Office of Environmental Guidance
EH-231-014/1292 (December 1992)

Use of Institutional Controls in a CERCLA Baseline Risk Assessment

Background: **The Comprehensive Environmental Response, Compensation and Liability Act (CERCLA) as amended, requires that the Department of Energy conduct a Remedial Investigation and Feasibility Study (RI/FS) for facilities listed on the National Priorities List, and that DOE's CERCLA response must be consistent with the guidelines established by the Environmental Protection Agency (EPA). EPA promulgated guidelines for hazardous substance response in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), and specified that lead agencies must assess the "baseline risk" posed by the contaminants under investigation in the RI/FS. In DOE Order 5400.4 ("CERCLA Requirements"), the Department established a policy of conducting CERCLA response actions "in accordance with the provisions of CERCLA...as well as...the NCP...."'**

The focus of this Information Brief is on the degree to which institutional controls can reconsidered in developing a CERCLA baseline risk assessment. An integral component of a baseline risk assessment is an exposure assessment. At Federal facilities, it is not unusual to find that controlling public access or limiting the activities of on-site personnel can reduce the exposure to hazardous substances which may have been released. Some of these controls are "institutional controls," e.g., land access or resource use restrictions, deed restrictions, or well drilling prohibitions. In the NCP, EPA directed that exposures that are limited by institutional controls may not be factored into a baseline risk assessment for a CERCLA RI/FS, but could be factored into a risk assessment for a limited action.

Statutes: **CERCLA, as amended by the Superfund Amendments and Reauthorization Act (SARA), Sections 120(a)(2) and 120(e).**

Regulations: **40 CFR 300 (revisions at 55 FR 6666, March 8, 1890).**

References: **DOE Order 5400.4 "CERCLA Requirements" (10-6-69); NCP Preamble (55 FR 8709, March 8, 1990); "Risk Assessment Guidance for Superfund, Vol. I, Human Health Evaluation Manual (Part A)," Interim Final (EPA/540/1-89/002), December 1989.**

What is a Baseline Risk Assessment?

During the Site Characterization phase of an RI/FS, a baseline risk assessment (RA) is used to evaluate the potential threat to human health and the environment in the absence of any remedial action. That is, the baseline RA describes the risk conditions under the "no action alternative." The baseline RA is extremely important because it provides the basis for determining whether remedial action is necessary. It also determines the extent of cleanup needed to reduce potential risk levels to within EPA's acceptable range (e.g., carcinogenic risks of 10^{-4} to 10^{-6}- 40 CFR 300.430(e)(2)(i)(A)(2)).

What is Meant by "No Action Alternative"?

EPA's interpretation of the term "no action alternative" may not strictly correspond to the meaning DOE may attach to this term for purposes of complying with Environmental Impact Statement (EIS) requirements of the National Environmental Policy Act (NEPA). In NEPA terminology, the "no action alternative" could be that alternative which involves nothing beyond the preexisting conditions at a site (including any built-in safeguards). In a CERCLA Record of Decision, however, the "no action alternative" equates with a determination to do nothing further at a site on the national priority list, and it can ONLY be selected if the RI/FS reveals that there are no remaining unacceptable health or environmental risks due to the site. In promulgating revisions to the NCP, EPA interpreted this to mean that the government could literally "walk away" from the site, essentially leaving it available for completely unrestricted use. Thus, EPA has given the term "no action alternative" a special meaning.

EPA's definition is important to DOE because EPA provides oversight for and must concur with DOE's decisions about remedial activities. Since current DOE policy (DOE Order 5400.4) requires integrating CERCLA and NEPA requirements. it is important that DOE continue to use the term "no action alternative" as required by NEPA, while at the same time recognizing the contrasting nature of the EPA/CERCLA interpretation.

How Does EPA's Interpretation of "No Action" Affect the Consideration of Institutional Controls During a Baseline Risk Assessment?

The EPA interpretation of the no action alternative under CERCLA means that the only actions that can properly be considered in establishing the "true" baseline risk during an RI/FS are those actions that have already been taken to reduce or eliminate contaminants as opposed to controlling or precluding potential exposure. Examples of such actions include removing contaminated surface soils, drums, and other waste containers or contaminated structures and applying technologies, such as pumping and treating ground water or taking measures to limit ground water migration. These are actions that actually remove contaminants from affected media. Such actions that have already been taken may properly be considered as contributing to a lower baseline risk at a site.

Actions that simply control future access to the site or limit exposures to existing contamination may not be considered when establishing the "true" baseline risk. Examples of such actions are 1) erecting fences: 2) covering the contaminated areas with tarpaulin: 3) utilizing security patrols and guard posts; and 4)

enacting other institutional controls such as deed restrictions or posting notices, warnings, and restrictions.

Why Does EPA Exclude Access or Institutional Controls from the Definition of "No Action"?

As discussed in the preamble to the revised NCP (55 FR 8711), EPA defines baseline risks to be those "associated with a site in the absence of any remedial action or control." Because institutional controls can reduce or preclude exposure while not actively cleaning up a site, they are considered by EPA to constitute "limited action alternatives." EPA takes this position because of its mandate to be protective of public health and the environment. In that role, EPA needs to account for maximum potential exposure at a CERCLA site so that it will not underestimate the potential risk. "Maximum potential exposure'' means exposure that could be experienced in the absence of any form of active control (institutional or otherwise). This scenario is considered by EPA to equate with the "true" baseline situation.

To reflect the true baseline, however, the estimates of maximum exposure must not be unrealistic (i.e., must not grossly overestimate potential risk). To develop conservative yet defensible estimates of upper bound risks, EPA now requires analysis of the "reasonable maximum exposure" (RME) scenario. As stated in 55 FR 8710, "The reasonable maximum exposure scenario is 'reasonable' because it is a product of factors, such as concentration and exposure frequency and duration, that are an appropriate mix of values that reflect averages and 95th percentile distributions." This newer approach reflects an EPA policy change aimed at reducing the uncertainty associated with the previous, "worst-case"' approach by applying exposure assumptions that "result in an overall exposure assessment that is conservative but within a realistic range of exposure" (55 FR 8710). EPA asserts that the RME approach is more sensible than the worst-case approach. One of the "trade-offs" EPA made in establishing the new approach however, was that existing or proposed institutional controls and other measures that limit exposure would not be considered as reflecting the true baseline for the reasonable maximum exposure.

What is the Impact of EPA's Policy on "True" Baseline Risk Assessment for DOE's Environmental Restoration Program?

For purposes of DOE CERCLA oversight, the impact of estimating true baseline risk (no access or institutional controls) is that even existing institutional controls or other measures that limit human or ecological exposures to the contamination, but do not result in actually eliminating contaminants from the site, cannot be considered in establishing the baseline maximum exposure. However, previous actions that actually removed contaminants from the site, may be considered.

As previously mentioned, EPA considers institutional controls to equate with limited action alternatives. As such, they may often be applied as a component of an overall site remediation plan, being necessary in cases where some residual contamination is left in place (as it is in many response actions) or where the primary response action is control of contaminant migration (as opposed to contaminant removal or destruction). But even existing institutional controls "shall not substitute for active response measures (e.g., treatment and/or containment...)" as the sole remedy unless such active measures are determined not to be practicable (55 FR 8846).

How Should DOE Integrate the "True" Baseline Risk Assessment with NEPA Requirements to Evaluate a "No Action Alternative" That May Include Existing Controls?

DOE can accomplish the integration of the two assessments by recognizing that the true baseline approach to "no action" does not preclude the consideration of other alternatives, such as "limited action," in an integrated RI/FS-EA or -EIS. Limited actions could include existing or proposed fences, guards, and other institutional controls. The suggested integration approach is as follows: when appropriate (i.e., at DOE environmental restoration sites destined to continue to be under government control after the remedial actions are completed), the baseline RA should include an analysis indicating that exposure estimates that assume no action (i.e., not even access or institutional controls) represent reasonable maximum exposure, but do not reflect realistic expectations for future uses of the site. With that in mind, and after analyzing the required reasonable maximum exposure, additional exposure scenarios could be developed wherein the benefits of maintaining existing institutional controls (or of proposing new controls) are accounted for in alternative risk assessments that reflect the more realistic expectations. The latter may be presented as the more likely exposure, but not as the required reasonable maximum exposure.

Are There Any Advantages to the Suggested Approach?

The true baseline approach does have certain advantages from DOE's point of view. First, it requires use of the reasonable maximum exposure scenario rather than worst-case scenarios (which rely on use of upper-bound values for parameters such as exposure duration and frequency, and contaminant concentration.) Worst-case analysis tends to unrealistically exaggerate risk estimates (which even EPA asserts is inappropriate). Second, the Department (when appropriate) can propose a remedial plan that takes advantage of the existing controls as limited actions. In this way, when sites require little or no additional remedial activity beyond the existing controls, DOE may be in a better position to communicate to the public that the Department is proposing the appropriate remedial actions at a particular site, albeit they may be "limited." That is, although the estimated true baseline risks may in fact be higher than risks actually posed by the site in its current condition (i.e., with existing DOE institutional controls in place). DOE cart present the effects of the existing institutional controls as a limited action that will reduce risks to within acceptable levels as contrasted against the no action (baseline) scenario. Thus, the true baseline approach actually provides DOE with a structured framework supporting a defensible demonstration of the risk-reduction benefits that can accrue through the ongoing implementation of institutional controls. In these cases, however. it is important to also clarify that the Department would only choose such actions if EPA concurs in the decision, and only if the existing measures are appropriate and sufficient to protect human health and the environment.

Questions of policy or questions requiring policy decisions will not be dealt with in EH-231 Information Briefs unless that policy has already been established through appropriate documentation. Please refer any questions concerning the subject material covered in this Information Brief to John Bascietto, EH-231, (202) 586-7917.