



Five-Year Review Process in the Superfund Program

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EPA as required by statute and, as a matter of policy, reviews the remedies at certain sites every five years. Section 121 of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA), requires that remedial actions which result in any hazardous substances, pollutants, or contaminants remaining at the site be subject to a Five-Year Review. The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) defines this to mean contamination left at levels that do not allow for unlimited use and unrestricted exposure. This fact sheet summarizes the guidance document, *Comprehensive Five-Year Review Guidance (EPA 540-R-01-007)* that EPA issued in June 2001.

This document summarizes previously issued guidance to EPA personnel. It is not a regulation and does not create any legal obligations on any person or entity. EPA will apply the guidance referenced in this document to any particular project only to the extent appropriate in light of the facts. EPA welcomes public comment on this document at any time.

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A. Overview

Under CERCLA §121(c), EPA is required to review the remedies at Superfund sites where hazardous substances remain at levels that potentially pose an unacceptable risk. Such reviews must be conducted every five years or may be conducted more frequently if necessary to ensure the protectiveness of the remedy. The Five-Year Review requirement applies to remedial actions selected under CERCLA §121 upon completion of which, hazardous substances, pollutants, or contaminants will remain on

site. Five-Year Reviews are also conducted as a matter of policy for other CERCLA actions. Removal actions conducted under CERCLA §104 and Corrective Actions conducted under the Resource Conservation and Recovery Act (RCRA) are not subject to the Five-Year Review requirement; however, Regions may conduct Five-Year Reviews for these or other remedies as a matter of policy or at their discretion. In June 2001, EPA issued the *Comprehensive Five-Year Review Guidance (EPA 540-R-01-007)* to aid Regions and other agencies with responsibilities for conducting Five-Year Reviews. This fact sheet was prepared as a brief summary of that guidance document.

B. When is a Five-Year Review conducted?

A Five-Year Review may be required or appropriate when a remedial action leaves hazardous substances on the site at levels that do not allow for unlimited use and unrestricted exposure. Unlimited use and

unrestricted exposure (UU/UE) means that there are no restrictions placed on the potential use of land or other natural resources. In general, if the selected remedy relies on restrictions of land, ground water, or surface water use by humans or if any physical or engineered barrier is part of the remedy, then the use has been limited and a Five-Year Review should be conducted. There are two types of Five-Year Reviews, statutory and policy. Statutory reviews are required by CERCLA at post-SARA remedial actions that upon completion of the action leave hazardous substances, pollutants or contaminants on site. Policy reviews are performed, as a matter of policy, for pre-SARA remedial actions that leave hazardous substances, pollutants or contaminants on site, and at removal-only NPL sites where hazardous substances, pollutants or contaminants were left on site at levels that do not permit unlimited use and unrestricted exposure. Policy reviews are also conducted at other sites, including pre- or post-SARA remedial actions, that will take more than five years to complete.

The initiation, or trigger date, that starts the Five-Year Review period depends upon whether it is a statutory or policy review and if the review is a first or subsequent review. A statutory review is triggered by the initiation of the first remedial action that leaves hazardous substances, pollutants or contaminants on site at levels that do not allow for unlimited use and unrestricted exposure. In cases where there are multiple remedial actions, the earliest remedial action that leaves such substances on site should trigger the initial review, even if it is an interim remedial action.

A policy review is initially triggered by the date that the construction phase for all remedies is completed at a site. The date of

construction completion is generally the date of the Preliminary Close Out Report (PCOR) or the date of the Final Close Out Report (FCOR) for sites that do not have a PCOR.

After completion of the first statutory or policy Five-Year Review, the trigger for subsequent reviews is the signature date of the previous Five-Year Review report. Lead agencies may choose to conduct a Five-Year Review earlier or more frequently than every five years to ensure protection of human health and the environment.

Five-Year Reviews continue throughout the life of the site until hazardous substances, pollutants or contaminants no longer remain on site at levels that do not allow for unlimited use and unrestricted exposure. The basis for this finding should be documented in the final Five-Year Review report.

C. Who is responsible for conducting the Five-Year Review?

The lead agency, the agency providing the remedial project manager, has primary responsibility for conducting the Five-Year Review, while the support agency provides information and review support.

EPA also encourages appropriate State and Tribal involvement for Fund-financed and Enforcement-lead remedial actions. Where the State or Tribe is the lead agency, the NCP provides that EPA concurrence is needed on the protectiveness determination contained in the Five-Year Review. At federal facilities, the Federal agency in charge of the facility has the responsibility to conduct the Five-Year Review. EPA should provide concurrence with the protectiveness determinations, or develop its own independent determinations.

D. What are the components of a Five-Year Review?

The Five-Year Review process integrates information taken from decision documents and operational data with the experiences of those responsible for and affected by actions at the site. There are six components to the Five-Year Review process: 1) community involvement and notification, 2) document review, 3) data review and analysis, 4) site inspection, 5) interviews and 6) protectiveness determination as shown in Figure 1. Together, the reviewer uses these components to assess the remedy's performance, and, ultimately, to determine the protectiveness of that remedy.

Community Involvement and Notification

The reviewer begins working with the site's Community Involvement Coordinator (CIC) during the initial planning stages of the Five-Year Review to determine the appropriate level of community involvement and to notify all potentially interested parties that the Five-Year Review will be conducted. This notification may include States, Tribes, appropriate representatives of the community, local officials, potentially responsible parties (PRPs), Federal and/or State Trustees for Natural Resources (Trustees) and appropriate EPA offices. It is recommended that EPA's community involvement activities during the review include notifying the community that the Five-Year Review will be conducted, notifying the community that the Five-Year Review has been completed, and providing the results of the review to the local site repository.

Document Review

A review of documents is an early step in the Five-Year Review process. All relevant documents and data are reviewed to obtain

information to assess performance of the response action. The lead agency reviews various documents to obtain the necessary information, including those for remedy decisions (*e.g.*, Records of Decision, Explanation of Significant Differences), enforcement decisions (*e.g.*, Consent Decrees, Administrative Orders on Consent), site investigations, remedial design and construction, and remedy performance.

Data Review and Analysis

The lead agency also reviews sampling and monitoring plans and results from monitoring activities, operation and maintenance (O&M) reports or other documentation of remedy performance, including previous Five-Year Review reports. The data contained in these reports form the primary basis for the technical analyses and for the subsequent protectiveness determination. The type and quality of these data will have a significant impact on findings and conclusions. In some cases, the lead agency may also need to conduct supplemental sampling or collect other data.

Site Inspections

EPA or the lead agency conducts site inspections to gather information about a site's current status and to visually confirm and document the conditions of the remedy, the site, and the surrounding area. The inspection should be recent, and be conducted no more than nine months before the expected signature date of the review. At Federal facility sites, a State and/or EPA representative may wish to be present and/or participate in site inspections.



Figure 1: Components of the Five-Year Review Process

Interviews

As necessary, interviews may be conducted to provide additional information about a site’s status and/or identify remedy issues. Individuals who may be interviewed include: the site manager; site personnel; Federal, State, and Tribal regulatory authorities; and people who live or work near the site.

E. How does EPA assess the protectiveness of a remedy?

The purpose of a Five-Year Review is to determine whether the remedy at a site is, or upon completion will be, protective of human health and the environment. EPA’s technical assessment of a remedy examines the three questions shown in Figure 2. These questions provide a framework for

organizing and evaluating data and ensure that all relevant issues are considered when determining the protectiveness of the remedy.

Question A: Is the remedy functioning as intended?

When answering Question A, the reviewer focuses on the technical performance of the remedy, whether that remedy is related to a single Operable Unit (OU) or the entire site. Data on monitoring, system performance and operation and maintenance of the remedy plays an important role in the determinations. In addition, EPA confirms that access and institutional controls (ICs) are in place and successfully prevent exposure. In answering Question A, the reviewer should consider the implementation status of the remedy.

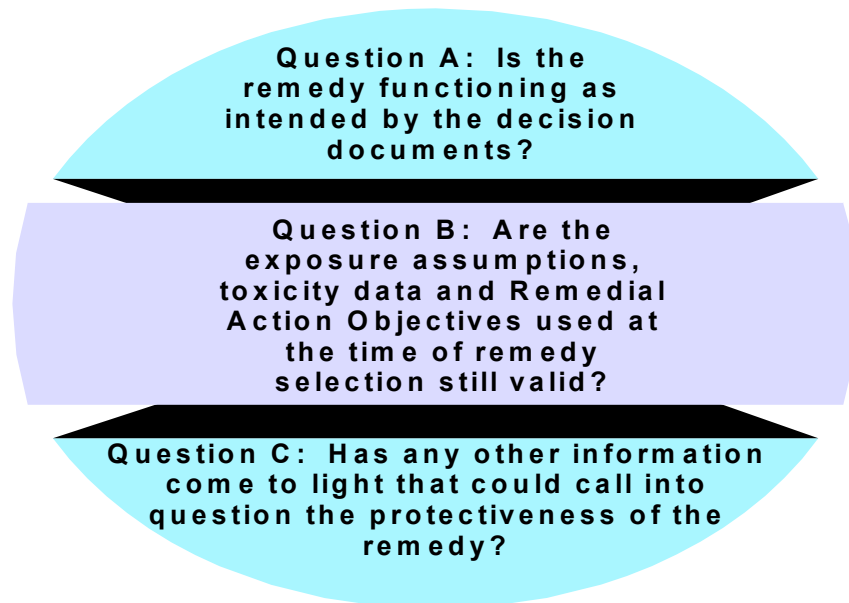


Figure 2: Three Questions for Assessing Protectiveness

When the Remedy is under Construction

The focus of the review is to determine if the remedy is being constructed in accordance with the requirements of the decision documents and design specifications, and if the remedy is expected to be protective when it is completed.

When the Remedy is Operating or Completed

Additional aspects of remedy implementation are addressed. In general, the following will be assessed:

- C Remedial action performance,
- C System operations/operation and maintenance (O&M),
- C Costs of system operations/O&M,
- C Implementation of institutional controls and other measures,
- C Monitoring activities,
- C Opportunities for optimization, and
- C Early indicators of potential remedy problems.

Question B: Are the exposure assumptions, toxicity data, cleanup levels, and Remedial Action Objectives still valid?

In answering Question B, the lead agency should review all the risk parameters on which the original remedy decision was based. This assessment should test the validity of all assumptions that underlie the original risk calculation. To reach its conclusions, the lead agency will generally consider changes in:

- Target populations,
- Exposure routes,
- Site characteristics and land use,
- Reference doses and slope factors,
- Applicable or Relevant and Appropriate Requirements (ARARs) and To Be Considered (TBCs), and
- Remedial Action Objectives (RAOs).

EPA generally will not reopen remedy selection decisions contained in RODs unless a new or modified requirement calls into question the protectiveness of the selected remedy.

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

The reviewer considers any other information that comes to light that could call into question the protectiveness of the remedy. Situations of interest to EPA may include the following:

- C Ecological risks had not been adequately evaluated or addressed at a site, and there is no plan in place to address these risks through a future action;
- The site, although located entirely above the 500-year flood boundary, was partially inundated by a 100-year flood; and
- Land use changes that are being considered by local officials.

F. How does the lead agency formulate its conclusions?

The conclusions of the Five-Year Review should include:

- Identification of issues,
- Recommendations and follow-up actions, and
- A determination of whether the remedy is, or is expected to be, protective of human health and the environment.

The reviewer arrives at these conclusions through a technical assessment of the information collected during the document review, data collection, interviews, site inspection, and other activities.

The reviewer identifies all issues that currently prevent or may prevent the response action from being protective. Examples of issues that may be identified in a Five-Year Review report include the following:

- C Inadequate ICs,

- C Cleanup levels are not protective due to changes in chemical characteristics, and
- C Remedial Action Objectives will not be achieved.

Section 4.4.1 of the Guidance contains additional examples.

The reviewer documents all such issues and follow-up actions needed to ensure the proper management of the remedy in the Five-Year Review report. The reviewer should also identify early indicators of potential remedy problems.

For each issue identified, the reviewer documents and ensures implementation of recommendations to resolve those issues. These recommendations are linked to follow-up actions in the Five-Year Review report. In addition, the reviewer may make additional recommendations that do not directly relate to achieving or maintaining the protectiveness of the remedy, such as activities related to O&M of the remedy and coordination with other public and government authorities. The following are the types of additional recommendations that may be included in the report:

- C Provide additional response actions,
- C Improve O&M activities,
- C Optimize remedy,
- C Enforce access controls and ICs, and
- C Conduct additional studies or investigations.

After addressing Questions A, B, and C, the reviewer determines the protectiveness of the remedy or remedies at a site and documents the rationale for its determination(s). The reviewer should make a protectiveness determination for each OU. For sites that have reached construction completion, it is recommended

the review include an additional, comprehensive site-wide protectiveness statement.

The determination of whether the remedy remains protective of human health and the environment generally will be based on the answers to Questions A, B, and C and the information obtained in the process of answering them. Although protectiveness generally is defined by the risk range and hazard index (HI), the answers to Questions A, B, and C may identify other factors and issues that may impact the protectiveness of a remedy.

At the end of the technical analysis and evaluation, if the answers to Questions A, B, and C are *yes, yes, and no*, respectively, then the remedy normally will be considered protective. However, if the answers to the three questions are other than *yes, yes, and no*, depending on the elements that affect each question, the remedy may be one of the following:

- C Protective,
- C Will be protective once the remedy is completed,
 - Protective in the short-term; however, in order for the remedy to be protective in the long-term, follow-up actions need to be taken,
- C Not protective, unless the following action(s) are taken in order to ensure protectiveness, or
- C Protectiveness cannot be determined until further information is obtained.

If a protectiveness statement cannot be made, a time frame should be provided when a protectiveness determination will be made. This is done through an addendum. If this is the case, the next Five-Year Review is due five years from the date that

the report is signed, not from the signature date of the addendum.

Even if there is a need to conduct further actions, it does not mean that the remedy is not protective. Normally, the remedy may be considered not protective when the following occur:

- C An immediate threat is present (*e.g.* exposure pathways that could result in unacceptable risks are not being controlled);
- C Migration of contaminants is uncontrolled and poses an unacceptable risk to human health or the environment;
- C Potential or actual exposure is present or there is evidence of exposure (*e.g.*, institutional controls are not in place or not enforced and exposure is occurring); or
- C The remedy cannot meet a new cleanup level and the previous cleanup level is outside of the risk range.

Once the Five-Year Review report is signed and placed in the local site repository, the lead agency should notify community members that the review is complete and the report is available.

As discussed in Section 1.3.3, the date EPA signs the report is the official completion date for the Five-Year Review, and this date becomes the trigger date for subsequent reviews. This date should be entered into WasteLan as soon as possible.

FOR MORE INFORMATION

For additional information on the Five-Year Review process, please contact your Regional or Headquarters Five-Year Review Coordinator.

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