



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
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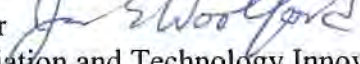
OFFICE OF  
SOLID WASTE AND  
EMERGENCY RESPONSE

OSWER 9200.2-111

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**MEMORANDUM**

**SUBJECT:** Clarifying the Use of Protectiveness Determinations for Comprehensive Environmental Response, Compensation, and Liability Act Five-Year Reviews

**FROM:** James E. Woolford, Director   
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**TO:** National Superfund Program Managers, Region 1-10

**PURPOSE**

The purpose of this memorandum is to clarify the use of protectiveness determinations in Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) Five-Year Reviews (FYR). It provides general guidance for the use of specific protectiveness determinations and recommends language to be used when drafting a protectiveness statement. The information provided in this memorandum supplements, but does not supersede, the language in the "Comprehensive Five-Year Review Guidance," OSWER No. 9355.7-03B-P (June 2001).

**BACKGROUND**

An audit by the Office of Inspector General (OIG) entitled "Stronger Management Controls Will Improve EPA Five-Year Reviews of Superfund Sites" issued February 6, 2012 identified situations where data provided in a FYR report did not fully support the region's protectiveness determination. Specifically, the OIG identified situations where the regions did not follow agency guidance for making protectiveness determinations for remedies under construction and concluded that short-term protectiveness was not adequately defined in Agency guidance. As a result, the OIG recommended that the Office of Solid Waste and Emergency Response (OSWER) clearly define the protectiveness categories used in Agency guidance and ensure that protectiveness definitions are consistently applied across the Agency.

The purpose of a FYR is to evaluate the implementation and performance of a remedy in order to determine if the remedy is or will be protective of human health and the environment. Protectiveness is generally defined in the National Contingency Plan (NCP) by the risk range for carcinogens and the hazard index (HI) for non-cancer effects. Evaluation of the remedy and the determination of protectiveness should be based on and sufficiently supported by data and observations. Consistent with the "*Comprehensive Five-Year Review Guidance*," a discussion of this evaluation should be described and presented in the FYR report, along with the protectiveness determination.

## **IMPLEMENTATION**

To assess the protectiveness of the remedy, it is important to evaluate human health risks, ecological risks, and the general performance of the selected remedy. To facilitate this evaluation, a technical assessment of a remedy is conducted to answer the following questions. The answers to these questions provide a framework for organizing and evaluating the FYR data and information:

Question A – Is the remedy functioning as intended by the decision documents?

Question B – Are the exposure assumptions, toxicity data, cleanup levels, and remedial action objectives (RAOs) used at the time of the remedy selection still valid?

Question C – Has any other information come to light that could call into question the protectiveness of the remedy?

### Evaluating Remedy Protectiveness

For CERCLA sites that require a FYR, a separate protectiveness statement is required for each operable unit (OU) where the remedial action is currently underway or remedial construction is complete. If the site is construction complete, a site-wide protectiveness determination is also required and will generally be the same protectiveness determination as the least protective OU at the site.

The OSWER "*Comprehensive Five-Year Review Guidance*" defines five protectiveness categories: protective, short-term protective, will be protective, protectiveness deferred, and not protective. The following discussion provides general guidance for the use of the specific protectiveness determinations and recommends language to be used when drafting the protectiveness statement for the FYR report.

### Protective

A protectiveness determination of "protective" may be appropriate for remedies where:

- Construction activities are complete and remedy is operating; or
- Construction activities are complete, remedial action objectives (RAOs) have been achieved, and operation and maintenance activities are occurring.

A protectiveness determination of "protective" is typically used when the answers to Questions A, B and C provide sufficient data and documentation to conclude that the remedy is functioning as intended and all human and ecological risks are currently under control and are anticipated to be under control in the

future.

### Recommended Language for a Protectiveness Determination of “Protective”

*“The remedy at OUX is protective of human health and the environment.”*

The Remedial Project Manager should briefly describe in a separate paragraph below the protectiveness statement the elements of the remedy that protect human health and the environment and how the RAOs have been met or are being met.

### Short-Term Protective

A protectiveness determination of “short-term protective” may be appropriate for remedies where:

- Construction activities are complete and remedy is operating; or
- Construction activities are complete, remedial action objectives have been achieved, and operation and maintenance activities are occurring.

A protective determination of “short-term protective” is typically used when the answers to Questions A, B and C provide sufficient data and documentation to conclude that the human and ecological exposures are currently under control and no unacceptable risks are occurring. However, the data and/or documentation review also raise issues that could impact future protectiveness or remedy performance but not current protectiveness. Examples of scenarios that may result in a short-term protectiveness determination may include:

- No exposure is occurring but institutional controls have not been fully implemented;
- Future land use assumptions may have changed;
- Engineering performance issues related to the operation of the remedy; or
- Monitoring data indicates that remedy will not achieve goals in the anticipated time frame

### Recommended Language for a Protectiveness Determination of “Short-Term Protective”

*“The remedy at OUX currently protects human health and the environment because (describe the elements of the remedy that protect human health and the environment in the short-term). However, in order for the remedy to be protective in the long-term, the following actions need to be taken (describe the actions needed) to ensure protectiveness.*

### Will be Protective

A protectiveness determination of “will be protective” may be appropriate for remedies where:

- Construction activities are ongoing

A protective determination of “will be protective” is typically used when the answers to Questions A, B and C provide sufficient data and documentation to conclude that the human and ecological exposures are currently under control and no unacceptable risks are occurring in those areas. In addition, answers



to Questions A, B and C also indicate that the remedy under construction is anticipated to be protective upon completion and no remedy implementation or performance issues have been identified.

#### Recommended Language for a Protectiveness Determination of “Will Be Protective”

*“The remedy at OUX is expected to be protective of human health and the environment upon completion. In the interim, remedial activities completed to date have adequately addressed all exposure pathways that could result in unacceptable risks in these areas.”*

#### Protectiveness Deferred

A protectiveness determination of “protectiveness deferred” may be appropriate for remedies where:

- Construction activities are ongoing;
- Construction activities are complete and remedy is operating; or
- Construction activities are complete, remedial action objectives have been achieved, and operation and maintenance activities are occurring.

This protective determination is generally used when the available information to answer Questions A, B and C does not provide sufficient data and documentation to conclude that all human and ecological risks are currently under control and no unacceptable exposures are occurring. Examples of scenarios that may result in a “protectiveness deferred” determination include:

- A new exposure pathway (e.g., vapor intrusion) has been identified and additional data are required to determine if an unacceptable risk is occurring;
- An emerging contaminant is present and the current risk has not been evaluated;
- An ecological risk assessment has never been adequately addressed at the site; or
- The toxicity value has changed and it unclear whether the current remedy at a site is protective or whether the selected remedy can achieve the new risk-based cleanup level.

When a protectiveness deferred determination is made, the protectiveness statement generally discusses the actions needed to collect the missing information and the timeframe anticipated to complete these actions. Once the necessary data and/or information are obtained, a Five-Year Review addendum is typically completed that documents the protectiveness determination for the OU(s) where the protectiveness had been deferred.

#### Recommended Language for a Protectiveness Determination of “Protectiveness Deferred”

*“A protectiveness determination of the remedy at OUX cannot be made at this time until further information is obtained. Further information will be obtained by taking the following actions (describe the actions). It is expected that these actions will take approximately (insert time frame) to complete, at which time a protectiveness determination will be made.”*

#### Not Protective

A protectiveness determination of “not protective” may be appropriate for remedies where:

- Construction activities are ongoing;
- Construction activities are complete and remedy is operating; or
- Construction activities are complete, remedial action objectives have been achieved, and operation and maintenance activities are occurring.

A protectiveness determination of “not protective” is generally used when the answers to Questions A, B and C provide adequate data and documentation to conclude that the human and/or ecological risks are not currently under control. Examples of scenarios that may result in a “not protective” determination include:

- An immediate threat is present (ex. new exposure pathway identified and it is reasonably likely to assume that unacceptable exposures are occurring)
- Migration of contaminants is uncontrolled and poses an unacceptable risk to human health and the environment; or
- Potential or actual exposure is clearly present or there is evidence of exposure

#### Recommended Language for a Protectiveness Determination of “Not Protective”

*“The remedy at OU X is not protective because of the following issue(s) (describe each issue). The following actions need to be taken (describe the actions needed) to ensure protectiveness.”*

#### **CONCLUSION**

A five-year review should determine whether the remedy at a site is or upon completion will be protective of human health and the environment. The level of effort necessary to conduct a five-year review is site-specific and should be tailored appropriately for the remedial action and its stage of implementation.

If you have any questions, please contact David Cooper at (703) 603-8763 or at [cooper.davide@epa.gov](mailto:cooper.davide@epa.gov).

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