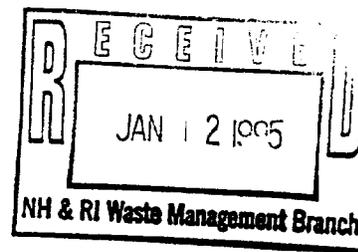


FAX TRANSMITTAL		# of pages ▶ 11
To <i>Dennis Russo</i>	From <i>Jim Brown</i>	
Dept./Agency <i>EPA</i>	Phone # <i>617-573-5719</i>	
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GENERAL SERVICES ADMINISTRATION		

MENTAL PROTECTION AGENCY
 ON, D.C. 20460



-9 1995

*CC Supervisor SC
 Bill Walsh Regional*

MEMORANDUM

SUBJECT: Transfer of Role and Responsibility in Overseeing Regional Requests to Allow PRPs to Conduct Risk Assessments

FROM: Bruce M. Diamond, Director 
 Office of Site Remediation Enforcement (OSRE)
 Office of Enforcement and Compliance Assurance (OECA)
 Stephen D. Luftig, Acting Director *Steve Luftig*
 Office of Emergency and Remedial Response (OERR)
 Office of Solid Waste and Emergency Response (OSWER)

TO: Hazardous Waste Management Division Director
 Regions III, VI, VIII, IX
 Waste Management Division Director
 Regions I, IV, V, VII
 Emergency and Remedial Response Division Director
 Region II
 Hazardous Waste Division Director
 Region X

This memo presents changes in the roles and responsibilities of OERR and the former OWPE under the recent Headquarters OECA reorganization for the review of regional requests for PRP lead risk assessments. In brief, the Regions still need to send to Headquarters a written request to allow PRPs to conduct the risk assessment; however the lead review of these requests will be conducted by OERR, instead of OWPE.

Background. In June 1990, EPA issued a policy stating that the RI/FS risk assessments would be conducted by the Agency and not by PRPs. This policy was challenged by litigation which resulted in a settlement where the Agency agreed to reassess its policy of not allowing PRPs to conduct the risk assessment.

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In September 1993, EPA issued a new risk assessment policy. According to the "revised" policy, PRPs can conduct risk assessments, but the Regions are required to consult with the OWPE Office Director before entering into an administrative order with the PRPs to perform the risk assessment.

Reorganization. In response to the recent reorganization of OECA Headquarters, OSRE and OERR met to discuss their roles and responsibilities in consulting with the Regions on PRP lead risk assessments. Several options were discussed ranging from who should conduct the consultation, to whether the decision should be delegated to the Regions. As a result of our meeting, we asked the Regions at the National Branch Chief Meeting in Kansas City about their perception of the need to continue the consultation process and we also reemphasized to the Regions the need to maintain nationally consistent risk assessments.

Transfer of Roles. Based on these discussions we agreed that Headquarters would maintain its current consultation role on PRP lead risk assessments, but OERR would assume the lead responsibility for receiving requests and consulting with the Regions. This transfer of the consultation process is consistent with a transfer of some technical functions and staff from OWPE to OERR under the reorganization. OSRE will play a support role in reviewing any Regional PRP risk assessment requests if OERR, or the Region, identifies an enforcement issue.

In the future, please send your requests for PRP lead risk assessments to Larry Reed, Director, Hazardous Site Evaluation Division, USEPA, 401 M Street Washington, DC 20460 (Mailcode 5204G). If you have any questions, please call Steve Ells at (703, 603-8822).

cc: Regional Superfund Branch and Section Chiefs
Sandra Connors, OSRE
Linda Boornazian, OSRE
Larry Reed, OERR
Bruce Means, OERR
Steve Ells, OERR



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)

FROM: Richard J. Guimond *Richard J. Guimond*
Assistant Surgeon General, USPHS
Acting Assistant Administrator

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 facilities.~~

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.

cc: Director, Waste Management Division,
Regions I, IV, V, VII
Director, Emergency & Remedial Response Division,
Region II
Director, Hazardous Waste Management Division,
Regions III, VI, VIII, & IX
Director, Hazardous Waste Division,
Region X
Regional Counsel, Regions I-X
Regional CERCLA Branch Chiefs, Regions I-X
Regional CERCLA Section Chiefs, Region I-X

[FRL-4105-8 and FRL-4605-3]

**Superfund Program; New Policy on Performance of Risk Assessments
During Remedial Investigation/Feasibility Studies (RI/FSs)
Conducted by Potentially Responsible Parties (PRPs); Response to
Public Comments on EPA's Current and Former Risk Assessment
Policies and Response to Public Comments on EPA's Risk Assessment
Evaluation Report - Notice of Availability**

AGENCY: Environmental Protection Agency

ACTION: Notice of Availability of the New Risk Assessment
Policy for Risk Assessments During PRP-lead RI/FSs and Responses
to Public Comments.

SUMMARY: This notice is the final of several notices resulting
from the settlement of litigation between EPA and the Chemical
Manufacturers' Association et al. (CMA), involving EPA's June 21,
1990 risk assessment policy which provided that all risk
assessments under CERCLA would henceforth be conducted by EPA
rather than by PRPs.

On February 20, 1992, EPA published a notice (57 FR 6616)
which requested comments on the 1990 risk assessment policy,
announced EPA's intent to conduct an evaluation of the 1990
policy, and requested comments on the methodology for such an
evaluation. On March 15, 1993, EPA announced the availability of
its response to public comments on the evaluation methodology and

the availability of its Risk Assessment Evaluation Report (58 FR 13757).

This notice announces the availability of EPA's new policy on PRP risk assessments at Superfund sites, which is contained in OSWER Directive No. 9835.15b (September 1, 1993). This notice also announces the availability of EPA's responses to public comments on the merits of the June 21, 1990 and pre-June 21, 1990 policies and to public comments on EPA's Risk Assessment Evaluation Report.

EPA considered the results of its evaluation, public comments on the 1990 policy, results of a 1993 Regional survey, and public comments on the risk assessment evaluation in developing its new risk assessment policy. In summary, the new policy states that it is generally more appropriate for the risk assessment to be conducted by EPA rather than by PRPs. However, EPA may, under certain circumstances, find it appropriate to allow PRPs to conduct the baseline risk assessment portion of the RI/FS. To determine whether this is appropriate in a particular case, the Agency will consider a variety of criteria based on the Agency's confidence in the PRP's ability to generate an accurate and timely risk assessment report.

EPA's responses to public comments are presented in "EPA's Response to Public Comments on the Merits of the Old and New Risk Assessment Policies" (August 31, 1993) and "EPA's Response to Public Comments on the Results of the Risk Assessment Evaluation Report" (August 31, 1993).

FOR FURTHER INFORMATION CONTACT: Matthew Charsky, U.S. Environmental Protection Agency, Office of Waste Programs Enforcement, Guidance and Evaluation Branch (5502-G), 401 M Street, S.W., Washington, DC 20460, (703) 603-8931. EPA staff will be able to obtain copies of OSWER Directive 9835.15b, which implements this new policy, and EPA's responses to public comments from the Superfund Document Center by calling (202) 260-3046. Other parties may obtain copies of EPA's responses to public comments by calling the Superfund Document Center and may order Directive 9835.15b from the National Technical Information Service (NTIS) by calling (703) 487-4600.

SUPPLEMENTARY INFORMATION: EPA's new policy supersedes the portion of the August 28, 1990 guidance, "Performance of Risk Assessments in RI/FSs Conducted by PRPs," OSWER Directive No. 9835.15, that entirely precluded PRPs from conducting the risk assessment activities of the RI/FS. All remaining portions of this Directive and the appropriate portions of the supplemental guidance, OSWER Directive No. 9835.15a (July 2, 1991) will still remain in effect under EPA's new policy.

Dated: September __, 1993

Richard J. Guimond,

Assistant Surgeon General, USPHS

Acting Assistant Administrator, Office of Solid Waste and
Emergency Response

{FR Doc.93- Filed 9-**1**-93;; : am}