has been amended to retain the 1993 process.

59. Comment: Section 3.3.4.1 Lead: ADEC states that EPA's Integrated Exposure Uptake Biokinetic Model for Lead in Children ("IEUBK model") can be used to develop alternative cleanup levels for lead, but that ADEC will not approve any residential cleanup level higher than the default residential cleanup level of 400 mg/kg in soil. This is illogical and unjustified. If the risk assessor has knowledge of the speciation of lead at a site and demonstrates that the bioavailability is lower than the model default bioavailability of 60%, then the true cleanup level for that site would be greater than 400 mg/kg. In accordance with EPA guidance for execution of the IEUBK model, ADEC should allow any site-specific residential alternative cleanup level that is demonstrated and properly documented. The effect of the proposed change would be to impose an alternative cleanup level for lead even where the science demonstrates that the cleanup level is not necessary to protect public health. Accordingly, the use of a default cleanup level has the effect of increasing the cost of remediating contaminated sites. As such, ADEC should provide the public with its views and analysis of the costs and associated impacts of this proposed change as required by law.

Response: There is no associated reference dose or slope factor for lead, thus the cleanup value is based off a distribution of a target blood lead concentration levels in children. The current standard is based on preventing child exposure to soil that might cause blood lead concentrations greater than 10 ug/dL. The 400mg/kg in soil is based off the IEUBK model using the default parameters with bioavailability set at 60%. Centers for Disease Control and Prevention (CDCP) recently updated the target blood level to 5 ug/dL, which is not accounted for in the 400 mg/kg cleanup level. However, CDCP has also noted that no "safe" threshold for blood lead has been identified and emphasized the importance of preventative measures. There is also scientific evidence that the physical and mental development of children can be adversely affected at blood lead levels below 10 ug/dL. Therefore, setting an alternative cleanup level higher than 400 mg/kg for residential land use is not advised.

Other state standards or guidelines for residential properties range from 50 mg/kg (Wisconsin) to 500 mg/kg (Pennsylvania). The Alaska value of 400 mg/kg falls within the upper end of that range and has been in use for risk assessments since the release of the 2011 draft RAPM. The 2015 version of the RAPM maintains the 400 mg/kg standard and is not adopting a more stringent value. As a result, costs are not impacted from current practice.

60. Comment: Section 3.3.5 Types of Exposures: Chronic, Subchronic, and Acute: ADEC proposes to change its definition of chronic and subchronic exposures as defined in the 2000 RAPM and the 2011 Draft RAPM. ADEC offers no support or rationale in support of the change.

The definition of chronic exposures changed from "seven years to a lifetime" to "more than approximately 10% of the human life span." Given that ADEC's default human life span is 70 years (Table 1), these definitions appear to be identical. ADEC should provide an explanation for the change in language.

Also in this section, ADEC states that "a 6-year old child with chronic toxicity values should be assessed separately due to the inherent difference in exposure from that of an adult." A child scenario with six years of exposure would not meet the definition of a chronic exposure using either the newly proposed definition of "chronic exposure" or the definitions in the 2000 RAPM or the proposed 2011 RAPM. The requirement to use chronic toxicity values for child exposure scenarios appears to result from ADEC's statement about "the inherent difference in exposure from that of an adult." ADEC should provide a detailed explanation of the meaning of this statement, because all differences between children and adults are already taken into account in the risk assessment process. ADEC should allow risk assessors to utilize the original subchronic toxicity factor before it was converted into a chronic one.

Response: The definition comes directly from EPA's Integrated Risk Information System, "repeated exposure by the oral, dermal, or inhalation route for more than approximately 10% of the life span in humans." ATSDR defines chronic exposure as, "contact with a substance that occurs over a long time (more than 1 year)." A fine line of 6 to 7 years should not be drawn for the child as the definition states approximately 10% and the default 70 years is based off an average. For a residential scenario where a newborn resides, they are not typically going to dwell for just 6 years and move on as implied by the commenter for their fine line of a subchronic exposure interpretation. There are inherent differences in the body weight and ingestion rates as noted in Table 1. Children consume more soil and groundwater per body weight than adults resulting in a higher body burden, which is not accounted for with adult exposure scenarios.

The document only discusses not allowing the derivation of subchronic from chronic. It does not make any inference to allowing for chronic toxicity to be derived from subchronic toxicity. Again ADEC would rely on

the toxicity hierarchy listed in section 3.3. Applying an uncertainty multiplier of 10 to a subchronic value is typically performed for extrapolation to a chronic value as noted by the commenter.

61. Comment: Sections 3.4.1 Carcinogenic Risk and 3.4.2 -- Noncarcinogenic Risk: ADEC requires that results be reported to two significant figures versus one significant figure as noted in the 2000 RAPM and the 2011 Draft RAPM. ADEC should state that all risk assessment results should be reported to one significant figure.

When discussing evaluation of risks from childhood exposure, ADEC says that the National Research Council ("NRC") recommended that EPA must assess risks to infants and children whenever it appears that their risks might be greater than those of adults. Again, the NRC said "should," but the proposed RAPM incorrectly changes it to "must." ADEC should explain the rationale for this change.

Response: No change is proposed. The final incremental lifetime cancer risk is presented using one significant figure as stated and is consistent with the cumulative risk guidance adopted in regulation. If only one chemical is presented on site the final incremental lifetime cancer risk is presented using one significant figure. Rounding to one significant digit early on will magnify the error associated with the final number when several individual compounds are present. For example:

Compounds	
Not rounded	Rounded
X = 1.5E-6	2E -6
Y = 1.5E -6	2E -6
Z = 1.5E -6	2E -6
W = 1.5E -6	2E -6
Sum = 6E-6 or	**8E-6**

The word "must" is used to convey to the responsible parties at hand when a particular step or approach is required; this helps to ensure and provides better consistency from site to site.

62. Comment: Section 3.4.2 -- Noncarcinogenic Risk: ADEC states that the evaluation will be performed using a hazard quotient ("HQ") and hazard index ("HI") approach consistent with USEPA's Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A)Interim Final (USEPA, 1989a), Guidelines for the Health Risk Assessment of Chemical Mixtures (USEPA, 1986), and Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures (USEPA, 2000f). However, the proposed RAPM then states that ADEC "will evaluate segregation of the HI by target organ alone." This requirement, which deviates from EPA policy, is scientifically inappropriate for a number of reasons. The proposed RAPM provides no clear definition of organ or organ system. Clearly, heart, lung, and spleen are organs, and chemicals for which the sensitive endpoints are based on heart, lung and spleen can all be so grouped. However, some chemicals have RfDs that are based on different aspects of a system, such as the immune system. RfDs based on adverse effects to the central nervous system, peripheral nervous system, brain, myelin, or specific nerve cells should be considered a group for endpoint-specific HI calculation. Accordingly, ADEC should change this section to allow for endpoint specific groupings consistent with EPA guidance as cited in the proposed RAPM.

Response: It is stated that the department will segregate by target organ or system endpoint: "To accurately assess the cumulative risk of possible effects for non-carcinogenic compounds, the HI can be further segregated by target organ or system endpoint and mechanism of toxicity consistent with USEPA's Risk Assessment Guidance for Superfund, Volume I: Human Health Evaluation Manual (Part A) – Interim Final (USEPA, 1989a), Guidelines for the Health Risk Assessment of Chemical Mixtures (USEPA, 1986), and Supplemental Guidance for Conducting Health Risk Assessment of Chemical Mixtures (USEPA, 2000f).".

For clarification the following sentence was modified to, "Since the mechanism of toxicity is not well understood for many compounds, the department will evaluate segregation of the HI by target organ or system endpoint."

63. Comment: Section 3.4.2 -- ADEC should reinstate, or explain why it omits the following sentences from the 2011 draft RAPM: "For non-carcinogens, the health threats resulting from exposure to two or more hazardous substance with similar types of toxic response are assumed to be additive. However, many non-carcinogens have varying toxic effects and therefore assuming that these effects are additive may not be valid." These sentences are important because the assumption of additivity is another health conservative assumption.

Response: The sentences referenced by the commenter provide no additional direction for the HI calculation of additivity and only state it may not be valid, which can be confusing to the reader. The statement would be appropriate for inclusion in any uncertainty discussion in the risk assessment report as noted in section 3.4.8. The removal of the sentence provides clearer direction on the process, but any uncertainty associated with the assumption can be discussed in the uncertainty section.

64. Comment: Section 3.4.3 -·Cumulative Risk: Compared to the 2000 RAPM and the draft 2011 RAPM, ADEC has added language to its process for calculating cumulative risk by indicating that it "should incorporate the most updated toxicity values from the hierarchy discussed in Section 3.3.1 at the time of the risk assessment". As discussed above, the most recent value may not be the best or scientifically appropriate value. For example, a toxicity value derived from a peer-reviewed study may offer a more robust, sound assessment than a value derived from a more recently completed PPRTV.

Response: The approach is consistent with other states and EPA directive 9285.7-53 for human health toxicity values in Superfund risk assessments to ensure a scientifically appropriate value.

65. Comment: Section 3.4.4 ··Development of Alternative Cleanup Levels: In describing development of alternative cleanup levels, ADEC now mentions reasonable maximum exposure expected to occur under current and future land use, but does not mention "unrestricted residential land use" as was added earlier. This appears to be an internal inconsistency in the proposed RAPM. Consistent with the comments regarding the risk assessment regulations in Section II.A above, ADEC should continue to regard as acceptable a risk range of 1 in 10,000 to 1 in 1,000,000, as does EPA under its regulations.

Response: Residential land use is not mentioned specifically at this stage because the alternative cleanup levels being proposed through the risk assessment process may be based on other land use scenarios, such as commercial or industrial use, subject to appropriate institutional and engineering controls. Likewise, with respect to cancer risk, the department will consider an alternative cancer risk other than 1 in 100,000 provided that institutional and engineering controls are incorporated to ensure that exposures are adequately controlled so that the site ultimately meets the 1 in 100,000 cancer risk standard.

66. Comment: Section 3.4.7 ··Uncertainty in the Exposure Assessment: Please clarify the meaning of the added language, "there is a level of uncertainty with estimating the exposure point concentration (EPC) from measurements (rather than if it is a calculated UCL or maximum detection) or from results of modeling."

Response: The 2011 RAPM only referred generally to the uncertainty in the exposure assessment. The new language expands on the parameters used in the exposure assessment and provides clarity to the section concerning exposure factors. Whether the 95 UCL or the maximum concentration is used, an inherent level of uncertainty is present because it is impractical to take an infinite number of samples to characterize a site. There is temporal and spatial variability associated with the respective media of interest that goes into the EPC. The exposure point concentration can also be modeled in environmental media in areas where existing

measured concentrations are unavailable. The level of uncertainty may vary between sites, thus additional detail is not provided.

67. Comment: Section 3.4.8 Uncertainty in the Toxicity Assessment: The reference to 1989 guidance from EPA contains a "checklist" of uncertainties that apply to toxicity studies, which should be updated given advances in uncertainty assessment in the last 25 years.

Response: The checklist is intended to be broad enough to ensure that specific uncertainties associated with the toxicity assessment are captured and discussed. Providing a detailed checklist that covers all the potential uncertainties that could be associated with toxicity assessment is not the intent of the procedures manual and would make the document too cumbersome. However, if the commenter can suggest specific references that are appropriate, ADEC will review them for citation.

68. Comment: Section 4.1.2 ··Preliminary Screening Evaluation Step 2: ADEC references "acceptable conservative screening values" provided in the "Risk Assessment Information System" without providing a citation. ADEC should make the source of these values clear and direct risk assessors in how to access the resource.

Response: Comment noted**.** Further direction is provided in the department's ecoscoping guidance, but a link is now provided in the RAPM. http://rais.ornl.gov/.

69. Comment: Section 4.2.2 ··Ecological Conceptual Site Models: Please explain why ADEC deleted the introductory sentence from the 2011 Draft RAPM, which compared human health and ecological conceptual models: "While the human health CSM relies on default exposure assumptions, the ecological CSM requires more site specific information."

Response: The factual statement provides no utility to the process and guidance on CSM is provided in a separate document. Deleting the sentence make the document cleaner and separates the two sections.

70. Comment: Section 4.4 Risk Characterization: Among the factors that "must" be evaluated in the risk assessment are: "The quality of data and study design used from the extrapolated studies." This appears to be an error in editing, as the 2011 Draft RAPM referred to "key studies."

Response: Key studies or extrapolated studies essentially mean the same thing as both refer to the studies used in the development of the respective value.

71. Comment: Section 3.2.3 Calculating Exposure Point Concentrations, regarding the Exposure Area text: The statement that the EPA soil screening levels (and the ADEC Method Two Cleanup levels) are based on a ½ acre residential lot exposure area has been deleted. I think it is valuable to keep the residential lot concept (½ acre or even an 1/8th of an acre) in the manual. In addition, the proposed definition of the source area is not helpful because it confuses the source area with the downgradient dissolved phase plume which should not be considered part of the source area. This text needs more work, and real world examples such as case studies with maps and data tables are recommended to support and clarify the text. I think that the solution to this problem should involve input from environmental professionals outside ADEC in a working group format.

Response: ADEC is only concerned with the source and the extent of the release, thus the source area is the exposure unit. Method four risk assessments are meant to be site-specific, therefore the default source size is not always appropriate. Typically the discussion occurs between the RP, consultant and ADEC during the scoping phase of the risk assessment prior to submittal of the work plan, thus there is input from all parties. Including case studies in the RAPM would increase the length of the document; rather we encourage consultants engaged in risk assessments to contact us with questions about their specific site. However, we

have noted your comment concerning the desire to have input in a working group format and we may consider this option for future revisions.

72. Comment: The discussion of the exposure area also states that "contamination from other nearby source areas that have comingled with those from the source area being addressed must be considered in the exposure assessment". This statement does not provide any information on how the problem should be addressed or resolved. It seems to open the door for a downgradient site to potentially exceed risk criteria due to the migration of contaminants from an upgradient source, but does not provide any follow-on information regarding how ADEC will use the information. I am concerned that the RP for the downgradient site may be held responsible for investigating and addressing the risk on the downgradient site which is pushed over the risk standard by contaminant migration from the upgradient site.

Response: The intent of the risk assessment is not to determine the liability of the releases, but to fully characterize the risk in an exposure unit. Discussions on liability are outside of the scope of a risk assessment.

73. Comment: Section 3.2.3 Calculating Exposure Point Concentrations, Exposure Area: The sentence stating that "future, let alone current land use may be readily defined at most contaminated sites…." is not clear. (Should it say something like "future land use is often not readily defined"?)

Response: The commenter is correct, the statement was corrected to read....

"However, current, let alone future, land use may not be readily defined at most contaminated sites, and this determination is further complicated with the remoteness of sites, subsistence use, and historic or cultural considerations unique to Alaska. Therefore, application of a default exposure unit is **not** appropriate for site characterization or risk assessment."

74. Comment: Section 3.2.3 Calculating Exposure Point Concentrations text: The proposed changes add the sentence "high concentrations within an area must not be "diluted out" by averaging with several lower concentrations over a larger area or outer boundary sampling." This sentence is problematic (and as written, it is unacceptable) in that it does not consider the size of the perceived/potential hot spot relative to a residential lot and it does not consider the geospatial representativeness of the sampling.

Response: Further clarification will be provided for the following, "high concentrations within an area must not be "diluted out" by averaging with several lower concentrations over a larger area or outer boundary sampling." The new wording includes the language below:

Site characterization data is typically focused on identifying and delineating the source area. However, a data set generated solely from characterization data does not exhibit a defined distribution and has a high degree of bias to the lower concentrations (i.e., delineation and extent of boundary), which generally will not produce a 95% UCL that is representative of the source area. A visual and/or geospatial assessment is required to decrease the bias of the representation.

75. Comment: Section 3.3.4.2 Risk from Bulk Hydrocarbons -- regarding how risk from each fuel fraction is presented.

The old RAPM text says "Individual risks from each petroleum fraction must be calculated and presented in the HHRA; however, they are not included in the cumulative risk calculation with other petroleum fractions or with other chemicals in the tables. "The proposed changes to the RAPM say "Individual risks from each petroleum fuel fraction (i.e., total GRO, DRO, and RRO) must be calculated and presented in the HHRA as follows:

GRO aliphatic risk + GRO aromatic risk = total GRO risk

DRO aliphatic risk + DRO aromatic risk = total DRO risk

RRO aliphatic risk + RRO aromatic risk = total RRO risk

The proposed new text completely changes the way bulk hydrocarbon risk is calculated from that used by ADEC for the last 16 plus years, and results in significantly lower, more conservative cleanup levels. Please explain the change.

Response: The process for proposing alternative cleanup levels through a risk assessment under Method Four is designed to be rigorous and to incorporate the latest science.

The method 2 approach assumes a back-calculation of the more toxic aromatic fraction to represent the total risk of the hydrocarbons within a given carbon range, disregarding the percentage attributed to aliphatic compounds. Thus,

50% GRO risk from aromatic and no risk from aliphatic = 100% total GRO risk

40% DRO risk from aromatic and no risk from aliphatic = 100% total DRO risk

30% RRO risk from aromatic and no risk from aliphatic = 100% total RRO risk

To only assume a percentage of the risk from the total fraction is not consistent with risk assessment best practices and fails to fully consider additive effects. Examination of the mixture risk estimates provided from the individual fractions is consistent with EPA practices (U.S. EPA, 2000).

The proposed language would ensure all the risk is accounted for and totals 100% for the respective range of hydrocarbons being assessed.

Reference mentioned:

U.S. EPA (U.S. Environmental Protection Agency). 2000. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. U.S. Environmental Protection Agency, Risk Assessment Forum, Washington, DC. EPA/630/R-00/002.