COMMENTS RECEIVED
ON THE RISK ASSESSMENT AMENDMENTS
TO
18 AAC 75

Schlichting, Sally G (DEC)

From: Schlichting, Sally G (DEC)
Sent: Tuesday, August 11, 2015 2:49 PM
To: Schlichting, Sally G (DEC)
Subject: Comments from Anonymous on Risk Assessment

Sally Schlichting
Phone: 907-465-5076

From: Alaska Online Public Notices [mailto:noreply@state.ak.us]
Sent: Tuesday, August 11, 2015 12:17 PM
To: Fishwick, Claire (DEC); Schlichting, Sally G (DEC)
Subject: New Comment on SUPPLEMENTAL NOTICE - Proposal to Change Regulations Dealing with how Risk is Calculated and Risk Assessments are Performed at Contaminated Sites

A new comment has been submitted on the public notice **SUPPLEMENTAL NOTICE - Proposal to Change Regulations Dealing with how Risk is Calculated and Risk Assessments are Performed at Contaminated Sites**.

Submitted:

8/11/2015 12:17:08 PM

Unknown city, US
Anonymous User

Comment:

We are concerned as to on how DEC will go about ensuring ACLs are protective of transport to other media. As written this is a very broad and wide-open request. 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.

You can review all comments on this notice by clicking here.

Alaska Online Public Notices

Schlichting, Sally G (DEC)

From: Luamarie Faverty <lfaverty@ahtna.net>
Sent: Tuesday, August 11, 2015 4:50 PM
To: Schlichting, Sally G (DEC)
Cc: John Spielman
Subject: Proposal to Change Regulations Dealing with how Risk is Calculated and Risk Assessments are Performed at Contaminated Sites
Attachments: ADEC RAPM Change Comments 8-11-15.pdf

Good Afternoon –
I agree that the process for conducting risk assessments needs to incorporate the most updated scientific information. However, this process needs to be decided carefully and Mr. Spielman and Mr. Acomb have brought up several logical and valid concerns.

Please regard this email as my agreement with Mr. Spielman's attached letter regarding his concern for the number of changes in regulations and his concern for the potential to lose consistency and coherence within these regulations.
Thank you

Luamarie Faverty
Project Manager
Ahtna Engineering Services LLC
Ahtna Engineering Services, LLC
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Schlichting, Sally G (DEC)

From: Pamela Miller <pamela@akaction.org>
Sent: Thursday, July 30, 2015 5:59 PM
To: Schlichting, Sally G (DEC)
Subject: Regulation changes

Dear Ms. Schlichting,
I have some questions concerning the proposal to change regulations pertaining to how risk is calculated and risk assessments are performed at contaminated sites:

1) What prompted this proposed change?
2) What are the implications of this for cleanup standards at contaminated sites?
3) What justification is there for the proposed change?
4) How is the risk calculated to be 1:100,000 as an "acceptable" risk?
5) Why should the risk standard be 1:100,000 compared with 1:1,000,000?
6) How can the public be assured that this standard is protective of human health?
7) What is the accompanying "non-cancer" risk standard?

Thank you for providing answers to my questions.
Sincerely,
Pamela Miller

Pamela Miller, Executive Director
Alaska Community Action on Toxics
505 West Northern Lights Boulevard, Suite 205, Anchorage, Alaska 99503
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Schlichting, Sally G (DEC)

From: Pamela Miller <pamela@akaction.org>
Sent: Friday, July 31, 2015 4:25 PM
To: Gardner, Kevin R (DEC)
Cc: Schlichting, Sally G (DEC)
Subject: RE: Regulation changes

Thank you for your timely responses to my questions.
Additionally, I would like to know and see references to support your statement that: "The proposed 2015 RAPM provides and 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?

Thanks again,
Pam

From: Gardner, Kevin R (DEC) [mailto:kevin.gardner@alaska.gov]
Sent: Friday, July 31, 2015 4:17 PM
To: pamela@akaction.org
Cc: Schlichting, Sally G (DEC)
Subject: RE: Regulation changes

Dear Ms. Miller,
Thank you for your interest regarding our current regulations update. Please find our responses to your questions below. If you have any additional questions regarding this update, feel free to contact us.

Regards,

Kevin Gardner and Sally Schlichting
Division of Spill Prevention and Response | Contaminated Sites Program
Alaska Department of Environmental Conservation
Kevin: 907.269.7658
Sally: 907.465.5076

From: Pamela Miller [pamela@akaction.org]
Sent: Thursday, July 30, 2015 5:59 PM
To: Schlichting, Sally G (DEC)
Subject: Regulation changes

Dear Ms. Schlichting,
I have some questions concerning the proposal to change regulations pertaining to how risk is calculated and risk assessments are performed at contaminated sites:

1) What prompted this proposed change?

There are two primary reasons – the first concerning the need for updating our risk assessment process. The current version of the department's *Risk Assessment Procedures Manual* (RAPM) was last adopted into regulation in 2000; thus it is outdated. The proposed 2015 RAPM provides and updated process for conducting

FLINT HILLS
RESOURCES

August 10, 2015

BY ELECTRONIC MAIL

Sally Schlichting
Alaska Department of Environmental Conservation
410 Willoughby Ave, Suite 303
PO Box 111800
Juneau, AK 99811-1800
sally.schlichting@alaska.gov

RE: Proposed Regulations Pertaining to Risk Calculation & Risk Assessments Performed at Contaminated Sites and Updates to Risk Assessment Procedures Manual to Be Adopted by Reference

Dear Ms. Schlichting:

On June 10, 2015, the Alaska Department of Environmental Conservation ("ADEC") proposed amendments to regulations pertaining to how risk is calculated at contaminated sites (18 AAC §§ 75.325(h), 75.340(f)) and to the 2000 version of ADEC's Risk Assessment Procedures Manual ("RAPM"), incorporated by reference into the regulations (18 AAC § 75.340(f)). Flint Hills Resources Alaska, LLC ("FHRA"), appreciates this opportunity to offer the attached comments on the proposed amendments to the risk assessment regulations and procedures.

As highlighted in the attached comments drafted by ARCADIS at the request of FHRA, 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 FHRA specifically. Alaska Statute 46.03.024 plainly provides that, when Alaska adopts a regulation concerning "the control, prevention, and abatement of air, water, or land or subsurface land pollution, the department shall give special attention to public comments concerning the cost of compliance with the regulation and to alternate practical methods of complying with the statute being interpreted or implemented by the regulation." *See also* Alaska Stat. §§ 44.62.190(d) ("Along with a notice [of proposed action], the state agency . . . shall include . . . the initial cost to the state agency of implementation [and] the estimated annual costs . . . to private persons to comply with the proposed action; the state agency for implementation and to other state agencies to comply with the proposed action; and municipalities to comply with the proposed action . . . ."), 44.62.210(a) ("[T]he agency shall pay special attention to the cost to private persons of the proposed regulatory action.").

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. FHRA has experienced the impact of such delay in connection with the North Pole Refinery site. We estimate that the costs to FHRA associated with the remediation of the North Pole Refinery site and the provision of drinking water will increase by several million dollars per year as a direct result ADEC's continuing and unwarranted delay in setting a cleanup level for sulfolane in groundwater.

As outlined in the attached comments, it is FHRA's strongly held view that ADEC's 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.

Please contact us with any questions or requests for additional information.

Sincerely,

Chip Hillarides, Senior Vice President
Environmental Health & Safety

ARCADIS
Infrastructure · Water · Environment · Buildings

Comments on:

1) June 10, 2015 Proposed Changes to 18 AAC 75.325(h) Pertaining to Risk Calculation and Risk Assessments Performed at Contaminated Sites; and

2) June 10, 2015 Proposed Changes to 18 AAC 75.340(f) to Incorporate by Reference the Proposed Risk Assessment Procedures Manual, dated February 16, 2015, and to the manual itself.

ARCADIS

On June 10, 2015, the Alaska Department of Environmental Conservation ("ADEC") proposed amendments to regulations pertaining to how risk is evaluated at contaminated sites (18 AAC §§ 75.325(h), 75.340(f)) and to the 2000 version of ADEC's Risk Assessment Procedures Manual ("RAPM"), incorporated by reference into the regulations (18 AAC § 75.340(f)). Thank you for the opportunity to offer the following comments on the proposed amendments to the risk assessment regulations and procedures.

I. General Comments

Immediately below are general comments on the proposed RAPM, followed by specific section-by-section comments on the proposed amendments to the regulations and RAPM.

The proposed modifications to the proposed RAPM will have the force and effect of a regulation, and therefore will make many discretionary risk assessment methods and processes mandatory. On page 1, 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.

For example, in the proposed RAPM, ADEC universally replaces "should" with "must," including changes to quotations from EPA guidance documents that properly contain the word "should." 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.

In addition, ADEC's proposed changes to the regulations and RAPM appear to have been made without consideration of costs. Alaska Statute 46.03.024 plainly provides that, when Alaska adopts a regulation concerning "the control, prevention, and abatement of air, water, or land or subsurface land pollution, the department shall give special attention to public comments concerning the cost of compliance with the regulation and to alternate practical methods of complying with the statute being interpreted or implemented by the regulation." We encourage ADEC to explicitly acknowledge this responsibility and provide the public with its views and analysis of the costs and associated impacts of the proposal.

Moreover, throughout the proposed RAPM, ADEC has made changes without explaining its bases for the proposed changes, offering a rationale for the proposed changes, or citing to established authority in support of the proposed changes. Without these references and justifications, reviewers and risk assessors are unable to determine ADEC's intent and understand whether and how a new requirement might be applied in particular circumstances. When agencies provide a preamble or statement of reasons, as EPA and other states do, regulated parties are better able to interpret and

comply with the regulations and guidance. State law requires as much. 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.

Finally, ADEC uses the term "conservative" in the proposed RAPM without further explanation, which creates ambiguity and is misleading. Presumably, ADEC intends the term "conservative" to mean "public health conservative" in the sense of preventing underestimates of exposure and risk. But in reality, these maximum values go beyond "conservative" in the common use of the word and would be more accurately termed "high-end" values. 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.

II. Specific Comments

A. ADEC's Proposed Changes to Risk Assessment Regulations

The proposed amendment to 18 AAC § 75.325(h) reflects a change in the cancer risk management threshold for unacceptable risk by removing reference to the EPA's acceptable cancer risk range of one in one million to one in ten thousand ($1x10^{-6}$ to $1x10^{-4}$), 40 C.F.R. § 300.430, as an allowed alternative and leaving a single cumulative carcinogenic risk threshold of one in one hundred thousand ($1x10^{-5}$) as the only option. ADEC states that its intention is to use a single cancer risk management threshold for all site-specific risk assessments. To effect this change, ADEC proposes to remove from 18 AAC § 75.325(h) the cross-reference to 40 C.F.R. § 300.430, and to eliminate the flexibility of a risk assessor to develop a well-tailored risk standard consistent with the range acceptable under EPA's National Contingency Plan through consideration of the very regulatory factors that ADEC now proposes to strike: site-specific conditions; land use; hazardous substance characteristics; statutory compliance; protection of human health, safety, and welfare, and the environment; ability of cleanup to be implemented; long-term and short-term effectiveness; use of treatment technologies; public comment and cost. ADEC offers no support for its proposed change. Moreover, there is no scientific basis for the $1x10^{-5}$ cancer risk threshold as a bright line for health effects, and it may lead to unnecessary cleanups. The intention of Method 3 risk assessments and Method 4 cleanup levels is to provide a site-specific approach for evaluating potential exposures and risks. 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.

ADEC's proposal amounts to a clear departure from EPA's well-established approach to risk management without any scientific support or analysis of the associated costs and impacts. EPA has specifically stated that risk management decisions are routinely based on a cumulative site-wide risk level of $1x10^{-4}$:

> Where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10(-4) and the non-carcinogenic hazard quotient is less than 1, action generally is not warranted unless there are adverse environmental impacts.

> The upper boundary of the risk range is not a discrete line at 1 x 10(-4), although EPA generally uses 1 x 10(-4) in making risk management decisions. A specific risk estimate around 10(-4) may be considered acceptable if justified based on site-specific conditions. (EPA. 1991. Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions. OSWER Directive 9355.0-30, pages 1, 4-5. April 22, 1991.)

Further, EPA defines "acceptable risk" as:

> An "acceptable" risk level (or range) of a contaminant, defined by law, that EPA uses 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 is between 10^{-4} (1 in 10,000) and 10^{-6} (1 in 1,000,000). (EPA. 2015. Risk Communication Manual – Attachment 6. http://www.epa.gov/superfund/community/pdfs/toolkit/risk_communication-attachment6.pdf.)

ADEC does not offer any justification for departing from EPA's approach to risk management decisions when risks are an order of magnitude lower that the risk level deemed acceptable by the federal government in many circumstances. Nor does ADEC offer an analysis of the costs associated with ADEC's proposed regulatory change. Again, I encourage ADEC to provide the public with its views and analysis of the costs and associated impacts of the proposal.

B. ADEC's Proposed Changes to Risk Assessment Procedures Manual

Section-by-section comments are noted below. In addition, ADEC should make a number of edits for consistency, including use of acronyms such as ADEC/DEC and COPEC/ECOPC, and updating references consistently throughout the proposed RAPM.

1. Section 1.0 Introduction

Section 1.3.3 -- Risk Assessment Reviews (p. 3): 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. Once the site characterization and risk assessment process has begun, ADEC should engage in comment resolution and revision, thereby allowing risk assessors the opportunity to address any concerns that ADEC may have, rather than simply rejecting a risk assessment document.

2. Section 2.0 Planning

Section 2.2 -- Risk Assessment Work Plan (pp. 6-7): The proposed 2015 RAPM states that "ADEC in coordination with the responsible person will consult with the Alaska Department of Health and Social Services (ADHSS) and/or the Agency for Toxic Substances and Disease Registry [ATSDR] for the appropriate evaluation of the subsistence food pathway." This sentence implies, although does not explicitly state, that every risk assessment in Alaska will require a subsistence food ingestion receptor and a consultation with ADHSS or the ATSDR regardless of size or setting. Although there are many sites in Alaska where such a receptor is appropriate, it is not appropriate at all sites. 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.

Section 2.4 -- Deterministic and Probabilistic Evaluations (pp. 7-8): The 2015 proposed RAPM appears to continue to state an ADEC preference for deterministic risk assessments over probabilistic risk assessments as evidenced by its statements that "[i]n general, deterministic risk assessments are adequate for the purpose of determining risk and providing a basis for calculating ACLs" and "[r]arely will sufficient data be available for [probabilistic] assessments." Although there may be limitations associated with probabilistic risk assessments at the present time, they will likely be the predominant type of risk assessment in the future. ADEC should make clear that it allows and promotes the use of probabilistic risk assessments in circumstances where there are sufficient data.

3. Section 3.0 Human Health Risk Assessment

Section 3.1.4 -- Selection of Contaminants of Potential Concern (pp. 12-14): In the proposed RAPM ADEC states: "[c]ompounds 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" (emphasis added). This new language represents a departure from both the 2000 RAPM, which states: "If inorganic contaminant concentrations are less than or equal to background for the site (as calculated according to ADEC's Technical Guidance Document on Determination of Background Concentrations) then the compound need not be retained as a COPC for human health or ecological risk assessment[,]" and from the 2011 Draft RAPM, which states: "[e]liminate compounds that do not exceed DEC-approved background concentrations." ADEC should provide a rationale for this change so that risk assessors can better understand its intent.

The following statement at p. 12, which is not found in the 2000 RAPM or the 2011 Draft RAPM, is ambiguous and potentially problematic: "Initial screening for all sites must be against residential chronic exposure scenarios with *the most updated toxicity value*" (emphasis added). The meaning of "most updated" is unclear. The most updated toxicity value could mean the most recent value listed in the Regional Screening Level (RSL) table, or it could mean some interim value since the last RSL table update. Because a risk assessment takes years to develop, it may be difficult to determine at what point in time the "most updated" value must be used. Moreover, the most recent value may not be the best or scientifically appropriate value—for example, the language may require the use of a recently completed Provisional Peer Reviewed Toxicity Value ("PPRTV") rather than a more robust, sound risk assessment. ADEC should make clear that the risk assessor should use the best scientifically appropriate value whether or not it is the most updated value.

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. ADEC should provide criteria for making this determination. In addition, 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." ADEC should make its intent clear by providing a thorough explanation for the basis for the proposed change. This is an instance where a potential opportunity for

simplifying or streamlining the risk assessment has been eliminated. The deleted language should be reinserted.

In the discussion of "Surface Water Consumption," 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. This statement is not in the 2000 RAPM or the draft 2011 RAPM. 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.

In the discussion of "Bioaccumulation in Wild Foods," ADEC has expanded its criteria for defining bioaccumulative compounds to chemicals with a log K_{ow} greater than 3.5. In the 2000 RAPM, ADEC is silent on the meaning of the term bioaccumulative. In the draft 2011 RAPM, ADEC states that chemicals are bioaccumulative if the bioconcentration factor ("BCF") is 1,000 or higher. The proposed RAPM adds the log K_{ow} > 3.5 criterion. This criterion is used again in Section 4.3.1.2 in the discussion of bioaccumulative compounds of potential ecological concern. ADEC provides no reference to support the new criterion. The use of a log K_{ow} of 3.5 would be a more stringent criterion for defining bioaccumulative than a BCF of 1,000. Commonly used algorithms for predicting BCFs predict values of 150 to 200 for chemicals with log Kow values of 3.5. Hence, ADEC should provide a reference and its rationale for using this value.

Section 3.2 -- Exposure Assessment (p. 14): 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 "[p]rior 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.

Section 3.2.2.2 -- Calculating Chemical Intake -- Exposure Assumptions (pp. 15-16): In this section, 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. http://www.epa.gov/oswer/riskassessment/habicht.htm.). ADEC should provide a thorough explanation for its approach.

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).

In Table 1, ADEC adopts EPA's default exposure factors for a child and adult resident and for a commercial/industrial worker as default exposure parameters for use in a site-specific risk assessment and derivation of ACLs, and allows use of alternative site-specific exposure assumptions with ADEC approval. The exposure factors used to derive the promulgated Method 2 soil standards (18 AAC § 75.341) and groundwater standards (18 AAC § 75.345) are based on different exposure parameters than those described in the proposed RAPM—e.g., in 18 AAC § 75.345, groundwater standards are based on an ingestion rate of 2 liters per day by a 70 kilogram adult over a 30-year exposure duration compared to the RAPM-proposed default exposure parameters of 2.5 liters per day, adult body weight of 80 kilograms and 20-year adult exposure duration. 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.

At page 15, ADEC states that "[s]ite-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. EPA has recognized for years that metals and organics measured in soil by the use of strong acid digestion or strong solvent extraction vastly overestimates the true bioavailable concentrations. For arsenic in soil, EPA has promulgated a default value of 60%, and ADEC should allow use of this default factor in risk assessments in Alaska. In addition, validated and approved *in vitro* methods are available for lead and arsenic, and ADEC should allow their use to derive site-specific bioavailability adjustment factors. For organics, site-specific studies have been performed for polycyclic aromatic hydrocarbons ("PAHs"), polychlorinated biphenyls ("PCBs"), dioxins/furans, and other classes of chemicals and EPA accepts such studies on a site-specific basis after review and comment on the study protocol. 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.

Section 3.2.3 -- Calculating Exposure Point Concentration (pp. 17-20): As noted in the General Comments section above, the global change of the word "should" to "must" has altered text that ADEC has quoted from other sources. For example, in two instances, language quoted from an EPA document discussing contaminant distribution and exposure considerations has been inappropriately altered. This change was likely unintended and should be corrected. If the change was intentional, then ADEC should provide a thorough explanation of the basis for the proposed change.

In the section titled "Exposure Point Concentration," ADEC states that 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. To justify its position, ADEC assumes that an individual well "is utilized as a residential drinking water source," which suggests that high exposure of a few individuals is driving the assessment for the entire exposed population. This approach is problematic for several reasons.

Typically, a conservative estimate (95th upper confidence limit ("UCL")) of average concentrations of constituents in groundwater representing current conditions is used to represent groundwater EPCs. (EPA. 2013. ProUCL 5.0 Technical Guide, EPA/600/R-07/041. September; EPA. 2006. On the Computation of a 95% Upper Confidence Limit of the Unknown Population Mean Based upon Data Sets with Below Detection Limit Observations. EPA/600/R-06/022. March; EPA, 2002. Supplemental Guidance to RAGS: Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites. OSWER Pub. No. 9285.6-10. December). This is because a risk estimate based solely on the maximum detected groundwater concentration does not address potential seasonal or temporal issues that may affect average exposures. To that end, EPA recently issued guidance for CERCLA and RCRA sites directing that groundwater EPCs be based on the 95% UCL of the mean concentration among the highest detected concentrations in recent groundwater samples collected from a minimum of three monitoring wells within the same aquifer or plume. (EPA. 2014. Determining Groundwater Exposure Point Concentrations, Supplemental Guidance. OSWER Directive 9293.1-42. March 11.) 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.

In the section titled "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. For primary and duplicate results, ADEC requires the "most conservative detectable sample result" to be used. Throughout the proposed RAPM, ADEC states that it will "require the most conservative" approach in site-specific risk assessments. However, compounding conservative assumption upon conservative assumption contributes to the likelihood that unjustified cleanups will be required. The more reasonable way to address duplicates and multiple analytical results is to average the results, which is the practice required in many states.

Section 3.3 -- Toxicity Assessment (p. 20): 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" (emphasis added). 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.

Section 3.3.1 -- Toxicity Hierarchy (pp. 20-21): 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.

Consistent with the 2000 RAPM and the draft 2011 RAPM, ADEC states that Tier 3 toxicity values cannot be used without ADEC's approval. New to the proposed RAPM is a list of five criteria (see page 20). Without offering any rationale or support, ADEC is rejecting the routine use of toxicity values derived and

carefully documented by California EPA ("CalEPA"), the New Jersey Department of Environmental Protection ("NJDEP"), ATSDR, and others unless ADEC approves them based on the five criteria listed in the proposed RAPM. This new policy will greatly increase the cost of risk assessments and will significantly delay risk assessments and cleanups. ADEC should provide the public with its views and analysis of the costs and associated impacts of this proposed change as required by law.

One criterion is that the value should be derived using the current best scientific information and practices. While a newly derived toxicity value using the best available science is preferred to an outdated toxicity value, derivation of toxicity values is very time consuming, and many values that are routinely used across the country were derived years ago. For instance, many values used routinely in risk assessments have been carefully derived by regulatory agencies, such as CalEPA, NJDEP and ATSDR. These values are accompanied by peer-reviewed toxicological reviews and should not be disregarded simply because of their age. EPA's 2003 Directive fully supports the use of such values: "EPA and state personnel may use and accept other technically sound approaches . . . ." ADEC should provide a definition of "current best scientific information" and a rationale for rejecting state agency-derived toxicity values.

Even the most robust and perfectly acceptable Tier 1 EPA toxicity values are decades old and may not meet ADEC's definition of "current." For instance, the following routinely assessed chemicals have EPA Integrated Risk Information System (IRIS) files that were prepared more than a decade ago: benzene (2003), toluene (2005), ethylbenzene (1991), xylene (2003), hexane (2005), heptane (1993), PCBs (1994), ammonia (1991), manganese (1995), and mercury (1995). Many other chemicals, such as pesticides were derived even earlier in time, but they are appropriate for use in risk assessment.

ADEC's requirement for a case-by-case approval for each and every toxicity factor that is not a Tier 1 or Tier 2 value will be burdensome, costly, and time-consuming, thus delaying and increasing the costs of risk assessments. ADEC should provide the public with its view of the benefits of the proposed change and analysis of the resulting costs and associated impacts. This detailed approval process is not necessary because most of the Tier 3 toxicity values with the exception of the EPA HEAST values are adequately peer-reviewed and more robustly peer- reviewed than the Tier 2 PPRTVs. For example, CalEPA toxicity values are subject to scientific peer review with the state's Science Review Panel and released for public review and comment. NJDEP's values are peer-reviewed and released for public review and comment. ATSDR's Minimum Risk Levels are peer-reviewed and also open to public review.

In contrast, 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.

Furthermore, 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.

Importantly, ADEC fails to define in Section 3.3.1 what constitutes an "insufficient toxicity database." EPA has stated that "the minimum dataset for a low confidence chronic RfD or RfC is a single subchronic study," while the "minimum dataset for a high confidence chronic RfD or RfC is a chronic study in two species, a single two-generation reproductive toxicity study, and a developmental toxicity study in two species by the appropriate route of exposure." (EPA.2002. Risk Assessment Forum. A Review of the Reference Dose and Reference Concentration Processes. EPA/630/P-02/002F. December). The Reference Dose/Reference Concentration (RfD/RfC) Technical Panel (2002) recommended a slightly different approach that involves a description of "minimal" and "robust" toxicological databases, where "robust" databases are preferred and the uncertainties for a minimal database are reflected in the magnitude of the uncertainty factor used in reference value derivation.

Other approaches should be considered as well. EPA's IRIS database currently provides reference doses for a host of chemicals with low confidence toxicological databases, including several polycyclic aromatic hydrocarbons, benzene, ethylbenzene, toluene, xylenes, and many commonly used solvents. Furthermore, there are at least three chemicals listed in IRIS with reference values based solely on the results of a single subchronic rodent bioassay (ethyl acetate, ethylbenzene, and pentabromodiphenyl ether). Accordingly, the uncertainties associated with these data gaps are reflected in the magnitude of the database uncertainty factors (10 to 30) and composite uncertainty factors (1,000 to 10,000) used to derive reference values for these chemicals.

Thus, toxicological reference values published by EPA for chemicals with limited toxicological databases are used routinely in risk assessments across the country. By definition, these RfDs represent "an estimate (with uncertainty spanning perhaps an order of magnitude) of daily oral exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of deleterious effects during a lifetime." (EPA. 2015. http://www.epa.gov/risk_assessment/glossary.htm.) Given that IRIS has published reference toxicological values for chemicals with limited toxicological databases and/or using toxicological data from a single toxicology study, ADEC should describe in more detail the characteristics that constitute a sufficient toxicological 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.

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).

Section 3.3.2 -- Exposure Route Toxicity Values (pp. 21-22): 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" (emphasis added). 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. EPA states that cancer slope factors and unit risks are used to estimate the risk of cancer associated with exposure to a carcinogenic or potentially carcinogenic substance. A slope factor is an upper bound, approximating a 95% confidence limit, on the increased cancer risk from a lifetime exposure to an agent by ingestion. This estimate, usually expressed in units of proportion (of a population) affected per mg of substance/kg body weight-day, is generally reserved for use in the low-dose region of the dose-response relationship, that is, for exposures corresponding to risks less than 1 in 100. EPA's definition of a unit risk on its "Terms and Acronyms" webpage also stresses the population, not the individual: "The upper-bound excess lifetime cancer risk estimated to result from continuous exposure to an agent at a concentration of 1 µg/L in water or 1 µg/m^3 in air. The interpretation of unit risk for a substance in drinking water would be as follows: if unit risk = 2 x 10^{-6} per µg/L, 2 excess cancer cases (upper bound estimate) are expected to develop per 1,000,000 people if exposed daily for a lifetime to 1 µg of the substance in 1 liter of drinking water." (EPA. 2015. https://ofmpub.epa.gov/sor_internet/registry/termreg/searchandretrieve/termsandacronyms/search.do).

ADEC further states that slope factors can be derived from drinking water unit risks, if needed. This is in error and unnecessary, because slope factors are derived from toxicological data and unit risks are derived from slope factors. 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.

Section 3.3.3 – Toxicity Equivalence Factors for Dioxins, Furans, and PCBs and Relative Potency Factors for cPAHs (p. 22): 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. ADEC's proposed approach requires that risk assessors adopt and use the draft relative potency factors that EPA presented in Development of a Relative Potency Factor (RPF) Approach for Polycyclic Aromatic Hydrocarbon (PAH) Mixtures (2010). In addition to the changes in the toxicity of PAHs relative to benzo(a)pyrene, the EPA's draft 2010 approach makes it requisite to increase the number of potentially carcinogenic PAHs included in risk assessments from 7 to 26 PAHs. However, the EPA has been criticized by industry, other federal agencies (including the National Aeronautics and Space Administration and Department of Defense), and EPA's own Science Advisory Board for not effectively documenting the basic scientific principles underlying the draft 2010 RPF approach. For instance, EPA has been criticized for not conducting or including in its documentation the following items:

1) A Weight of Evidence evaluation as required by EPA's 2005 Guidelines for Carcinogen Risk Assessment.

2) A demonstration that the PAHs included in the draft approach act by a similar mode of action.

3) A demonstration that PAHs show dose additivity.

4) An evaluation of other toxicity studies that exceeded that maximum tolerated dose in the RPF derivation of PAHs.

5) A validation of the derived RPFs using cancer response data from real world complex mixtures.

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.

Section 3.3.4.1 -- Lead (pp. 23-24): 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 clean up level that is demonstrated and properly documented. The effect of the proposed change would be to impose an alternative clean up level for lead even where the science demonstrates that the clean up level is not necessary to protect public health. Accordingly, the use of a default clean up 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.

Section 3.3.5 -- Types of Exposures: Chronic, Subchronic, and Acute (pp. 24-25): 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. All differences in exposures (the daily exposure amount, the frequency of exposure, and the duration of exposure) are already explicitly addressed in ADEC's default exposure parameters in Table 1. Any differences in toxicokinetics and toxicodynamics are explicitly addressed by the use of the intraspecies uncertainty factor of 10 in the derivation of both chronic and subchronic Reference Doses. Thus, there is no scientific basis for using a chronic toxicity value for a child subchronic exposure.

ADEC further states that subchronic toxicity factors "may not be derived from chronic toxicity values using additional uncertainty factors based on the study used to develop the chronic toxicity value." This

directive which appears in the proposed RAPM as well as the draft 2011 RAPM, deviates from the 2000 RAPM, which explicitly allowed risk assessors to derive subchronic values: "For subchronic effects, toxicity values should be changed from standard protocol to reflect the shorter exposure duration." However, ADEC now appears to ignore the fact that many chronic toxicity factors are derived from subchronic studies by the application of a ten-fold uncertainty factor to convert subchronic toxicity factors into a chronic toxicity factors. ADEC should allow risk assessors to utilize the original subchronic toxicity factor before it was converted into a chronic one.

Sections 3.4.1 -- Carcinogenic Risk (p. 26) and 3.4.2 -- Noncarcinogenic Risk (p. 27): 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. Risk assessment results are overly conservative, but imprecise values. As an example, there are no differences between cancer risks of 1.7E-6 and 2E-06. Adding additional significant figures is unnecessary and misleading. 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. (NRC. 1994. Science and Judgment in Risk Assessment).

Section 3.4.2 -- Noncarcinogenic Risk (p. 27): ADEC states that the evaluation will be performed using a hazard quotient ("HQ") and hazard index ("HI") approach. ADEC recognizes that non-carcinogenic compounds can induce "toxicity by acting on different target organs or systems by different mechanisms" and "that 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)" (emphasis added). 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. The organs of the immune system include the thymus, bone marrow, spleen, lymph nodes, and others. An adverse effect on the immune system can be noted by effects on these organs or also on effects that result from organ damage, like modifications to the numbers of circulating lymphocytes or a decrease in number of antibody forming cells against sheep red blood cells in male mice. Similarly, chemicals can adversely affect the nervous system and manifest the damage in different ways. 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. Another example is the reproductive endpoint grouping. Some RfDs are based on "reproductive toxicity," changes in sperm count or sperm motility, or adverse effects in the testes. These chemicals should all be grouped to derive a HI for male reproductive effects. Accordingly, ADEC should

change this section to allow for endpoint specific groupings consistent with EPA guidance as cited in the proposed RAPM.

Also in this section, ADEC omits a critical discussion on additivity by deleting from the 2011 Draft RAPM the following sentences: "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, and the sentences should be included, or at a minimum, ADEC should thoroughly explain why they have been removed.

Section 3.4.3 -- Cumulative Risk (pp. 27-28): 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" (emphasis added). 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.

Section 3.4.4 -- Development of Alternative Cleanup Levels (p. 28): 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.

Section 3.4.7 -- Uncertainty in the Exposure Assessment (p. 29): ADEC has added a provision about uncertainty analysis that is not in the 2000 RAPM or the draft 2011 RAMP. ADEC states: "there is a level of uncertainty with estimating the exposure point concentration from measurements (rather than if it is a calculated UCL or maximum detection) or from results of modeling." Given that exposure point concentrations must be UCLs or maximum detections, ADEC should clarify what this statement means.

Section 3.4.8 -- Uncertainty in the Toxicity Assessment (p. 29): 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.

4. Section 4.0 Ecological Risk Assessment

Section 4.1 -- ERA Process in Alaska (p. 30): This section illustrates the impact of the universal change to "must" from "should," including statements such as "the process must result in a decision point" and "the ERA process must continue," which are inappropriately worded as "must" statements. ADEC should revise these statements.

Section 4.1.2 -- Preliminary Screening Evaluation -- Step 2 (p. 31): ADEC references "acceptable conservative screening values" provided in the "Risk Assessment Information System" without providing a citation to this resource. ADEC should make the source of these values clear and direct risk assessors in how to access the resource.

Section 4.2.2 -- Ecological Conceptual Site Models (p. 33): 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." It is unclear why this factual statement was deleted. ADEC should provide a thorough explanation for the proposed deletion.

Section 4.3.1.2 -- Selection of Compounds of Potential Ecological Concern (pp. 37-38): ADEC added Log K_{ow} > 3.5 as a criterion to define a bioaccumulative compound without providing a reference for it. As noted above, this criterion is more stringent than the other criterion, a measured BCF of 1,000 and, therefore, is not scientifically appropriate.

Section 4.3.4 -- Bioaccumulation and Field Tissue Residue Studies (pp. 41-42): 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.

Section 4.4 Risk Characterization (p. 42): Among the factors that "must" be evaluated in the risk assessment are: "The quality of data and study design used from the *extrapolated* studies" (emphasis added). This appears to be an error in editing, as the 2011 Draft RAPM referred to "*key* studies."

ALASKCHEM Engineering
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phone (907)746-4587; email hulbert@alaska.net

August 10, 2015

Via email: Sally.Schlichting@alaska.gov

Sally Schlichting
Alaska Department of Environmental Conservation
410 Willoughby Ave., Suite 303
P.O. Box 111800
Juneau, AK 99811-1800

Re: Proposed Changes to 18 AAC 75 and Risk Assessments

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.

All the public asked of DEC regarding contaminated sites is to do more good than harm:

Sec. 46.09.020. Containment and cleanup of a released hazardous substance.
(a) A person who causes a release of a hazardous substance shall make reasonable efforts to contain and clean up the hazardous substance promptly after learning of the release, unless the commissioner determines
(1) after consulting the Environmental Protection Agency or appropriate public safety agencies, that containment or cleanup is technically infeasible;
(2) that containment or cleanup would cause greater environmental damage than if the release were not contained or cleaned up; or
(3) that containment or cleanup would pose a greater threat to human life or health than if the release were not contained or cleaned up.

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.

It is easy to see why many site remediations cause far greater health risks than no action. The best example is CSP's migration to groundwater soil cleanup level for diesel range organics (DRO), intended to protect individuals from drinking diesel contaminated water. There have been over 5000 diesel spills (the most common contaminant) reported to DEC, with many more unreported. Although groundwater has been contaminated, the CSP reports no active drinking water well in Alaska with contamination exceeding DRO limits. Regardless, the typical required cleanup of excavation, long distance transport, thermal remediation, and restoration costs several thousand dollars and creates mortality risks far exceeding no action.

The "risk management decisions that must be made by ADEC" (RAPM p2) logically would quantify and compare the harm caused by contamination (RAPM, etc.) and the harm/good of mitigation options; the least harmful option could be readily selected. Ideally, comparisons would use a probabilistic common metric or at least common sense.

In essence, the statues 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.

For instance, in 2006 the CSP proposed regulating propylene glycol (PG) to <1/5 the DRO soil cleanup level – the same antifreeze found in foods, used for winterizing potable water systems, and for deicing airplanes. The listing was buried amongst 55 newly listed chemicals; it was posted only on the CSP web page with no attempt to consult affected agencies or user groups. These new chemicals were claimed to result from updates to EPA's peer reviewed IRIS database, but many were not. The attached email thread describes researching the derivation of the provisional PG limit and the discovery that its listing had expired with no current support. The CSP had not seen the listing but claimed the derived PG value (for cats) was valid. Public uproar about safety resulted in the CSP withdrawing the proposed PG regulations – classic common sense probabilistic risk management trumping deterministic risk assessment.

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 fiasco, or even referenced the toxicity data source for each chemical.

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.

Comprehensive risk management guidance is unlikely in the near future. Simply acknowledging that risk management is a statutory requirement will free the CSP site managers to apply the collective common sense acquired in the past three decades. The public will be grateful.

Thank you for your consideration.

Ralph Hulbert, P.E.

Att: email chain; propylene glycol PPRTV.pdf

Subject: transparency!! Fw: Fw: propylene glycol PPRTV
From: "Ralph Hulbert, AlaskChem Engineering" <hulbert@alaska.net>
Date: 7/6/2007 4:23 PM
To: "Powell, James E \(DEC\)" <jim.powell@alaska.gov>

Jim

Thanks for the call today, and the concurrence on the needs - and difficulty - in effecting greater transparency in regulations and guidance.

The following email thread, first entry at bottom, illustrates both. It covers my tracking down why propylene glycol (food additive, common airplane deicer, etc.) was on ADEC/CSP's new list of contaminants, with soil cleanup limits a fraction of that found in cake mixes. As far as I know, it's still on their list. Generally, the most restrictive cleanup limit found in any of a half dozen or more lists is chosen, no matter what the credibility or original purpose.

Ralph

----- Original Message -----
From: Ralph Hulbert, AlaskChem Engineering
To:
Sent: Tuesday, February 13, 2007 6:23 PM
Subject: Fw: Fw: propylene glycol PPRTV

Tom

This Q&A with ADEC about PG dates from their public comment period last May, when I noted (among many other items) that their PG and EG limits made no sense and needed greater transparency to get any public confidence. They replied that all their proposed limits had the highest quality peer review. When questioned further, they gave IRIS as the first list, as does everyone, and PPRTV as the second tier; PG was not listed on either. The following email thread is my chase for the original PPRTV basis, since it had been withdrawn.

I don't think such ill-conceived screening limits should be used as basis for even more conservative cleanup limits, at least without a little more public scrutiny, especially for a widely used chemical commonly applied to the ground for life/death safety issues.

Call me, give me insights please.
Ralph
746-4587

----- Original Message -----
From: Ralph Hulbert, AlaskChem Engineering
To: Crapps, Earl ; Janes, Bill
Sent: Thursday, February 08, 2007 1:20 PM
Subject: Fw: Fw: propylene glycol PPRTV

Bill and Earl

I finally was able to get a copy of the retired, unsupported, and otherwise unavailable PPRTV for propylene glycol (attached). Given the preponderance of contrary human empirical evidence, it is easy to see why it never made IRIS status and EPA retired it.

I also found some clues as to why it is still listed by some regions - they apparently rely on the RAIS database, which is the very convenient web page at EPA. Fred's comments below are quite amusing, and severely damage credibility of relying on any secondary database, even if EPA listed.

Few other listed chemicals have such obvious "safe" exposure gulf between human empirical evidence and the listing reference. Perhaps the basic process of listing chemicals by the CSP, or the use of such lists, needs to be changed. For instance, low-quality high-bias dosage or media levels (PPRTV) are tolerable for screening only but not for setting remediation goals. CERCLA has such distinction, but the CSP uses only screening quality dosage and exposure models to set mandatory cleanup levels.

Hope to see you at the Forum,
Ralph

----- Original Message -----
From: Fred Dolislager
To: Ralph Hulbert, AlaskChem Engineering
Sent: Thursday, February 08, 2007 10:44 AM
Subject: Re: Fw: propylene glycol PPRTV

Dear Ralph,

I'm glad I could enlighten you.

As to why the RAIS has values.....we are not a government web site. We do whatever our sponsor wishes us to do. Our sponsor is currently Bechtel Jacobs Inc. LLC. Our toxicity selection process is up to them. They like to have everything. We typically will retain a withdrawn value as well and add a footnote so the user knows it's withdrawn. Because the RAIS is not supposed to have PPRTVs anyway, we can't add a footnote that says, this is an archived PPRTV. BTW, most PPRTVs are 5 years and out then they have to be reinstated. The PPRTV people are on the verge of making the PPRTVs public and also reinstating all the archived papers. There are more archived papers than there are currently listed. Archived only happens based on time and not merit. Many decent values get archived.

You are more than welcome to use a FDA daily allowance number in your risk numbers. I've done it before.

If your company/agency wanted to sponsor the RAIS, you might be surprised at how cheap we could be had. :-)

Also, we sit in Region 4 and follow most of their guidance because or client is in R4. R4 will soon be releasing new guidance and the RAIS will adapt.

Contact me with any questions,

fred d.

At 02:18 PM 2/8/2007, you wrote:

Fred

Ahah! Maybe now I see where the PG limits originated. Page 17 of the PPRTV for PG shows how the oral RfD for human ingestion of PG was derived. This chronic RfD of 0.5 mg/kg-d cited in RAIS became the controlling factor for some CERCLA regions and states lists regulating PG contaminated soil. My perhaps naive observations include:

- One small study of cats (Bauer, 1991) found some "minimally adverse" effects and suggested the LOAEL. Although all other studies with more applicable species indicated much greater tolerance to PG and higher LOAELs, the lowest LOAEL was selected.
- This one study has moderate intrinsic uncertainty and high uncertainty for application to humans. The higher the uncertainty (UF) in the data quality, the lower the RfD (RfD = LOAEL/UF). This explains why the known toxic ethylene glycol with low uncertainty (many cadavers) with a much lower LOAEL ends up with a much higher RfD than PG.
- By extension, a chemical causing very minimal adverse effects to cats but with almost no application to humans would result in a near zero RfD.
- Meanwhile, the FDA recognizes PG as safe for foods, and estimates per capita PG consumption of 14 mg/kg-d.

While it's obvious why PG is not listed on IRIS, with apparent reasons why this PPRTV is retired and no longer supported by headquarters, it is unclear why and how the RfD etc. is still listed on RAIS. Could you please comment?

Thanks for your help,
Ralph

> ----- Original Message -----
> From: Fred Dolislager
> To: Ralph Hulbert, AlaskChem Engineering
> Sent: Thursday, February 08, 2007 5:07 AM
> Subject: Re: Fw: propylene glycol PPRTV

Hi Ralph,

Don' tell Dave where you got it!

fred d.

Fredrick Gary Dolislager
The University of Tennessee
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http://web.utk.edu/~dolislag/

At 12:00 AM 2/8/2007, you wrote:

Mr. Dolislager

As illustrated in the threads below, I am trying to find the basis for EPA's listing of propylene glycol, specifically in the RAIS database. It is not listed in IRIS and Dave Crawford indicates the PPRTV for PG is currently retired and not supported by Superfund headquarters, and no supporting documentation for its initial listing can be found. Regions 3 and 6 also have no reason for its listing. The RAIS webpage lists PG without source reference.

This is critical in Alaska where the ADEC has proposed a soil cleanup limit of 5 mg/kg for PG (magnitudes lower than found in many foods), despite widespread use of PG for airplane and road deicing, besides potable water system freeze protection. This limit (lower than the more toxic EG listed on IRIS) is derived from the 18 mg/L drinking water standard listed as a RAIS PRG. ADEC assumed RAIS's listing came from a supported PPRTV, but where did the RAIS value for PG come from? Can you please provide references to the original peer reviewed sources or secondary sources for the RAIS listing?

Thanks,
Ralph Hulbert

----- Original Message ----- From: <Hubbard.Jennifer@epamail.epa.gov>
To: "Ralph Hulbert, AlaskChem Engineering" <hulbert@alaska.net>
Cc: <Overstreet.cheryl@epa.gov>
Sent: Tuesday, February 06, 2007 9:20 AM
Subject: Re: propylene glycol PPRTV

I oversee the Region 3 RBC table, which has no listing for propylene glycol. We only have listings for the monoethyl ether (based on a HEAST RfD) and mmomethyl ether (based on a HEAST RfD and IRIS CSF). Since our table is produced to support the Superfund program, and we have not had a Superfund site with propylene glycol, we have not needed to obtain a provisional number and I have no files on this chemical.

ATSDR has a Minimum Risk Level for propylene glycol, but it is an inhalation number, at http://www.atsdr.cdc.gov/mrls.html

You might try California EPA, which derives its own numbers for a wide range of chemicals.

"Ralph Hulbert, AlaskChem Engineering" hulbert@alaska.
To Jennifer Hubbard/R3/USEPA/US@EPA net>

cc Cheryl Overstreet/R6/USEPA/US@EPA
02/06/2007 01:08 PM
> Subject propylene glycol PPRTV

Jennifer

I am trying to find the basis for various Regions listing of propylene glycol as a CoC with resulting soil screening levels. According to Dave Crawford (see thread, below), headquarters has retired the PPRTV for glycol, the only known basis for listing it as a CoC, but Regions are free to use whatever they like. He could not provide any backup for its original listing.

Here in Alaska, the ADEC recently proposed regulating PG, citing Region 10 which relies on Region 6; the proposed soil cleanup (not screening) level is 5 mg/kg based on the migration to groundwater pathway. Cheryl Overstreet, Region 6, could not locate the PPRTV files either, but noted their residential soil screening level is much higher, 30,000 mg/kg. She offered to forward the Region 6 url for screening levels, and suggested I contact you for PPRTV listing documentation.

Since we use PG widely for many deicing applications, we need to rationally evaluate its potential toxicity. Can you help?
Thanks,
Ralph
907/746-4587

----- Original Message -----
From: <Crawford.Dave@epamail.epa.gov>
To: "Ralph Hulbert, AlaskChem Engineering" <hulbert@alaska.net>
Sent: Friday, December 01, 2006 3:11 AM
Subject: Re: pprtv listing basis for propylene glycol

Ralph, here's the deal on this. In the past, PPRTV assessments had a 3-year shelf life, after which we retired them and no longer supported their use. We are aware that some parties and states continued to use PPRTVs after they have been retired, but there is not much we (the EPA Superfund Program) can do about that. Some of the confusion about this in the future will be eliminated because we will no longer simply be retiring PPRTV assessments after 3 years, but instead reassessing them and reissuing them as new assessements. Nonetheless, the fact exists that there will still be some previously retired PPRTV assessments that some parties chose to continue to use. With respect to Propylene Glycol, we currently have no PPRTV assessment on this contaminant.

Dave Crawford
U.S. Environmental Protection Agency
Office of Superfund Remediation and Technology Innovation
telephone: 703-603-8891
email: Crawford.Dave@epa.gov

"Ralph Hulbert, AlaskChem Engineering" <hulbert@alaska.net>
To Dave.Crawford/DC/USEPA/US@EPA 11/30/2006 07:45 PM
Subject pprtv listing basis for propylene glycol

Dave
Propylene glycol is listed in RAIS, apparently based only on the PPRTV listings. IRIS does not list propylene glycol, but notes a "screening-level literature review findings message". The PPRTV

database and reference bases for listing are not web accessible.

Could you please provide all studies used as a basis for the PPRTV propylene glycol listing (or links to the data)?

I realize the PPRTVs were meant only for CERCLA screening, but several state agencies are quick to use them as cleanup limits. I'm confused, as other EPA sections maintain that PG is safe for the environment, and we find very high PG concentrations in food and medicine.

Thanks,
Ralph

Attachments:

PropyleneGlycol PPRTV.pdf 157 KB

August 11, 2015

Alaska Department of Environmental Conservation
Juneau, AK
ATTN: Ms Sally Schlichting

Subject: Comments- Proposed Changes to 18 AAC 75 (site cleanup Rules) and Risk Assessment Procedures Manual

Dear Ms Schlichting:

I 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.**

GENERAL COMMENTS

Multiple sets of proposed changes to the contaminated sites regulations have come out in the last year. The small incremental changing of the regulations is problematic because the small changes may not be fully reviewed before adoption, adoption of small changes cause consistency issues later on and insufficient evaluation of the proposed changes is not provided to the public.

A working group of individuals outside of ADEC should be tasked with making significant revisions to the ADEC regulations and Guidance documents.

I have discussed and reviewed the proposed changes with Larry Acomb of Geosphere, Inc and completely agree with his presentation of the concerns related to the proposed changes. These concerns are presented belwo.

Risk Assessment Procedures Manual

1. Section 3.1.4 .....regarding the selection of risk based screening levels and toxicity values:

The proposed RAPM text changes indicate 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. The proposed text includes the sentence "Initial screening for all sites must be.....with the most updated toxicity data". The proposed change does not describe if, or when the screening levels or toxicity values become locked in (otherwise, the screening criteria and the risk calculations could be a moving target). Are the screening criteria and toxicity values locked in or frozen when the risk assessment work plan is submitted, when the work plan is approved, when the screening is conducted, or when the risk assessment is approved?

2. Table 1 Summary of Default Exposure Factors:

Changes to the default exposure factors in the RAPM should be accomplished as part of an integrated program, and at the same time as, the exposure factors used in the Method Two default cleanup level calculations are updated. There should not be different default exposure factors in the RAPM than used for the Method Two cleanup level calculations. 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 per year in southcentral and interior Alaska? That would mean residents wearing shorts and tee-shirts are working and/or playing in the soil in their yards every day from March 1 to November 30).

3. Section 3.2.3 Calculating Exposure Point Concentrations....regarding the Exposure Area text block:

The proposed changes to the exposure area text deletes 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. I think it is valuable to keep the residential lot concept (½ acre or even an 1/8th of an acre) in the manual. Individual samples or small groups of samples are not exposure areas. In addition, the proposed definition of the source area is not helpful because it confuses the source area with the downgradient dissolved phase plume (residents may be exposed to the downgradient dissolved phase plume, but the downgradient dissolved phase plume should not be considered part of the source area). This text needs more work, and real world examples are recommended to support and clarify the text (e.g. case studies with maps, data tables and text saying this is the exposure area and this is the source area). I think that the solution to this problem should involve input from environmental professionals (consultants & RPs) outside ADEC in a working group format.

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. This text needs more work and real world examples to support and clarify the text and describe how ADEC proposes to resolve these issues (e.g. case studies with maps, data tables and text). I think that the solution to this problem should involve input from environmental professionals (consultants & RPs) outside ADEC in a working group format.

4. Section 3.2.3 Calculating Exposure Point Concentrations....regarding the Exposure Area text block:

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"?)

5. Section 3.2.3 Calculating Exposure Point Concentrations....regarding the Exposure Point Concentration text block:

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. I worked at a site where there were several relatively high concentration results from a relatively small portion of the site (small compared to the size of the source area and small compared to a residential lot or even half of a residential lot). ADEC expressed concern that the hot spot was being "diluted out", when I think that by including multiple high results from a small portion of the site, the small portion of the site was being over emphasized in the 95% UCL calculation (i.e. the sampling was not geospatially representative – it was biased high). This text needs more work and real world examples to support and clarify the text and describe how this potential problem should be addressed (e.g. case studies with maps, data tables and text). I think that the solution to this problem should involve input from environmental professionals (consultants & RPs) outside ADEC in a working group format.

6. 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 old text is not specific about how the bulk hydrocarbon risks are to be calculated and presented, but the obvious default assumption, is that the bulk hydrocarbon risk would be calculated and presented using the same approach that ADEC used, when ADEC was developing the Method Two cleanup levels. The acceptability of the ADEC Method Two bulk hydrocarbon risk calculation approach was validated when ADEC approved the hydrocarbon risk calculator for Method Three and Four.

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.

- As written, there is not enough documentation of the proposed change to implement the change – that is, the above equations are only partially complete. They need to say, for example, how the GRO aliphatic risk is calculated and how the GRO aromatic risk is calculated (what pathways are included, what equations are used/acceptable, and what assumptions are used?).

- If the proposed change is implemented, it will create a significant, fundamental difference in the way bulk hydrocarbon risk and cleanup levels are calculated under Method Four versus under Methods Two and Three. Is ADEC planning to change the bulk hydrocarbon calculation approach under Methods Two and Three "for consistency" in the near future? If yes, then the proposed RAPM changes should be part of the ADEC integrated package and not presented as piecemeal changes. If the ADEC is not planning on proposing changes to the way bulk hydrocarbon risk is calculated under Methods Two and Three, then why change the Method Four calculation approach? Is the proposed change to make the use of Method Four undesirable for hydrocarbon sites?

- As stated above, the proposed change in the bulk hydrocarbon risk calculation approach results in significantly lower, more conservative cleanup levels. I evaluated the impact of the proposed calculation approach on 41 separate hydrocarbon contaminated sites which meet the ADEC risk standard using the bulk hydrocarbon risk calculation approach used by ADEC in developing Method Two cleanup levels. I found that 21 of the 41 sites (over 50% of the sites evaluated) which currently meet the risk standard, would exceed the risk standard using the proposed new calculation approach. Clearly the cost (tens of millions; maybe a hundred million dollars if implemented for Methods Two and Three, in addition to Method Four?) and cost-benefit of adopting the proposed change needs to be fully assessed before implementing the change.

Sincerely,

Ahtna Engineering Services, LLC

John Spielman
Program/Project Manager

U.S. Department
of Transportation
**Federal Aviation
Administration**

11 August 2015

ADEC
Attn: Sally Schlichting
410 Willoghby Ave, Suite 303
PO Box 111800
Juneau, AK 99811-1800

Subject: Comments on Proposed Changes to Risk Assessment Guidance.

Dear Ms. Schlichting:

The Federal Aviation Administration (FAA) is submitting the following comments on the proposed changes to Title 18, Chapter 75 of the Alaska Administrative Code (18 AAC 75).

The FAA is struggling with the process that the State is using for changes to their regulations and guidance documents. The professional staff at the FAA 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. The FAA believes 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).

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.

Sincerely,

Lance Raymore For
Bradley Platt
Manager, Operations Infrastructure Engineering Center B

Geosphere, Inc.

Lawrence Acomb • 3120 Legacy Drive • Anchorage, Alaska • 99516

Date: August 5, 2015

To: ADEC
Juneau, Alaska

Attn: Ms. Sally Schlichting

Re: Comments on Proposed Modifications to 18 AAC 75 (Site Cleanup Rules) and Risk Assessment Procedures Manual

Dear Ms. Schlichting:

I reviewed the proposed changes to the ADEC site cleanup regulations and the risk assessment procedures manual (RAPM) and I am providing comments on the proposed changes. Note that the comments are relatively brief and focus on what I see as the most important proposed changes. The most significant conclusion drawn from my review is that **the proposed regulation package should not be adopted**.

General comments:

1. 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.
2. There is not enough discussion of the changes and there are no examples of the changes to understand how the proposed changes will work. Requests for examples are provided in my detailed comments.
   Note that in the recent past there have been very significant differences in what I (and multiple colleagues) think the regulations say and what ADEC thinks the regulations say. Consequently, 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.
3. Several proposed changes identify an issue but don't provide information on how to analyze or resolve the problem.
4. There is not an assessment of the impact of the proposed regulation changes.
5. 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).

18 AAC 75 Oil and Other Hazardous Substances Pollution Control

1. 325(h).....change to acceptable risk range, and 340(f)....change in the date of the risk assessment procedures manual.
   There is not a need to revise 18 AAC 75 at this time because the revisions to the risk assessment procedures manual should not be adopted.

Risk Assessment Procedures Manual

1. Section 3.1.4 .....regarding the selection of risk based screening levels and toxicity values:

   The proposed RAPM text changes indicate 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. The proposed text includes the sentence "Initial screening for all sites must be.....with the most updated toxicity data". The proposed change does not describe if, or when the screening levels or toxicity values become locked in (otherwise, the screening criteria and the risk calculations could be a moving target). Are the screening criteria and toxicity values locked in or frozen when the risk assessment work plan is submitted, when the work plan is approved, when the screening is conducted, or when the risk assessment is approved?

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piecemeal changes. If the ADEC is not planning on proposing changes to the way bulk hydrocarbon risk is calculated under Methods Two and Three, then why change the Method Four calculation approach? Is the proposed change to make the use of Method Four undesirable for hydrocarbon sites?

- As stated above, the proposed change in the bulk hydrocarbon risk calculation approach results in significantly lower, more conservative cleanup levels. I evaluated the impact of the proposed calculation approach on 41 separate hydrocarbon contaminated sites which meet the ADEC risk standard using the bulk hydrocarbon risk calculation approach used by ADEC in developing Method Two cleanup levels. I found that 21 of the 41 sites (over 50% of the sites evaluated) which currently meet the risk standard, would exceed the risk standard using the proposed new calculation approach. Clearly the cost (tens of millions; maybe a hundred million dollars if implemented for Methods Two and Three, in addition to Method Four?) and cost-benefit of adopting the proposed change needs to be fully assessed before implementing the change.

As stated previously, I am opposed to adopting these regulation changes. I hope my comments are useful. Should you have any questions, please contact me at (907) 345-7596 or at acomb@ak.net.

Sincerely,

Lawrence J. Acomb
Geosphere, Inc.

DEPARTMENT OF THE AIR FORCE
REGIONAL ENVIRONMENTAL COORDINATOR, REGION 10
50 Fremont Street, Suite 2450; San Francisco CA 94105

27 July 2015

Alaska Department of Environmental Conservation
410 Willoughby Ave., Suite 303
P.O. Box 111800
Juneau, AK 99811-1800

Subject: Proposed Changes to 18 AAC 75.325(h) and 75.340(f)

Dear Ms. Sally Schlichting:

I am the Department of Defense (DoD) Regional Environmental Coordinator within EPA Region 10 and represent the military interests of the Services and installations on environmental matters within those states, to include Alaska. I am responsible for coordinating responses to various environmental policies and regulatory matters of interest. The DoD appreciates the opportunity to provide comments on the Alaska Department of Environmental Conservation proposal to adopt regulation changes in Title 18, Chapter 75 of the Alaska Administrative Code, dealing with how risk is calculated and risk assessments are performed.

DoD and Alaska have a long and proud history of cooperation; the military installations and training range areas within the state are crucial to DoD's worldwide mission. Alaska offers vital capabilities for sustainable military readiness training for our service members. The military presence in Alaska includes over 33,000 active duty military, Reserve, National Guard, and civilian employees, with expenditures close to $4.9 billion. Alaska's military installations are confronted with numerous challenges. Our installations, inland and offshore training areas, airspace, and frequency spectrum requirements -- essential components to our missions -- face compatible-use and other environmental challenges.

We have outlined some specific comments in the attached comment pages for your consideration. The DoD remains committed to working with the State of Alaska and the Department of Environmental Conservation on environmental cleanup and other issues. Thank you again for this opportunity to provide comments on the proposed regulations. Please let me now if you have any questions or would like to discuss our comments in more detail. I can be reached at (415) 977-8846 or by email at robert.shirley.2@us.af.mil.

Sincerely,

ROBERT SHIRLEY
DoD Regional Environmental Coordinator
Region 10

Attachment:
DoD Comments on proposed revisions to 18 ACC 75.325(h)

General Comment: The Alaska Department of Environmental Conservation (ADEC) has proposed to revise regulation 18 AAC 75.325(h) to "Remove a reference to 40 CFR 300.430 [the National Contingency Plan (NCP)] and accompanying language that allows the department to consider an alternative cancer risk standard between 1 in 10,000 (1 x 10-4) and 1 in 1,000,000 (1 x 10-6) on a site specific basis at a contaminated site during a formal risk assessment. The intended effect of this change is to ensure continued use of the currently adopted cancer risk standard of 1 in 100,000 (1 x 10-5) for all site specific risk assessments" which is not consistent with the NCP and conflicts with state law.

Specific Comments:

1. The proposed change to regulation 18 AAC 75.325(h) does NOT comply with ADEC's statutory authority. Alaska Statute, AS 46.09.020 [Containment and Cleanup of a Released Hazardous Substance] provides: "The commissioner shall develop guidelines prescribing general procedures and methods to be used in the containment and cleanup of a hazardous substance. The guidelines shall be consistent with the national contingency plan revised and republished under 42 U.S.C. 9605." However, the NCP provides that acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10−4 and 10−6, and does not limit excess cancer risk to 1 x 10 -5.(See 40 CFR Section 300.430(e)(2)(i)(A)(2*)*). Accordingly, the Department's proposal would violate a governing state mandate in that it would be inconsistent with the NCP's acceptable cancer risk range.

2. 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? The NCP specifies "in cases involving multiple contaminants or pathways where attainment of chemical-specific ARARs will result in cumulative risk in excess of 10−4, criteria in paragraph (e)(2)(i)(A) of this section may also be considered when determining the cleanup level to be attained." (See 40 CFR Section 300.430(e)(2)(i)(D)). Again, this change would directly conflict with the NCP and controlling state statutory direction.

3. Alaska Statute AS 46.04.070 [Scope of Regulations] specifies "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?

4. 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?

Citations to CERCLA and the NCP follow below the dashed line-

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CERCLA:
42 U.S.C. Section 9605 National Contingency Plan-
"(a)... the President shall, ... revise the and republish the national contingency plan, [...] Such revision shall include a section of the plan known as the national hazardous substance response plan which shall establish procedures and standards for responding to releases of hazardous substances, pollutants, and contaminants, [...]"

National Contingency Plan (NCP):
40 CFR Section 300.430(e)(2)(i)
"(A) Applicable or relevant and appropriate requirements under federal environmental or state environmental or facility siting laws, if available, and the following factors:
(1) For systemic toxicants, acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, incorporating an adequate margin of safety;
(2) For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10−4 and 10−6 using information on the relationship between dose and response. The 10−6 risk level shall be used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure;

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