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by responsible parties is appropriate; or

(iii) The remedial investigation has shown that the release poses no significant threat to public health or the environment and, therefore, taking of remedial measures is not appropriate.

(2) Releases shall not be deleted from the NPL until the state in which the release was located has concurred on the proposed deletion. EPA shall provide the state 30 working days for review of the deletion notice prior to its publication in the FEDERAL REGISTER.

(3) All releases deleted from the NPL are eligible for further Fund-financed remedial actions should future conditions warrant such action. Whenever there is a significant release from a site deleted from the NPL, the site shall be restored to the NPL without application of the HRS.

(4) To ensure public involvement during the proposal to delete a release from the NPL, EPA shall:

(i) Publish a notice of intent to delete in the FEDERAL REGISTER and solicit comment through a public comment period of a minimum of 30 calendar days;

(ii) In a major local newspaper of general circulation at or near the release that is proposed for deletion, publish a notice of availability of the notice of intent to delete;

(iii) Place copies of information supporting the proposed deletion in the information repository, described in § 300.430(c)(2)(iii), at or near the release proposed for deletion. These items shall be available for public inspection and copying; and

(iv) Respond to each significant comment and any significant new data submitted during the comment period and include this response document in the final deletion package.

(5) EPA shall place the final deletion package in the local information repository once the notice of final deletion has been published in the FEDERAL REGISTER.

§ 300.430 Remedial investigation/feasibility study and selection of remedy.

(a) *General*—(1) *Introduction.* The purpose of the remedy selection process is to implement remedies that eliminate, reduce, or control risks to human health and the environment. Remedial actions are to be implemented as soon as site data and information make it possible to do so. Accordingly, EPA has established the following program goal, expectations, and program management principles to assist in the identification and implementation of appropriate remedial actions.

(i) *Program goal.* The national goal of the remedy selection process is to select remedies that are protective of human health and the environment, that maintain protection over time, and that minimize untreated waste.

(ii) *Program management principles.* EPA generally shall consider the following general principles of program management during the remedial process:

(A) Sites should generally be remediated in operable units when early actions are necessary or appropriate to achieve significant risk reduction quickly, when phased analysis and response is necessary or appropriate given the size or complexity of the site, or to expedite the completion of total site cleanup.

(B) Operable units, including interim action operable units, should not be inconsistent with nor preclude implementation of the expected final remedy.

(C) Site-specific data needs, the evaluation of alternatives, and the documentation of the selected remedy should reflect the scope and complexity of the site problems being addressed.

(iii) *Expectations.* EPA generally shall consider the following expectations in developing appropriate remedial alternatives:

(A) EPA expects to use treatment to address the principal threats posed by a site, wherever practicable. Principal threats for which treatment is most likely to be appropriate include liquids, areas contaminated with high concentrations of toxic compounds, and highly mobile materials.

(B) EPA expects to use engineering controls, such as containment, for waste that poses a relatively low long-term threat or where treatment is impracticable.

(C) EPA expects to use a combination of methods, as appropriate, to achieve protection of human health and the environment. In appropriate site situations, treatment of the principal threats posed by a site, with priority placed on treating waste that is liquid, highly toxic or highly mobile, will be combined with engineering controls (such as containment) and institutional controls, as appropriate, for treatment residuals and untreated waste.

(D) EPA expects to use institutional controls such as water use and deed restrictions to supplement engineering controls as appropriate for short- and long-term management to prevent or limit exposure to hazardous substances, pollutants, or contaminants. Institutional controls may be used during the conduct of the remedial investigation/feasibility study (RI/FS) and implementation of the remedial action and, where necessary, as a component of the completed remedy. The use of institutional controls shall not substitute for active response measures (e.g., treatment and/or containment of source material, restoration of ground waters to their beneficial uses) as the sole remedy unless such active measures are determined not to be practicable, based on the balancing of trade-offs among alternatives that is conducted during the selection of remedy.

(E) EPA expects to consider using innovative technology when such technology offers the potential for comparable or superior treatment performance or implementability, fewer or lesser adverse impacts than other available approaches, or lower costs for similar levels of performance than demonstrated technologies.

(F) EPA expects to return usable ground waters to their beneficial uses wherever practicable, within a timeframe that is reasonable given the particular circumstances of the site. When restoration of ground water to beneficial uses is not practicable, EPA expects to prevent further migration of the plume, prevent exposure to the contaminated ground water, and evaluate further risk reduction.

(2) *Remedial investigation/feasibility study*. The purpose of the remedial investigation/feasibility study (RI/FS) is to assess site conditions and evaluate alternatives to the extent necessary to select a remedy. Developing and conducting an RI/FS generally includes the following activities: project scoping, data collection, risk assessment, treatability studies, and analysis of alternatives. The scope and timing of these activities should be tailored to the nature and complexity of the problem and the response alternatives being considered.

(b) *Scoping.* In implementing this section, the lead agency should consider the program goal, program management principles, and expectations contained in this rule. The investigative and analytical studies should be tailored to site circumstances so that the scope and detail of the analysis is appropriate to the complexity of site problems being addressed. During scoping, the lead and support agencies shall confer to identify the optimal set and sequence of actions necessary to address site problems. Specifically, the lead agency shall:

(1) Assemble and evaluate existing data on the site, including the results of any removal actions, remedial preliminary assessment and site inspections, and the NPL listing process.

(2) Develop a conceptual understanding of the site based on the evaluation of existing data described in paragraph (b)(1) of this section.

(3) Identify likely response scenarios and potentially applicable technologies and operable units that may address site problems.

(4) Undertake limited data collection efforts or studies where this information will assist in scoping the RI/FS or accelerate response actions, and begin to identify the need for treatability studies, as appropriate.

(5) Identify the type, quality, and quantity of the data that will be collected during the RI/FS to support decisions regarding remedial response activities.

(6) Prepare site-specific health and safety plans that shall specify, at a minimum, employee training and protective equipment, medical surveillance requirements, standard operating procedures, and a contingency plan

that conforms with 29 CFR 1910.120 (l)(1) and (l)(2).

(7) If natural resources are or may be injured by the release, ensure that state and federal trustees of the affected natural resources have been notified in order that the trustees may initiate appropriate actions, including those identified in subpart G of this part. The lead agency shall seek to coordinate necessary assessments, evaluations, investigations, and planning with such state and federal trustees.

(8) Develop sampling and analysis plans that shall provide a process for obtaining data of sufficient quality and quantity to satisfy data needs. Sampling and analysis plans shall be reviewed and approved by EPA. The sampling and analysis plans shall consist of two parts:

(i) The field sampling plan, which describes the number, type, and location of samples and the type of analyses; and

(ii) The quality assurance project plan, which describes policy, organization, and functional activities and the data quality objectives and measures necessary to achieve adequate data for use in selecting the appropriate remedy.

(9) Initiate the identification of potential federal and state ARARs and, as appropriate, other criteria, advisories, or guidance to be considered.

(c) *Community relations.* (1) The community relations requirements described in this section apply to all remedial activities undertaken pursuant to CERCLA section 104 and to section 106 or section 122 consent orders or decrees, or section 106 administrative orders.

(2) The lead agency shall provide for the conduct of the following community relations activities, to the extent practicable, prior to commencing field work for the remedial investigation:

(i) Conducting interviews with local officials, community residents, public interest groups, or other interested or affected parties, as appropriate, to solicit their concerns and information needs, and to learn how and when citizens would like to be involved in the Superfund process.

(ii) Preparing a formal community relations plan (CRP), based on the community interviews and other relevant information, specifying the community relations activities that the lead agency expects to undertake during the remedial response. The purpose of the CRP is to:

(A) Ensure the public appropriate opportunities for involvement in a wide variety of site-related decisions, including site analysis and characterization, alternatives analysis, and selection of remedy;

(B) Determine, based on community interviews, appropriate activities to ensure such public involvement, and

(C) Provide appropriate opportunities for the community to learn about the site.

(iii) Establishing at least one local information repository at or near the location of the response action. Each information repository should contain a copy of items made available to the public, including information that describes the technical assistance grants application process. The lead agency shall inform interested parties of the establishment of the information repository.

(iv) Informing the community of the availability of technical assistance grants.

(3) For PRP actions, the lead agency shall plan and implement the community relations program at a site. PRPs may participate in aspects of the community relations program at the discretion of and with oversight by the lead agency.

(4) The lead agency may conduct technical discussions involving PRPs and the public. These technical discussions may be held separately from, but contemporaneously with, the negotiations/settlement discussions.

(5) In addition, the following provisions specifically apply to enforcement actions:

(i) Lead agencies entering into an enforcement agreement with de minimis parties under CERCLA section 122(g) or cost recovery settlements under section 122(h) shall publish a notice of the proposed agreement in the FEDERAL REGISTER at least 30 days before the agreement becomes final, as required

by section 122(i). The notice must identify the name of the facility and the parties to the proposed agreement and must allow an opportunity for comment and consideration of comments; and

(ii) Where the enforcement agreement is embodied in a consent decree, public notice and opportunity for public comment shall be provided in accordance with 28 CFR 50.7.

(d) *Remedial investigation*. (1) The purpose of the remedial investigation (RI) is to collect data necessary to adequately characterize the site for the purpose of developing and evaluating effective remedial alternatives. To characterize the site, the lead agency shall, as appropriate, conduct field investigations, including treatability studies, and conduct a baseline risk assessment. The RI provides information to assess the risks to human health and the environment and to support the development, evaluation, and selection of appropriate response alternatives. Site characterization may be conducted in one or more phases to focus sampling efforts and increase the efficiency of the investigation. Because estimates of actual or potential exposures and associated impacts on human and environmental receptors may be refined throughout the phases of the RI as new information is obtained, site characterization activities should be fully integrated with the development and evaluation of alternatives in the feasibility study. Bench- or pilot-scale treatability studies shall be conducted, when appropriate and practicable, to provide additional data for the detailed analysis and to support engineering design of remedial alternatives.

(2) The lead agency shall characterize the nature of and threat posed by the hazardous substances and hazardous materials and gather data necessary to assess the extent to which the release poses a threat to human health or the environment or to support the analysis and design of potential response actions by conducting, as appropriate, field investigations to assess the following factors:

(i) Physical characteristics of the site, including important surface features, soils, geology, hydrogeology, meteorology, and ecology;

(ii) Characteristics or classifications of air, surface water, and ground water;

(iii) The general characteristics of the waste, including quantities, state, concentration, toxicity, propensity to bioaccumulate, persistence, and mobility;

(iv) The extent to which the source can be adequately identified and characterized;

(v) Actual and potential exposure pathways through environmental media;

(vi) Actual and potential exposure routes, for example, inhalation and ingestion; and

(vii) Other factors, such as sensitive populations, that pertain to the characterization of the site or support the analysis of potential remedial action alternatives.

(3) The lead and support agency shall identify their respective potential ARARs related to the location of and contaminants at the site in a timely manner. The lead and support agencies may also, as appropriate, identify other pertinent advisories, criteria, or guidance in a timely manner (see § 300.400(g)(3)).

(4) Using the data developed under paragraphs (d)(1) and (2) of this section, the lead agency shall conduct a site-specific baseline risk assessment to characterize the current and potential threats to human health and the environment that may be posed by contaminants migrating to ground water or surface water, releasing to air, leaching through soil, remaining in the soil, and bioaccumulating in the food chain. The results of the baseline risk assessment will help establish acceptable exposure levels for use in developing remedial alternatives in the FS, as described in paragraph (e) of this section.

(e) *Feasibility study*. (1) The primary objective of the feasibility study (FS) is to ensure that appropriate remedial alternatives are developed and evaluated such that relevant information concerning the remedial action options can be presented to a decision-maker and an appropriate remedy selected. The lead agency may develop a feasibility study to address a specific site problem or the entire site. The development and evaluation of alternatives

shall reflect the scope and complexity of the remedial action under consideration and the site problems being addressed. Development of alternatives shall be fully integrated with the site characterization activities of the remedial investigation described in paragraph (d) of this section. The lead agency shall include an alternatives screening step, when needed, to select a reasonable number of alternatives for detailed analysis.

(2) Alternatives shall be developed that protect human health and the environment by recycling waste or by eliminating, reducing, and/or controlling risks posed through each pathway by a site. The number and type of alternatives to be analyzed shall be determined at each site, taking into account the scope, characteristics, and complexity of the site problem that is being addressed. In developing and, as appropriate, screening the alternatives, the lead agency shall:

(i) Establish remedial action objectives specifying contaminants and media of concern, potential exposure pathways, and remediation goals. Initially, preliminary remediation goals are developed based on readily available information, such as chemical-specific ARARs or other reliable information. Preliminary remediation goals should be modified, as necessary, as more information becomes available during the RI/FS. Final remediation goals will be determined when the remedy is selected. Remediation goals shall establish acceptable exposure levels that are protective of human health and the environment and shall be developed by considering the following:

(A) Applicable or relevant and appropriate requirements under federal environmental or state environmental or facility siting laws, if available, and the following factors:

(*1*) For systemic toxicants, acceptable exposure levels shall represent concentration levels to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, incorporating an adequate margin of safety;

(*2*) For known or suspected carcinogens, acceptable exposure levels are generally concentration levels that represent an excess upper bound lifetime cancer risk to an individual of between 10^{-4} and 10^{-6} using information on the relationship between dose and response. The 10^{-6} risk level shall be used as the point of departure for determining remediation goals for alternatives when ARARs are not available or are not sufficiently protective because of the presence of multiple contaminants at a site or multiple pathways of exposure;

(*3*) Factors related to technical limitations such as detection/quantification limits for contaminants;

(*4*) Factors related to uncertainty; and

(*5*) Other pertinent information.

(B) Maximum contaminant level goals (MCLGs), established under the Safe Drinking Water Act, that are set at levels above zero, shall be attained by remedial actions for ground or surface waters that are current or potential sources of drinking water, where the MCLGs are relevant and appropriate under the circumstances of the release based on the factors in § 300.400(g)(2). If an MCLG is determined not to be relevant and appropriate, the corresponding maximum contaminant level (MCL) shall be attained where relevant and appropriate to the circumstances of the release.

(C) Where the MCLG for a contaminant has been set at a level of zero, the MCL promulgated for that contaminant under the Safe Drinking Water Act shall be attained by remedial actions for ground or surface waters that are current or potential sources of drinking water, where the MCL is relevant and appropriate under the circumstances of the release based on the factors in § 300.400(g)(2).

(D) In cases involving multiple contaminants or pathways where attainment of chemical-specific ARARs will result in cumulative risk in excess of 10^{-4}, criteria in paragraph (e)(2)(i)(A) of this section may also be considered when determining the cleanup level to be attained.

(E) Water quality criteria established under sections 303 or 304 of the Clean Water Act shall be attained where relevant and appropriate under the circumstances of the release.

(F) An alternate concentration limit (ACL) may be established in accordance with CERCLA section 121(d)(2)(B)(ii).

(G) Environmental evaluations shall be performed to assess threats to the environment, especially sensitive habitats and critical habitats of species protected under the Endangered Species Act.

(ii) Identify and evaluate potentially suitable technologies, including innovative technologies;

(iii) Assemble suitable technologies into alternative remedial actions.

(3) For source control actions, the lead agency shall develop, as appropriate:

(i) A range of alternatives in which treatment that reduces the toxicity, mobility, or volume of the hazardous substances, pollutants, or contaminants is a principal element. As appropriate, this range shall include an alternative that removes or destroys hazardous substances, pollutants, or contaminants to the maximum extent feasible, eliminating or minimizing, to the degree possible, the need for long-term management. The lead agency also shall develop, as appropriate, other alternatives which, at a minimum, treat the principal threats posed by the site but vary in the degree of treatment employed and the quantities and characteristics of the treatment residuals and untreated waste that must be managed; and

(ii) One or more alternatives that involve little or no treatment, but provide protection of human health and the environment primarily by preventing or controlling exposure to hazardous substances, pollutants, or contaminants, through engineering controls, for example, containment, and, as necessary, institutional controls to protect human health and the environment and to assure continued effectiveness of the response action.

(4) For ground-water response actions, the lead agency shall develop a limited number of remedial alternatives that attain site-specific remediation levels within different restoration time periods utilizing one or more different technologies.

(5) The lead agency shall develop one or more innovative treatment technologies for further consideration if those technologies offer the potential for comparable or superior performance or implementability; fewer or lesser adverse impacts than other available approaches; or lower costs for similar levels of performance than demonstrated treatment technologies.

(6) The no-action alternative, which may be no further action if some removal or remedial action has already occurred at the site, shall be developed.

(7) As appropriate, and to the extent sufficient information is available, the short- and long-term aspects of the following three criteria shall be used to guide the development and screening of remedial alternatives:

(i) *Effectiveness.* This criterion focuses on the degree to which an alternative reduces toxicity, mobility, or volume through treatment, minimizes residual risks and affords long-term protection, complies with ARARs, minimizes short-term impacts, and how quickly it achieves protection. Alternatives providing significantly less effectiveness than other, more promising alternatives may be eliminated. Alternatives that do not provide adequate protection of human health and the environment shall be eliminated from further consideration.

(ii) *Implementability*. This criterion focuses on the technical feasibility and availability of the technologies each alternative would employ and the administrative feasibility of implementing the alternative. Alternatives that are technically or administratively infeasible or that would require equipment, specialists, or facilities that are not available within a reasonable period of time may be eliminated from further consideration.

(iii) *Cost.* The costs of construction and any long-term costs to operate and maintain the alternatives shall be considered. Costs that are grossly excessive compared to the overall effectiveness of alternatives may be considered as one of several factors used to eliminate alternatives. Alternatives providing effectiveness and implementability similar to that of another alternative by employing a similar method of treatment or engineering control, but at greater cost, may be eliminated.

(8) The lead agency shall notify the support agency of the alternatives that will be evaluated in detail to facilitate the identification of ARARs and, as appropriate, pertinent advisories, criteria, or guidance to be considered.

(9) *Detailed analysis of alternatives.* (i) A detailed analysis shall be conducted on the limited number of alternatives that represent viable approaches to remedial action after evaluation in the screening stage. The lead and support agencies must identify their ARARs related to specific actions in a timely manner and no later than the early stages of the comparative analysis. The lead and support agencies may also, as appropriate, identify other pertinent advisories, criteria, or guidance in a timely manner.

(ii) The detailed analysis consists of an assessment of individual alternatives against each of nine evaluation criteria and a comparative analysis that focuses upon the relative performance of each alternative against those criteria.

(iii) *Nine criteria for evaluation.* The analysis of alternatives under review shall reflect the scope and complexity of site problems and alternatives being evaluated and consider the relative significance of the factors within each criteria. The nine evaluation criteria are as follows:

(A) *Overall protection of human health and the environment.* Alternatives shall be assessed to determine whether they can adequately protect human health and the environment, in both the short- and long-term, from unacceptable risks posed by hazardous substances, pollutants, or contaminants present at the site by eliminating, reducing, or controlling exposures to levels established during development of remediation goals consistent with § 300.430(e)(2)(i). Overall protection of human health and the environment draws on the assessments of other evaluation criteria, especially long-term effectiveness and permanence, short-term effectiveness, and compliance with ARARs.

(B) *Compliance with ARARs.* The alternatives shall be assessed to determine whether they attain applicable or relevant and appropriate requirements under federal environmental laws and state environmental or facility siting laws or provide grounds for invoking one of the waivers under paragraph (f)(1)(ii)(C) of this section.

(C) *Long-term effectiveness and permanence.* Alternatives shall be assessed for the long-term effectiveness and permanence they afford, along with the degree of certainty that the alternative will prove successful. Factors that shall be considered, as appropriate, include the following:

(*1*) Magnitude of residual risk remaining from untreated waste or treatment residuals remaining at the conclusion of the remedial activities. The characteristics of the residuals should be considered to the degree that they remain hazardous, taking into account their volume, toxicity, mobility, and propensity to bioaccumulate.

(*2*) Adequacy and reliability of controls such as containment systems and institutional controls that are necessary to manage treatment residuals and untreated waste. This factor addresses in particular the uncertainties associated with land disposal for providing long-term protection from residuals; the assessment of the potential need to replace technical components of the alternative, such as a cap, a slurry wall, or a treatment system; and the potential exposure pathways and risks posed should the remedial action need replacement.

(D) *Reduction of toxicity, mobility, or volume through treatment.* The degree to which alternatives employ recycling or treatment that reduces toxicity, mobility, or volume shall be assessed, including how treatment is used to address the principal threats posed by the site. Factors that shall be considered, as appropriate, include the following:

(*1*) The treatment or recycling processes the alternatives employ and materials they will treat;

(*2*) The amount of hazardous substances, pollutants, or contaminants that will be destroyed, treated, or recycled;

(*3*) The degree of expected reduction in toxicity, mobility, or volume of the waste due to treatment or recycling and the specification of which reduction(s) are occurring;

(*4*) The degree to which the treatment is irreversible;

(*5*) The type and quantity of residuals that will remain following treatment, considering the persistence, toxicity, mobility, and propensity to bioaccumulate of such hazardous substances and their constituents; and

(*6*) The degree to which treatment reduces the inherent hazards posed by principal threats at the site.

(E) *Short-term effectiveness.* The short-term impacts of alternatives shall be assessed considering the following:

(*1*) Short-term risks that might be posed to the community during implementation of an alternative;

(*2*) Potential impacts on workers during remedial action and the effectiveness and reliability of protective measures;

(*3*) Potential environmental impacts of the remedial action and the effectiveness and reliability of mitigative measures during implementation; and

(*4*) Time until protection is achieved.

(F) *Implementability.* The ease or difficulty of implementing the alternatives shall be assessed by considering the following types of factors as appropriate:

(*1*) Technical feasibility, including technical difficulties and unknowns associated with the construction and operation of a technology, the reliability of the technology, ease of undertaking additional remedial actions, and the ability to monitor the effectiveness of the remedy.

(*2*) Administrative feasibility, including activities needed to coordinate with other offices and agencies and the ability and time required to obtain any necessary approvals and permits from other agencies (for off-site actions);

(*3*) Availability of services and materials, including the availability of adequate off-site treatment, storage capacity, and disposal capacity and services; the availability of necessary equipment and specialists, and provisions to ensure any necessary additional resources; the availability of services and materials; and availability of prospective technologies.

(G) *Cost.* The types of costs that shall be assessed include the following:

(*1*) Capital costs, including both direct and indirect costs;

(*2*) Annual operation and maintenance costs; and

(*3*) Net present value of capital and O&M costs.

(H) *State acceptance.* Assessment of state concerns may not be completed until comments on the RI/FS are received but may be discussed, to the extent possible, in the proposed plan issued for public comment. The state concerns that shall be assessed include the following:

(*1*) The state's position and key concerns related to the preferred alternative and other alternatives; and

(*2*) State comments on ARARs or the proposed use of waivers.

(I) *Community acceptance.* This assessment includes determining which components of the alternatives interested persons in the community support, have reservations about, or oppose. This assessment may not be completed until comments on the proposed plan are received.

(f) *Selection of remedy*—(1) Remedies selected shall reflect the scope and purpose of the actions being undertaken and how the action relates to long-term, comprehensive response at the site.

(i) The criteria noted in paragraph (e)(9)(iii) of this section are used to select a remedy. These criteria are categorized into three groups.

(A) *Threshold criteria.* Overall protection of human health and the environment and compliance with ARARs (unless a specific ARAR is waived) are threshold requirements that each alternative must meet in order to be eligible for selection.

(B) *Primary balancing criteria.* The five primary balancing criteria are long-term effectiveness and permanence; reduction of toxicity, mobility, or volume through treatment; short-term effectiveness; implementability; and cost.I11(C) *Modifying criteria.* State and community acceptance are modifying criteria that shall be considered in remedy selection.

(ii) The selection of a remedial action is a two-step process and shall proceed in accordance with § 300.515(e). First, the lead agency, in conjunction with the support agency, identifies a preferred alternative and presents it to the public in a proposed plan, for review and comment. Second, the lead

agency shall review the public comments and consult with the state (or support agency) in order to determine if the alternative remains the most appropriate remedial action for the site or site problem. The lead agency, as specified in § 300.515(e), makes the final remedy selection decision, which shall be documented in the ROD. Each remedial alternative selected as a Superfund remedy will employ the criteria as indicated in paragraph (f)(1)(i) of this section to make the following determination:

(A) Each remedial action selected shall be protective of human health and the environment.

(B) On-site remedial actions selected in a ROD must attain those ARARs that are identified at the time of ROD signature or provide grounds for invoking a waiver under § 300.430(f)(1)(ii)(C).

(*1*) Requirements that are promulgated or modified after ROD signature must be attained (or waived) only when determined to be applicable or relevant and appropriate and necessary to ensure that the remedy is protective of human health and the environment.

(*2*) Components of the remedy not described in the ROD must attain (or waive) requirements that are identified as applicable or relevant and appropriate at the time the amendment to the ROD or the explanation of significant difference describing the component is signed.

(C) An alternative that does not meet an ARAR under federal environmental or state environmental or facility siting laws may be selected under the following circumstances:

(*1*) The alternative is an interim measure and will become part of a total remedial action that will attain the applicable or relevant and appropriate federal or state requirement;

(*2*) Compliance with the requirement will result in greater risk to human health and the environment than other alternatives;

(*3*) Compliance with the requirement is technically impracticable from an engineering perspective;

(*4*) The alternative will attain a standard of performance that is equivalent to that required under the otherwise applicable standard, requirement, or limitation through use of another method or approach;

(*5*) With respect to a state requirement, the state has not consistently applied, or demonstrated the intention to consistently apply, the promulgated requirement in similar circumstances at other remedial actions within the state; or

(*6*) For Fund-financed response actions only, an alternative that attains the ARAR will not provide a balance between the need for protection of human health and the environment at the site and the availability of Fund monies to respond to other sites that may present a threat to human health and the environment.

(D) Each remedial action selected shall be cost-effective, provided that it first satisfies the threshold criteria set forth in § 300.430(f)(1)(ii)(A) and (B). Cost-effectiveness is determined by evaluating the following three of the five balancing criteria noted in § 300.430(f)(1)(i)(B) to determine overall effectiveness: long-term effectiveness and permanence, reduction of toxicity, mobility, or volume through treatment, and short-term effectiveness. Overall effectiveness is then compared to cost to ensure that the remedy is cost-effective. A remedy shall be cost-effective if its costs are proportional to its overall effectiveness.

(E) Each remedial action shall utilize permanent solutions and alternative treatment technologies or resource recovery technologies to the maximum extent practicable. This requirement shall be fulfilled by selecting the alternative that satisfies paragraph (f)(1)(ii)(A) and (B) of this section and provides the best balance of trade-offs among alternatives in terms of the five primary balancing criteria noted in paragraph (f)(1)(i)(B) of this section. The balancing shall emphasize long-term effectiveness and reduction of toxicity, mobility, or volume through treatment. The balancing shall also consider the preference for treatment as a principal element and the bias against off-site land disposal of untreated waste. In making the determination under this paragraph, the modifying criteria of state acceptance and community acceptance described

in paragraph (f)(1)(i)(C) of this section shall also be considered.

(2) *The proposed plan*. In the first step in the remedy selection process, the lead agency shall identify the alternative that best meets the requirements in § 300.430(f)(1), above, and shall present that alternative to the public in a proposed plan. The lead agency, in conjunction with the support agency and consistent with § 300.515(e), shall prepare a proposed plan that briefly describes the remedial alternatives analyzed by the lead agency, proposes a preferred remedial action alternative, and summarizes the information relied upon to select the preferred alternative. The selection of remedy process for an operable unit may be initiated at any time during the remedial action process. The purpose of the proposed plan is to supplement the RI/FS and provide the public with a reasonable opportunity to comment on the preferred alternative for remedial action, as well as alternative plans under consideration, and to participate in the selection of remedial action at a site. At a minimum, the proposed plan shall:

(i) Provide a brief summary description of the remedial alternatives evaluated in the detailed analysis established under paragraph (e)(9) of this section;

(ii) Identify and provide a discussion of the rationale that supports the preferred alternative;

(iii) Provide a summary of any formal comments received from the support agency; and

(iv) Provide a summary explanation of any proposed waiver identified under paragraph (f)(1)(ii)(C) of this section from an ARAR.

(3) *Community relations to support the selection of remedy*. (i) The lead agency, after preparation of the proposed plan and review by the support agency, shall conduct the following activities:

(A) Publish a notice of availability and brief analysis of the proposed plan in a major local newspaper of general circulation;

(B) Make the proposed plan and supporting analysis and information available in the administrative record required under subpart I of this part;

(C) Provide a reasonable opportunity, not less than 30 calendar days, for submission of written and oral comments on the proposed plan and the supporting analysis and information located in the information repository, including the RI/FS. Upon timely request, the lead agency will extend the public comment period by a minimum of 30 additional days;

(D) Provide the opportunity for a public meeting to be held during the public comment period at or near the site at issue regarding the proposed plan and the supporting analysis and information;

(E) Keep a transcript of the public meeting held during the public comment period pursuant to CERCLA section 117(a) and make such transcript available to the public; and

(F) Prepare a written summary of significant comments, criticisms, and new relevant information submitted during the public comment period and the lead agency response to each issue. This responsiveness summary shall be made available with the record of decision.

(ii) After publication of the proposed plan and prior to adoption of the selected remedy in the record of decision, if new information is made available that significantly changes the basic features of the remedy with respect to scope, performance, or cost, such that the remedy significantly differs from the original proposal in the proposed plan and the supporting analysis and information, the lead agency shall:

(A) Include a discussion in the record of decision of the significant changes and reasons for such changes, if the lead agency determines such changes could be reasonably anticipated by the public based on the alternatives and other information available in the proposed plan or the supporting analysis and information in the administrative record; or

(B) Seek additional public comment on a revised proposed plan, when the lead agency determines the change could not have been reasonably anticipated by the public based on the information available in the proposed plan or the supporting analysis and information in the administrative record. The lead agency shall, prior to adoption of the selected remedy in the ROD, issue a revised proposed plan, which

shall include a discussion of the significant changes and the reasons for such changes, in accordance with the public participation requirements described in paragraph (f)(3)(i) of this section.

(4) *Final remedy selection.* (i) In the second and final step in the remedy selection process, the lead agency shall reassess its initial determination that the preferred alternative provides the best balance of trade-offs, now factoring in any new information or points of view expressed by the state (or support agency) and community during the public comment period. The lead agency shall consider state (or support agency) and community comments regarding the lead agency's evaluation of alternatives with respect to the other criteria. These comments may prompt the lead agency to modify aspects of the preferred alternative or decide that another alternative provides a more appropriate balance. The lead agency, as specified in § 300.515(e), shall make the final remedy selection decision and document that decision in the ROD.

(ii) 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 initiation of the selected remedial action.

(iii) The process for selection of a remedial action at a federal facility on the NPL, pursuant to CERCLA section 120, shall entail:

(A) Joint selection of remedial action by the head of the relevant department, agency, or instrumentality and EPA; or

(B) If mutual agreement on the remedy is not reached, selection of the remedy is made by EPA.

(5) *Documenting the decision.* (i) To support the selection of a remedial action, all facts, analyses of facts, and site-specific policy determinations considered in the course of carrying out activities in this section shall be documented, as appropriate, in a record of decision, in a level of detail appropriate to the site situation, for inclusion in the administrative record required under subpart I of this part. Documentation shall explain how the evaluation criteria in paragraph (e)(9)(iii) of this section were used to select the remedy.

(ii) The ROD shall describe the following statutory requirements as they relate to the scope and objectives of the action:

(A) How the selected remedy is protective of human health and the environment, explaining how the remedy eliminates, reduces, or controls exposures to human and environmental receptors;

(B) The federal and state requirements that are applicable or relevant and appropriate to the site that the remedy will attain;

(C) The applicable or relevant and appropriate requirements of other federal and state laws that the remedy will not meet, the waiver invoked, and the justification for invoking the waiver;

(D) How the remedy is cost-effective, i.e., explaining how the remedy provides overall effectiveness proportional to its costs;

(E) How the remedy utilizes permanent solutions and alternative treatment technologies or resource recovery technologies to the maximum extent practicable; and

(F) Whether the preference for remedies employing treatment which permanently and significantly reduces the toxicity, mobility, or volume of the hazardous substances, pollutants, or contaminants as a principal element is or is not satisfied by the selected remedy. If this preference is not satisfied, the record of decision must explain why a remedial action involving such reductions in toxicity, mobility, or volume was not selected.

(iii) The ROD also shall:

(A) Indicate, as appropriate, the remediation goals, discussed in paragraph (e)(2)(i) of this section, that the remedy is expected to achieve. Performance shall be measured at appropriate locations in the ground water, surface water, soils, air, and other affected environmental media. Measurement relating to the performance of the treatment processes and the engineering controls may also be identified, as appropriate;

(B) Discuss significant changes and the response to comments described in paragraph (f)(3)(i)(F) of this section;

(C) Describe whether hazardous substances, pollutants, or contaminants will remain at the site such that a review of the remedial action under paragraph (f)(4)(ii) of this section no less often than every five years shall be required; and

(D) When appropriate, provide a commitment for further analysis and selection of long-term response measures within an appropriate time-frame.

(6) *Community relations when the record of decision is signed.* After the ROD is signed, the lead agency shall:

(i) Publish a notice of the availability of the ROD in a major local newspaper of general circulation; and

(ii) Make the record of decision available for public inspection and copying at or near the facility at issue prior to the commencement of any remedial action.

§ 300.435 Remedial design/remedial action, operation and maintenance.

(a) *General.* The remedial design/remedial action (RD/RA) stage includes the development of the actual design of the selected remedy and implementation of the remedy through construction. A period of operation and maintenance may follow the RA activities.

(b) *RD/RA activities.* (1) All RD/RA activities shall be in conformance with the remedy selected and set forth in the ROD or other decision document for that site. Those portions of RD/RA sampling and analysis plans describing the QA/QC requirements for chemical and analytical testing and sampling procedures of samples taken for the purpose of determining whether cleanup action levels specified in the ROD are achieved, generally will be consistent with the requirements of § 300.430(b)(8).

(2) During the course of the RD/RA, the lead agency shall be responsible for ensuring that all federal and state requirements that are identified in the ROD as applicable or relevant and appropriate requirements for the action are met. If waivers from any ARARs are involved, the lead agency shall be responsible for ensuring that the conditions of the waivers are met.

(c) *Community relations.* (1) Prior to the initiation of RD, the lead agency shall review the CRP to determine whether it should be revised to describe further public involvement activities during RD/RA that are not already addressed or provided for in the CRP.

(2) After the adoption of the ROD, if the remedial action or enforcement action taken, or the settlement or consent decree entered into, differs significantly from the remedy selected in the ROD with respect to scope, performance, or cost, the lead agency shall consult with the support agency, as appropriate, and shall either:

(i) Publish an explanation of significant differences when the differences in the remedial or enforcement action, settlement, or consent decree significantly change but do not fundamentally alter the remedy selected in the ROD with respect to scope, performance, or cost. To issue an explanation of significant differences, the lead agency shall:

(A) Make the explanation of significant differences and supporting information available to the public in the administrative record established under § 300.815 and the information repository; and

(B) Publish a notice that briefly summarizes the explanation of significant differences, including the reasons for such differences, in a major local newspaper of general circulation; or

(ii) Propose an amendment to the ROD if the differences in the remedial or enforcement action, settlement, or consent decree fundamentally alter the basic features of the selected remedy with respect to scope, performance, or cost. To amend the ROD, the lead agency, in conjunction with the support agency, as provided in § 300.515(e), shall:

(A) Issue a notice of availability and brief description of the proposed amendment to the ROD in a major local newspaper of general circulation;

(B) Make the proposed amendment to the ROD and information supporting the decision available for public comment;

(C) Provide a reasonable opportunity, not less than 30 calendar days, for submission of written or oral comments on the amendment to the ROD. Upon