

**ADEC, Division of Spill Prevention and Response**  
**Proposed Amendments to 18 AAC 75 concerning how risk is calculated and risk**  
**assessments are performed**  
**Reponses to questions received during the public comment period-**  
**June 10, 2015 to August 11, 2015**

**1) What prompted this proposed change?**

There are two primary reasons for the proposed changes – the first reason was the need to update our risk assessment process. The current version of the department’s *Risk Assessment Procedures Manual* (RAPM) was last adopted into regulation in 2000; thus it is outdated. 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 as well as current risk assessment practices in general.

The second reason is related to the current wording in 18 AAC 75.325(h) that allows the department to consider carcinogenic risk standards consistent with 40 CFR 300.430. That risk range,  $1 \times 10^{-4}$  to  $1 \times 10^{-6}$ , allows for an option to consider a less stringent risk standard than the department’s carcinogenic risk standard of  $1 \times 10^{-5}$ . This provision has never been invoked since 1999 when it was adopted. Removing that wording from our regulations removes a potential question as to whether state cleanup standards are applicable and relevant or appropriate requirements under CERCLA and ensures a consistent risk standard at all sites. Additionally, since first responding to this question, we want to clarify that it does not change the state’s authority to consider a higher risk standard or to approve remedies that include appropriate engineering and institutional controls to achieve the  $1 \times 10^{-5}$  risk standard.

**2) What are the implications of this for cleanup standards at contaminated sites?**

The carcinogenic risk standard of 1:100,000 is consistent with cleanup values in the regulation tables and also establishing alternative cleanup values. The risk range,  $1 \times 10^{-4}$  to  $1 \times 10^{-6}$ , allows an option to consider a less stringent risk standard than the department’s carcinogenic risk standard of  $1 \times 10^{-5}$ . There is no implication for contaminated sites since the 1:100,000 standard is, and has been, consistently used, however; the state does have flexibility to approve remedies or alternative cleanup levels at sites where institutional and engineering controls are incorporated as part of the remedy in order to meet the risk standard.

**3) What justification is there for the proposed change?**

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

toxicological sources is important for the department to effectively regulate the investigation and cleanup of emerging and other new contaminants.

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

**4) How is the risk calculated to be 1:100,000 as an “acceptable” risk?**

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

**5) Why should the risk standard be 1:100,000 compared with 1:1,000,000?**

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

**6) How can the public be assured that this standard is protective of human health?**

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

**7) What is the accompanying “non-cancer” risk standard?**

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

**8) Does the ADEC have a summary of proposed changes comparing the 2015 RAPM document with the 2000 RAPM document, and is there a redline-strikeout version of the 2015 RAPM?**

ADEC posted a side-by-side summary of the changes from the 2000 version to the 2015 version of the RAPM in response to this comment during the public comment period. ADEC could not

provide a redline-strikeout version of the 2000 RAPM with 2015 changes because the changes were so extensive it would be unreadable.

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

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

**10) 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?**

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

**11) 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 ( $1 \times 10^{-5}$ ) would trigger the necessity to take cleanup action? Also, is ADEC asserting that cleanup is required if cumulative cancer risk exceeds  $1 \times 10^{-5}$  when there are multiple contaminants and/or pathways?**

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

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

The updates to the risk assessment procedures are mainly associated with updates to the science on exposure. New assessment procedures are included to more accurately and comprehensively

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