



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

SEP - 1 1993

OSWER Directive No. 9835.15b

MEMORANDUM

SUBJECT: New Policy on Performance of Risk Assessments During Remedial Investigation/Feasibility Studies (RI/FS) Conducted by Potentially Responsible Parties (PRPs)

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TO: Regional Administrators, Regions I-X

Purpose

This memorandum announces EPA's new policy on conducting risk assessments at Superfund sites where PRPs are conducting the RI/FS and the Agency's reasons for adopting this policy. This supplements and supersedes in part the policy stated in "Performance of Risk Assessments in RI/FSs Conducted by PRPs," OSWER Directive No. 9835.15 (August 28, 1990).

Background

On June 21, 1990, EPA announced that thereafter it (or a state if designated) would conduct the risk assessment portion of the RI/FS in all cases, and would not allow risk assessments to be performed by PRPs. That policy was later elaborated upon in OSWER Directive No. 9835.15. The policy was challenged in litigation brought by the Chemical Manufacturers' Association and others. In December 1991, EPA entered into a settlement of that litigation under which it agreed to evaluate and reassess the 1990 risk assessment policy.

The EPA/CMA settlement committed EPA to evaluate the 1990 policy and to provide an opportunity for public comment on the pre-1990 and post-1990 policies as well as on the results of EPA's evaluation. EPA's evaluation included a review of timing, coordination, and settlement issues relating to both EPA and PRP-conducted risk assessments within PRP-lead RI/FS projects. EPA evaluated RI/FSs commenced both before and after June 21, 1990. The specific findings and conclusions of EPA's evaluation are

contained in the "1992 Risk Assessment Evaluation Report," dated March 9, 1993.

EPA recognizes the critical role that the risk assessment plays in site cleanups. Prior to the 1990 policy, EPA relied upon oversight to ensure that PRP-conducted risk assessments measured site risks appropriately. EPA adopted the 1990 policy to reduce delays and resource demands involved in finalizing risk assessments performed by PRPs. Although the 1990 policy did reduce the number of PRP documents to be reviewed and the delays associated with EPA review and approval, data obtained through the risk assessment evaluation report indicate that other delays are created when EPA conducts the risk assessment. Specifically, the available data shows that additional delays were generated during data transfer between EPA and PRPs.

New Policy for Orders or Decrees for PRP RI/FS

1) General Statement of Policy

It remains EPA's position that, for reasons stated below, it is generally more appropriate for risk assessments to be conducted by EPA than by PRPs, even where PRPs are performing the remainder of the RI/FS. However, effective immediately, EPA may, in appropriate cases, enter into orders for PRP RI/FSs under which risk assessments can be conducted by PRPs. To the extent that OSWER Directive No. 9835.15 precludes doing so, it is hereby superseded. Suggested criteria are discussed below for determining whether allowing a PRP to conduct a risk assessment is appropriate in a given case.

If, under the terms of an order, PRPs are given an opportunity to conduct the risk assessment, EPA will perform stringent oversight and require appropriate PRP deliverables as outlined in "Guidance on Oversight of PRP RI/FSs," OSWER Directive No. 9835.1(c), July 1991. EPA will review and provide comments to PRPs on their deliverables in a timely fashion, in order to minimize the potential for delays.

If the Region chooses to conduct the risk assessment itself at a particular site, it should adhere to the remaining applicable portions of the August 28, 1990 and July 2, 1991 directives (OSWER Nos. 9835.15 and 9835.15a, respectively). This includes providing PRPs with EPA risk assessment interim deliverables. This will serve to facilitate early resolution of risk assessment issues and minimize the potential for delays during the RI/FS.

This policy also applies to the risk evaluation or risk assessment portion of an Engineering Evaluation and Cost Analysis (EE/CA) performed by PRPs. This policy does not, nor did the previous policies, apply to risk assessments at Federal facility

sites. The term "risk assessment" in this directive includes ecological risk assessments as well as assessments of risks to human health.

2) Site-specific Considerations

EPA's determination on whether to allow a PRP to conduct the risk assessment will be made on a site-by-site basis, using site-specific considerations. These considerations will ensure compliance with section 104(a)(1) of CERCLA which states that "no remedial investigation or feasibility study (RI/FS) shall be authorized except on a determination by the President that the party is qualified to conduct the RI/FS." Criteria to be considered should generally include:

- o EPA's prior experience with the requesting PRPs at this or other sites and in particular whether excessive oversight and revisions were necessary when that PRP previously conducted a risk assessment;
- o PRP or PRP contractor's experience in conducting Superfund risk assessments;
- o PRP or PRP contractor's knowledge of current Superfund risk assessment processes and guidance documents;
- o PRP or PRP contractor's ability to submit data to EPA in the proper format; and
- o Available EPA resources and schedule for RI/FS completion.

In addition, Regions may consider other factors such as the level of public concern at the site. To facilitate this determination, Regions may request that PRPs submit information on all of the relevant criteria.

The site-specific decision on whether to allow PRPs to conduct the risk assessment is a matter of Agency discretion. This Agency policy does not confer any legal rights upon private parties to perform risk assessments. Regional staff should briefly document their response to a PRP's request to perform the risk assessment based on the above criteria and any other criteria the Region considers appropriate.

3) Headquarters Consultation Requirements

Before agreeing to an EPA-PRP order allowing PRPs to perform the risk assessment, an EPA Region must consult with the OWPE Office Director. The Region must provide a memorandum documenting the basis for its decision.

4) RI/FS Order Documentation Requirements

For new consent orders where PRPs are allowed to conduct the risk assessment, EPA will follow the existing procedures (e.g., certification of the PRP risk assessment) contained in the August 28, 1990 directive. EPA's new policy reemphasizes the use of EPA's penalty and takeover procedures in case of PRP non-compliance with the terms of the order.

Consent orders already in existence for PRP RI/FSs may be amended to allow PRPs to conduct the risk assessment. In these situations, however, Regions must consider the available EPA oversight resources and schedule to complete the RI/FS before amending an order.

Basis for New Policy

In developing this policy, OSWER considered several sources of information, including among other things: 1) public comments on the merits of the pre- and post-June 21, 1990 policies, 2) the results of its risk assessment evaluation, 3) the results of its Regional survey, and 4) public comments on the risk assessment evaluation report. Each of these contained information weighing both for and against allowing PRPs to conduct risk assessments.

EPA's principal concern cited in the 1990 policy was that when PRPs conducted the risk assessment, extensive EPA oversight and repeated revisions of the risk assessment were required to obtain a satisfactory product. EPA's March 1993 evaluation of the 1990 policy attempted to measure the delay associated with PRP risk assessments, as well as considering delays and coordination problems arising from EPA risk assessments. In general, the evaluation found that the need for oversight and revisions significantly affected the time required for completion of PRP risk assessments. At the same time, it was found that coordination problems with PRPs (in particular, data transfer) caused delays at sites where EPA conducted risk assessments.

EPA believes that procedures can be developed to reduce delays resulting from data transfer; some Regions have already developed such procedures. Over time, therefore, EPA expects the timing advantages of EPA-conducted risk assessments will become more apparent.

Furthermore, an underlying concern remains about the level of public confidence in risk assessments performed by PRPs. Because the risk assessment is a central component of the response decision, EPA places great importance upon a high level of public confidence in the risk assessment. Because risk assessments are complex technical documents involving difficult and subtle professional judgments, it can be difficult for the public to evaluate the accuracy of a risk assessment. When the

party performing the risk assessment has a financial incentive to minimize the cost of the response, it is foreseeable that, in many cases, the public may be skeptical about its reliability, and the difficulty of evaluating the risk assessment makes such skepticism difficult to dispel.

EPA can attempt to address public concerns by overseeing the preparation of the risk assessment. The Risk Assessment Guidance for Superfund (RAGS), issued just prior to the June 1990 policy, should enhance a PRP's ability to conduct and EPA's ability to oversee PRP-conducted risk assessments. However, the risk assessment document remains identified with the PRP, and the public may not consider this document prepared under EPA oversight the equivalent of a document fully prepared by EPA. Moreover, oversight can have practical limitations; information received in the course of EPA's review of its policy indicated that, in some cases, risk assessments were accepted which, although satisfactory, were not entirely in a form that EPA desired. Furthermore, performing oversight poses a significant burden on limited EPA resources, a burden that is likely to be greater than where the contractor performing the risk assessment has been selected by EPA. Therefore, EPA maintains its view that it is generally preferable for risk assessments to be performed by the Agency rather than by PRPs.

At the same time, the evaluation suggests that the delays attributable to PRP risk assessments may not be as great as was previously believed. In general, PRP risk assessments did not add significantly more time to the RI/FS process than EPA risk assessments (although, as noted above, EPA expects that procedures will be developed to reduce delays in performing EPA risk assessments). In addition, more detailed risk assessment guidance has now been issued which may make clearer what is expected in the document and may reduce to some extent the difficulty of overseeing PRP risk assessments.

Therefore, EPA believes that in some cases it will be appropriate to allow PRPs to conduct risk assessments. The critical factor in making this determination is EPA's past experience with the individual PRP and its contractor. When EPA is confident that this factor and the other criteria noted earlier can be satisfied favorably, EPA's burden of oversight and likelihood of public concern will be significantly reduced. These factors must be considered by the Region on a case-by-case basis. Therefore, the 1990 policy is being revised so as to allow regional personnel discretion to consider the criteria outlined earlier in this directive.

If you have any questions about this policy, please contact Stephen Ells, Acting Chief, Guidance and Evaluation Branch, Office of Waste Programs Enforcement, at (703) 603-8934.

Notice

The policy and procedures set out in this document are intended for the guidance of Government personnel. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. U.S. Environmental Protection Agency officials may decide to follow the guidance provided in this document, or act at variance with the guidance, based on an analysis of site circumstances. The Agency also reserves the right to change this guidance at any time without public notice.

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