



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

REGION 1

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OFFICE OF THE
REGIONAL ADMINISTRATOR

December 2, 2019

Kim Kastens, PhD
Community Representative
Green Acton
Kastens@ldeo.columbia.edu

Sent via Electronic Mail

Re: EPA response to Dr. Kastens October 22, 2019 statement regarding 1,4-dioxane in groundwater at the W.R. Grace (Acton Plant) Superfund Site.

Dear Dr. Kastens:

EPA has received your October 22, 2019, statement concerning issues related to 1,4-dioxane in groundwater at the W.R. Grace Superfund Site, located in Acton, Massachusetts. Region 1 has been asked to respond to your letter on behalf of the Administrator. As you wrote, EPA has not selected a cleanup level for 1,4-dioxane at the Site. Your statement outlined the reasons Green Acton is concerned with this decision, and requests that EPA do the following:

- Reopen the Record of Decision (ROD) for the groundwater cleanup of the W.R. Grace Superfund Site, and add 1,4-dioxane to the remediation plan;
- Thoroughly characterize the distribution of 1,4-dioxane in the groundwater in and around the W.R. Grace Superfund Site;
- Develop a plan to extract the worst of the 1,4-dioxane contaminated groundwater; and
- Apply the same cleanup level to the Grace Site that is used at the Nuclear Metals Superfund Site (0.46 micrograms-per-liter, or ug/L).

On November 13, 2019, representatives from EPA Region 1 met with you and Matthew Mostoller, Environmental Compliance Manager for the Water Supply District of Acton, to discuss these requests. EPA representatives included Bryan Olson, the Director of the Region 1 Superfund and Emergency Management Division; Lynne Jennings, the Section Chief for the Massachusetts Superfund Section; and Christopher Smith, the Remedial Project Manager for the W.R. Grace Site. During the meeting, EPA explained the regulations, policy and guidance that governs EPA's decision to modify a ROD. The purpose of this letter is not to provide a comprehensive summary of the meeting, but to address key points of discussion directly related

to your requests, and to outline next steps as EPA works to respond to the concerns raised by you and Mr. Mostoller.

The discussion began with an explanation of the criteria that EPA generally considers before modifying a ROD's cleanup standards. Once EPA determines that a site poses unacceptable risks pursuant to a federal risk assessment, the agency develops and selects cleanup levels based on a combination of both Federal and State requirements (e.g., Maximum Contaminant Levels or MCLs) and risk-based levels. Generally, the cleanup levels EPA selects at the time of the ROD are not modified unless EPA determines that the remedy is no longer protective in light of new information (e.g., updated risk, newly discovered contaminants, new data.)

As discussed, EPA's policy memo, "Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions" (OSWER Directive 9355.0-30; April 22, 1991) (attached), identifies the criteria for taking action at a Superfund site. EPA documents in the ROD the site-specific basis for taking action. The memo further explains that for carcinogens identified as contaminants of potential concern, remedial actions are generally warranted when the calculated cumulative risks a site poses exceed EPA's risk range of 10^{-6} to 10^{-4} . In the case of a new contaminant found after the ROD is issued, EPA will evaluate the risks posed by the presence of this newly identified contaminant. If the existing remedy remains within EPA's acceptable risk range, the remedy may not need to be modified because it is still considered to be protective.¹ As we explained, EPA has not set a federal enforceable drinking water standard (known as an MCL) for 1,4-dioxane. To evaluate the potential risk posed by 1,4-dioxane at this site, EPA compared the concentrations of 1,4-dioxane in groundwater to risk-based screening levels set at the upper boundary of EPA's acceptable risk range (i.e., 10^{-4}) assuming the groundwater is used for drinking water. This screening level equates to 46 ug/L (1×10^{-4}). In order to pose an unacceptable risk from exposure to 1,4-dioxane, groundwater concentrations at the site would need to exceed 46 ug/L. The highest concentration of 1,4-dioxane ever detected in groundwater at the Grace Site was 36 ug/L. This sample was taken from a well downgradient of the Industrial Landfill, where groundwater flow is not in the direction of the Town's well fields, as further explained below. More recent data show that the contaminant concentrations in this area have decreased, and the highest concentration detected in 2018 was 26 ug/L. Because these concentrations are below 46 ug/L, the upper limit of EPA's acceptable risk range, the current remedy is still protective and therefore reopening the ROD for 1,4-dioxane in groundwater is not warranted.

EPA also noted that the 1991 policy memo provides EPA with some flexibility to take action at a risk lower than 1×10^{-4} . A risk manager may decide that a lower level of risk to human health is unacceptable and that remedial action is warranted where, for example, there are uncertainties in the risk assessment results. In addition, where current conditions have not resulted in a release posing risks that warrant action but there is a significant possibility that a release will occur that is likely to result in an unacceptable risk, remedial action may also be taken.² Historically, the

¹ ARARs Q's & A's: General Policy, RCRA, CWA, SDWA, Post-ROD Information, and Contingent Waivers, OSWER 9234.2-01/FS/-A, July 1991. In addition, the contaminant must be site-related and incorporated into the remedy as a contaminant of concern.

² Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions" (OSWER Directive 9355.0-30; April 22, 1991, pages 4-5.

concentrations of 1,4-dioxane in the Town's wells have generally been less than 0.46 ug/L, which equates to a 1×10^{-6} cancer risk (the most protective end of EPA's risk range). There have been isolated detections slightly exceeding this threshold over the past decade-plus of monitoring. However, these higher concentrations have not persisted in follow-up sampling, and there have been no consistent increasing trends in contaminant levels over time. Because the Town's water supply wells are the Site's primary contaminant exposure route for human receptors, EPA will continue to monitor and evaluate the sampling results of all the Town's wells to determine if further future CERCLA action is warranted.

The group went on to discuss the nature and extent of 1,4-dioxane at the Grace Site. The highest concentrations in groundwater (presently 26 ug/L, as noted above) are downgradient of the Industrial Landfill. Groundwater in this area of the Site flows towards the Assabet River, rather than towards either of the Town of Acton's well fields (the Assabet and School Street Well Fields). Upgradient of the School Street Well Field, the available data demonstrates that concentrations of 1,4-dioxane generally range from zero to 3 ug/L, with one monitoring well (AR-30D) adjacent to the Christofferson water supply well that consistently shows detections above 3 ug/L. Upgradient of the Assabet Well Field, the available data show concentrations of 1,4-dioxane in groundwater are generally less than 2 ug/L. These upgradient groundwater plumes are not significantly impacting the Town's public water supply wells, because, as noted above, the concentrations in the public water supply wells are consistently below 0.46 ug/L. EPA will continue to evaluate data upgradient from the Town's water supply wells to determine if conditions change that may warrant further action.

You and Mr. Mostoller expressed the concern that the extent of 1,4-dioxane at the Grace Site has not been appropriately characterized, especially in relation to the extent of the volatile organic compound plume. You also identified several locations where you believe the existing well network may not adequately constrain potential off-site migration pathways for contaminated groundwater. EPA agreed that it would be appropriate to re-evaluate the historic sampling for 1,4-dioxane at the Site to determine if there is a need for additional site characterization.

The group discussion spanned a range of other topics, including groundwater sampling at the Site for per- and polyfluoroalkyl substances, the potential for the Acton Water District to activate an additional extraction well in the Assabet Wellfield, and future requests that W.R. Grace may make to modify the existing groundwater treatment system. The group discussed how many of these issues are interrelated and agreed that they should all be considered when making decisions related to 1,4-dioxane in groundwater.

The group agreed on several next steps to be taken to address the concerns raised by you and Mr. Mostoller. EPA will work with W.R. Grace to compile the historic 1,4-dioxane groundwater data for the Site and will share these results with you on figures which show the nature and extent and any trends in the data. EPA expects to receive and share these figures in January 2020. EPA will use this information to re-evaluate how thoroughly the presence of the compound has been characterized, especially in the areas you noted during the meeting. EPA will then work with the Massachusetts Department of Environmental Protection, Acton Water District, W.R. Grace, and community representatives to determine whether a more extensive sampling effort is needed.

Following this evaluation, it may be appropriate for EPA to coordinate a meeting with W.R. Grace representatives and the other stakeholders to discuss a path forward.

EPA is committed to working with you as we pursue our shared interest to protect drinking water in the Town of Acton. If you have any questions, please feel free to contact Christopher Smith, the Remedial Project Manager for the Site, at (617) 918-1139.

Sincerely,

A handwritten signature in black ink, appearing to read 'Dennis Deziel', written in a cursive style.

Dennis Deziel,
Regional Administrator

cc: Chris Allen and Matthew Mostoller, Acton Water District

Enclosures



ARARs Q's & A's: General Policy, RCRA, CWA, SDWA, Post-ROD Information, and Contingent Waivers

Office of Emergency and Remedial Response
Office of Program Management OS-240

Quick Reference Fact Sheet

Section 121(d)(2) of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA), as amended by the 1986 Superfund Amendments and Reauthorization Act (SARA), requires that on-site remedial actions must attain (or waive) Federal and more stringent State applicable or relevant and appropriate requirements (ARARs) of environmental laws upon completion of the remedial action. The revised National Contingency Plan of 1990 (NCP) requires compliance with ARARs during remedial actions as well as at completion, and compels attainment of ARARs during removal actions to the extent practicable, considering the exigencies of the situation. See the NCP, 40 CFR section 300.415(i) (55 FR 8666, 8843) and section 300.435(b)(2) (55 FR 8666, 8852) (March 8, 1990).

To implement the ARARs provision, EPA has developed guidance, CERCLA Compliance With Other Laws Manual: Parts I and II (Publications 9234.1-01 and 9234.1-02), and has provided training to Regions and States on the identification of and compliance with ARARs. These "ARARs Q's and A's" are part of a series of Fact Sheets that provide guidance on a number of questions that arose in developing ARAR policies, in ARARs training sessions, and in identifying and complying with ARARs at specific sites. This particular Q's and A's Fact Sheet, **which updates and replaces a Fact Sheet first issued in May 1989**, addresses the ARARs general policy; compliance with the Resource Conservation and Recovery Act (RCRA), the Clean Water Act (CWA), and the Safe Drinking Water Act (SDWA); Post-ROD Information and Administrative Record requirements; and "contingency" waivers of ARARs.

I. General Policy

Q1. What difference does it make whether a requirement is "applicable" or "relevant and appropriate"? Why make that distinction?

- A. It is true that once a requirement is determined to be relevant and appropriate, it must be complied with as if it were applicable. However, there are significant differences between the identification and analysis of the two types of requirements (see **Highlight 1**). "Applicability" is a legal and jurisdictional determination, while the determination of "relevant and appropriate" relies on professional judgment, considering environmental and technical factors at the site. There is more flexibility in the relevance and appropriateness determination: a requirement may be "relevant," in that it covers situations similar to that at the site, but may not be "appropriate" to apply for various reasons and, therefore, not well suited to the site. In some situations, only portions of a requirement or regulation may be judged relevant and appropriate; if a requirement is applicable, however, all substantive parts must be followed. (See Overview of ARARs: Focus on ARAR Waivers, Publication 9234.2-03/FS, December 1989, for further discussion on compliance with ARARs.)

For example, if closure requirements under Subtitle C of RCRA are applicable (e.g., at a landfill that received RCRA hazardous waste after 1980 or where the Superfund action constitutes disposal of hazardous waste), the landfill must be closed in compliance with one of the closure options available in Subtitle C regulations. These options are closure by removal (clean closure), which requires decontamination to health-based levels, or closure with waste in place (landfill closure), which requires impermeable caps and long-term maintenance.

However, if Subtitle C closure requirements are not applicable, but are determined to be relevant and appropriate, then a "hybrid closure," which includes other types of closure designs, may also be used. The hybrid closure option arises from a determination that only certain closure requirements in the two Subtitle C closure alternatives are relevant and appropriate. (See proposed NCP, 53 FR at 51446, and preamble to the NCP, 55 FR at 8743, for further discussion of RCRA closure requirements and the concept of hybrid closure.)

Highlight 1: DEFINITIONS OF "APPLICABLE" AND "RELEVANT AND APPROPRIATE"

"Applicable requirements mean those cleanup standards, standards of control, and other substantive environmental protection requirements, criteria, or limitations promulgated under Federal environmental or State environmental or facility siting law that specifically address a hazardous substance, pollutant, contaminant, remedial action, location, or other circumstance at a CERCLA site." [Section 300.5 of the NCP, 55 FR at 8814] In other words, an applicable requirement is one with which a private party would have to comply by law if the same action was being undertaken apart from CERCLA authority. All jurisdictional prerequisites of the requirement must be met in order for the requirement to be applicable.

If a requirement is not applicable, it still may be relevant and appropriate. **"Relevant and appropriate requirements** mean those cleanup standards [that] ... address problems or situations sufficiently similar to those encountered at the CERCLA site that their use is well suited to the particular site." [Section 300.5 of the NCP, 55 FR at 8817] A requirement that is relevant and appropriate may "miss" on one or more jurisdictional prerequisites for applicability but still make sense at the site, given the circumstances of the site and release.

Q2. Does an applicable requirement take precedence over one that is relevant and appropriate? In other words, if an applicable requirement is available, will that be the ARAR, rather than one that might otherwise be relevant and appropriate?

- A. No, a requirement may be relevant and appropriate even if another requirement legally applies to that situation, particularly when the applicable requirement was not really intended to address the type or magnitude of problems encountered at Superfund sites. For example, RCRA Subtitle D requirements for covers for solid waste facilities may be applicable when RCRA hazardous waste is not present at the site. However, the soil cover required under Subtitle D may not always be sufficient to limit leachate at a Superfund site that has substantial amounts of waste similar to RCRA hazardous waste. In such a situation, some Subtitle C closure requirements may be relevant and appropriate to some parts of the site, even though Subtitle D requirements legally apply.

However, one factor that affects whether a requirement is relevant and appropriate is whether another requirement exists that more fully matches the circumstances at the site. In some cases, this might be a requirement that was directly intended for,

and is applicable to, the particular situation. For example, Federal Water Quality Criteria generally will not be relevant and appropriate and, therefore, not ARAR when there is an applicable State Water Quality Standard promulgated specifically for the pollutant and water body, which therefore "more fully matches" the situation. (See Overview of ARARs: Focus on ARAR Waivers, Publication 9234.2-03/FS, December 1989, for further discussion on compliance with ARARs, and CERCLA Compliance With the CWA and SDWA, Publication 9234.2-06/FS, February 1990, for additional discussion on the resolution of potentially conflicting water ARARs.)

Q3. Is compliance with ARARs required for a "no action" decision?

- A. No. CERCLA Section 121 cleanup standards, including compliance with ARARs, apply only to remedial actions that the Agency determines should be taken under CERCLA Sections 104 and 106 authority. A "no action" decision can only be made when no remedial action is necessary to reduce, control, or mitigate exposure because the site or portion of the site is already protective of human health and the environment. See Guidance on Preparing Superfund Decision Documents (OSWER Directive 9355.3-02) for further discussion of "no action" decisions.

Q4. Does an ARAR always have to be met, even if it is not necessary to ensure protectiveness?

- A. Yes, unless one of the six waivers can be used. Attainment of ARARs is a "threshold requirement" in SARA, as is the requirement that the remedies be protective of human health and the environment. If a requirement is applicable or relevant and appropriate, it must be met, unless an ARAR waiver can be used. ARARs represent the minimum that a remedy must attain; it may sometimes be necessary, where there are multiple contaminants with potentially cumulative or synergistic effects, to go beyond what ARARs require to ensure that a remedy is protective. (See Overview of ARARs: Focus on ARAR Waivers, Publication 9234.2-03/FS, December 1989 for further discussion on compliance with ARARs.)

Q5. If wastes from non-contiguous facilities are combined on one site for treatment, is the treatment viewed as off-site activity, and the unit therefore subject to permitting?

- A. No. Because the combined remedial action constitutes on-site action, compliance with permitting or other administrative requirements would not be required (see **Highlight 2**). CERCLA Section 104(d)(4) authorizes EPA to treat two or more non-contiguous facilities as one site for purposes of response, if such facilities are reasonably related on

Highlight 2: ON-SITE VS. OFF-SITE ACTIONS

The requirements under CERCLA for compliance with other laws differ in two significant ways for on-site and off-site actions. **First, the ARARs provision applies only to on-site actions; off-site actions must comply fully only with any laws that legally apply to that action.** Therefore, off-site actions need only comply with "applicable" requirements, not with "relevant and appropriate" requirements; ARAR waivers are not available for requirements that apply to off-site actions.

Second, on-site actions must comply only with the substantive portions of a given requirement; on-site activities need not comply with administrative requirements, such as obtaining a permit or record-keeping and reporting. (Monitoring requirements are considered substantive requirements.) **Off-site actions must comply with both substantive and administrative requirements of all applicable laws.**

[Note: ARARs are the requirements of environmental and facility siting laws only. Independent of ARARs, on-site activities also must comply with applicable requirements of non-environmental laws (e.g., building codes and safety requirements), excluding permit requirements.]

the basis of geography or their potential threat to public health, welfare, or the environment. In keeping with the statutory criteria under CERCLA Section 121(b), combining facilities as one site for remedial action must also be shown to be cost-effective and not result in any significant additional short-term impacts on public health and the environment. (See preamble to the NCP, 55 FR at 8690-8691; Interim RCRA/CERCLA Guidance on Non-Contiguous Sites and On-Site Management of Waste Residue, OSWER Directive 9347.0-1, March 1986; and 49 FR at 37076, September 21, 1984.)

Q6. Are environmental resource laws, such as the Endangered Species Act, the National Historic Preservation Act (NHPA), and the Wild and Scenic Rivers Act, potential ARARs for CERCLA actions?

A. Yes, requirements in these laws are potential ARARs. However, these laws frequently require consultation with, and under some laws, concurrence of, other Agencies or groups, such as the Fish and Wildlife Service or the Advisory Council on Historic Preservation. Administrative requirements such as consultation or obtaining approval are not required for on-site actions. However, it is strongly recommended that the lead agency nevertheless consult with the administering agencies to ensure compliance with substantive requirements, e.g., the NHPA requirement that actions must avoid or minimize impacts on cultural resources. (See preamble to the NCP, 55 FR at 8757. Also, see Summary of Part II: CAA, TSCA, and Other Statutes, Publication 9234.2-07/FS, April 1990, for further discussion of resource protection laws.)

Q7. Are environmental standards and requirements of Indian Tribes potential ARARs?

A. Yes. Indian Tribal requirements are potential ARARs for CERCLA actions taken on Tribal lands and are treated consistently with State requirements. Tribal requirements that meet the eligibility criteria for State ARARs, i.e., those that are promulgated (legally enforceable and of general applicability), are more stringent than Federal requirements, and are identified in a timely manner, are potential ARARs. (See preamble to the NCP, 55 FR at 8741-8742; section 300.5 of the NCP, 55 FR at 8816 for a definition of Indian Tribe; and the Revised Interim Final Guidance on Indian Involvement in the Superfund Program, OSWER Directive 9375.5-02A, November 28, 1989.)

II. Resource Conservation and Recovery Act (RCRA)

Q8. How can RCRA listed waste be "delisted" when wastes will remain on-site?

A. By documenting in the ROD that the substantive requirements in RCRA for delisting have been met, a RCRA listed waste may be "delisted" when wastes remain on-site.

Once a listed waste is "delisted," it is no longer considered a "hazardous waste" and is, therefore, subject to RCRA Subtitle D requirements for solid waste, rather than the more stringent RCRA Subtitle C requirements.

The substantive requirements that must be met for delisting a RCRA hazardous waste that will remain on-site are the standards in 40 CFR sections 260.22(a)(1) and (2), which state that a waste that "does not meet any of the criteria under which the waste was listed as hazardous or an acutely hazardous waste" and for which there is no "reasonable basis to believe that factors (including other constituents) other than those for which the waste was listed could cause the waste to be a hazardous waste" is "delistable." Administrative requirements, which include requirements to undergo a petition and rulemaking process and to develop and supply specific

information, need not be met on-site. (See A Guide to Delisting of RCRA Wastes for Superfund Remedial Responses, Publication 9347.3-09/FS, September 1990.)

Wastes containing constituents at health-based levels, assuming direct exposure, generally will meet the standards for delisting. Wastes with constituents at higher levels may also be delistable, since the RCRA delisting process allows fate-and-transport modeling, generally based on the waste being managed in a solid waste unit. The models used by the RCRA program for delisting are recommended for use in determining whether constituent concentrations above health-based levels are delistable, e.g., for wastes that will be land disposed (See 50 FR 48886, November 27, 1985 and 51 FR 41082, November 13, 1986). The Waste Identification Branch in the Office of Solid Waste (FTS 382-4770) can also provide assistance and advice in delisting a waste.

Substantive requirements for a waste to meet delisting levels should be documented in the RI/FS and the ROD, and a general discussion of why delisting is warranted should be included (see A Guide to Delisting of RCRA Wastes for Superfund Remedial Responses, Publication 9347.3-09/FS, September 1990). Generally, the constituent levels that must be achieved in order for the waste to be considered non-hazardous should be identified in the ROD. Unless treatability studies done during the RI/FS make delisting reasonably certain, the ROD should also address, as a contingency, how the waste will be handled if it does not achieve delistable levels, based on full-scale treatability studies or actual performance of the remedy during RD/RA. If the waste cannot be delisted, and this contingency is expressly noted in the ROD, a fact sheet may be needed to notify the public that the contingency remedy will be implemented.

Q9. Are RCRA financial responsibility requirements potential ARARs for Superfund?

A. No, because they are considered to be administrative requirements, not substantive environmental requirements. RCRA financial responsibility requirements support implementation of RCRA technical standards by ensuring that RCRA facility owners or operators have the financial resources available to address releases and comply with closure and post-closure requirements. CERCLA agreements with PRPs and, ultimately, the Fund itself, achieve essentially the same purpose.

Q10. RCRA hazardous waste is placed into an existing pit that had received hazardous waste in the past, but is not subject to RCRA Subtitle C regulations because the pit closed before 1980. Would the minimum technology requirements (MTR) be applicable?

A. Yes; although the pit is not considered a "new unit," all surface impoundments (i.e., both new and existing) are subject to MTR if they receive hazardous wastes (i.e., wastes that were hazardous as of November 7, 1984) after November 1988. In addition, the land disposal restrictions (LDRs) prohibit placement of restricted wastes (which are under a national capacity variance) in landfills or surface impoundments that are not in compliance with MTR. If such a waste is placed in the existing waste pit, the pit would have to comply with MTR, even though it is not a "new unit." See Superfund LDR Guide #3: Treatment Standards and Minimum Technology Requirements Under Land Disposal Restrictions (LDRs), Publication 9347.3-03/FS, July 1989.

III. Clean Water Act (CWA) & Safe Drinking Water Act (SDWA)

Q11. Do antidegradation laws for ground water, which are increasingly common in State laws, mean that the aquifer must be restored to its original quality before contamination from the site occurred?

A. In most cases, no. Antidegradation laws are prospective and are intended to prevent further degradation of water quality. At a CERCLA site, therefore, a State ground-water antidegradation law might preclude the injection of partially treated water into a pristine aquifer. It would not, however, require cleanup to the aquifer's original quality prior to contamination. If more stringent State standards than those imposed under Federal law are determined to be ARARs for the site, they would have to be met (e.g., by meeting the discharge requirements) or

waived (e.g., by the interim remedy waiver). Where temporary degradation of the ground water may be required during remedial action, protection should be provided by restricting access or providing institutional controls, and EPA response actions should ultimately result in restoration of the ground water's beneficial uses. (See ARARs Q's & A's: State Ground-Water Antidegradation Issues, Publication 9234.2-11/FS, July 1990.)

Q12. There are some situations where an aquifer that is a current or potential drinking-water source, treatable to MCLs at the tap, cannot be remediated to non-zero MCLGs or MCLs in the aquifer. Would non-zero MCLGs or MCLs still be relevant and appropriate?

- A. In general, yes. The non-zero MCLGs and, if none, the MCLs, are generally relevant and appropriate for any aquifer that is a potential drinking-water source (see **Highlight 3**) (see section 300.430(c)(2)(i)(B)-(D) of the NCP, 55 FR at 8848). If they cannot be attained (e.g., because of complex hydrogeology due to fractured bedrock), an ARAR waiver for technical impracticability should be used. If attainment of a non-zero MCLG or MCL is impossible because the background level of the chemical subject to CERCLA authority (e.g., a man-made chemical) is higher than that of the MCLG or MCL, attainment of the MCLG or MCL would not be relevant and appropriate. (See CERCLA Compliance With the CWA and SDWA, Publication 9234.2-06/FS, January 1990.)

**Highlight 3:
ARARs FOR GROUND-WATER CLEANUP**

Non-zero MCLGs, and, if none, MCLs promulgated under SDWA, generally will be the relevant and appropriate standard for ground water that is or may be used for drinking, considering its use, value, and vulnerability as described in the EPA's Ground-Water Protection Strategy (August 1984), e.g., for Class I and II aquifers.

Q13. Many new MCLGs and MCLs will be promulgated or existing ones revised in upcoming years. Will new or revised MCLGs and MCLs, when promulgated, need to be incorporated into the remedy, possibly altering it? Should a proposed non-zero MCLG or MCL be used as the remediation goal in the ROD?

- A. Under the NCP, if a new requirement is promulgated after the ROD is signed, and the requirement is determined to be applicable or relevant and appropriate, the remedy should be examined in light of the new requirement (at the 5-year review or earlier) to ensure that the remedy is still protective. If the remedy is still protective, it would not have to be modified, even though it does not meet the new requirement. Since non-zero MCLGs and MCLs often are a key component in defining remediation levels, new or revised MCLGs and MCLs may reveal that the chosen remedy is not protective. In such cases, the remedy would have to be modified accordingly. This could occur at any time after the ROD is signed -- during remedial design, remedial action, or at the 5-year review.

However, a new non-zero MCLG or MCL usually will not mean the remedy must be changed. If the existing remedy is still within the risk range, even considering the new MCLG or MCL, the remedy would not have to be modified because the remedy is still protective. For example, if the new non-zero MCLG or MCL represents a risk of 10^{-6} , while the selected remediation level results in a 10^{-5} risk, the remedy is still considered protective.

At some sites, however, a new MCLG or MCL could require modification to the remedy after implementation of the remedy has begun. Therefore, if a proposed non-zero MCLG or MCL is available before the ROD is signed, the preferred remedy should be evaluated to determine how the MCLG or MCL, if promulgated as proposed, would affect the remedy. Will the preferred remedy achieve the proposed MCLG or MCL? Could the remedy achieve the proposed MCLG or MCL with minor design modifications? Would the proposed MCLG or MCL require significant changes, such as requiring remediation in ground water that is currently deemed fully protective?

The proposed non-zero MCLG or MCL may be used as a "to-be-considered" (TBC) in establishing a protective remediation level in the ROD, provided that: (1) the new standard would make a remedy based on the current standard unprotective; and (2) the proposed standard is not controversial or otherwise is unlikely to change. This reflects the importance of non-zero MCLGs and MCLs in Superfund's determination of protectiveness and as a cleanup standard for the community. It also minimizes the need for later changes to the remedy when changes may be more difficult and costly to make. (See CERCLA Compliance With the CWA and SDWA, Publication 9234.2-06/FS, January 1990.)

Note: In the May 1989 version of this fact sheet, Question 14 addressed the use of the 10^{-6} risk level when non-zero MCLGs or MCLs exist for some, but not all, significant contaminants. Question 14 has been omitted from this fact sheet because this issue is currently being clarified by the Agency. Final resolution of this issue will be addressed in guidance in the near future.

IV. Post-ROD Information and the Administrative Record

Q14. Should remedies be revised to attain requirements of Federal or State environmental law that are promulgated or modified after signature of the ROD?

- A. In general, no. The requirements that are determined to be ARARs for a site "freeze" at the time of signature. Requirements that are newly promulgated or modified post-ROD need to be attained (or waived) only when EPA determines that these requirements are ARARs and that they must be met in order for the remedy to be protective (see section 300.430(f)(1)(ii)(B)(1) of the NCP). Newly promulgated or modified requirements will be considered during the five-year review or sooner, if appropriate, to determine whether the remedy is still protective. (See Question 13 of this fact sheet and Question 6 of the fact sheet entitled ARARs Q's & A's: Compliance With the Toxicity Characteristics Rule, Part I, (Publication 9234.2-08/FS, May 1990) for examples of how the "freezing" regulation applies to specific ARARs.)

Q15. What ARARs apply if information not known at the time of ROD signature is discovered post-ROD (e.g., RCRA hazardous wastes are identified on the site for the first time during construction activities)?

- A. If, based on the new information, the Region decides to change the remedy (e.g., in order to assure protection), the Region must meet or waive all ARARs identified at that time.

First, Regions must determine whether the new information is such that the ROD should be revised (and an Explanation of Significant Differences (ESD) issued), or amended (and a ROD amendment issued). If the Region believes that significant, but non-fundamental, changes should be made in the selected remedy based on new information (e.g., the discovery of a new contaminant triggers an MCL that is more difficult to meet, resulting in a decision to operate the pump-and-treat system for 15 years instead of 10 years), then an ESD should be issued (see section 300.435(c)(2)(i) of the NCP). If the Region decides to make a fundamental change in the remedy based on the new information (e.g., to change from an engineering control to an incineration remedy), the process for a ROD amendment must be followed (see section 300.435(c)(2)(ii) of the NCP). Regions should include in the administrative record file any documents upon which they base their determinations to issue an ESD or ROD amendment (see section 300.825(a)(2) of the NCP). For additional information on this issue, see Guide to Addressing Pre-ROD and Post-ROD Changes, Publication 9355.3-02FS/4, April 1990.

If, however, the Region decides not to revise or amend the ROD based on the new information, then no new ARARs apply because the remedy is not being changed. To the extent that the Region wishes to document its reasoning on this point (e.g., to explain why the remedy remains protective even taking into account newly-discovered RCRA wastes), this information could be included in the administrative record file. (Note: section 300.825(a)(1) of the NCP allows EPA to add documents to the administrative record file, after ROD signature, that "concern a portion of a response action decision that the decision document does not address or reserves to be decided at a later date.")

Q16. If a ROD does address an action, location, or chemical such that the proper set of ARARs could have been identified prior to the signing of the ROD, but one or more ARARs were not identified, how should the Regions respond if those requirements are identified post-ROD?

- A. The selected remedy would generally not be required to meet such late-identified requirements. If the promulgated requirement existed prior to ROD signature, and the waste, action, or location to which the requirement potentially applied was also known at the time of ROD signature, the failure of a party to identify the requirement as an ARAR within the meaning of CERCLA, during the public comment period of the proposed plan, would likely preclude the party from raising the issue after ROD signature.

[Note that section 300.825(c) of the NCP requires EPA to consider comments submitted by interested persons after the close of the comment period only "to the extent that the comments contain significant information not contained elsewhere in the administrative record file which could not have been submitted during the public comment period and which would substantially support the need to significantly alter the response action." This may be a difficult test to meet where information on the requirement was available during the public comment period, and therefore, in most cases, could have been brought to the Agency's attention at that time.]

With regard to State ARARs, CERCLA Section 121(d)(2)(A)(ii) specifically provides that a requirement of a State environmental or facility siting law may be considered to be an ARAR only if it is identified in a timely manner. (Sections

300.400(g)(5), 300.515(d)(1), and 300.515(h)(2) of the NCP indicate that State ARARs identification must take place well before the signature of the ROD in order to be considered "timely.")

EPA could decide to take a newly-identified requirement into consideration on a site-specific basis. However, because no new information on the waste composition or nature of the site is being brought before the Region, it is likely that the risk assessment performed at the site in question will have considered all appropriate risks, and that the site is protective of human health and the environment even in light of the late-identified regulatory standard. In rare cases where the Region evaluates the standard and decides that the remedy should be changed or amended (e.g., based on a finding that the ARAR was incorrectly

analyzed and the remedy is not protective), an ESD or ROD amendment should be considered. In such cases any new components of the remedy would be required to attain (or waive) those ARARs identified at the time the ESD or ROD amendment is issued. (Note: the ESD or ROD amendment would be documented in the administrative record file pursuant to section 300.825(a)(2) of the NCP.) If the Region were to decide not to change the remedy, but wanted to memorialize the analysis of the late-identified requirement, an optional Remedial Design Fact Sheet could be added to the post-decision document file. Alternatively, the issue could be addressed in a new comment period and the analysis placed in the administrative record file for the site, as discussed in section 300.825(b) of the NCP.

V. Contingent Waivers

Q17. What are "contingent waivers" and when should they be used?

- A. When sufficient information is available at the time of ROD signature indicating the possibility that an ARAR waiver may be invoked at a site (e.g., the RI/FS indicates that it may be technically impracticable to attain non-zero MCLGs or MCLs in the ground water based upon final determinations of the size and scope of the contaminated plume), the lead agency may consider including a contingent waiver in the ROD. RODs with contingent waivers should provide a detailed and objective level or situation at which the waiver would be triggered. In addition, the ROD should specify that the contingency is "reserved to be decided at a later date," so that if the contingency is invoked, the resulting documentation becomes part of the administrative record (see NCP section 300.825(a)(1), 55 FR at 8861). [Note: in

some situations, the Agency may not wish to identify a separate trigger for waivers. For example, in some ground-water cleanups, the Agency may wish to retain the flexibility to vary pump rates or assess the effects of temporary shutdown before invoking a technical impracticability waiver.]

The decision to invoke the contingency should be documented in a fact sheet which is placed in the administrative record file. The Region may also decide to issue a public notice (e.g., in a major local newspaper of general circulation) that the contingency has been invoked. An ESD is not required to invoke a contingency specifically contemplated in the ROD. (See Guide to Developing Superfund No Action, Interim Action, and Contingency Remedy RODs, Publication 9355.3-02/FS-3, April 1991, for a general discussion of contingent remedies.)

* * * * *

NOTICE: The policies set out in this fact sheet are not final Agency action, but are intended solely as guidance. They are not intended, nor can they be relied upon, to create any rights enforceable by any party in litigation with the United States. Response personnel may decide to follow the guidance provided in this fact sheet, or to act at variance with the guidance, based on an analysis of site-specific circumstances. The Agency also reserves the right to change this guidance at any time without public notice.

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DIRECTIVE NUMBER: 9355.0-30

TITLE: Role of the Baseline Risk Assessment in Superfund
Remedy Selection Decision

APPROVAL DATE: April 1991

EFFECTIVE DATE: April 1991

ORIGINATING OFFICE: OERR

FINAL

DRAFT

STATUS: [] A- Pending OMB approval
[] B- Pending AA-OSWER approval
[] C- For review &/or comment
[] D- In development or circulating

REFERENCE (other documents): headquarters

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United States Environmental Protection Agency
Washington, DC 20460

OSWER Directive Initiation Request

1. Directive Number
9355.0-30

2. Originator Information

Name of Contact Person SF Document Center Coordinator	Mail Code OS-245	Office OERR	Telephone Code 202-260-9760
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3. Title

Role of the Baseline Risk Assessment in Superfund Remedy Selection Decision

4. Summary of Directive (include brief statement of purpose)

This memo provides further guidance on how to use the baseline risk assessment to make risk management decisions such as determining whether remedial action under CERCLA Section 104 or 106 is necessary. It clarifies the use of the baseline risk assessment in selecting appropriate remedies under CERCLA Section 121, promotes consistency in preparing site specific risk assessments and helps insure appropriate documentation is included

5. Keywords

Risk Assessment

6a. Does This Directive Supersede Previous Directive(s)?



What directive (number, title)

b. Does It Supplement Previous Directive(s)?



What directive (number, title)

7. Draft Level



- Signed by AA/DAA



- Signed by Office Director



- For Review & Comment



- In Development

8. Document to be distributed to States by Headquarters?



This Request Meets OSWER Directives System Format Standards.

9. Signature of Lead Office Directives Coordinator

Bette Van Egge

Date

10. Name and Title of Approving Official

Don R. Clay, Assistant Administrator
Office of Solid Waste and Emergency Response

Date

April 1991

EPA Form 1315-17 (Rev. 5-87) Previous editions are obsolete.

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UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON, D.C. 20460

APR 22 1991

OFFICE OF
SOLID WASTE AND EMERGENCY RESPONSE

OSWER DIRECTIVE 9355.0-30

MEMORANDUM

SUBJECT: Role of the Baseline Risk Assessment in Superfund
Remedy Selection Decisions

FROM: Don R. Clay *DRClay*
Assistant Administrator

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

Purpose

The purpose of this memorandum is to clarify the role of the baseline risk assessment in developing Superfund remedial alternatives and supporting risk management decisions.

Specifically, the following points are made in the memorandum:

- o Where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10^{-6} , and the non-carcinogenic hazard quotient is less than 1, action generally is not warranted unless there are adverse environmental impacts. However, if MCLs or non-zero MCLGs are exceeded, action generally is warranted.
- o Other chemical-specific ARARs may also be used to determine whether a site warrants remediation.
- o A risk manager may also decide that a baseline risk level less than 10^{-6} is unacceptable due to site specific reasons and that remedial action is warranted.

- o Compliance with a chemical-specific ARAR generally will be considered protective even if it is outside the risk range (unless there are extenuating circumstances such as exposure to multiple contaminants or pathways of exposure).
- o The upper boundary of the risk range is not a discrete line at 1×10^{-6} , although EPA generally uses 1×10^{-6} in making risk management decisions. A specific risk estimate around 10^{-6} may be considered acceptable if justified based on site-specific conditions.
- o The ROD should clearly justify the use of any non-standard exposure factors and the need for remedial action if baseline risks are within the generally acceptable risk range. The ROD should also include a table listing the final remediation goals and the corresponding risk level for each chemical of concern.

Background

The 1990 National Contingency Plan (NCP) (55 Fed. Reg. 8665-8865 (Mar. 8, 1990)) calls for a site-specific baseline risk assessment to be conducted, as appropriate, as part of the remedial investigation (Section 300.430(d)(1)). Specifically, the NCP states that the baseline risk assessment should "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" (Section 300.430(d)(4)). The primary purpose of the baseline risk assessment is to provide risk managers with an understanding of the actual and potential risks to human health and the environment posed by the site and any uncertainties associated with the assessment. This information may be useful in determining whether a current or potential threat to human health or the environment exists that warrants remedial action.

The "Risk Assessment Guidance for Superfund: Volume I, Human Health Evaluation Manual - Part A" (HHEM) (EPA/540/1-89/002) provides guidance on how to conduct the human health portion of the baseline risk assessment. Volume II of the "Risk Assessment Guidance for Superfund" the "Environmental Evaluation Manual" (EPA/540/1-89/001) and the companion manual, "Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference" (EPA/600/3-89/013) provide guidance on conducting the environmental portion of the baseline risk assessment. Other pertinent guidance includes the "Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA" (RI/FS guidance, EPA/540/G-89/004), which describes how the baseline risk assessment fits into the overall RI/FS process. "Guidance on Preparing Superfund Decision Documents" (ROD guidance)

(EPA/624/1-87/001) provides information on how to document the results of the baseline risk assessment in the ROD.

Objective

The objective of this memorandum is to provide further guidance on how to use the baseline risk assessment to make risk management decisions such as determining whether remedial action under CERCLA Sections 104 or 106 is necessary. This memorandum also clarifies the use of the baseline risk assessment in selecting appropriate remedies under CERCLA Section 121, promotes consistency in preparing site-specific risk assessments, and helps ensure that appropriate documentation from the baseline risk assessment is included in Superfund remedy selection documents.

Implementation

RISKS WARRANTING REMEDIAL ACTION

Whenever there is a release or substantial threat of release of a hazardous substance into the environment (or a release or threat of release into the environment of a pollutant or contaminant "which may present an imminent and substantial danger to public health or welfare"), Section 104(a)(1) of CERCLA provides EPA with the authority to take any response action consistent with the National Contingency Plan it deems necessary to protect public health or welfare or the environment. Section 106 of CERCLA grants EPA the authority to require potentially responsible parties (or others) to perform removal or remedial actions "when the President determines that there may be an imminent and substantial endangerment to the public health or welfare or the environment because of an actual or threatened release of a hazardous substance from a facility."

As a general policy and in order to operate a unified Superfund program, EPA generally uses the results of the baseline risk assessment to establish the basis for taking a remedial action using either Section 104 or 106 authority. EPA may use the results of the baseline risk assessments to determine whether a release or threatened release poses an unacceptable risk to human health or the environment that warrants remedial action and to determine if a site presents an imminent and substantial endangerment. The risk assessment methodology for all sites should be the same regardless of whether the RI/FS or remedial design and remedial action is performed by EPA or potentially responsible parties.

Generally, where the baseline risk assessment indicates that a cumulative site risk to an individual using reasonable maximum exposure assumptions for either current or future land use exceeds the 10^{-6} lifetime excess cancer risk end of the risk

range, action under CERCLA is generally warranted at the site. For sites where the cumulative site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10^{-6} , action generally is not warranted, but may be warranted if a chemical specific standard that defines acceptable risk is violated or unless there are noncarcinogenic effects or an adverse environmental impact that warrants action. A risk manager may also decide that a lower level of risk to human health is unacceptable and that remedial action is warranted where, for example, there are uncertainties in the risk assessment results. Records of Decision for remedial actions taken at sites posing risks within the 10^{-6} to 10^{-6} risk range must explain why remedial action is warranted.

The cumulative site baseline risk should include all media that the reasonable maximum exposure scenario indicates are appropriate to combine and should not assume that institutional controls or fences will account for risk reduction. For noncarcinogenic effects of toxicants, unacceptable risk occurs when exposures exceed levels which represent concentrations to which the human population, including sensitive subgroups, may be exposed without adverse effect during a lifetime or part of a lifetime, as appropriate to address teratogenic and developmental effects.

Chemical specific standards that define acceptable risk levels (e.g., non-zero MCLGs, MCLs) also may be used to determine whether an exposure is associated with an unacceptable risk to human health or the environment and whether remedial action under Section 104 or 106 is warranted. For ground water actions, MCLs and non-zero MCLGs will generally be used to gauge whether remedial action is warranted.

EPA uses the general 10^{-6} to 10^{-6} risk range as a "target range" within which the Agency strives to manage risks as part of a Superfund cleanup. Once a decision has been made to take an action, the Agency has expressed a preference for cleanups achieving the more protective end of the range (i.e., 10^{-6}), although waste management strategies achieving reductions in site risks anywhere within the risk range may be deemed acceptable by the EPA risk manager. Furthermore, the upper boundary of the risk range is not a discrete line at 1×10^{-6} , although EPA generally uses 1×10^{-6} in making risk management decisions. A specific risk estimate around 10^{-6} may be considered acceptable if justified based on site-specific conditions, including any remaining uncertainties on the nature and extent of contamination and associated risks. Therefore, in certain cases EPA may consider risk estimates slightly greater than 1×10^{-6} to be protective.

When an ARAR for a specific chemical (or in some cases a group of chemicals) defines an acceptable level of exposure,

compliance with the ARAR will generally be considered protective even if it is outside the risk range (unless there are extenuating circumstances such as exposure to multiple contaminants or pathways of exposure). Conversely, in certain situations EPA may determine that risks less than 1×10^{-6} are not sufficiently protective and warrant remedial action.

Where current conditions have not resulted in a release posing risks that warrant action but there is a significant possibility that a release will occur that is likely to result in an unacceptable risk, remedial action may also be taken. The significance of the potential future release may be evaluated in part based on the quantities of material at the site and the environmental setting.

RISKS CONSIDERED IN RISK MANAGEMENT DECISION

As noted above, both current and reasonably likely future risks need to be considered in order to demonstrate that a site does not present an unacceptable risk to human health and the environment. An adequate consideration of future risk may necessitate the assessment of risks assuming a land use different from that which currently exists at the site. The potential land use associated with the highest level of exposure and risk that can reasonably be expected to occur should be addressed in the baseline risk assessment. Further, this land use and these exposure assumptions should be used in developing remediation goals.

The preamble to the NCP states that EPA will consider future land use as residential in many cases. In general, residential areas should be assumed to remain residential; and undeveloped areas can be assumed to be residential in the future unless sites are in areas where residential land use is unreasonable. Often the exposure scenarios based on potential future residential land use provide the greatest risk estimates (e.g., reasonable maximum exposure scenario) and are important considerations in deciding whether to take action (55 Fed. Reg. at 8710).

However, the NCP also states that "the assumption of future residential land use may not be justifiable if the probability that the site will support residential use in the future is small." Sites that are surrounded by operating industrial facilities can be assumed to remain as industrial areas unless there is an indication that this is not appropriate. Other land uses, such as recreational or agricultural, may be used, if appropriate. When exposures based on reasonable future land use are used to estimate risk, the NCP preamble states that the ROD "should include a qualitative assessment of the likelihood that the assumed future land use will occur" (55 Fed. Reg. at 8710).

Unacceptable environmental risks also may prompt remedial action and may occur where there is no significant risk to human health. Threats or potential threats to sensitive habitats, such as wetlands, and critical habitats of species protected under the Endangered Species Act are especially important to consider when determining whether to take an action under CERCLA Section 104 or 106. Ambient Water Quality Criteria for aquatic organisms are chemical-specific standards that will generally be considered when determining whether to take an action based on the environmental risk of releases to surface waters.

NO-ACTION DECISIONS

If the baseline risk assessment and the comparison of exposure concentrations to chemical-specific standards indicates that there is no unacceptable risk to human health or the environment and that no remedial action is warranted, then the CERCLA Section 121 cleanup standards for selection of a Superfund remedy, including the requirement to meet applicable or relevant and appropriate requirements (ARARs), are not triggered. CERCLA section 121 (a) requires only that those remedial actions that are "determined to be necessary ... under section 104 or ... 106 ... be selected in accordance with section 121." If EPA determines that an action is necessary, the remedial action must attain ARARs, unless a waiver is invoked. Of course, sites that do not warrant action under CERCLA sections 104 or 106 may warrant action under another State or Federal statute, such as RCRA subtitle D requirements for the appropriate closure of a solid waste landfill.

The decision not to take action at an NPL site under section 104 and 106 should also be documented in a ROD. The decision documentation process should include the preparation of a proposed plan for public comment, ROD and eventually a closeout report and Federal Register deletion notice.

POINT OF DEPARTURE WHEN ACTION WARRANTED

Once remedial action has been determined to be warranted, the results of the baseline risk assessment may be used to modify preliminary remediation goals. These preliminary goals are developed at scoping based on ARARs and the 10^{-6} cancer risk point of departure pursuant to NCP section 300.430(e)(2)(i).

USE OF BASELINE RISK ASSESSMENT TO MODIFY PRELIMINARY REMEDIATION GOALS

Remediation goals developed under CERCLA Section 121 are generally medium-specific chemical concentrations that will pose no unacceptable threat to human health and the environment. Preliminary remediation goals are developed early in the RI/FS process based on ARARs and other readily available information,

such as concentrations associated with 10^{-6} cancer risk or a hazard quotient equal to one for noncarcinogens calculated from EPA toxicity information. These preliminary goals may be modified based on results of the baseline risk assessment, which clarifies exposure pathways and may identify situations where cumulative risk of multiple contaminants or multiple exposure pathways at the site indicate the need for more or less stringent cleanup levels than those initially developed as preliminary remediation goals. In addition to being modified based on the baseline risk assessment, preliminary remediation goals and the corresponding cleanup levels may also be modified based on the given waste management strategy selected at the time of remedy selection that is based on the balancing of the nine criteria used for remedy selection (55 Fed.Reg. at 8717 and 8718).

EARLY AND INTERIM ACTIONS

Early operable unit actions (e.g., hot spot removal and treatment) and interim actions (e.g., temporary storage or ground water plume containment) may be taken to respond to an immediate site threat or to take advantage of an opportunity to significantly reduce risk quickly (55 Fed. Reg. at 8705). For example, an interim containment action may be particularly useful early in the process for complicated ground water remedial actions, where concentrations greater than MCLs provide a good indication that remediation of a potential drinking water source is necessary; such quick remedial action is important to prevent further spread of the contaminant plume while a final ground water remedy is being developed.

Early and interim action RODs do not require a completed baseline risk assessment, although enough information must be available to demonstrate the potential for risk and the need to take action. Data sufficient to support the interim action decision can be extracted from the ongoing RI/FS for the site and set out in a focused feasibility study or other appropriate document that includes a short analysis of a limited number of alternatives (55 Fed. Reg. at 8704). These data should include a summary of contaminants of concern, concentrations and relevant exposure information. A discussion should accompany these data explaining the need for immediate remedial action based on the presence of contamination that, if left unaddressed in the short-term, either contributes immediate risk or is likely to contribute to increased site risk or degradation of the environment/natural resources. The early and interim action RODs should note that some exposure pathways at the site may not be addressed by the action.

An interim action ROD eventually must be followed by a subsequent ROD for that operable unit based on the complete RI/FS, that includes the baseline risk assessment, in order to document long-term protection of human health and the environment

at that portion of the site. The interim action ROD, however, should demonstrate qualitatively (and quantitatively if possible) that there is a risk or potential for risk and explain how the temporary measures selected will address a portion of this risk.

DOCUMENTATION OF BASELINE RISK ASSESSMENT RESULTS IN THE ROD

The Summary of Site Risks section of the ROD should include a discussion of the risks associated with current and future land use and a table presenting these risk levels for each exposure medium (e.g., direct contact with soil by potential future residents exposed via incidental soil ingestion and dermal contact). In some situations, risks from exposure via more than one medium (e.g., soil and drinking water) will affect the same potentially exposed individual at the same time. It is appropriate in these situations to combine the risks from the different media to give an indication of total risk that an individual may be exposed to from a site.

In addition to summarizing the baseline risk assessment information, the ROD (except no-action RODs) should include how remedial alternatives will reduce risks by achieving cleanup levels through treatment or by eliminating exposures through engineering controls for each contaminant of concern in each appropriate medium.

The Comparative Analysis should include a discussion of each of the nine criteria; consideration of risk is part of the discussion of several of the criteria. The discussion of overall protection of human health and the environment should include a discussion of how the remedy will eliminate, reduce, or control risks identified in the baseline risk assessment posed through each pathway and whether exposure levels will be reduced to acceptable levels. For example, if direct human contact with contaminated soil is identified as a significant risk at a site, the ROD (except no-action RODs) should indicate how the selected remedy will eliminate or control exposures to ensure protection of human health. The discussion of long-term effectiveness and permanence should include, where appropriate, an assessment of the residual risk from untreated residual waste remaining at the site. The short-term effectiveness discussion should address risks during remedial action to those on-site and nearby.

Finally, that part of the Decision Summary in the ROD that focuses on the selected remedy should show:

- o the chemical-specific remediation level and corresponding chemical-specific risk level(s) to be attained at the conclusion of the response action and the points (or area) of compliance for the media being addressed; and

- o The lead agency's basis for the remediation levels (e.g., risk calculation, ARARs).

The attached table, "Remediation Levels and Corresponding Risks," provides a direct means of displaying this information for health risks and, where appropriate, environmental protection (Table 1). The table should be completed for all media for which the ROD selects final cleanup levels. The table should serve as a summary of text in the selected remedy section of the ROD Decision Summary. For interim action RODs, only qualitative statements may be possible.

Additional guidance on the baseline risk assessment and its role in remedy selection is available from several sources. For guidance on the baseline risk assessment contact:

David Bennett, Chief
Toxics Integration Branch (OS-230)
Hazardous Site Evaluation Division
Office of Emergency and Remedial Response
phone: (FTS) or (202) 475-9486.

For additional guidance on the interaction of the baseline risk assessment and Superfund remedy selection, contact:

David Cooper
Remedial Operations and Guidance Branch (OS-220W)
Hazardous Site Control Division
Office of Emergency and Remedial Response
phone: (FTS) 398-8361
(commercial phone: (703) 308-8361)

For guidance on enforcement-lead sites contact:

Stephen Ells
Guidance and Evaluation Branch (OS-510)
CERCLA Enforcement Division
Office of Waste Programs Enforcement
phone: (FTS) or (202) 475-9803.

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TABLE 1
Remediation Goals and Corresponding Risks^a

Final Remediation Levels^b					Corresponding Risk Levels^c	
Medium	Chemical	Remediation Level^e	Point of Compliance^f	Basis of Goal	Chemical-Specific RME Risk^d Cancer	Non-Cancer
SOIL	A	2.0 ppm	All facility grounds	HI	N/A	0.5
	B	17.0 ppm		Risk	1.0×10^{-5}	N/A
	C	5.0 ppm		GW Risk	N/A	N/A
GROUND WATER	B	0.1 ppm	Waste Management Unit Boundary	Risk	1.0×10^{-5}	N/A
	C	4.0 ppm		MCL	1.0×10^{-5}	N/A
	F	7.0 ppm		MCLG	N/A	0.2
	G	15.0 ppm		MCL	6.0×10^{-6}	0.09
SEDIMENT	Q	100.0 ppm	Downstream from point A	Ecological Effects	N/A	N/A

a. Prepare summary sheets for selected remedy.

b. Final Remediation Levels are based on preliminary remediation goals developed in the Feasibility Study (FS) (RI/FS Guidance 4.2.1) as modified through the nine criteria evaluation and engineering design. In the process of achieving remediation levels for each chemical, some chemicals will be reduced to concentrations below their remediation levels.

c. Chemical-specific risks correspond to associated remediation levels. Risks do not consider effects of exposures to other chemicals or media. If appropriate, risks may be summed to calculate media-specific risks. Short-term effectiveness is not considered.

d. Cancer risks are measured as individual incremental lifetime; non-cancer, as Hazard Quotients.

e. Bases for values should be explained in the earlier Record Of Decision (ROD) table.

f. Bases for location and method for determining attainment (e.g., maximum value detected over area XYZ) should be explained in the description of the selected remedy.

N/A - Not applicable