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Comprehensive Five-Year Review Guidance

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Preface

The U.S. Environmental Protection Agency (EPA) is issuing this "Comprehensive Five-Year Review Guidance" to assist EPA Headquarters (HQ), Regional staff, and support agencies responsible for conducting five-year reviews under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). This guidance generally is intended to promote consistent implementation of the five-year review process.

Section 121 of 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) further provides that remedial actions which result in any hazardous substances, pollutants, or contaminants remaining at the site above levels that allow for unlimited use and unrestricted exposure be reviewed every five years to ensure protection of human health and the environment.

The Five-Year Review requirement applies to all remedial actions selected under CERCLA §121. Therefore, sites with CERCLA remedial actions may be subject to a five-year review. Consistent with Executive Order (EO) 12580, other Federal agencies are responsible for ensuring that five-year reviews are conducted at sites where five-year reviews are required or appropriate.

This guidance is designed and intended to:

- Provide an approach for conducting five-year reviews;
- Facilitate consistency across the ten EPA Regions;
- Clarify current policy; and
- Discuss roles and responsibilities of various entities in conducting or supporting five-year reviews.

This guidance supersedes the following directives on five-year reviews:

- Office of Solid Waste and Emergency Response (OSWER) Directive 9355.7-02 (May 23, 1991), *Structure and Components of Five-Year Reviews*;
- OSWER Directive 9355.7-02FS1 (August 1991), Factsheet: *Structure and Components of Five-Year Reviews;*

- OSWER Directive 9355.7-02A (July 26, 1994), *Supplemental Five-Year Review Guidance;* and

- OSWER Directive 9355.7-03A (December 21, 1995), *Second Supplemental Five-Year Review Guidance.*

In addition, this guidance updates and supersedes the text regarding five-year reviews in:

- OSWER 9200.1-23P (July 1999), *A Guide to Preparing Superfund Proposed Plans, Records of Decision, and Other Remedy Selection Decision Documents*.

Questions or comments concerning this guidance should be directed to the appropriate EPA Headquarters Regional Center.

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List of Acronyms

AOC	Administrative Order on Consent
ARARs	Applicable or Relevant and Appropriate Requirements
CA	Cooperative Agreement
CAG	Community Advisory Group
CD	Consent Decree
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CERCLIS	Comprehensive Environmental Response, Compensation, and Liability Information System
CFR	Code of Federal Regulations
CIC	Community Involvement Coordinator
CIP	Community Involvement Plan
DOD	Department of Defense
DOE	Department of Energy
EO	Executive Order
EPA	United States Environmental Protection Agency
ESD	Explanation of Significant Differences
FCOR	Final Close Out Report
FFA	Federal Facility Agreement
FFRRO	Federal Facilities Restoration and Reuse Office
FR	Federal Register
HASP	Health and Safety Plan
IAG	Interagency Agreement
IC	Institutional Control
IRIS	Integrated Risk Information System
LOAEL	Lowest Observed Adverse Effect Level
MCLs	Maximum Contaminant Levels
MNA	Monitored Natural Attenuation
NCP	National Oil and Hazardous Substances Pollution Contingency Plan
NOAEL	No Observed Adverse Effect Level
NPL	National Priorities List
O&M	Operation and Maintenance
OECA	Office of Enforcement and Compliance Assurance
OERR	Office of Emergency and Remedial Response
OSHA	Occupational Safety and Health Administration
OSWER	Office of Solid Waste and Emergency Response
OU	Operable Unit
PCOR	Preliminary Close Out Report
PRP	Potentially Responsible Party
RA	Remedial Action
RAGS	Risk Assessment Guidance for Superfund

RAO	Remedial Action Objective
RCRA	Resource Conservation and Recovery Act
RD/RA	Remedial Design/Remedial Action
RI/FS	Remedial Investigation/Feasibility Study
ROD	Record of Decision
RPM	Remedial Project Manager
SARA	Superfund Amendments and Reauthorization Act of 1986
SMOA	Superfund Memorandum of Agreement
SPIM	Superfund Program Implementation Manual
SSC	Superfund State Contract
TAG	Technical Assistance Grant
TBCs	To Be Considereds
USACE	United States Army Corps of Engineers
USCG	United States Coast Guard
UU/UE	Unlimited Use/Unrestricted Exposure
WasteLan	The Regional database related to CERCLIS

1.0 OVERVIEW

This chapter covers the purpose of five-year reviews, when are reviews required or appropriate, discontinuation of five-year reviews, and triggering actions for five-year reviews. This chapter also discusses the application of the Five-Year Review policy to sites with multiple operable units (OUs), division of large complex sites, pre- and post-Superfund Amendments and Reauthorization Act of 1986 (SARA) sites, Records of Decision (RODs), and deleted or partially deleted sites. You will also find information on Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) remedial actions (RAs), CERCLA remedial actions at sites with Resource Conservation and Recovery Act (RCRA) response, and interim/early remedial actions. Finally, the chapter discusses how no action or no further action RODs, monitored natural attenuation (MNA), and institutional controls (ICs) impact five-year reviews.

1.1 What is the purpose of a five-year review?

The purpose of a five-year review 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 and the hazard index (HI). Evaluation of the remedy and the determination of protectiveness should be based on and sufficiently supported by data and observations.

1.2 When are five-year reviews required or appropriate?

Five-year reviews should be conducted either to meet the statutory mandate under CERCLA §121(c) or as a matter of EPA policy. Consequently, five-year reviews are classified in this guidance as either "statutory" or "policy." The Five-Year Review requirement applies to all remedial actions selected under CERCLA §121. Regions may also conduct other five-year reviews at their discretion.

You should consider a number of factors when determining whether to conduct a five-year review, as discussed in the following two sections (see Sections 1.2.1 and 1.2.2). In general, five-year reviews are required whenever a remedial action results in hazardous substances, pollutants, or contaminants remaining on site. Under the Agency's interpretation contained in the NCP, the requirement in CERCLA §121(c) is triggered when remaining on-site hazardous substances, pollutants, or contaminants are above levels that allow for "unlimited use and unrestricted exposure." See 40 CFR §300.430(f)(4)(ii).

CERCLA §121(c) states the following:

> *If the President selects a remedial action that results in any hazardous substances, pollutants, or contaminants remaining at the site, the President shall review such remedial action no less often than each five years after the initiation*

> *of such remedial action to assure that human health and the environment are being protected by the remedial action being implemented. In addition, if upon such review it is the judgment of the President that action is appropriate at such site in accordance with section [104] or [106], the President shall take or require such action. The President shall report to the Congress a list of facilities for which such review is required, the results of all such reviews, and any actions taken as a result of such reviews.*

The Agency interpreted this requirement further in the National Contingency Plan (NCP) (40 CFR §300.430(f)(4)(ii)) which states:

> *If a remedial action is selected that results in hazardous substances, pollutants, or contaminants remaining at the site above levels that allow for unlimited use and unrestricted exposure, the lead agency shall review such action no less often than every five years after the initiation of the selected remedial action.*

"Unlimited use and unrestricted exposure" (UU/UE) means that the selected remedy will place no restrictions on the potential use of land or other natural resources. In general, if the selected remedy relies on restrictions of land and/or groundwater use by humans and/or ecological populations to be protective, then the use has been limited and a five-year review should be conducted. For example, if a site is cleaned up to an industrial-use level, and/or other types of uses are restricted (*e.g.*, residential use), then, generally, UU/UE is not met. Exhibit 1-1, "Types of Actions Subject to Five-Year Reviews," provides examples of the types of remedial actions subject to statutory and policy reviews.

1.2.1 When is a statutory review required?

CERCLA requires five-year reviews if both of the following conditions are true:

- Upon completion of the remedial action, hazardous substances, pollutants, or contaminants will remain on site[1]; and
- The ROD for the site was signed on or after October 17, 1986 (the effective date of SARA[2]) and the remedial action was selected under CERCLA §121.

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[1] The general response authority of CERCLA §104(c)(4) applies to both removal and remedial actions. 104(c)(4). Also see 40 CFR §300.430(f)(4)(ii).

[2] Generally, SARA became effective the date it was passed (October 17, 1986). See Pub. L. 99-499, Oct. 17, 1986, 100 Stat. 1672.

Exhibit 1-1: Types of Actions Subject to Five-Year Reviews

If the action/site is . . .	then a review is . . .	and examples of actions or components of actions include . . .
a ***post-SARA*** remedial action that, upon completion, will leave hazardous substances, pollutants, or contaminants on site above levels that allow for unlimited use and unrestricted exposure	required by ***statute***	– waste stabilization, fixation, or encapsulation on site – landfill cap or covers and slurry walls – institutional controls **S** sediment capping
a ***pre- or post-SARA*** remedial action that, upon completion, will not leave hazardous substances, pollutants, or contaminants on site above levels that allow for unlimited use and unrestricted exposure, **but requires five or more years to complete**	conducted as a matter of EPA ***policy***, until cleanup levels are achieved, allowing unlimited use and unrestricted exposure	– long-term monitored natural attenuation – long-term groundwater pump and treatment – long-term bioremediation of groundwater or soil – other long-term remedies, such as soil washing and land farming **S** monitored natural recovery (sediments)
a ***pre-SARA*** remedial action that will leave hazardous substances, pollutants, or contaminants on site above levels that allow for unlimited use and unrestricted exposure	conducted as a matter of EPA ***policy***	– waste stabilization, fixation, or encapsulation on site – landfill cap or covers and slurry walls – institutional controls
a ***removal*** **action that takes place at a site on *the NPL*** that leaves hazardous substances, pollutants, or contaminants on site above levels that allow for unlimited use and unrestricted exposure and **where no remedial action has or will take place**	conducted as a matter of EPA ***policy***	– excavation and treatment where hazardous substances, pollutants, or contaminants remain on site above levels that allow for unlimited use and unrestricted exposure

1.2.2 When is a policy review appropriate?

Five-year reviews generally should be conducted as a matter of policy for the following types of actions:

- A pre- or post-SARA remedial action that, upon completion, will not leave hazardous substances, pollutants, or contaminants on site above levels that allow for unlimited use and unrestricted exposure, but requires five years or more to complete;
- A pre-SARA remedial action that leaves hazardous substances, pollutants, or contaminants on site above levels that allow for unlimited use and unrestricted exposure; or

- A removal-only site on the NPL where a removal action leaves hazardous substances, pollutants, or contaminants on site above levels that allow for unlimited use and unrestricted exposure and where no remedial action has or will take place.

1.2.3 When should five-year reviews be completed?

The first five-year review generally should be completed and signed by the EPA Region within five years of the initial trigger date (see Sections 1.3.1 and 1.3.2). As a matter of policy, you should complete subsequent statutory or policy five-year reviews no later than five years following the signature date of the previous Five-Year Review report. Five-year reviews may be conducted earlier or more frequently than every five years, if needed, to ensure the protection of human health and the environment.

1.2.4 When can five-year reviews be discontinued?

Five-year reviews may no longer be needed when no hazardous substances, pollutants, or contaminants remain on site above levels that allow for unlimited use and unrestricted exposure. The basis for this finding should be documented in your final Five-Year Review report. When you make this determination prior to the first five-year review, you should record it in a document subject to public comment, such as a Proposed Plan or a Notice of Intent to Delete. When notice of five-year review discontinuation is given in a document other than a Five-Year Review report, the Region should submit a memorandum, signed by the Regional Administrator or his/her designee, to Headquarters. The memorandum should provide the reason for not conducting five-year reviews and cite the document in which this decision was made and supported.

1.3 When does the five-year review period begin?

The initiation or trigger date that starts the five-year review period depends upon whether the review is categorized as statutory or policy. However, the review should be completed within 5 years of its trigger date regardless of its category. Lead agencies may choose to conduct a five-year review earlier, or more frequently, than every five years to ensure the protection of human health and the environment. A discussion of the first and subsequent triggers for both statutory and policy review is provided below.

1.3.1 What actions first trigger a statutory review?

In accordance with CERCLA §121 and the NCP, a statutory review is triggered by the initiation of the first remedial action that leaves hazardous substances, pollutants, or contaminants on site above levels that allow for unlimited use and unrestricted exposure. In cases where there are multiple remedial actions, the earliest remedial action that leaves hazardous

substances, pollutants, or contaminants on site should trigger the initial review, even if it is an interim remedial action.

For the purpose of a five-year review, a remedial action typically is initiated on the date of "actual RA on-site construction" or the "actual RA start" date for Federal facilities. The date of actual RA on-site construction generally corresponds to the date the contractor begins work at a site for the remedial action, typically the date of on-site mobilization. The definition of the "actual RA start" varies as outlined in the Superfund/Oil Program Implementation Manual (SPIM). For remedies where on-site mobilization may not occur, as a matter of policy, the date of the first monitoring event following ROD signature or the ROD signature itself should be used to trigger the five-year review period.

1.3.2 What actions first trigger a policy review?

A policy review initially should be triggered by the date that construction 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. The PCOR or FCOR date also triggers the initial five-year review at NPL removal-only sites.

1.3.3 What are triggers for subsequent statutory and policy reviews?

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. For reviews led by other Federal agencies, States, or Tribes, and where EPA has a concurrence role, the trigger for subsequent reviews corresponds to EPA's concurrence signature date of the preceding Five-Year Review report (see Sections 3.7.2 and 3.7.3).

1.4 How do five-year reviews apply to a site with multiple operable units?

Five-year reviews for sites with multiple OUs, as a matter of policy, should address all OUs and remedial actions that have been initiated at the time of the review, except for situations as described in Section 1.4.2. At the Regions' discretion, the five-year review may also include and consider areas of a site where no remedial action has been selected or initiated.

1.4.1 How is a multiple operable unit site categorized?

Five-year reviews for multiple OU sites can be categorized as either statutory or policy. As a matter of policy, a site is subject to a statutory review if any one of its initiated remedial actions is subject to a statutory review. A site is subject to a policy review if no initiated actions are subject to a statutory review and at least one action is subject to a policy review.

1.4.2 When is it appropriate to conduct a separate five-year review for different areas of a large and complex site?

At some large and complex sites, individual OUs, or groups of OUs, may have been treated as separate sites throughout the remedial process. Under these circumstances, Regions may continue to treat these areas separately and conduct individual five-year reviews for each area. Each five-year review should include the status and protectiveness determination of the five-year reviews conducted for the other areas of the entire site. Regions may choose to combine the separate reviews of different areas into a single five-year review prior to, or following, construction completion for the entire site. However, no area should be reviewed later than five years after its trigger date or previous review.

Actions within each area may trigger its respective statutory or policy review. However, in cases where site-wide construction completion will not be achieved for an extended period of time, the initial trigger date for a policy review should correspond to the date that physical construction is complete at the area under consideration. The Region should establish this date on a site-specific basis which should be based on the signature date of the Interim or Final RA Report.

1.4.3 How is a site with pre- and post-SARA RODs categorized?

At sites where there are both pre- and post-SARA RODs, the pre-SARA remedial actions are subject under this policy to post-SARA Five-Year Review procedures. For example, suppose a pre-SARA remedial action initially is subject to a policy review because hazardous substances, pollutants, or contaminants are permanently left on site above levels that allow for unrestricted use and unlimited exposure. If a post-SARA ROD is signed for that same site, a five-year review should be conducted, unless the post-SARA ROD selects a remedy that removes all on site hazardous substances, pollutants, or contaminants including the hazardous substances, pollutants, or contaminants left on site by the pre-SARA action. In such cases, the original five-year review schedule should be maintained as a matter of policy. If no schedule has been established, the post-SARA trigger should be utilized.

1.5 What are some other considerations for five-year reviews?

This section discusses other considerations (*i.e.*, deletions, RCRA responses, interim and early remedial actions, no action or no further action RODs, monitored natural attenuation, and institutional controls) that may affect the need for and conduct of five-year reviews.

1.5.1 Are five-year reviews required for a site that has been deleted or partially deleted from the NPL?

It is EPA's policy that the Five-Year Review requirement is independent of and unaffected by the deletion process.[3] Consistent with the NCP, a site can be deleted or partially deleted from the NPL once the deletion criteria have been satisfied. If a site has been deleted or is in the process of being deleted, your Five-Year Review report should address the status of any deletion action. Five-year reviews continue as needed after deletion.

1.5.2 Are five-year reviews required for a site with a RCRA response?

In 1996, EPA established a policy to defer some CERCLA cleanup activities to the RCRA program. The policy is outlined in the memorandum "Coordination Between RCRA Corrective Action and Closure and CERCLA Site Activities."[4] This policy allows site managers to defer cleanup activities for all or part of a site from CERCLA to RCRA (or vice versa). If a site is deferred to RCRA prior to being placed on the NPL, or is deleted from the NPL prior to the selection of the remedy and deferred to RCRA for corrective action, you do not need to conduct a five-year review.

In cases where full deferral is not appropriate, it is possible that both RCRA and CERCLA authorities will be used to address a site. When a RCRA action is included as a part of a CERCLA action, the RCRA action should be included in the five-year review as a matter of policy, if a five-year review is required or appropriate.

1.5.3 How is a site that has an interim or early remedial action handled?

Regions should conduct five-year reviews for interim or early actions selected under CERCLA §121 consistent with Section 1.2 of this guidance.[5] For instance, Regions should conduct a review if an alternate water supply is installed and hazardous substances, pollutants, or contaminants remain on site above levels that allow for unlimited use and unrestricted exposure. If a subsequent action reduces the hazardous substances, pollutants, or contaminants on site to

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[3] In 1991, EPA clarified its policy on whether a site deleted from the NPL is subject to a five-year review. See "Notice of Policy Change," 56 FR 66601 (December 24, 1991). In appropriate circumstances, a site does not need to be kept on the NPL solely for the purposes of conducting five-year reviews (See 55 Fed Reg at p. 8699).

[4] The memorandum "Coordination Between RCRA Corrective Action and Closure and CERCLA Site Activities" was issued by Steven A. Herman, Assistant Administrator, Office of Enforcement and Compliance Assurance, and Elliott P. Laws, Assistant Administrator, OSWER (September 24, 1996).

[5] Interim and Early actions are defined in Chapter 8 in *A Guide to Preparing Superfund Proposed Plans, Records of Decision, and other Remedy Selection Decision Documents*. EPA 540-R-98-031, OSWER 9200.1-23P (July 1999)

levels that allow unlimited use and unrestricted exposure, then reviews may be discontinued (see Section 1.2.4).

1.5.4 How is a site that has a no action or a no further action ROD handled?

Consistent with Section 1.2, Regions should conduct a five-year review for a remedy where a no action or no further action ROD leaves hazardous substances, pollutants, or contaminants on site above levels that allow for unlimited use and unrestricted exposure. For example, as a matter of policy Regions should conduct a review for an NPL site with a no action ROD where a removal-only action leaves hazardous substances, pollutants, or contaminants on site above levels that allow for unlimited use and unrestricted exposure, or where groundwater monitoring or other types of monitoring of contamination above action levels is the only remedial action selected. However, no five-year review may be needed when monitoring is used only to verify absence of contamination.

1.5.5 How is a ROD that includes monitored natural attenuation handled?

CERCLA §121 remedies relying on monitored natural attenuation or natural attenuation may be subject to five-year reviews consistent with Section 1.2. If monitored natural attenuation is included in a no action or a no further action ROD, then that ROD is not considered to be no action or no further action and therefore, Regions may need to conduct a five-year review, consistent with this guidance.

1.5.6 How is a ROD that includes institutional controls handled?

Institutional controls may be part of remedies selected under CERCLA §121 and consistent with Section 1.2 of this guidance may be subject to five-year reviews.[6] If institutional controls are included in a no action or a no further action ROD, and protectiveness relies on the institutional control, then that ROD is not considered to be no action or no further action and therefore, Regions may need to conduct a five-year review.

[6] Regions should refer to OSWER 9355.0-74FS-P, dated September 2000, entitled *Institutional Controls: A Site Manager's Guide to identifying, evaluating and selecting Institutional Controls at Superfund and RCRA Corrective Action Cleanups* for further information on institutional controls and remedy selection.

2.0 ROLES AND RESPONSIBILITIES FOR EPA, STATES, TRIBES, AND OTHER FEDERAL AGENCIES

This chapter discusses the roles and responsibilities of U.S. Environmental Protection Agency (EPA), other Federal agencies, State agencies, and Tribes, in conducting five-year reviews. As a general matter, for remedies selected under Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) §121, except at non-NPL Federal facility sites, EPA has the ultimate authority for determining whether a remedy subject to the Five-Year Review requirements in CERCLA §121(c) is protective. The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) addresses, in general, the involvement of State agencies and Tribes in CERCLA actions in 40 CFR §300.515 and §300.520. Finally, CERCLA §120 and Executive Order (EO) 12580[7] address the responsibilities of Federal agencies in carrying out CERCLA cleanups.[8]

2.1 What are the roles of the lead and support agencies?

Under the NCP, the lead agency provides for the remedial project manager (RPM) "to plan and implement [the] response action;"[9] a response action would include conducting a five-year review. A support agency "furnish[es] necessary data to the lead agency, reviews response data and documents, and provides other assistance."[10] The NCP also encourages appropriate State and Tribal involvement for Fund-financed and Enforcement-lead remedial actions (see 40 CFR §300.515 and §300.520). Where the State or Tribe is the lead agency, the NCP provides that EPA concurrence is needed on remedy selection decisions (see 40 CFR §300.515(e) and §300.520).

The relative roles and responsibilities for lead and support agencies can vary significantly depending on ability, resources, and legal authorities. There are a number of documents that can be used to specify roles and responsibilities of lead and support agencies. Some of these are general in scope, while others are more narrow in scope and apply solely to a specific site. General instruments include Superfund Memoranda of Agreement (SMOAs), Cooperative Agreements (CAs), and Superfund State Contracts (SSCs). Normally, SMOAs are general, non-site-specific agreements that EPA uses to define roles and interactions in conducting a response action. EPA uses CAs to transfer Superfund monies to States or Tribes for response activities. SSCs are used to identify EPA and State or Tribal roles and responsibilities required under

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[7]Executive Order No. 12580 of January 23, 1987, as amended on August 28, 1996.

[8]As discussed in section 2.4, State enforcement-lead cleanups are not subject to this guidance.

[9]See 40 CFR §300.5.

[10]Id.

CERCLA §104. Site-specific agreements include Consent Decrees, Administrative Orders on Consent, and Federal Facility Agreements (FFAs). If no SMOA, SSC, or CA is available, a letter of agreement should be written to define roles and responsibilities for the five-year review, consistent with the NCP (see 40 CFR §300.515). Wherever possible, the specific roles and responsibilities regarding the conduct of a five-year review should be detailed in a single document to avoid confusion and disputes at a later date.

2.1.1 What are the roles of the lead agency?

The lead agency conducts the five-year review, prepares the Five-Year Review report, and submits the report to the support agency for review and comment. The lead agency is also responsible for conducting community involvement activities and for ensuring that recommendations and follow-up actions identified during five-year reviews are completed. Generally, funding for five-year reviews is provided by EPA for Fund-financed sites, Potentially Responsible Parties (PRPs) for Enforcement-lead sites (through appropriate mechanisms), and by other Federal agencies or departments for Federal facility sites.

Where EPA is the lead agency pursuant to 40 CFR §300.515, the Region should submit a copy of its final Five-Year Review report to EPA Headquarters (HQ) within 10 days of signature, and provide copies to the support agency and site information repositories. Where the State or Tribe is the lead agency, pursuant to 40 CFR §300.515, the State should submit a copy of the final Five-Year Review report to the Region; once the Region has concurred, the Region should provide a copy to EPA HQ within 10 days of signature, to any other support agencies, and to site information repositories. Where another Federal agency or department is the lead agency, pursuant to CERCLA §120 and EO 12580, the Federal agency or department should submit a copy of the final Five-Year Review report to the Region; once the Region has concurred, the Region should provide a copy to HQ within 10 days of signature, to any other support agencies, and to site information repositories.

2.1.2 What are the roles of the support agency?

The role of the support agency is to participate in the review process, if requested, and review and comment on the Five-Year Review report. Where the State or Tribe is the lead agency for a response action (such as conducting a five-year review), the NCP provides that it must obtain EPA's concurrence (see 40 CFR §300.515(e)).

The lead agency should give the support agency an adequate opportunity to participate in the five-year review process and to review and comment on the draft Five-Year Review report before it is finalized. When there is more than one support agency involved, time allowances for review and comment should be the same for all support agencies who choose to participate in the review process. The amount of time that a support agency will have to review the Five-Year Review report should be documented in the SMOA, SSC, CA, or other agreement documents,

but should not be less than review times for other remedy decision documents (see 40 CFR §300.515(h)(3)). The goal should be to resolve any concerns of support agencies before drafting the final report. In any case, the support agency or agencies may provide written comments on the Five-Year Review report. Lead and support agencies should work together throughout the five-year review process to ensure that concerns are resolved in a timely manner, and to the extent practicable, prior to finalizing the Five-Year Review report.

2.2 Who conducts the review at a Fund-financed site?

At Fund-financed sites, the ultimate responsibility for the protectiveness determination rests with EPA. As described in Section 2.1, EPA may be the lead or support agency.

Regions may acquire the services of a contractor or establish agreements with other agencies (*e.g.*, the U.S. Army Corps of Engineers) to perform studies, conduct investigations, and/or develop draft Five-Year Review reports. In all cases, Regions should ensure the quality and completeness of review activities and the content of the final Five-Year Review report.

2.3 What if a site is an Enforcement-lead site?

At CERCLA Enforcement-lead sites, the ultimate responsibility for the quality and completeness of review activities and the content and protectiveness determinations of the Five-Year Review report rests with EPA. As described in Section 2.1, EPA may be the lead or support agency.

At sites in which EPA is the lead agency Regions may acquire the services of a contractor or establish agreements with other agencies (*e.g.*, the U.S. Army Corps of Engineers) to perform studies, conduct investigations, and/or develop draft Five-Year Review reports.

PRPs or PRP-hired contractors may perform certain support activities (*e.g.*, data collection, studies or analysis) according to provisions of an enforceable agreement.

2.4 What if site activities are led by a State or Tribe?

As described in Section 2.1, States and Tribes can be the lead agency in carrying out a five-year review. In those cases, States or Tribes should ensure the quality and completeness of review activities and the content of the final Five-Year Review report, prior to submitting the report to the Region for EPA's concurrence. When a State or Tribe provides EPA with a Five-Year Review report, EPA can choose to concur with the report and protectiveness statements or make its own protectiveness determinations.

Where a State or Tribe conducts a cleanup using its own legal authorities (*e.g.*, State enforcement action under a CERCLA-equivalent State law), the remedy is not selected pursuant to CERCLA §121 and is not subject to the Five-Year Review requirement.

Exhibit 2-1 provides an overview of the typical roles of different parties for each type of response action.

Exhibit 2-1: Typical Roles in the Five-Year Review Process*

If the response action is...	at...	under...	then conducting the review is the responsibility of...	with funding by...	and with the EPA Region...
Fund-financed	a site	CERCLA §121,and CERCLA §104	the lead agency; when the lead agency is a State or Tribe, EPA concurs;	Superfund	making or concurring with the protectiveness determination.
Enforcement-lead	a site	CERCLA §104 and §121, along with a Consent Decree or other enforcement document	the lead agency; when the lead agency is a State or Tribe, EPA concurs. (PRPs may be allowed to provide certain support for five-year reviews);	PRPs	making or concurring with the protectiveness determination.
Other Federal agency or department (*e.g.*, led by Department of Defense, Department of Energy or Department of the Interior)	a Federal facility NPL site	CERCLA §104, §120 and §121, Executive Order 12580, and a Federal Facility Agreement	the respective Federal agency or department	the respective Federal agency or department	making or concurring with the protectiveness determination.
Other Federal agency	a Federal facility non-NPL site	CERCLA §104 and §121, and Executive Order 12580	the respective Federal agency or department	the respective Federal agency or department	commenting on the protectiveness determination (if requested).

Note: * The scenarios presented in the exhibit are not all inclusive. Regions should determine the respective roles in the five-year review process when other circumstances exist. EPA does not have a role in five-year reviews at non-NPL Federal facility sites; however, EPA Regions may comment or be asked to comment on a site-specific basis.

2.5 What if site activities are led by another Federal agency or department?

CERCLA §104, §120, and §121 identify functions and responsibilities vested in the President for undertaking response efforts and coordinating all other efforts at the scene of a

release on or from Federally-owned property (or vessels). The President, in EO 12580, delegates some of these responsibilities to the respective Federal agencies and departments for Federally-owned or Federally-operated facilities over which these lead agencies have jurisdiction, custody, or control.

Therefore, at sites where activities are led by another Federal agency or department, the Federal agency or department has responsibilities for selecting remedies and implementing the remedial actions, and for conducting all required five-year reviews. The Federal agency or department is responsible for planning, coordinating, funding, and conducting five-year reviews and for making protectiveness determinations upon conclusion of each five-year review. Federal agencies or departments are encouraged to have EPA, States, and Tribes participate and comment throughout the five-year review process, as appropriate. Federal agencies or departments are also responsible for initiating resolutions to issues and following up on all recommendations that result from these five-year reviews. Federal agencies or departments may not adopt or utilize guidelines that are inconsistent with EPA's Five-Year Review guidance or certain other EPA guidance, as specified in CERCLA §120(a)(2).

- ***Federal facility sites that are listed on the NPL*** – EO 12580 paragraphs 2(d) and (g) delegate remedial responsibilities to the Department of Defense (DOD) and the Department of Energy (DOE), and to EPA, respectively. In addition, at all Federal facility NPL sites, CERCLA §120 requires Federal agencies or departments to perform remedial investigation and feasability studies (RI/FS) (see CERCLA §120(e)(1)), to enter into Inter-Agency Agreements (IAGs) (frequently called Federal Facility Agreements), and to initiate remedial actions, subject to EPA concurrence. Therefore, five-year reviews are conducted by the Federal agency or department that has jurisdiction, custody, or control, but EPA retains final authority over whether the five-year reviews adequately address the protectiveness of remedies. EPA will either concur with the final Federal agency or department protectiveness determination, or EPA may provide independent findings. Disputes which arise related to protectiveness determinations or independent findings by EPA may be resolved on a site-specific basis through formal dispute resolution procedures, typically established in FFAs. Exhibits 2-2 and 2-3 and Sections 2.5.1 and 2.5.2 discuss Federal facility NPL sites and FFAs in more detail.

- ***Non-NPL Federal facilities*** – EO 12580, paragraphs 2(d) and (e), give remedial responsibilities, and therefore five-year review responsibilities, to the Federal agency or department having jurisdiction, custody, or control. EPA may also be asked to comment, to the extent practical, on five-year reviews or protectiveness determinations at non-NPL Federal facilities. Section 2.5.3 discusses non-NPL Federal facilities in more detail.

Exhibit 2-2 below provides an overview of relevant EO 12580 sections and their applicability.

Exhibit 2-2: Federal Responsibilities Under Executive Order 12580

In EO 12580 section(s)…	the President delegates to…	certain remedial functions and responsibilities in CERCLA section(s)…		and those remedial functions and responsibilities at Federal facilities generally pertaining to…
2(b)	***EPA*** (in consultation with the National Response Team)	121(f)(1)		promulgation of regulations assuring substantial and meaningful State involvement (in initiation, development, and selection of remedial actions to be undertaken in the State).
2(d)	***DOD, DOE,*** (subject to the requirements described in CERCLA §120)	104(a), 104(b), 104(c)(4),	and 121	selecting and taking NPL and non-NPL[(1) (2)] remedial actions, which includes both conducting five-year reviews and making protectiveness determinations (with EPA concurrence at NPL sites).
2(e)	***Federal Departments/ Agencies*** (for non-NPL Federal facility sites.)	104(a), 104(b), 104(c)(4),	and 121	selecting and taking non-NPL remedial actions, which includes both conducting five-year reviews and making protectiveness determinations.
2(g)	***EPA*** (subject to the above delegations)	104(a), 104(b), 104(c)(4),	and 121	selecting and taking NPL remedial actions, which includes conducting five-year reviews and making protectiveness determinations at Fund-lead and Enforcement-lead NPL sites.

Note: [(1)] EPA does not have a role in five-year reviews at non-NPL Federal facility sites; however, EPA Regions may be asked to comment on a site-specific basis.

[(2)] In addition to the EO 12580 delegation of remedy selection and remedial action responsibilities to all Federal agencies and departments for non-NPL Federal facility sites, CERCLA §120(e) establishes remedy selection and remedial action responsibilities for Federal agencies and departments for all Federal facility NPL sites, as well. For example, CERCLA §120(e)(2) requires Federal agencies and departments to enter into NPL IAGs (frequently called FFAs) with EPA (States may participate.) CERCLA §120(e)(4) requires FFAs to address selection of remedies and completion of remedial actions at Federal facility NPL sites. FFAs, where applicable, should specify the procedures to be followed with respect to conducting five-year reviews at Federal facility NPL sites.

The following subsections detail responsibilities for conducting five-year reviews at sites led by other Federal departments and agencies.

2.5.1 What is the purpose of FFAs at other Federal agency NPL sites?

CERCLA §120(e)(2) requires that EPA sign an IAG (frequently called an FFA) with responsible Federal agencies or departments to detail respective roles and responsibilities for remedial actions at NPL sites. CERCLA §120(e)(1) requires Federal agencies or departments to conduct remedial investigations in consultation with EPA and appropriate State authorities at Federal facility NPL sites. Most Federal facility NPL sites will have site-specific roles and responsibilities specified in the FFA. CERCLA §120(e)(4) requires FFAs to include selection of remedies, completion of remedial actions, and arrangements for long-term operation and maintenance of the facility. Therefore, the procedures for conducting five-year reviews and making protectiveness determinations fall within the scope of FFAs. FFAs should specify in detail the procedures governing five-year reviews at Federal facility NPL sites.

OSWER Directive 9320.0-75 (November 29, 1996), "Federal Facilities Streamlined Oversight Directive" reiterates EPA's responsibility for oversight of remedial activities at Federal facility NPL sites. States and Tribes, as regulators, may also have an oversight role, defined in the FFA, at a facility. Exhibit 2-3 describes the topics to be addressed in an FFA.

Exhibit 2-3: Federal Facility Agreements and Five-Year Reviews

CERCLA § 120(e)(2) requires that the relevant Federal agency or department must enter into an FFA (IAG in the statute) with EPA within six months after EPA's review of the Remedial Investigation/Feasibility Study (RI/FS) is completed. States may be signatories to the FFA and under CERCLA §120 (f) must be included in the decision-making process at Federal facility NPL sites. Whenever a Federal facility is located on Tribal lands, the appropriate Tribal government should be involved.

CERCLA §120(e)(4), in the case of schedules, requires that the EPA/DOD and EPA/DOE Model FFA contain procedures for the submission and review of documents, schedules of cleanup activities, and provisions for dispute resolution. Regions should examine FFAs with respect to the performance of five-year reviews to clarify:

- Roles, responsibilities, and milestones;
- Arrangements for long-term operation and maintenance of the facility; and
- Opportunities for public involvement.

For Federal facilities only, EPA considers Five-Year Review reports to be stand-alone primary documents or part of another related primary document that should have an enforceable schedule within the framework of the FFA. Where EPA enters into an FFA, the agreement should include all site-specific Five-Year Review requirements, such as provisions for reviews, public participation, and addressing or resolving issues.

Where the roles and responsibilities for conducting five-year reviews and making protectiveness determinations are not specified in an FFA (for example, the FFA may not have been signed, or it may be silent or unclear with respect to five-year reviews), then the parties should rely on this guidance for fulfilling EPA's obligations under CERCLA §120 and §121, including making protectiveness determinations. Five-year review requirements should be

identified early in the FFA process, so that the parties to the Agreement have clearly defined roles and responsibilities for implementing CERCLA §121(c) with respect to five-year reviews. However, consistent with CERCLA §120(g), FFAs cannot re-delegate EPA's final authority over whether the five-year reviews adequately address the protectiveness of remedies.

2.5.2 What is EPA's role at NPL sites under the jurisdiction of another Federal agency or department?

CERCLA §120 and EO 12580 provide the basis for EPA's oversight role at other Federal agency NPL sites. This role includes the following:

- Assisting in the determination of cleanup remedies or potentially selecting the remedies, in consultation with the lead agency and appropriate State authorities, beginning at the commencement of remedial investigations and feasibility studies;
- Ensuring that Federal agencies or departments appropriately consider all relevant guidance and policies that EPA determines are appropriate;
- Ensuring compliance with signed FFAs; and
- Determining that decisions protect human health and the environment and that such decisions are adequately supported in the Five-Year Review report (whether as a stand-alone primary document or part of a related primary document).

EPA is not responsible for conducting five-year reviews at Federal facility NPL sites. However, EPA's final remedy selection authority at Federal facility NPL sites requires that EPA retain final authority to make protectiveness determinations. Accordingly, EPA will either concur with any protectiveness determinations to ensure protection of human health and the environment, consistent with EPA's statutory and regulatory authorities or EPA may provide independent findings. EPA Regions should review Federal facility NPL Five-Year Review reports (whether as a stand-alone primary document or part of a related primary document) and protectiveness determinations for consistency with this guidance and adequacy of the supporting basis, and should participate or comment throughout the five-year review process, as appropriate.

2.5.3 What is EPA's role at a non-NPL site under the jurisdiction of another Federal agency or department?

EO 12580 paragraphs 2(d) and (e)(1) delegates the authority in CERCLA §104 and §121 to the Federal agencies or departments for selecting and conducting remedial actions addressing releases or threatened releases at sites that are not on the NPL. Consistent with CERCLA §121 and this guidance, Federal agencies or departments should conduct five-year reviews for all CERCLA non-NPL remedial actions that require a review (discussed in Section 1.2.1 of this

guidance). It is EPA's expectation that Federal agencies or departments will also conduct five-year reviews as a matter of policy at sites that would be subject to policy reviews if they were on the NPL (see Section 1.2.2). EPA does not have a statutorily defined role in five-year reviews at non-NPL Federal facility sites. However, where EPA has had active and substantial involvement at a non-NPL Federal facility, or where agencies, States, Tribes, or citizens seek EPA comment on five-year reviews conducted at a non-NPL Federal facility, EPA may, to the extent practicable on a site-specific basis, comment on five-year reviews and protectiveness determinations made by other Federal agencies or departments at non-NPL Federal facilities, and/or provide independent findings, where applicable.

2.5.4 What are States' roles at non-NPL sites under the jurisdiction of a Federal agency or department?

Consistent with CERCLA §120(a)(4), at non-NPL Federal facilities sites, States generally have remedial oversight responsibilities and should be provided with adequate opportunity to participate in the five-year review process and to review the draft Five-Year Review document before it is finalized.

2.5.5 What happens when Federal agencies or departments transfer real property?

In instances of Federal-to-Federal transfer of jurisdiction, custody, or control of real property, the Federal agency or department having initiated CERCLA remedial actions generally should conduct any required or appropriate five-year reviews. Alternatively, the lead agency may assure that reviews are conducted by entering into reliable site-specific agreements with the Federal agency or department gaining control of the property, where those arrangements remain consistent with CERCLA and EO 12580. In instances of deed transfer of Federal property to third parties, the Federal agency or department having initiated CERCLA remedial actions generally should conduct any required or appropriate five-year reviews, unless other reliable site-specific procedures are arranged with the transferee (or others), and those arrangements remain consistent with CERCLA and EO 12580. Generally, however, the ultimate responsibility for conducting five-year reviews should remain with the Federal agency or department that initiated the CERCLA remedial actions.

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3.0 COMPONENTS OF THE FIVE-YEAR REVIEW PROCESS

This chapter discusses components of the five-year review process, including notifying potentially interested parties, developing a review schedule, establishing a review team, involving the community, and signing and submitting the Five-Year Review report. Data and other site-specific information that form the foundation for the technical assessment of the remedy at the time of the five-year review are discussed in this chapter, including data and document review, site interview, site inspection, and components of a Five-Year Review report.

3.1 Who is notified when planning the five-year review?

In the initial planning stages of the five-year review, all potentially interested parties should be notified that the five-year review will be conducted. This notification may include States and/or Tribes, appropriate representatives of the community, local officials, Federal and/or State Trustees for Natural Resources (Trustees)[11], appropriate EPA offices, and the Community Involvement Coordinator (CIC) for the site. Potentially responsible parties should be notified for Enforcement-lead sites.

3.2 How should I develop a review schedule?

You should develop a review schedule to meet the appropriate five-year review date of completion. The review schedule should allow sufficient time for each component of the five-year review process, including document review, site inspection, interviews, the assessment of the protectiveness of the remedy (see Chapter 4), and report development and final submission. You should incorporate into the five-year review schedule appropriate time for internal and inter-agency review and comment periods, community involvement activities, if needed, and finalizing the report with all required signatures.

3.3 How should I establish a review team?

You should determine the appropriate level of assistance and team structure. For some reviews, the project manager may be the only member of the team, consulting with technical experts as necessary. For other reviews, a multi-disciplinary team may be needed to adequately review the protectiveness of the remedy. Once team members are identified their roles should be clearly defined. Communication among team members, agencies, and organizations is critical to ensure that all parties remain informed throughout the entire five-year review process.

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[11] OSWER Directive 9200.4-22A *CERCLA Coordination with Natural Resource Trustees*, dated July 31, 1997.

Exhibit 3-1 below provides examples of potential team members for a five-year review.

Exhibit 3-1: Potential Members of the Five-Year Review Team

- Project Manager (EPA, State, Tribal, DOD, DOI)
- Regional Biological Technical Assistance Groups (BTAGs)
- Federal and State Natural Resource Trustees
- Community Involvement Coordinator (CIC)
- State and/or local regulatory agency representatives
- Tribal representatives
- TAG representatives and/or community representatives
- Other Federal agency representatives (*e.g.*, U.S. Army Corps of Engineers, U.S. Fish and Wildlife Service, Agency for Toxic Substances and Disease Registry, U.S. Geological Survey, National Oceanic and Atmospheric Administration)
- Technical Experts
  - S Construction representative
  - S Engineers (*e.g.*, civil, geo-technical, structural, chemical, process)
  - S Hydrogeologist
  - S Chemist
  - S Risk assessor
  - S Biologist
  - S Ecologist/ecological risk assessor
  - S Attorney/legal advisor
  - S Environmental regulatory specialist

3.4 How should I involve the community?

You should begin working with the site's CIC during the initial planning stages of your five-year review to determine the appropriate level of community involvement. At a minimum, your community involvement activities during the five-year review should 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 (see Exhibit 3-2).

Together with the CIC, you should consider conducting additional community involvement activities at high profile sites, those with significant public interest, and any other sites for which the Region determines a need for additional community involvement activities. This may include notifying local public officials, including the primary local health agency, and the leadership of any relevant neighborhood and civic groups. (For ideas on notifying the public see *Publishing Effective Public Notices*, which is part of the CIC Toolkit (Web address: http://www.epa.gov/superfund/action/community/index.htm).)

In addition to this notification, you may also wish to interview several community members, at least some of whom live or work near the site, to get their views about current site conditions, problems, or related concerns. If there was or is a Community Advisory Group or a

Technical Assistance Grant related to the site, representatives of these groups should be briefed at the outset of the five-year review process, and, if requested, at other appropriate points. You may also want to consider appropriate ways, such as public meetings or an opportunity for submitting written comments, to get broader public involvement. For further information on community involvement during the five-year review process, see Appendix A, "Community Involvement."

Exhibit 3-2: Notification Requirements for Five-Year Reviews

At the beginning: Your notice to the community that a five-year review will be conducted should identify:

- The site name, its location and web address (if available);
- The lead agency conducting the review;
- A brief description of the selected remedy;
- A summary of contamination addressed by the selected remedy;
- How the community can contribute during the review process;
- A contact name and telephone number for further information; and
- The scheduled completion date of the five-year review.

At the end: Your notice to the community that a five-year review has been completed should include:

- The site name, its location and web address (if available);
- The lead agency conducting the review;
- A brief description of the selected remedy;
- A summary of contamination addressed by the selected remedy as provided in the initial notice;
- A brief summary of the results of the five-year review;
- The protectiveness statement(s);
- A brief summary of data and information that provided the basis for determining protectiveness, issues, recommendations, and follow-up actions directly related to the protectiveness of the remedy;
- Location(s) where a copy of the five-year review can be obtained or viewed (including site repositories);
- A contact name and telephone number where community members can obtain more information or ask questions about the results; and
- The date of the next five-year review or a statement and supporting rationale that five-year reviews will no longer be required.

3.5 What data do I need to evaluate the remedy?

Data and other pertinent site specific information that you should review include 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. These are the primary bases of the technical analyses and subsequent protectiveness determination(s). The type and quality of data are essential to your five-year review and its findings and conclusions. You may collect these types of data through a variety of means, including document review, interviews, and a site inspection. You also may need to conduct supplemental sampling or collect other data.

3.5.1 How are documents reviewed?

A review of documents is one of the first steps in the five-year review process. You are responsible for gathering all relevant documents, data, and other information in support of the five-year review. Generally, for an initial five-year review, this may require you to evaluate record keeping and the location of pertinent data and information. In cases where records are difficult to obtain, you should establish appropriate record keeping procedures to minimize future efforts needed to gather all necessary documents for subsequent five-year reviews.

Documents should be reviewed to obtain relevant information and data concerning a response action from which to base an assessment of its performance. The scope of the review is dependent on the complexity of the remedy(s) and the stage of remedy construction. You may need to review various documents to obtain the necessary information, including those for remedy decisions (*e.g.*, Records of Decision (RODs), Explanation of Significant Differences (ESDs)), enforcement (*e.g.*, Consent Decrees (CDs), Administrative Orders on Consent (AOCs)), site investigations (*e.g.*, remedial investigation/feasibility study (RI/FS)), design (*e.g.*, remedial design (RD)) and construction (*e.g.*, Preliminary Closeout Reports (PCOR), remedial action (RA) reports), and remedy performance and post-closure. (See Appendix B, "Document Review," for a more complete discussion of document review for the five-year review).

Your review team should be familiar with appropriate site-specific data and information including the items listed below:

- Remedial action objectives and cleanup levels, as specified in the ROD and other decision documents;
- Remedial action design and remedial action construction;
- O&M status;
- Implementation of institutional controls;
- Changes that affect the validity of cleanup levels (*e.g.*, standards identified as Applicable or Relevant and Appropriate Requirements (ARARs), "to be considereds" (TBCs), assumptions about contaminant characteristics and potential exposure); and
- Data supporting the effectiveness of the remedy in meeting cleanup levels and remedial action objectives.

3.5.2 How should I conduct interviews?

Interviews should be conducted, if necessary, to provide additional information about a site's status. The scope of interviews should be tailored to the remedy evaluation on a site-specific basis. Those interviewed may include the site manager; site personnel; Federal, State, and Tribal regulatory authorities; local officials; community action groups or associations;

residents and businesses located near the site; and other pertinent organizations or individuals. At an Enforcement-lead site, the lead agency should conduct the interviews. A Potentially Responsible Party (PRP) generally should not conduct interviews because there is a potential for a conflict of interest (see Appendix C, "Five-Year Review Interviews," for additional information). For Federal facility sites, a State and/or EPA representative may wish to be present at and/or participate in conducting interviews.

3.5.3 How should I conduct site inspections?

Your five-year review should include a recent site inspection. For purposes of conducting site inspections for five-year reviews, "recent" generally means no more than nine months from the expected signature date of the review. The review should be performed by objective parties without bias or preconceived views or conclusions about the remedy and conditions at the site. Site inspections are conducted to provide information about a site's status and to visually confirm and document the conditions of the remedy, the site, and the surrounding area.

At an Enforcement-lead site, the lead agency should conduct the site inspection. A PRP generally should not conduct the site inspection because of the potential for a conflict of interest. At Federal facility sites, a State and/or EPA representative may wish to be present and/or participate in conducting site inspections.

Appendix D, "Five-Year Review Site Inspection Checklist," may serve as your guide for planning and documenting a site inspection for containment, groundwater, and surface water remedies. Using this checklist should aid you in the planning and documentation of the site inspection. Therefore, you may adapt this checklist for other types of remedies or use other site inspection tools and checklists that have been developed by others for this purpose. You can find other checklists by accessing the web site: http://www.frtr.gov/optimization/general/ and clicking on " USACE Remediation System Evaluation Checklists."

3.6 What should I include in Five-Year Review reports?

In your Five-Year Review report, you should present the findings and conclusions of the review, including recommendations, follow-up actions to issues, and protectiveness determination(s). The report should also contain the data and information necessary to support all findings and conclusions.

Where your review only addresses a portion of a site, the report should provide a summary of the status of other operable units (OUs) and/or the remainder of the site. Similarly, for sites where you conduct a separate five-year review for different areas of a large or complex site (see Section 1.4.2), you should provide a summary of the status of the other areas of the site in your Five-Year Review report. Additionally, if you receive written comments on the Five-Year Review report from support agencies and/or the community (*e.g.*, States, Tribes, other

Federal agencies or departments, local governments, citizens, PRPs, other interested parties), you should attach a copy of these comments to the report.

A suggested "Five-Year Review Report Template" and "A Sample Five-Year Review Report" are provided in Appendices E and F, respectively. Exhibit 3-3 summarizes the recommended contents of a Five-Year Review report.

Exhibit 3-3: Contents of a Five-Year Review Report

The following report sections...	**should include these topics when appropriate:**
I. Introduction	– the purpose of the review – who conducted the review – when the review was initiated and completed – whether it is the first review or a subsequent review at the site – status of other five-year reviews, OUs, and/or areas of the entire site
II. Site Chronology	– dates of major events (such as the initial discovery of contamination, NPL listing, decision and enforcement documents, start and completion of remedial and removal actions, construction completion, and prior five-year reviews)
III. Background	– physical characteristics – land and resource use – history of contamination – initial response – summary of basis for taking action
IV. Remedial Actions	– remedy selection – remedy implementation – system operations/O&M
V. Progress Since Last Review (as applicable)	– protectiveness statements from last review – status of recommendations and follow-up actions from last review – results of implemented actions, including whether they achieved the intended purpose – status of any other prior issues
VI. Five-Year Review Process	– notification of potentially interested parties of start of review – identification of five-year review team members – components and schedule of your five-year review – document review – data review and evaluation – community notification – other community involvement activities – site inspection – site interviews

Exhibit 3-3: Contents of a Five-Year Review Report

The following report sections...	should include these topics when appropriate:
VII. Technical Assessment	*Question A: Is the remedy functioning as intended by the decision documents?* – remedial action performance and monitoring results – system operations/O&M – costs of system operations/O&M – opportunities for optimization – early indicators of potential remedy problems – implementation of institutional controls and other measures *Question B: Are the exposure assumptions, toxicity data, cleanup levels, and remedial action objectives (RAOs) used at the time of the remedy still valid?* – changes in exposure pathways – changes in land use – new contaminants and/or contaminant sources – remedy byproducts – changes in standards, newly promulgated standards, and TBCs – changes in toxicity and other contaminant characteristics **S** expected progress towards meeting RAOs – risk recalculation/assessment (as applicable) *Question C: Has any other information come to light that could call into question the protectiveness of the remedy?* – ecological risks – natural disaster impacts – any other information that could call into question the protectiveness of the remedy Summary of Technical Assessment – summary of findings and conclusions related to Questions A, B, and C
VIII. Issues	– issues that were identified during the technical assessment and other five-year review activities (*e.g.*, site inspection) – a determination of whether issues affect current or future protectiveness – a discussion of unresolved concerns or items raised by support agencies and the community (States, Tribes, other Federal agencies or departments, local governments, citizens, PRPs, other interested parties)
IX. Recommendations and Follow-up Actions	– list of any recommendations, including follow-up actions to ensure protectiveness – parties responsible for implementation – agencies with oversight authority – schedule for completion
X. Protectiveness Statement(s)	– protectiveness statement(s) developed at the OU level – protectiveness statement developed for the site as a whole at construction complete sites
XI. Next Review	– statement of when the next review is to be completed, or explanation of why no further five-year reviews are needed

3.7 How should I submit a Five-Year Review report?

The procedures for submitting reports to EPA Regions and Headquarters are described below. This process takes place after all reviews of draft reports, and other interagency reviews are completed, appropriate concurrences and signatures are obtained, and, to the extent practicable, issues are resolved.

3.7.1 How is an EPA-lead report submitted?

A report prepared by EPA is complete when it is signed by the EPA Regional Administrator or his/her designee. The Region should submit one copy of the signed Five-Year Review report to EPA Headquarters within ten days of the signature date. The Region should also place a copy of the report in each site information repository.

3.7.2 How is a Federal facility-lead report submitted?

When a Federal agency or department other than EPA conducts a five-year review, the report should be submitted to the Region for review pursuant to the terms of the Federal Facility Agreement or other authorized agreement. The Region should review the report for accuracy, protectiveness determination/statement, and the basis/support for such determination and consistency with this guidance. The EPA Regional Administrator or his/her designee should issue a memorandum that documents any unresolved items or concerns and either concurs with the report findings or provides EPA's own independent findings and protectiveness determination. Within ten days of the signature date of the memorandum, the Region should forward a copy of the report, with the memorandum attached, to EPA Headquarters, and a copy should be placed in each site information repository.

In some cases, EPA may have minimal involvement at the site or in the development of the Five-Year Review report or protectiveness statements. In such cases, Regions should determine whether to rely solely on the information presented by the other Federal agency or department without independent verification. When the Region relies solely on the representations of another Federal agency or department, the Regional Administrator or his/her designee should note this in the memorandum. It is important to consider who signed the Five-Year Review report at the other Federal agency or department. EPA expects that a Five-Year Review report generally will be signed by the other Federal agency or department at the senior management level.

3.7.3 How is a State or Tribal-lead report submitted?

When a State or Tribe conducts a five-year review, the report should be submitted to the respective Region for review of accuracy, protectiveness determination/statement and the basis/support for such determination and consistency with this guidance. The EPA Regional Administrator or his/her designee should issue a memorandum that documents any unresolved

items or concerns and either concurs with the report findings and protectiveness statement(s) or provides EPA's own independent findings and protectiveness determination. Within ten days after the memorandum is signed, the Region should forward a copy of the report, with the memorandum attached, to EPA Headquarters and a copy should be placed in each site information repository.

3.8 What are the annual reporting requirements to EPA Headquarters?

Each EPA Region should report annually to EPA Headquarters on the progress of the five-year reviews for each of their sites. At a minimum, at the end of each fiscal year each Region should provide to EPA Headquarters the following:

- A list of sites that had five-year reviews due for that fiscal year;
- If a five-year review due date changes for any site, or a site no longer needs a five-year review, identify the sites and the basis for the change or discontinuation;
- A list of those sites where five-year reviews were completed;
- For each completed five-year review, a summary of the protectiveness determination(s), issues that impact protectiveness, follow-up actions, and the schedule and entity responsible for implementing such actions;
- Status of protectiveness when Five-Year Review reports from previous fiscal years made a "not protective" determination or "needed further information" before making a protectiveness determination, or deferred protectiveness; and
- Status of follow-up actions identified in Five-Year Review reports from previous fiscal years.

The exact date for submitting the annual report should be provided at the work planning sessions at the beginning of each fiscal year or through your Headquarters Regional Center contact.

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4.0 ASSESSING THE PROTECTIVENESS OF THE REMEDY

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. In general, five-year reviews of remedial actions under construction are narrower in scope than five-year reviews of remedies that have been constructed.

Your technical assessment of a remedy should examine the following three questions, which provide a framework for organizing and evaluating data and information and ensure that all relevant issues are considered when determining the protectiveness of the remedy:

- ***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?

The following sections present Questions A, B, and C in more detail. Exhibit 4-1 summarizes a number of items that you should consider in answering questions A, B, and C in your evaluation of a remedial action.

Exhibit 4-1: Three Questions Used to Determine Whether a Remedy is Protective

When you ask...	you should consider whether...
Question A: Is the remedy functioning as intended by the decision documents?	• performance standards (*e.g.*, cleanup levels, plume containment, pumping rates) are or will likely be met; • there are problems with the remedy that could ultimately lead to the remedy not being protective or suggest protectiveness is at risk (*e.g.*, shrubs or bushes growing on a landfill cap that was designed to have a grass vegetative cover, extent of plume not fully delineated); • access (*e.g.*, fencing, security guards) and institutional controls needed at the particular stage of the remediation are in place and prevent exposure; • other actions (*e.g.*, removals) necessary to ensure that there are no exposure pathways that could result in unacceptable risks have been implemented; and • maintenance activities (*e.g.*, pumping and treating, monitoring slurry walls, mowing cap), as implemented, will maintain the effectiveness of response actions.

Exhibit 4-1: Three Questions Used to Determine Whether a Remedy is Protective

When you ask...	you should consider whether...
Question B: Are the exposure assumptions, toxicity data, cleanup levels, and remedial action objectives used at the time of the remedy selection still valid?	• there are changes in standards identified as Applicable or Relevant and Appropriate Requirements (ARARs) in the ROD, newly promulgated standards, and/or changes in TBCs identified in the ROD, that could call into question the protectiveness of the remedy; • there are changes in land use or the anticipated land use on or near the site; • new human health or ecological exposure pathways or receptors have been identified; • new contaminants or contaminant sources have been identified; • there are unanticipated toxic byproducts of the remedy not previously addressed by the decision documents; • there are changes in the physical site conditions; and • there are changes in the toxicity factors for contaminants of concern.
Question C: Has any other information come to light that could call into question the protectiveness of the remedy?	• ecological risks have been adequately addressed at the site, and/or there is a plan to address them through a future action; and • the site is/was subject to natural disasters, such as a 100-year flood.

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

In general, to determine if the remedy is functioning as described in the decision documents, you should first consider its implementation status, (*e.g.*, whether the remedy is under construction, operating, or completed). You should also look for available information about the remedy and compare it to the requirements in the decision documents and remedial design/construction specifications. For purposes of this guidance, definitions of remedial actions under construction, operating remedial actions, and completed remedial actions are as follows:

- ***Remedial actions under construction*** are those actions where physical construction has been initiated, but is not yet complete.

- ***Operating remedial actions*** are those actions that are ongoing, but where cleanup levels have not yet been achieved. Such actions typically have remedial components requiring several years to reach cleanup levels (*e.g.*, groundwater and surface water restoration, monitored natural attenuation, soil vapor extraction, and bioremediation).

- ***Completed remedial actions*** are those actions where construction is complete and cleanup levels have been achieved.

4.1.1 How do I answer Question A for a remedial action that is under construction?

In the case where a remedy is under construction, the focus of your review should be 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. In addition, you should confirm that access controls (*e.g.*, fencing, security guards) necessary at this stage of the remediation are in place and successfully prevent exposure. If the remedial action includes institutional controls (ICs), then your five-year review should also consider the implementation status of those controls. For example, answer the following questions: Have specific ICs been identified? Are there ICs needed at this stage of remediation to prevent exposure? Who is responsible for implementing ICs? What is the plan, schedule, and current status for IC implementation?

4.1.2 How do I answer Question A for a remedial action that is operating or completed?

Your review of an operating or completed remedial action generally will address more aspects of the remedy implementation than a review of a remedial action under construction. In general, you should assess the following:

- ***Remedial action performance*** – Determine whether the remedial action continues to operate and function as designed (*e.g.*, extent of groundwater plume is well defined and updated plume maps confirm containment), and has achieved, or is expected to achieve, cleanup levels.

- ***System operations/operation and maintenance (O&M)*** – Determine whether maintenance procedures, as implemented, will maintain the effectiveness of response actions. This evaluation might include, but is not limited to, visual inspection of the system and the review and evaluation of monitoring reports (*e.g.*, groundwater data from extraction and monitoring wells, biological monitoring data, discharge requirements, wetland monitoring data, leachate monitoring for containment remedies).

- ***Costs of system operations/O&M*** – Review and consider system operations/O&M costs if they are available. Compare actual/current annual O&M costs to the original cost estimate; large variances from the original cost estimate might indicate potential remedy problems. (Note: This information may not be readily available at Enforcement-lead sites, but should be requested.)

- ***Implementation of institutional controls and other measures*** – Determine whether access controls (*e.g.*, fencing, security guards) and ICs that are needed at this stage of the remediation are in place and successfully prevent exposure. If

ICs are not in place, determine why not, and obtain the schedule for implementation; determine whether other actions (*e.g.*, removals) necessary to ensure that exposure pathways that could result in unacceptable risks have been implemented.

- ***Monitoring activities*** – Determine whether monitoring activities required to ensure the effectiveness of the remedy (*e.g.*, performance and environmental data collected and results evaluated) are being conducted and whether they are adequate to determine the protectiveness and effectiveness of the remedy.

- ***Opportunities for optimization*** – If readily apparent during the course of conducting five-year review activities, identify any opportunities to improve the performance and/or reduce the costs of sampling and monitoring activities and operating treatment systems. If changes in these activities are recommended in the Five-Year Review report, you should also provide the rationale/basis for such changes. If appropriate, your report can also recommend that an optimization study be conducted.

- ***Early indicators of potential remedy problems*** – Investigate and identify problems that could lead to the remedy being not protective or suggest protectiveness is at risk unless changes are made. Problems could include frequent equipment breakdowns or replacement, or large variances in operating costs (if cost data are available). Some examples of indicators of potential remedy problems could include erosion and/or subsidence of a cap, trend analysis of sampling data showing no decrease in contaminant levels, monitoring data showing evidence of leachate migration, or that the extent of the groundwater contamination plume exceeds the outer reaches of the monitoring network.

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

In conducting your five-year review, you should evaluate the effects of significant changes in standards and assumptions that were used at the time of remedy selection. Changes in the promulgated standards or "to be considereds" (TBCs) may impact the protectiveness of the remedy. Similarly, you should investigate the effect of significant changes in the risk parameters that were used to support the remedy selection, such as reference doses, cancer potency factors[12], and exposure pathways of concern. Finally, you should evaluate whether the original assumptions regarding current and future land/groundwater uses and contaminants of concern are

[12] Note that risk parameters in EPA publications such as the Integrated Risk Information System (IRIS) (see http://www.epa.gov/IRIS) are guidance only, and should be applied only as appropriate for the remedy being reviewed.

still valid, and whether any physical features (or understanding of physical sites conditions) have changed (*e.g.*, changes in anticipated direction or rate of groundwater or identification of a new groundwater divide). All of these factors may have a bearing on the validity of the remedial action objectives and may affect the protectiveness of the remedy.

Exhibit 4-2 presents a series of example questions that you should consider in determining whether the exposure assumptions and toxicity data used at the time of remedy selection are still valid and, if you determine that they are no longer valid, whether they call into question the protectiveness of the remedy. Exhibit 4-2 also groups the questions according to the type of assumption.

Exhibit 4-2: Example Questions to Determine if Assumptions Upon Which the Remedy was Based Have Changed

For an assumption based on ...	an example question may be...
standards and TBCs	Are there changes in the standards identified as ARARs in the ROD that bear on the protectiveness of the remedy? Are there newly promulgated standards that might apply or be relevant and appropriate to the site and that bear on the protectiveness of the remedy? Are there changes in TBCs identified in the ROD that bear on the protectiveness of the remedy?
cleanup levels	What is the basis for each cleanup level identified in the ROD (*e.g.*, risk-based or promulgated standards as ARARs)? Have there been changes to the basis of the cleanup levels? (See sample questions for "standards or TBCs" above, and for "toxicity and other contaminants characteristics" below.)
exposure pathways	Has land use or expected land use on or near the site changed (*e.g.*, industrial to residential, commercial to residential)?
exposure pathways	Have any human health or ecological routes of exposure or receptors changed or been newly identified (*e.g.*, dermal contact where none previously existed, new populations or species identified on site or near the site)?
exposure pathways	Are there newly identified contaminants or contaminant sources?
exposure pathways	Are there unanticipated toxic byproducts of the remedy not previously addressed by the decision documents (*e.g.*, byproducts not evaluated at the time of remedy selection)?
exposure pathways	Have physical site conditions changed such that protectiveness may be affected (*e.g.*, changes in anticipated direction or rate of groundwater flow)? Has understanding of physical site conditions changed (*e.g.*, identification of a new groundwater divide)?
toxicity and other contaminant characteristics	Have toxicity factors for contaminants of concern at the site changed (*e.g.*, Integrated Risk Information System (IRIS) evaluations? (See http://www.epa.gov/IRIS) Have other contaminant characteristics changed? Have ecological toxicity reference values and/or ecological "no observed adverse effect levels/lowest observed adverse effect" (NOAELs/LOAELs) levels changed.

4.2.1 How should I check the impact of changes in standards and TBCs?

Cleanup levels or actions may be based on ARARs identified in the Record of Decision (ROD) (as opposed to calculated site-specific risk, as discussed in Section 4.2.3). For example, the cleanup levels for a groundwater remedy may be based on the Safe Drinking Water Act maximum contaminant levels (MCLs) if these were identified as ARARs in the ROD.

In the preamble to the final National Contingency Plan (NCP), EPA states its policy that it will not reopen remedy selection decisions contained in RODs (*i.e.*, ARARs are normally frozen at the time of ROD signature) unless a Anew or modified requirement calls into question the protectiveness of the selected remedy.@ 55 FR 8757 (March 8, 1990). The preamble goes on to state that "a policy of freezing ARARs at the time of ROD signing will not sacrifice protection of human health and the environment because the remedy will be reviewed for protectiveness every five years, considering new or modified requirements at that point, or more frequently, if there is reason to believe that the remedy is no longer protective of health and environment." 55 FR 8758 (March 8, 1990). The preamble also states that a remedy would not necessarily need to Abe modified solely to attain a newly promulgated or modified requirement,@ but that "newly promulgated or modified requirements contribute to [the] evaluation of protectiveness." 55 FR 8758 (March 8, 1990).

Therefore, although ARARs generally are "frozen" at the time of ROD signature, in conducting a five-year review, you should determine the effect of a newly promulgated or modified standard on the protectiveness of the remedy originally selected in the ROD. You should evaluate the newly promulgated or modified requirement to determine if the cleanup level established in the ROD remains protective. TBCs may also have been used to select cleanup levels. Therefore, you should also review any new or modified TBCs to ensure that any changes will not impact the protectiveness of the remedy.

Generally, you should only consider changes in standards that were identified as ARARs in the ROD, newly promulgated standards for chemicals of potential concern, and TBCs identified in the ROD that bear on the protectiveness of the remedy. As such, you should review any newly promulgated standards, including revised chemical-specific requirements (such as MCLs, ambient water quality criteria), revised action and location-specific requirements, and State standards if they were considered ARARs in the ROD.

In evaluating a change in a standard that was identified as an ARAR in the ROD, or a newly promulgated standard or TBC, you should establish whether the new requirement indicates that the remedy is no longer protective. You should recommend a follow-up action when the remedy is not protective. For example, based on revised risk information for a specific chemical, a new standard (*e.g.*, more stringent MCL for a chemical) may result in a situation where the cleanup level to be achieved by the original remedy would pose a 10^{-3} cancer risk. In that circumstance, the five-year review could recommend that a new cleanup level based on the new

standard be adopted and, if necessary, that the remedy be modified. However, a change in a standard may not necessarily result in a change in the resulting risk and therefore may not always impact protectiveness. An illustration of a method and an example for evaluating changes in standards is provided in Appendix G, "Methods and Examples for Evaluating Changes in Standards and Toxicity," Exhibit G-1, "Evaluating Changes in Standards," Exhibit G-2, "Hypothetical Scenario for a Change in a Standard," and Exhibit G-3, "Decision Process for a Hypothetical Change in Standard."

4.2.2 How should I check the impact of changes in exposure pathways?

You should consider changes in site conditions that could result in increased exposure. These changes could include changed or new land uses, including zoning changes, changed or new routes of exposure or receptors, changed physical site conditions that may affect the protectiveness of the remedy, new contaminants, or a new understanding of geological conditions. In evaluating this information, you should work closely with a risk assessor to establish the impact that such changes may have on the estimated risk associated with your site. Depending on the significance of the changes, it may be necessary for you to recalculate human health risk and re-examine ecological risks. Generally, your human health determination should be based on whether the cancer risk could now be greater than 10^{-4} and/or the hazard index could be greater than 1 for non-carcinogenic effects.

In some cases, it may be necessary to revise or expand the previous risk assessment as part of your five-year review. For example, you may need to revise the risk assessment when there is a new exposure pathway, a new potential contaminant of concern, or an unanticipated toxic byproduct of the remedy. In all cases, you should evaluate whether the remedy can mitigate any unacceptable risk or whether additional actions may need to be taken. Your five-year review can also recommend further investigation to determine whether an additional response action is needed.

4.2.3 How should I check the impact of changes in toxicity and other contaminant characteristics?

Cleanup levels at a site may be based on the calculated risk for chemicals and/or media where there are no promulgated standards (*e.g.*, site-specific soil and sediment action levels) or existing standards are not sufficiently protective for site-specific conditions. If the remedy is intended to meet a site-specific, risk-based cleanup level, you should check to see whether toxicity or other contaminant characteristics used to determine the original cleanup level have changed. In addition to toxicity, you should examine other contaminant characteristics that determine the nature and extent of contaminant migration and effects on receptors (*e.g.* sorption characteristics, ability to bioaccumulate, bioavailability). If there have been changes in the understanding or in our knowledge of these physical/chemical characteristics, you may need to recalculate risk using the original cleanup level or using the current concentration if it has not been identified as a contaminant of concern. An increase in the cancer slope factor, for example,

may suggest that the risk from a chemical concentration is above the generally acceptable cancer risk range (10^{-4} to 10^{-6}). You should also consider changes in toxicity and other contaminant characteristics relating to ecological receptors.

You may work with your Region's risk assessor to determine whether there have been changes in toxicity or other contaminant characteristics and whether further investigation is needed. The risk assessor is also familiar with efficient use of the Superfund Technical Support Center and its hotline. One preferred resource for checking changes in toxicity information is EPA's Integrated Risk Information System (IRIS) (http://www.epa.gov/IRIS). However, many contaminants found at Superfund sites are not found in IRIS. You may find it useful to refer to the Superfund Risk Assessment Tools of the Trade page for databases and additional links and pointers (http://www.epa.gov/superfund/programs/risk/tooltrad.htm#gp). Beginning in the summer of 2001, this page should link risk-based concentration tables which provide screening levels for specific exposure scenarios, a risk calculation tool, and should identify recent toxicity data and their sources.

The flowchart presented in Appendix G, Exhibit G-4, "Evaluating Changes in Toxicity and Other Contaminant Characteristics," shows the process you should use to evaluate the significance of changes in toxicity values and other contaminant characteristics when conducting a five-year review. You should first identify any site-specific, risk-based, cleanup levels and investigate relevant changes in contaminant characteristics. If the estimated risk for a contaminant has not changed, your analysis on this point should be complete.

If the estimated risk has increased, then you should determine whether the new estimated risk is acceptable. In most cases, you should base this determination on whether the risk is within or below the generally acceptable risk range of 10^{-4} to 10^{-6} for carcinogenic risk and the hazard index is below 1 for non-carcinogenic effects. If the estimated risk is not protective, you should determine what actions need to be taken to achieve an acceptable level of risk. Appendix G, Exhibit G-5, "Hypothetical Scenario for a Change in Toxicity," and Exhibit G-6, "Decision Process for a Hypothetical Change in Toxicity," provide an example of the evaluation process when there are changes in toxicity and other characteristics. Note: Future guidance will address the appropriateness of using various statistical methods in making the determination about when remedial action objectives (RAOs) have been attained.

4.2.4 How should I review RAOs and evaluate their impact?

As part of the five-year review, you should conduct an evaluation of the RAOs stated in the ROD to determine whether the remedy is meeting or will meet RAOs. Depending on the outcome of the evaluation, you may find it necessary to modify the RAOs, modify the remedy, or conduct further response actions. For example, an RAO phrased in terms of "achieving the drinking water standard in ten years" may be significantly affected by a new MCL that establishes a more stringent standard. Conversely, an RAO may be general enough to accommodate a new or modified requirement.

If your evaluation of data indicates that the remedy is not meeting and will not be able to meet the RAO stated in the ROD, then you may need to determine if the remedy is protective and, if not protective, what additional actions are needed. For example, if the risk associated with the cleanup levels currently being achieved by the remedy are within EPA's acceptable risk range, the remedy generally should be considered protective. However, if the remedy will not be able to meet the RAOs, further actions may be needed, depending on the specificity of the original RAOs in the ROD. Your Five-Year Review report should identify such further actions as recommendations and/or follow-up actions.

New site conditions, such as discovery of new contaminants, can also impact the RAOs and remedy protectiveness. During your five-year review, you should evaluate whether the RAOs in the ROD are sufficiently comprehensive to cover any new or changed conditions at a site. If a new condition at the site is not covered by the RAOs, you should recommend further investigation in the Five-Year Review report to determine whether additional response actions are needed.

Further response actions may not necessarily involve additional physical construction activities but could include sampling, studies, and/or investigations. For example, modifying RAOs will require a ROD Amendment, but does not require a physical site activity.

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

You should consider any other information that comes to light that could call into question the protectiveness of the remedy. It is expected that most considerations related to the protectiveness of the remedy will be covered by Questions A and B. However, in some instances, there may be other factors about the remedy or the site that you should consider during the review.

Situations to watch for include the following:

- Ecological risks have not been adequately addressed at a site, and there is not a plan to address them through a future action;
- The site, although located entirely above the 500-year flood boundary, was partially inundated by a 100-year flood (which now may require a flood plain redesignation of the region); and
- Land use changes that are being considered by local officials.

If ecological risks have not been adequately addressed at a site, and there is not a plan to address them through a future action, then you may need to address them by conducting a screening ecological risk assessment as part of the Five-Year Review using *Final Guidance: Ecological Risk Assessment and Risk Management Principles for Superfund Sites*, OSWER

Directive 9285.7-28P (October 7, 1999). The ecological risk assessor on your team can help streamline the process appropriately.

4.4 How should I develop the conclusions of my five-year review?

The conclusions of your five-year review should include: 1) an identification of issues; 2) recommendations and follow-up actions; and 3) a determination of whether the remedy is, or is expected to be, protective of human health and the environment. You should arrive at these conclusions through a technical assessment of the information collected during the document review, data collection, interviews, site inspection, and other activities. Your evaluation should focus on the information collected through answering the three questions shown in Exhibit 4-1. (See Sections 4.1, 4.2, and 4.3, above, for a detailed discussion of how to assess the remedy by answering these three questions.) These conclusions should be documented in the Five-Year Review report as a technical assessment summary.

4.4.1 How should I identify issues?

You should identify all issues that currently prevent the response action from being protective, or may do so in the future. You should document all such issues and follow-up actions needed to ensure the proper management of the remedy in your Five-Year Review report. You should also identify early indicators of potential remedy problems. Early indicators of remedy problems may include operating costs that are greater than originally anticipated. For instance, excessive replacement of pumps or other equipment may indicate the need to reconsider system design or re-evaluate aquifer conditions.

Examples of issues that may be identified in a Five-Year Review report include the following:

- Inadequate access controls (*e.g.*, fencing has been breached, or fencing is not adequate to restrict access);
- Incomplete response action, including ICs (*e.g.*, environmental easements or well restrictions are not in place);
- Inadequate ICs (*e.g.*, well restrictions are in place but are not preventing exposure);
- Response action is not expected to achieve cleanup levels; plume containment has not been confirmed or achieved;
- Cleanup levels are not protective due to changes in chemical characteristics;
- Discharge requirements are exceeded;
- Inadequate operation and maintenance of physical remedial structures (*e.g.*, vegetative cover of cap mowed infrequently);

- Differences found in actual or proposed land use other than those assumed in the selection of the response action;
- RAOs will not be achieved;
- Monitoring is not being completed in a timely manner; and
- Inadequate monitoring activities to determine the protectiveness of the remedy (*e.g.*, the number and location of monitoring wells are not appropriate for monitoring remediation progress of the groundwater contamination plume).

You should describe each issue in sufficient detail so that EPA can appropriately track the progress to resolution. For each issue, you should determine if it currently affects the protectiveness of the remedy or may do so in the future.

Exhibit 4-3 provides an example of a tabular format that you can use to list issues in your Five-Year Review report.

Exhibit 4-3: Example Table for Listing Issues

Issues	Affects Protectiveness (Y/N)	
	Current	Future

4.4.2 When and how should I develop recommendations?

For each issue identified, the Region should document and ensure implementation of recommendations to resolve those issues. These recommendations should be identified along with follow-up actions in your Five-Year Review report. Follow-up actions should be completed to ensure long-term protectiveness of the remedy, or to bring about protectiveness of a remedy that is currently not protective. You may also have follow-up actions where a protectiveness determination cannot be made at the time of the five-year review. In addition, you may wish to 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 types of recommendations that generally are considered appropriate as part of a five-year review:

- ***Provide additional response actions*** – For example, additional response actions may be necessary to ensure protectiveness if new risk information indicates that a remedy is not protective (*e.g.*, a treatment process will not be able to achieve soil cleanup levels). EPA may implement such further response any time pursuant to CERCLA §104 or §106 authority. In your Five-Year Review report, you can recommend further investigation and the implementation of further response actions.

- ***Improve O&M activities*** – For example, when a cap's vegetative cover is not mowed on a regular basis and/or vegetation other than that specified in the remedial construction contract specifications is present, you may recommend that actions be taken to improve compliance with the O&M Manual/Plan. The lack of O&M activities can lead to more serious remedy problems if not addressed. Your Five-Year Review report should recommend that O&M activities be conducted if they currently are not being performed or inadequately conducted and, if needed, expanded, reduced, or terminated. The report should also provide the rationale/basis for any of these recommendations.

- ***Optimize remedy*** – For example, when the limits of a groundwater plume have contracted due to pumping, and some monitoring wells no longer register contamination levels above cleanup levels, it may be appropriate to revise the sampling plan to eliminate these wells from the sampling routine or reduce the frequency of their sampling. It may also be possible to remove specific groundwater extraction wells from service and increase or reduce the pumping rate on others to optimize groundwater remediation. Similarly, it may be possible to remove treatment units that no longer contribute to the achievement of remedial goals.

- ***Enforce access controls and ICs*** – For example, when repeated site trespassing has been observed, you could recommend repair of the fence and an evaluation of the need for additional security measures. When you have evidence that groundwater wells continue to be installed despite well restrictions that are currently in place, you can recommend an evaluation of the need for further enforcement of institutional controls (*e.g.*, prohibit well drilling).

- ***Conduct additional studies or investigations*** – For example, after reviewing and evaluating all available data and information it is apparent that contaminant levels have not decreased as expected in the estimated time frame. Additional information will be needed to determine if the remedy, as is, will be able to achieve remediation goals within the estimated time frame. Other studies may include, but are not limited to, site characterization, ecological assessment,

focused feasibility studies, groundwater modeling, treatability studies, and/or sampling.

For each recommendation, you should identify the party responsible for implementation, the agency with oversight authority, a recommended schedule for implementation and completion, and the impact, if any, on current or future protectiveness. Exhibit 4-4 provides an example of a table that you can use in your Five-Year Review report for documenting both recommendations and follow-up actions.

Exhibit 4-4: Example Table for Listing Recommendations and Follow-up Actions

Recommendations/ Follow-up Actions	Party Responsible	Oversight Agency	Milestone Date	Follow-up Actions: Affects Protectiveness (Y/N)	
				Current	Future

Regions should track the progress and completion of recommendations and/or followup actions with documentation in the site file, and upon completion update the administrative record in the site information repository. See Section 3.8 for annual reporting responsibilities to EPA Headquarters.

4.5 How do I determine protectiveness?

After addressing Questions A, B, and C, you should be ready to determine the protectiveness of the remedy or remedies at a site and to document the rationale for your determination(s). You should make a protectiveness statement for each OU and an additional, comprehensive site-wide protectiveness statement for those sites that have reached construction completion.

Your determination of whether the remedy remains protective of human health and the environment generally should 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), your 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 your technical analysis and evaluation, if the answers to Questions A, B, and C are *yes, yes, and no*, respectively, then your remedy normally should be considered

protective. However, if the answers to the three questions are other than *yes, yes, no,* depending on the elements that affect each question, your remedy may be one of the following:

- Protective;
- 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;
- Not protective, unless the following action(s) are taken in order to ensure protectiveness; or
- Protectiveness cannot be determined until further information is obtained. (A time frame should be provided when a protectiveness determination will be made. This should be done through an addendum. If this is the case, your next five-year review should be due five years from the date this report is signed, not 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 should be considered as not protective when the following occur:

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

Exhibit 4-5 presents examples of protectiveness determinations. These examples cover only some of the possible situations you may observe at your site but should serve to guide your decision-making.

Exhibit 4-5: Examples of Protectiveness Determinations

1. Remedies Under Construction			
If the remedy involves...	**and you observe in your five-year review that...**	**then your answers to Questions A, B and C should be...**	**and...**
any remedial action under construction	• no changes to site conditions or any other parameters would impact protectiveness	A - Yes B - Yes C - No	the remedy will be protective.
a groundwater pump-and-treat system expected to operate for 30 years with institutional controls to restrict well drilling of groundwater wells	• an MCL for one of the contaminants of concern (COCs) has become more stringent since the ROD was signed; and the risk associated with the previous MCL is now outside of the risk range; • the remedy cannot meet the new standard (even with design modifications); and • ICs are in place,	A - Yes B - No C - No	the remedy is not protective because the remedy is not able to meet the new standard (ARAR) and the previous MCL is outside of the risk range. However, since ICs are in place there are no current exposures. Recommend that follow-up actions be taken to address the new MCL (ARAR) issue.
rerouting of contaminated surface runoff from tailings	• remedy in the ROD did not address ecological risks; • sediment sampling data from adjacent wetlands indicate high levels of heavy metals; • there were dead fish, and land animals with physical abnormalities; or • an ecological risk assessment was not previously conducted,	A - Yes B - Yes C - Yes	defer protectiveness because more information is needed to make a protectiveness determination. Recommend that follow-up actions be taken to address inadequate ecological risk data.

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?

Exhibit 4-5: Examples of Protectiveness Determinations

2. Operating Remedies			
If the remedy involves...	**and you observe in your five-year review that...**	**then your answers to questions A, B and C should be...**	**and...**
any operating remedy	• no changes to site conditions or any parameters under Questions A, B, and C occurred,	A - Yes B - Yes C - No	the remedy is protective.
groundwater pump-and-treat system expected to operate for 15 years with ICs to restrict well drilling	• no well drilling restriction in place as required by ROD; • there is no known current exposure to groundwater, based on site visits, interviews with local officials and residents,	A - No B - Yes C - No	the remedy is considered protective in the short-term, because there is no evidence that there is current exposure. However, in order for the remedy to remain protective in the long-term, ICs restricting well drilling must be put in place.
groundwater pump-and-treat for 20 years; ICs restricting well drilling; RAO: restore groundwater to drinking water standards	• based on data and current groundwater modeling, the RAOs will not be met; • ICs are in place; • the system has been operating for ten years; • there are no changes in standards or contaminant characteristics for COCs; • there are no new standards; • contaminant levels of COCs have leveled off in the last five years; • optimization efforts have not been effective in further decreasing COC levels; • current levels of contamination are within EPA's risk range, however, RAOs have not yet been achieved,	A - No B - No C - No	the remedy is considered protective in the short-term because ICs are in place, and therefore, there is no current or potential exposure. Follow-up actions are necessary to address long-term protectiveness because RAOs are not expected to be met. Recommend that the remedial action objectives may need to be reevaluated and other potential actions be further evaluated.

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?

Exhibit 4-5: Examples of Protectiveness Determinations

If the remedy involves...	**and you observe in your five-year review that...**	**then your answers to questions A, B and C should be...**	**and...**
groundwater pump-and-treat for 10 years; ICs on well drilling; RAO: groundwater restoration to beneficial use	• ICs are in place; • there is a new State MCL for one of the COCs; • the standard (ARAR) in the original ROD is still protective because it is within the same order of magnitude as the new State MCL and remains within EPA's risk range; • there is no current exposure - residents with private wells in the area are on alternate water supply; • the State considers all groundwater to be a potential source of drinking water (However, there is no Comprehensive State Groundwater Protection Plan [CSGWPP]); and • the existing remedy (system) can achieve the new MCL,	A - Yes B - No C - No	the remedy is considered protective because the cleanup levels are still within EPA's risk range and there is no current or potential exposure.

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?

Exhibit 4-5: Examples of Protectiveness Determinations

If the remedy involves...	and you observe in your five-year review that...	then your answers to questions A, B and C should be...	and...
groundwater pump-and-treat for 20 years; ICs restricting well drilling; RAO: groundwater restoration to drinking water standards	• ICs are in place; • new Federal standard for one of the COCs; • the standard (ARAR) in the original ROD is still protective, within EPA's risk range; • no current or potential exposure to groundwater; and • existing remedy can remediate groundwater to the new standard,	A - Yes B - No C - No	the remedy is considered protective because cleanup levels are still within the risk range and there is no current or potential exposure. However, if the new MCL is not met, the groundwater will not meet the RAO of restoration to drinking water standards. Recommend consideration of follow-up actions to address the new standard and the issue of not achieving the RAO. However, in this case, the remedy can meet the new standard, and therefore, another option is to recommend that the new standard be adopted as the new cleanup level, which would then allow you to achieve the original RAOs. Adopting a new cleanup level would have to be done through the remedy decision process with a ROD Amendment or Explanation of Significant Differences (ESD).

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?

Exhibit 4-5: Examples of Protectiveness Determinations

3. Completed Remedies			
If the remedy involves...	**and you observe in your five-year review that...**	**then your answers to questions A, B and C should be...**	**and...**
any remedy that is complete with a five-year review requirement	• there were no changes to site conditions or parameters under questions A, B, and C,	A - Yes B - Yes C - No	the remedy is protective.
capping of 30-acre landfill with ICs to prevent disturbance of cap	• ICs were never put in place; • mowing and cap maintenance activities are ongoing and adequate; • there is no cracking, sliding, settlement of cap or other indicators of cap breaches; and • there is no evidence of an exposure (human or ecological),	A - No B - Yes C - No	the remedy is considered protective in the short-term because there is no evidence of a cap breach and thus no current exposure. However, in order for the remedy to remain protective in the long-term, ICs must be put in place.
groundwater pump-and-treat for 10 years; ICs restricting well drilling; RAO: restore groundwater to drinking water standards; cleanup goals were achieved and RAOs were met (third five-year review is being conducted as a matter of policy in order to facilitate the deletion process)	• there is a new standard for one of the COCs; • Standard in original ROD (ARAR) is now outside of the risk range (due to a change in toxicity); and • ICs are no longer in place because RAOs were met last year,	A - Yes B - No C - No	the remedy is not protective because the standard in the ROD is no longer within the risk range and therefore no longer protective. In addition, the RAO is no longer being met. Recommend follow-up actions necessary to make remedy protective and deletion should not occur until this issue is resolved.

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?

Exhibit 4-5: Examples of Protectiveness Determinations

If the remedy involves...	**and you observe in your five-year review that...**	**then your answers to questions A, B and C should be...**	**and...**
excavation and disposal of top two feet of contaminated soil; ICs prohibiting residential and recreational use of the property; RAO: cleanup site to allow for industrial use; site was deleted three years ago	• ICs are still in place; • the remedy is intact, no physical disturbances, top two feet of clean soil remain undisturbed; and • the local government is considering changing the zoning of the property to allow for recreational use,	A - Yes B - Yes C - No	the remedy is considered to be currently protective. However, should the zoning of the property change to recreational use, the remedy may no longer be protective. Recommend follow-up actions with local officials to ensure that in the event that zoning changes the remedy will remain protective.

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?

4.5.1 How do I formulate protectiveness statements?

You should develop a protectiveness statement for each OU at which a remedial action has been initiated. For sites that have reached construction completion and have more than one OU, you should develop an additional comprehensive site-wide protectiveness statement covering all of the remedies at the site. You should not include this additional protectiveness statement until construction completion because, until then, all remedies at the site may not necessarily have been selected and constructed.

In order to promote consistency, you are strongly encouraged to model your protectiveness statements on the sample protectiveness statements provided in Exhibits 4-6 and 4-7. Your Five-Year Review report should present the protectiveness statements at the beginning of a discussion that should explain and provide the supporting rationale of the protectiveness determination.

Exhibit 4-6: Protectiveness Statements

If the remedial action at the OU is:	**then use this statement ...**
under construction and...	
protective or will be protective	"The remedy at OU X is expected to be protective of human health and the environment upon completion, and in the interim, exposure pathways that could result in unacceptable risks are being controlled."
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."
protectiveness deferred	" A protectiveness determination of the remedy at OU X 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."

Exhibit 4-6: Protectiveness Statements

If the remedial action at the OU is:	**then use this statement ...**
operating or completed and...	
protective	"The remedy at OU X is expected to be protective upon completion or is protective of human health and the environment, and in the interim, exposure pathways that could result in unacceptable risks are being controlled."
protective in the short-term	"The remedy at OU X 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 long-term protectiveness."
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.
protectiveness deferred	" A protectiveness determination of the remedy at OU X 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."

Exhibit 4-7: Comprehensive Protectiveness Statements for Sites That Have Reached Construction Completion

If the remedy(ies) is/are ...	**then use this statement:**
protective	"Because the remedial actions at all OUs are protective, the site is protective of human health and the environment."
not protective	"The remedial actions at OUs X and Y are protective. However, because the remedial action at OU Z is not protective, the site is not protective of human health and the environment at this time. The remedial action at OU Z 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."