

Human Health Risks In Setting Sediment Cleanup Standards

Issue

What Sediment Management Standards (SMS) rule revisions (if any) are needed to provide clear and predictable sediment cleanup standards that protect human health at contaminated sediment sites?

Overview

The intent of cleanup requirements in the [MTCA](#) and [SMS](#) rules is to protect human health and the environment. However, differences in the two rules make it unclear how to consider human health when setting sediment cleanup standards at cleanup sites. These differences include:

- **How cost and feasibility are considered in the cleanup process.** The SMS allows cost and feasibility to be considered when setting sediment cleanup standards, as well as in the remedy selection process. Cost is not considered when setting cleanup standards in the MTCA rule, but is considered during the remedy selection process.
- **How to determine acceptable levels of human health protection.** The MTCA rule has specific acceptable risk levels and procedures to protect human health for both soil and water contamination. The SMS, however, has narrative criteria that generally require “no significant human health threats” from sediment contamination.
- **How background concentrations of chemical contaminants are considered** when setting sediment cleanup standards, and how background is defined for sediments.

To clarify how to address human health risks when setting sediment cleanup standards, Ecology is considering revisions to the SMS rule. This paper discusses how and why Ecology is considering clarifying and harmonizing the two rules to protect human health from sediment contamination. As part of this evaluation, Ecology is considering a number of options related to:

1. How the decision for sediment cleanup standards will be made.

- Whether cost and feasibility will be considered when setting sediment cleanup standards, as well as in remedy selection.

- Whether sediment cleanup requirements will have the same level of human health protection as MTCA.
 - How background will be used in setting sediment cleanup standards, and how it will be defined.
 - What exposure pathways are significant for sediment sites.
- 2. The technical and procedural details for setting sediment cleanup standards.**
- What process will be used for setting sediment cleanup standards based on human health.
 - Will exposure equations be used to calculate risks to human health, or does enough information exist to develop tissue or sediment standards.
 - What are appropriate background reference locations and procedures for evaluating data.

Not all parts of the issue may be addressed in rule revision at this time. Some elements may be addressed through guidance. Some elements may be addressed in future rule revision processes.

Problem Statement

History

Ecology published the SMS rule in 1991. At that time, Ecology acknowledged the need for clearer requirements for human health protection and began to work on several technical and policy tasks to support rule amendments on that issue. Ecology initiated a process to amend the SMS rule in 1997. The 1997 process for rule amendments was highly controversial and Ecology halted the rulemaking process in 1999.

Several relevant scientific and regulatory developments have occurred since that time. These developments include extensive amendments to the Model Toxics Control Act (MTCA) rule in 2001 to clarify risk policies and define “Reasonable Maximum Exposure.” New information and guidance documents that are relevant to human health protection have recently been published by other agencies.

Current Approach for Evaluating Human Health Protection.

The SMS at 173-204-570 WAC identifies the sediment cleanup objective as “no significant health threat to humans.” However the SMS does not have details on how this objective should be accomplished.

Currently sediment cleanup standards to protect human health are decided based on the MTCA rule. The approach described in the MTCA rule includes a site-specific analysis of all potential [exposure pathways](#) in each [medium](#) based on current and future potential

land use. A cleanup level¹ (cleanup standard) is calculated that protects reasonable maximum exposure of any receptor at acceptable risk levels.

The acceptable risk levels described in the MTCA cleanup rule are:

- One in one million (1×10^{-6}) for any one carcinogenic chemical and single exposure pathway.²
- One in one hundred thousand (1×10^{-5}) for all of the carcinogenic chemicals combined and multiple exposure pathways.
- A hazard index of 1 for multiple non-carcinogenic chemicals and/or multiple exposure pathways.

The current approach for calculating sediment cleanup standards is to use the MTCA rule cleanup level¹. This is the highest of any of the following:

- The lowest concentration, based on the risk level and hazard quotient as described above, for the most sensitive receptor.
- Natural background – a background area not influenced by “localized human activities.”
- Practical quantitation limit – the lowest concentration that can be reliably measured within specified limits of precision and accuracy.

Calculating risk-based sediment cleanup standards is often based on the U.S. Environmental Protection Agency (EPA) exposure equations.³ Site-specific parameters may be developed for these exposure equations.

In some cases, the MTCA rule does allow a higher cleanup standard of one in one hundred thousand (1×10^{-5}) excess cancer risks for single or multiple chemicals at a site in groundwater, surface water or air. In this case, MTCA Method C may be used if it is not technically possible, regardless of cost, to meet the cleanup standards of MTCA Methods A or B.⁴ MTCA Method C may also be used for soil at industrial sites.

The MTCA rule does not consider cost when setting cleanup standards. In cleanup sites on land, there is more flexibility in achieving the cleanup standards because of institutional controls that can limit exposure, and having points of compliance at the edge of the site. These controls are difficult to implement at sediment sites, so there is less flexibility.

¹ The MTCA term of *cleanup level* is roughly equivalent to the SMS term of *sediment cleanup standard*, meaning the concentration that must be achieved to complete cleanup at the site. In MTCA, *cleanup standard* means a *cleanup level* with a point of compliance and all applicable ARARs.

² A 1×10^{-6} risk level means an estimated risk of one additional cancer above the background cancer rate per 1,000,000 individuals.

³ U.S. Environmental Protection Agency 1989. *Risk Assessment Guidance for Superfund Volume 1 Human Health Evaluation Manual (Part A)*. EPA Document EPA/540/1-89/002.

⁴ WAC 173-340-706 (1) (a) and WAC 173-340-706(2).

Differences between SMS and MTCA Rules for Human Health Protection

	MTCA Rule	SMS Rule
Decision-making framework	Cleanup standard is a single concentration.	Sediment cleanup standards are set within a range of concentrations.
Cost and feasibility consideration	Does not consider cost when setting cleanup standards. Costs are considered during the remedy selection phase.	Sediment cleanup standards are set within a range of concentrations, achieving concentrations as low as possible with consideration of cost and technical feasibility.
Media considered	Soil, surface water, groundwater, vapor.	Sediment
Pathways considered	Drinking water, fish consumption, direct contact (including incidental soil ingestion and dermal exposure), and inhalation.	None specified. When a sediment cleanup site takes human health into consideration, pathways are identified on a case-by-case basis.
Level of protection	<p>The MTCA rule <i>cleanup level</i> is the highest of either:</p> <ul style="list-style-type: none"> • Risk levels of 1×10^{-6} for any one carcinogenic chemical and single exposure pathway, and 1×10^{-5} for all of the carcinogenic chemicals combined and/or multiple exposure pathways, and a hazard index of 1 for multiple non-carcinogenic chemicals and/or multiple pathways. • <i>Natural background</i> • Practical quantitation limit. <p>For surface and groundwater, MTCA Method C allows a maximum of 1×10^{-5} total excess cancer risk from the site, without consideration of cost. For soils and air, Method C is only used at industrial sites.</p>	<p>Human health narrative states “no significant health risk to humans.”</p> <p>For cleanup standards based on benthic toxicity: Goal is “no effects.”</p> <p>Maximum of “minor adverse effects” when considering cost and feasibility.</p>

	MTCA Rule	SMS Rule
How level of protection is determined	Equations and default parameters for most single exposure pathways with a single contaminant. Some numeric criteria for simple sites (Method A).	Numeric criteria for 47 chemicals in Puget Sound – benthic invertebrates’ toxicity only. Not specified for other pathways or receptors.
How multiple exposure routes are evaluated	Assumed to be additive unless scientific evidence is available to demonstrate otherwise.	Not specified.
How background is considered in setting cleanup levels.	“Natural background” defined as not influenced by localized human activities.	If non-anthropogenic background is above the Cleanup Screening Level (CSL), may develop area background. Otherwise, not specified.
What statistical analysis is used to determine background?	Assumed to be lognormal distribution, unless otherwise demonstrated. For lognormal distribution, background shall be lowest of: upper 90 th percentile or 4 times 50 th percentile. For normal distribution, background shall be lowest of: upper 80 th percentile or 4 times 50 th percentile. MTCA rule also allows other statistical approaches, with department approval.	Not specified.
How many samples are needed to determine background?	10 or more samples to determine natural background for soil. 20 or more samples to determine area background for soil.	Not specified.
How will non-detect concentrations be treated in determining background?	If < <u>Method Detection Limit</u> , use ½ Method Detection Limit. If between Method Detection Limit and <u>Practical Quantitation Limit</u> , use Method Detection Limit.	Not specified.

Options

When setting sediment cleanup standards, human health considerations are complex. The options identified range from doing nothing to revising the rule or developing guidance. The options considered focus on three areas: **1) Decision-making framework, 2) Level of protection, and 3) Procedures.** These options are described in more detail below.

1. Decision-making framework in setting cleanup standards.

The decision-making framework provides a regulatory approach for making decisions about setting cleanup standards and choosing remedial actions. MTCA and SMS rules currently have different approaches.

As shown in Figure 1, the MTCA rule uses a decision-making framework that calculates a single cleanup standard. Cost is not considered when setting the cleanup standard, but is considered when selecting the remedy. The SMS uses a framework that allows the cleanup level to be set within a range of concentrations, with consideration of cost and feasibility.

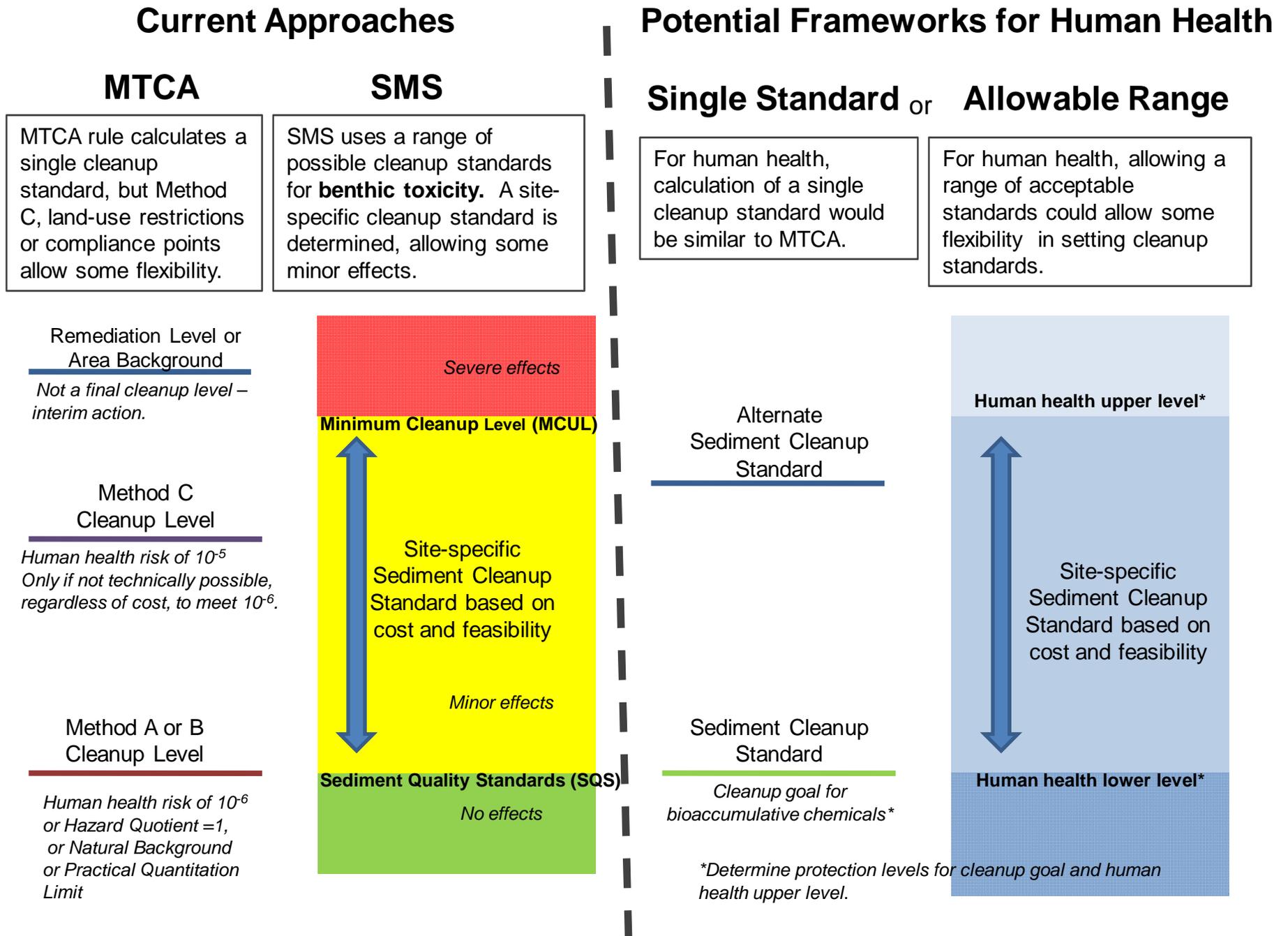
Ecology is considering a number of options for a decision-making framework.

- **Do nothing** and continue to address human health concerns on a site-specific basis.
- Develop **sediment cleanup standards based on one level of protection.**⁵
- **Allow an alternate level of protection** when developing sediment cleanup standards for sites where it is not technically possible to achieve the sediment cleanup goal.⁶
- Develop sediment cleanup standards that are **based on a range of acceptable values.** The lower end of the range would be the goal, while the upper end of the range would be a maximum acceptable level. The cleanup standards would be selected within the range, as close as possible to the lower concentration while considering certain factors, including cost and feasibility. This approach is similar to current SMS approach.

⁵ This approach is similar to MTCA Method B cleanup levels as described in WAC 173-340-705.

⁶ This approach is similar to MTCA Method C cleanup levels as described in WAC 173-340-706.

Figure 1. Comparison of potential frameworks for human health to current decision-making framework in the SMS and MTCA rules.



2. Level of protection.

A. What is the best approach for specifying the level of protection for human health?

The approach in the MTCA rule (and in EPA guidance) defines an acceptable level of human health protection based on incremental risk levels for carcinogenic chemicals or hazard quotients for non-carcinogenic chemicals. [MTCA risk levels](#) and [EPA risk levels](#) are different, with EPA allowing a wider range of acceptable risk.

To calculate a sediment cleanup standard from an acceptable risk level or hazard quotient/index requires addressing a number of considerations

- **How much exposure?** When setting cleanup standards, the MTCA rule says that exposure scenarios should be based on the [reasonable maximum exposure](#) for a human under current and potential future site use. A site-specific baseline risk assessment usually includes two human exposure scenarios: reasonable maximum exposure, and a central tendency exposure.
- **What exposure routes?** Potential exposure routes are [food ingestion](#) (including contaminants that have [biomagnified](#) in seafood), [dermal contact](#), [incidental ingestion](#), and inhalation.
- **How to consider [multiple exposure pathways](#)?** The MTCA rule allows a one in one hundred thousand (1×10^{-5}) risk level when considering multiple chemicals and exposure pathways.
- **How do sediment concentrations at a site relate to risks from chemicals that biomagnify in seafood (fish and shellfish) eaten by people?** This includes consideration of amounts and types of seafood consumed, tissue concentrations, and a myriad of factors that affect how tissue concentrations relate to sediment concentrations at a site.

Ecology is considering a number of options for setting the level of protection.

- **Do nothing** and retain the SMS rule narrative criteria.
- Identify the **acceptable risk levels (10^{-6} to 10^{-5}) that are consistent with the MTCA rule.**
- Specify **how sediment or tissue concentrations can be calculated** from risk levels.
- Identify a range of **acceptable risk levels (10^{-6} to 10^{-4}) consistent with the EPA approach.**
- Develop **criteria based on tissue concentrations**, with the focus on certain indicator species.

- Develop **exposure input parameters for the significant exposure pathways** and most susceptible human populations that tend to be the risk-drivers at sediment cleanup sites, such as tribal seafood ingestion exposure pathway.

B. How will background concentrations be considered when setting sediment cleanup standards?

Because sediment contaminants are widespread, it may not be technically feasible to achieve the level of human health protection that we would like. It may be appropriate to consider how widespread background concentrations of chemicals should be considered when setting sediment cleanup standards. This issue is addressed in more detail in the “Background Concentrations In Setting Sediment Cleanup Standards” Issue Paper, and is briefly summarized here.

The SMS rule does not specify how background is defined when setting sediment cleanup standards for human health protection. In rare cases where there are elevated concentrations from nonanthropogenic sources, an area background may be used.⁷

MTCA allows cleanup standards to be set at “natural background” which is not influenced by “localized sources.” The ambiguity of this definition has caused difficulty in selecting appropriate reference locations for sediment.

Ecology is considering a number of options for defining background.

- **Do nothing.**
- Clarify what is meant by *natural background* for setting cleanup standards.⁸
- Use **another definition of background** specific to sediments. This may include differentiating between main and sub-basins, or urban and non-urban areas.

C. Which parts of the SMS rule should be revised?

In the rule revision we want to provide more detail on how to evaluate “no significant threats to human health.” This narrative appears at several different places in the rule:

- 173-204-320 to -340 WAC Sediment Quality Standards.
- 173-204-420 WAC Sediment Impact Zone Maximum criteria.
- 173-204-520 WAC Cleanup Screening Levels criteria.
- 173-204-570 WAC Sediment Cleanup Standards.

⁷ WAC 173-204-320 (6) Puget Sound marine **nonanthropogenically affected sediment quality criteria**. Whenever the nonanthropogenically affected sediment quality is of a lower quality ... than the applicable cleanup screening levels or minimum cleanup levels criteria established under this section, the existing sediment chemical and biological quality shall be identified on an area-wide basis as determined by the department and used in place of the standards of WAC 173-204-520.

⁸ See “Background” issue paper for more details.

The objective for revising the rule is to clarify and harmonize the SMS and MTCA rule for setting cleanup standards. Changing only the section on Sediment Cleanup Standards would be sufficient for harmonizing the two regulations.

However, revising all of the sections with human health criteria would provide greater consistency within the SMS rule. But this approach would bring up additional implementation issues in applying the human health criteria to NPDES permits and the site listing process. Since these parts of the rule are also promulgated under authority of the Water Pollution Control Act 90.48 RCW, we would have to ensure consistency with that statute.

Ecology recognizes that if only the sediment cleanup standards section address the human health pathways, then there will likely be more stringent standards for cleanup sites than for controlling sources from NPDES permits or for listing sites as cleanup sites. This could increase the potential for recontamination of sites that are cleaned up.

Ecology is considering a number of options regarding the SMS.

- Do nothing and retain the SMS rule narrative criteria.
- Revise the human health narrative criteria in all sections of the SMS rule.
- Revise the human health narrative criteria only in section WAC 173-204-570 Sediment Cleanup Standards.

3. Procedures – What are the processes and technical details needed to provide clear, consistent implementation?

Several complex technical issues need to be resolved to provide clarity in implementing the rule. These technical details may be addressed in the regulations or guidance. Some of the relevant questions include:

- How to determine sediment cleanup standards for a specific cleanup site?
 - What equations, acceptable risk level or hazard quotients, and exposure input parameters should be used when calculating risk-based cleanup levels?
 - How to determine “background” levels for comparison?
- How to evaluate different cleanup actions alternatives?
- How to determine compliance with cleanup standards after the cleanup is completed?

Ecology is considering a number of procedural options.

- **Do nothing** and continue to evaluate human health on a case-by-case basis.
- **Bioaccumulation testing methods and interpretation.** Determine contaminants in laboratory bioassays, field-exposed organisms, or field-collected organisms to determine potential risks from bioaccumulative pollutants.
- **Develop formulas in the SMS to calculate safe sediment concentrations** with acceptable risk levels or hazard quotients, reasonable maximum exposure input parameters, and biota-sediment accumulation factors (BSAF). This **approach is similar to the MTCA rule** formulas that are currently used for bioaccumulative chemicals in water. Default parameters and allowable modifications could be specified.
- **Develop guidance on specific issues** for human health risk assessments.
- **Guidance could focus on the following:**
 - When and how to perform baseline human health risk assessments at cleanup sites.
 - Exposure scenarios for significant sediment exposure pathways for humans.
 - Subpopulation sensitivity for bioaccumulative chemicals.
 - Estimating exposure from fish consumption.
 - Background concentrations or practical quantitation limit (PQL) for tissue or sediment concentrations.
 - Estimates of bioaccumulation factors (BSAF) or use of food web models.
- **Revise the SMS rule to address specific issues for** human health risk assessments:
 - Exposure scenarios for significant sediment exposure pathways for humans.
 - Subpopulation sensitivity for bioaccumulative chemicals.
 - Estimating exposure from fish consumption.
 - Background concentrations or PQL for tissue or sediment concentrations.
 - Estimates of bioaccumulation factors or use of food web models.

Factors to Consider When Selecting an Option

The development of the amendments will involve the consideration and balancing of a number of issues and interests. The proposed amendments will also be developed to satisfy several, sometimes conflicting, regulatory goals, including the following:

- Providing for the selection of cleanup actions that protect human health and the environment.

- Developing scientific and legally defensible cleanup standards.
- Providing consistent standards and methodologies for assessing and managing risk.
- Providing flexibility to address site-specific factors.
- Promoting efficient and cost-effective cleanup of contaminated sites.
- Improving the clarity and usability of the rule.
- Whether the option complies with key requirements of the Administrative Procedures Act.