CHAPTER 2

IDENTIFICATION OF PRELIMINARY REMEDIATION GOALS

This chapter provides guidance on the initial identification of PRGs during the scoping phase of the RI/FS. As discussed in Chapter 1, medium-specific PRGs (ARAR-based and/or risk-based) should be identified during scoping for all chemicals of potential concern using readily available information. Sections are provided in this chapter on how to use this information to identify media and chemicals of potential concern, the most appropriate future land use, potential exposure pathways, toxicity information, potential ARARs, and risk-based PRGs. Finally, a section is provided on the modification of PRGs.

When using PRGs developed during scoping, the design engineers should understand that these may be modified significantly depending on information gathered about the site. The subsequent process of identifying key site contaminants, media, and other factors (i.e., during the baseline risk assessment) may require that the focus of the RI/FS be shifted (e.g., chemicals without ARARs may become more or less important). Thus, the design of remedial alternatives should remain flexible until the modified (i.e., more final) PRGs are available.

Prior to identifying PRGs during scoping, a conceptual site model should be developed (see the next box). Originally developed to aid in planning site activities (e.g., the RI/FS), the conceptual site model also contains information that is valuable for identifying PRGs. For example, it can be relied upon to identify which media and chemicals need PRGs. More information on developing and using a conceptual site model during the RI/FS process can be found in Chapter 2 of the RI/FS Guidance and Chapter 4 of RAGS/HHEM Part A.

To illustrate the process of calculating risk-based PRGs at the scoping stage of remediation, hypothetical CERCLA sites will be examined in boxes in appropriate sections throughout Chapters 2, 3, and 4. See the box on the next page for an introduction to the first site. (The radiation case study is addressed in Chapter 4.) The information (e.g., toxicity values) contained in these case studies is for illustration only, and should not be used for any other purpose. These case studies have been simplified (e.g., only ground water will be examined) so that the steps involved in developing risk-based PRGs can be readily discerned.

CONCEPTUAL SITE MODEL

During project planning, the RPM gathers and analyzes available information and develops the conceptual site model (also called the conceptual evaluation model). This model is used to assess the nature and the extent of contamination. It also identifies potential contaminant sources, potential exposure pathways, and potential human and/or environmental receptors. Further, this model helps to identify data gaps and assists staff in developing strategies for data collection. Site history and PA/SI data generally are extremely useful sources of information for developing this model. The conceptual site model should include known and suspected sources of contamination, types of contaminants and affected media, known and potential routes of migration, and known or potential human and environmental receptors.

2.1 MEDIA OF CONCERN

During scoping, the first step in developing PRGs is to identify the media of potential concern. The conceptual site model should be very useful for this step. These media can be either:

- currently contaminated media to which individuals may be exposed or through which chemicals may be transported to potential receptors; or

CASE STUDY: INTRODUCTION

The XYZ Co. site contains an abandoned industrial facility that is adjacent to a high-density residential neighborhood. Remnants of drums, lagoons, and waste piles were found at the site. Ground water in the area of the site is used by residents as a domestic water supply. There is also a small lake downgradient from the site that is used by some of the local residents for fishing and swimming.

- currently uncontaminated media that may become contaminated in the future due to contaminant transport.

Several important media often requiring direct remediation are ground water, surface water, soil, and sediment. Currently, only the first three of these media are discussed in this chapter and addressed by the equations provided in Chapters 3 and 4. If other media that may require the development of risk-based concentrations (e.g., sediments) are identified at scoping, appropriate equations for those media should be developed. Regional risk assessors should be consulted as early as possible to assist with this process.

CASE STUDY: IDENTIFY MEDIA OF CONCERN

The PA/SI for the example site indicates that ground water beneath the site is contaminated. The source of this contamination appears to have been approximately 100 leaking drums of various chemicals that were buried in the soil but have since been removed. Lagoons and waste piles also may have contributed to the contamination. Thus, ground water and soil are media of concern.

Although evidence of lake water contamination was not found during the PA/SI, there is a reasonable possibility that it may become contaminated in the future due to contaminant transport either via ground-water discharge or surface water run-off. Thus, surface water (the lake) and sediments also may be media of concern.

2.2 CHEMICALS OF CONCERN

This step involves developing an initial list of chemicals for which PRGs need to be developed. Chapters 4 and 5 of RAGS/HHEM Part A provide important additional information on identifying chemicals of potential concern for a site and should be consulted prior to development of the conceptual site model and PRGs at scoping.

Initially, the list of chemicals of potential concern should include any chemical reasonably expected to be of concern at the site based on what is known during scoping. For example, important chemicals previously detected at the site, based on the PA/SI, the conceptual site model, or other prior investigations, generally should be included. In addition, the list may include chemicals that the site history indicates are likely to be present in significant quantities, even though they may not yet be detected. Sources of this latter type of information include records of chemicals used or disposed at the facility, and interviews with current or former employees. The list also may include chemicals that are probable degradation products of site contaminants where these are determined to be potential contributors of significant risk. An environmental chemist should be consulted for assistance in determining the probable degradation products of potential site-related chemicals and their persistence under site conditions. Generally, the chemicals for which PRGs should be developed will correspond to the list of suspected site contaminants included in the sampling and analysis plan.

2.3 FUTURE LAND USE

This step involves identifying the most appropriate future land use for the site so that the appropriate exposure pathways, parameters, and equations (discussed in the next section) can be used to calculate risk-based PRGs. RAGS/HHEM Part A (Chapter 6) and an EPA Office of Solid Waste and Emergency Response (OSWER) directive on the role of the baseline risk assessment in remedy selection decisions (EPA 1991b) provide additional guidance on identifying future land use. The standard default equations provided in Chapter 3 of Part B only address residential and commercial/industrial land uses. If land uses other than these are to be assumed (e.g., recreational), then exposure pathways, parameters,

CASE STUDY: IDENTIFY CHEMICALS OF CONCERN

The PA/SI for the XYZ Co. site identified the following seven chemicals in ground-water samples: benzene, ethylbenzene, hexane, isophorone, triallate, 1,1,2-trichloroethane, and vinyl chloride. Therefore, these chemicals are obvious choices for chemicals of potential concern.

Although not detected in any of the PA/SI samples, site history indicates that one other solvent — carbon tetrachloride — also was used in significant quantities by the facility that operated at the site. This chemical, therefore, is added to the list of chemicals of potential concern.

and equations will need to be developed for the others as well.

In general, residential areas should be assumed to remain residential. Sites that are surrounded by operating industrial facilities can be assumed to remain industrial areas unless there is an indication that this is not appropriate. Lacking site-specific information (e.g., at scoping), it may be appropriate to assume residential land use. This assumption will generally lead to conservative (i.e., lower concentration) risk-based PRGs. If not enough site-specific information is readily available at scoping to select one future land use over another, it may be appropriate to develop a separate set of risk-based PRGs for each possible land use.

When waste will be managed onsite, land-use assumptions and risk-based PRG development become more complicated because the assumptions for the site itself may be different from the land use in the surrounding area. For example, if waste is managed onsite in a residential area, the risk-based PRGs for the ground water beneath the site (or at the edge of the waste management unit) may be based on residential exposures, but the risk-based PRGs for the site soils may be based on an industrial land use with some management or institutional controls.

If a land-use assumption is used that is less conservative (i.e., leads to higher risk-based concentrations) than another, it generally will be necessary to monitor the future uses of that site. For example, if residential land use is not deemed to be appropriate for a particular site because local zoning laws prohibit residential development, any changes in local zoning would need to be monitored. Such considerations should be clearly documented in the site's ROD.

CASE STUDY: IDENTIFY FUTURE LAND USE

Based on established land-use trends, local renovation projects, and population growth projections in the area of the XYZ Co. site, the most reasonable future use of the land is determined to be residential use. Thus, site-specific information is sufficient to show that the generally more conservative assumption of residential land use should serve as the basis for development of risk-based PRGs.

2.4 APPLICABLE OR RELEVANT AND APPROPRIATE REQUIREMENTS

Chemical-specific ARARs are evaluated as PRGs because they are often readily available and provide a preliminary indication about the goals that a remedial action may have to attain. This step involves identifying all readily available chemical-specific potential ARARs for the chemicals of potential concern (for each medium and probable land use). Because at scoping it often is uncertain which potential ARAR is the most likely one to become the ARAR-based PRG, all potential ARARs should be included in a tabular summary (i.e., no potential ARAR should be discarded). If there is doubt about whether a value is a potential ARAR, and therefore whether it could be used as a PRG, it should be included at this stage.

This section summarizes the concept of ARARs and identifies the major types of ARARs, but provides only limited guidance on identifying the most appropriate (likely) ARAR of all possible ARARs to use as the chemical-specific PRG. More detailed information about the identification and evaluation of ARARs is available from two important sources:

- the NCP (see specifically 55 *Federal Register* 8741-8766 for a description of ARARs, and

8712-8715 for using ARARs as PRGs; see also 53 *Federal Register* 51394); and

- CERCLA Compliance Manuals (EPA 1988a and 1989a).

2.4.1 CHEMICAL-, LOCATION-, AND ACTION-SPECIFIC ARARs

The Agency has identified three general types of federal and state ARARs:

- chemical-specific, are usually health- or risk management-based numbers or methodologies that, when applied to site-specific conditions, result in the establishment of numerical values (e.g., chemical-specific concentrations in a given medium);

- location-specific, are restrictions placed upon the concentration of hazardous substances or the conduct of activities solely because they are in special locations (e.g., wetlands); and

- action-specific, are usually technology- or activity-based requirements or limitations on actions taken with respect to hazardous wastes.

This guidance primarily addresses only chemical-specific ARARs since it focuses on the identification of chemical-specific concentrations that represent target goals (e.g., PRGs) for a given medium.

2.4.2 SELECTION OF THE MOST LIKELY ARAR-BASED PRG FOR EACH CHEMICAL

This section briefly describes which, if any, of several potential ARAR values for a given chemical is generally selected as the most likely ARAR-based PRG (and therefore the most likely PRG at this point). Although the process for identifying the most likely ARAR-based PRG is specific to the medium, in general the process depends on two considerations: (1) the applicability of the ARAR to the site; and (2) the comparative stringency of the standards being evaluated. The previously cited documents should be carefully considered for specific recommendations on identifying ARARs.

Ground Water. SDWA maximum contaminant levels (MCLs), non-zero MCLGs, state drinking water standards, and federal water quality criteria (FWQC) are common ARARs (and, therefore, potential PRGs) for ground water. Other types of laws, such as state anti-degradation laws, may be PRGs if they are accompanied by allowable concentrations of a chemical. (Although state anti-degradation laws that are expressed as qualitative standards may also be potential ARARs, they generally would not be considered PRGs.)

As detailed in the NCP (see next box), the first step in identifying ground-water PRGs is to determine whether the ground water is a current or potential source of drinking water. If the aquifer is a potential source of drinking water, then potential ARARs generally will include the federal non-zero MCLG, MCL, or state drinking water standard, and the most stringent (i.e., the lowest concentration) is identified as the most likely ARAR-based PRG.

NCP ON GROUND-WATER GOALS
(NCP Preamble;
55 *Federal Register* 8717, March 8, 1990)

"Ground water that is not currently a drinking water source but is potentially a drinking water source in the future would be protected to levels appropriate to its use as a drinking water source. Ground water that is not an actual or potential source of drinking water may not require remediation to a 10^{-4} to 10^{-6} level (except when necessary to address environmental concerns or allow for other beneficial uses; . . .)."

If the aquifer is not a potential source of drinking water, then MCLs, MCLGs, state drinking water requirements, or other health-based levels generally are not appropriate as PRGs. Instead, environmental considerations (i.e., effects on biological receptors) and prevention of plume expansion generally determine clean-up levels. If an aquifer that is not a potential source of drinking water is connected to an aquifer that is a drinking water source, it may be appropriate to use PRGs to set clean-up goals for the point of interconnection.

For chemicals without MCLs, state standards, or non-zero MCLGs, the FWQC may be potentially relevant and appropriate for ground water when that ground water discharges to surface water that is used for fishing or shellfishing.

Surface Water. FWQC and state water quality standards (WQS) are common ARARs for surface water. An important determination for identifying ARARs and other criteria as potential PRGs for surface water is the current designated and future expected use of the water body. Because surface water potentially could serve many uses (e.g., drinking and fishing), several ARARs may be identified as potential PRGs for a chemical, with each ARAR corresponding to an identified use. A state WQS is generally the most likely ARAR for surface water unless a federal standard is more stringent.

If surface water is a current or potential source of drinking water, MCLs, state drinking water standards, non-zero MCLGs, and FWQC are potential ARARs. The analysis to determine which of these drinking water standards is the most likely ARAR-based PRG is the same as that conducted for ground water. An FWQC based on ingestion of water and fish might be an ARAR for surface water used for drinking.

If the designated or future expected use of surface water is fishing or shellfishing, and the state has not promulgated a WQS, an FWQC should be considered as a potential ARAR. The particular FWQC (i.e., for water and fish ingestion or fish ingestion alone) selected as the potential ARAR depends on whether exposure from one or both of the routes is likely to occur and, therefore, on the designated use of the water body. If other uses of the water are designated (e.g., swimming), a state WQS may be available.

Soil. In general, chemical-specific ARARs may not be available for soil. Certain states, however, have promulgated or are about to promulgate soil standards that may be ARARs and thus may be appropriate to use as PRGs. In addition, several EPA policies may be appropriate to use in developing PRGs (e.g., see EPA 1990c for guidance on PCB clean-up levels).

2.5 EXPOSURE PATHWAYS, PARAMETERS, AND EQUATIONS

This step is generally conducted for each medium and land-use combination and involves identifying the most appropriate (1) exposure pathways and routes (e.g., residential ingestion of drinking water), (2) exposure parameters (e.g., 2 liters/day of water ingested), and (3) equations (e.g., to incorporate intake). The equations include calculations of total intake from a given medium and are based on the identified exposure pathways and associated parameters. Information gathered in this step should be used to calculate risk-based PRGs using the default equations identified in Chapters 3 and 4. Site-specific equations can be derived if a different set of exposure pathways is identified for a particular medium; this option also is discussed in Chapters 3 and 4.

When risk-based concentrations are developed during scoping, readily available site-specific information may be adequate to identify and develop the exposure pathways, parameters, and equations (e.g., readily available information may indicate that the exposure duration should be 40 years instead of the standard default of 30 years). In the absence of readily available site-specific information, the standard default information in Chapters 3 and 4 generally should be used for the development of risk-based PRGs.

Exhibit 2-1 lists a number of the potential exposure pathways that might be present at a CERCLA site. The exposure pathways included in the medium-specific standard default equations (see Chapters 3 and 4) are italicized in this exhibit. Note that Chapters 3 and 4 may not address all of the exposure pathways of possible importance at a given CERCLA site. For example, the consumption of ground water that continues to be contaminated by soil leachate is not addressed. Guidance on goal-setting to address this exposure pathway is currently under development by EPA. In addition, the standard default equations do not address pathways such as plant and animal uptake of contaminants from soil with subsequent human ingestion. Under certain circumstances, these or other exposure pathways may present significant risks to human health. The standard default information, however, does address the quantifiable exposure pathways that are often significant contributors of risk for a particular medium and land use.

Chapters 3 and 4 show how exposures from several pathways are addressed in a single equation for a medium. For example, in the equation for ground water and surface water under the residential land-use assumption, the coefficients incorporate default parameter values for ingestion of drinking water and inhalation of volatiles during

EXHIBIT 2-1

TYPICAL EXPOSURE PATHWAYS BY MEDIUM FOR RESIDENTIAL AND COMMERCIAL/INDUSTRIAL LAND USES[a,b]

Medium	Exposure Pathways, Assuming: Residential Land Use	Exposure Pathways, Assuming: Commercial/Industrial Land Use
Ground Water	***Ingestion from drinking***	Ingestion from drinking[d]
	Inhalation of volatiles	Inhalation of volatiles
	Dermal absorption from bathing	Dermal absorption
	Immersion - external[c]	
Surface Water	***Ingestion from drinking***	Ingestion from drinking[d]
	Inhalation of volatiles	Inhalation of volatiles
	Dermal absorption from bathing	Dermal absorption
	Ingestion during swimming	
	Ingestion of contaminated fish	
	Immersion - external[c]	
Soil	***Ingestion***	***Ingestion***
	Inhalation of particulates	***Inhalation of particulates***
	Inhalation of volatiles	***Inhalation of volatiles***
	Direct external exposure[c]	***Direct external exposure***[c]
	Exposure to ground water contaminated by soil leachate	Exposure to ground water contaminated by soil leachate
	Ingestion via plant uptake	Inhalation of particulates from trucks and heavy equipment
	Dermal absorption from gardening	

[a] Lists of land uses, media, and exposure pathways are not comprehensive.

[b] Exposure pathways included in RAGS/HHEM Part B standard default equations (Chapters 3 and 4) are italicized.

[c] Applies to radionuclides only.

[d] Because the NCP encourages protection of ground water to maximize its beneficial use, risk-based PRGs generally should be based on residential exposures once ground water is determined to be suitable for drinking. Similarly, when surface water will be used for drinking, general standards (e.g., ARARs) are to be achieved that define levels protective for the population at large, not simply worker populations. Residential exposure scenarios should guide risk-based PRG development for ingestion and other uses of potable water.

household water use. Full details of parameters used to develop each equation and a summary of the "reduced" standard default equations are provided in the text of these chapters.

Certain modifications of the default equations may be desirable or necessary. For example, if an exposure pathway addressed by an equation in Chapter 3 seems inappropriate for the site (e.g., because the water contains no volatiles and, therefore, inhalation of volatiles is irrelevant), or if information needed for a pathway (e.g., a chemical-specific inhalation slope factor [see Section 2.6]) is not readily available or derivable, then that pathway can be disregarded at this stage.

The decision about whether the risk assessor should collect site-specific human exposure pathway information (e.g., exposure frequency, duration, or intake rate data) is very important. There will frequently be methods available to gather such information, some of which are more expensive and elaborate than others. Determining whether the resulting data are reasonably representative of populations in the surrounding area, however, is often difficult. Collecting data by surveying those individuals most convenient or accessible to RPMs or risk assessors may not present a complete population exposure picture. In fact, poorly planned data gathering efforts may complicate the assessment process. For example, those surveyed may come to believe that their contributions will play a more meaningful role in the risk assessment than that planned by the risk assessors; this can result in significant demands on the risk assessor's time.

Before such data collection has begun, the risk assessor should determine, with the aid of screening analyses, what benefits are likely to result. <u>Collection of the exposure data discussed in this section generally should not be attempted unless significant differences are likely to result in final reasonable maximum exposure (RME) risk estimates</u>. If data collection is warranted, systematic and well-considered efforts that minimize biases in results should be undertaken. Estimates of future exposures are likely to rely heavily on conservative exposure assumptions. By definition, these assumptions will be unaffected by even the most extensive efforts to characterize current population activity.

At this stage, the risk assessor, site engineer, and RPM should discuss information concerning the absence or presence of important exposure pathways, because remediation goals should be designed for specific areas of the site that a particular remedy must address, and exposures expected for one area of the site may differ significantly from those expected in another area.

2.5.1 GROUND WATER/SURFACE WATER

The residential land-use default equations presented in Chapters 3 and 4 for ground water or surface water are based on ingestion of drinking water and inhalation of volatile (vapor phase) chemicals originating from the household water supply (e.g., during dish washing, clothes laundering, and showering).

Ingestion of drinking water is an appropriate pathway for all chemicals with an oral cancer slope factor or an oral chronic reference dose. For the purposes of this guidance, however, inhalation of volatile chemicals from water is considered routinely only for chemicals with a Henry's Law constant of 1×10^{-5} atm-m^3/mole or greater <u>and</u> with a molecular weight of less than 200 g/mole. Before determining inhalation toxicity values for a specific chemical (Section 2.6), it should be confirmed that the Henry's Law constant and molecular weight are in the appropriate range for inclusion in the inhalation pathway for water.

Default equations addressing industrial use of ground water are not presented. Because the NCP encourages protection of ground water to its maximum beneficial use, once ground water is determined to be suitable for drinking, risk-based PRGs generally should be based on residential exposures. Even if a site is located in an industrial area, the ground water underlying a site in an industrial area may be used as a drinking water source for residents several miles away due to complex geological interconnections.

2.5.2 SOIL

The residential land-use standard default equations for the soil pathway are based on exposure pathways of ingestion of chemicals in soil or dust. The industrial land-use equations are based on three exposure pathways: ingestion of soil and dust, inhalation of particulates, and inhalation of volatiles. Again, for the purposes of this guidance, inhalation of volatile chemicals is relevant only for chemicals with a Henry's Law constant of 1×10^{-5} atm-m^3/mole or greater and with a molecular weight of less than 200 g/mole. For the inhalation pathways, in addition to toxicity information, several chemical- and site-specific values are needed. These values include molecular diffusivity, Henry's Law constant, organic carbon partition coefficient, and soil moisture content (see Chapter 3 for details).

CASE STUDY: IDENTIFY EXPOSURE PATHWAYS, PARAMETERS, AND EQUATIONS

For the potential residential land use identified at the XYZ Co. site, the contaminated ground water (one of several media of potential concern) appears to be an important source of future domestic water. Because site-specific information is not initially available to develop specific exposure pathways, parameters, and equations, the standard default assumptions and equations provided in Chapter 3 will be used to calculate risk-based PRGs. Exposure pathways of concern for ground water, therefore, are assumed to be ingestion of ground water as drinking water and inhalation of volatiles in ground water during household use.

2.6 TOXICITY INFORMATION

This step involves identifying readily available toxicity values for all of the chemicals of potential concern for given exposure pathways so that the appropriate slope factors (SFs; for carcinogenic effects) and reference doses (RfDs; for noncarcinogenic effects) are identified or derived for use in the site-specific equations or the standard default equations. Therefore, Chapter 7 of RAGS/HHEM Part A should be reviewed carefully before proceeding with this step.

The hierarchy for obtaining toxicity values for risk-based PRGs is essentially the same as that used in the baseline risk assessment. Briefly, Integrated Risk Information System (IRIS) is the primary source for toxicity information; if no verified toxicity value is available through IRIS, then Health Effects Assessment Summary Tables (HEAST) is the next preferred source. When the development of a toxicity value is required (and appropriate data are available), consultation with the Superfund Health Risk Assessment Technical Support Center is warranted. EPA staff can contact the Center by calling FTS-684-7300 (513-569-7300) or by FAX at FTS-684-7159 (513-569-7159). Others must fax to the above number or write to:

Superfund Health Risk Technical Support Center
Environmental Criteria and Assessment Office
U.S. Environmental Protection Agency
Mail Stop 114
26 West Martin Luther King Drive
Cincinnati, Ohio 45268

Other toxicity information that should be obtained includes EPA's weight-of-evidence classification for carcinogens (e.g., A, B1) and the source of the information (e.g., IRIS, HEAST).

Note that throughout this document, the term hazard index (HI) is used to refer to the risk level associated with noncarcinogenic effects. An HI is the sum of two or more hazard quotients (HQs). An HQ is the ratio of an exposure level of a single substance to the RfD for that substance. Because RfDs are generally exposure pathway-specific (e.g., inhalation RfD), the HQ is a single substance/single exposure pathway ratio. An HI, on the other hand, is usually either a single substance/multiple exposure pathway ratio, a multiple substance/single exposure pathway ratio, or a multiple substance/multiple exposure pathway ratio. In this document, however, only one exposure pathway is included in the default equation for some land-use and medium combinations (e.g., residential soil). In order to remain consistent, the term HI has been used throughout RAGS/HHEM Part B, even though for such a pathway, the term HQ could apply.

2.7 TARGET RISK LEVELS

This step involves identifying target risk concentrations for chemicals of potential concern. The standard default equations presented in Chapters 3 and 4 are based on the following target risk levels for carcinogenic and noncarcinogenic effects.

- For carcinogenic effects, a concentration is calculated that corresponds to a 10^{-6} incremental risk of an individual developing cancer over a lifetime as a result of exposure to the potential carcinogen from all significant exposure pathways for a given medium.

CASE STUDY: IDENTIFY TOXICITY INFORMATION[a]

Reference toxicity values for cancer and noncancer effects (i.e., SFs and RfDs, respectively) are required for chemicals without ARAR-based PRGs (only the case study chemicals without ARARs are listed here). Considering the ground-water medium only, ingestion and inhalation are exposure pathways of concern. Toxicity information is obtained from IRIS and HEAST, and is shown in the table below.

Chemical	RfD (mg/kg-day)	Source	SF $(mg/kg\text{-}day)^{-1}$	Weight of Evidence	Source
EXPOSURE ROUTE: INGESTION					
Hexane	0.06	HEAST	—	—	—
Isophorone	0.2	IRIS	0.0039	C	HEAST
Triallate	0.013	IRIS	—	—	—
EXPOSURE ROUTE: INHALATION					
Hexane	0.04	HEAST	—	—	—
Isophorone	—	—	—	C	HEAST
Triallate	—	—	—	—	—

[a] All information in this example is for illustration purposes only.

- For noncarcinogenic effects, a concentration is calculated that corresponds to an HI of 1, which is the level of exposure to a chemical from all significant exposure pathways in a given medium below which it is unlikely for even sensitive populations to experience adverse health effects.

At scoping, it generally is appropriate to use the standard default target risk levels described above and discussed in the NCP. That is, an appropriate point of departure for remediation of carcinogenic risk is a concentration that corresponds to a risk of 10^{-6} for one chemical in a particular medium. For noncarcinogenic effects, the NCP does not specify a range, but it generally is appropriate to assume an HI equal to 1.

2.8 MODIFICATION OF PRELIMINARY REMEDIATION GOALS

Upon completion of the baseline risk assessment (or as soon as data are available), it is important to review the future land use, exposure assumptions, and the media and chemicals of potential concern originally identified at scoping, and determine whether PRGs need to be modified. Modification may involve adding or subtracting chemicals of concern, media, and pathways or revising individual chemical-specific goals.

2.8.1 REVIEW OF ASSUMPTIONS

Media of Concern. As a guide to determining the media and chemicals of potential concern, the OSWER directive *Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions* (EPA 1991c) indicates that action is generally warranted at a site when the cumulative carcinogenic risk is greater than 10^{-4} or the cumulative noncarcinogenic HI exceeds 1 based on RME assumptions. Thus, where the baseline risk assessment indicates that either the cumulative current or future risk associated with a medium is greater than 10^{-4} or that the HI is greater than 1, that medium presents a concern, and it generally is appropriate to maintain risk-based PRGs for contaminants in that medium or develop risk-based PRGs for additional media where PRGs are not clearly defined by ARARs.

When the cumulative current or future baseline cancer risk for a medium is within the range of 10^{-6} to 10^{-4}, a decision about whether or not to take action is a site-specific determination. Generally, risk-based PRGs are not needed for any chemicals in a medium with a cumulative cancer risk of less than 10^{-6}, where an HI is less than or equal to 1, or where the PRGs are clearly defined by ARARs. However, there may be cases where a medium appears to meet the protectiveness criterion but contributes to the contamination of another medium (e.g., soil contributing to ground-water contamination). In these cases, it may be appropriate to modify existing or develop new risk-based PRGs for chemicals of concern in the first medium, assuming that fate and transport models can adequately predict the impacts of concern on other media. EPA is presently developing guidance on quantifying the impact of soil contamination on underlying aquifers.

Chemicals of Concern. As with the initial media of potential concern, the initial list of specific chemicals of potential concern in a given medium may need to be modified to reflect increased information from the RI/FS concerning the importance of the chemicals to the overall site risk. Chemicals detected during the RI/FS that were not anticipated during scoping should be considered for addition to the list of chemicals of potential concern; chemicals anticipated during scoping that were not detected during the RI/FS should be deleted from the list. Ultimately, the identity and number of contaminants that may require risk-based PRGs depends both on the results of the baseline risk assessment and the extent of action required, given site-specific circumstances.

Following the baseline risk assessment, any chemical that has an associated cancer risk (current or future) within a medium of greater than 10^{-6} or an HI of greater than 1 should remain on the list of chemicals of potential concern for that medium. Likewise, chemicals that present cancer risks of less than 10^{-6} generally should not be retained on the list unless there are significant concerns about multiple contaminants and pathways.

Land Use. After the RI/FS, one future land use can usually be selected based on the results of the baseline risk assessment and discussions with the RPM. In many cases, this land use will be the same as the land use identified at scoping. In other cases, however, additional information from the baseline risk assessment that was not available at scoping may suggest modifying the initial land-use and exposure assumptions. A qualitative assessment should be made — and should be available from the baseline risk assessment — of the likelihood that the assumed future land use will occur.

Exposure Pathways, Parameters, and Equations. For exposure pathways, this process of modifying PRGs consists of adding or deleting exposure pathways from the medium-specific equations in Chapters 3 and 4 to ensure that the equation accounts for all significant exposure pathways associated with that medium at the site. For example, the baseline risk assessment may indicate that dermal exposure to contaminants in soil is a significant contributor to site risk. In this case, the risk-based PRGs may be modified by adding equations for dermal exposure. EPA policy on assessing this pathway is currently under development; the risk assessor should consult the Superfund Health Risk Technical Support Center (FTS-684-7300 or 513-569-7300) to determine the current status of guidance. Likewise, when appropriate data (e.g., on exposure frequency and duration) have been collected during the RI/FS, site-specific values can be substituted for the default values in the medium-specific equations.

2.8.2 IDENTIFICATION OF UNCERTAINTIES

The uncertainty assessment for PRGs can serve as an important basis for recommending further modifications to the PRGs prior to setting final remediation goals. It also can be used during the post-remedy assessment (see Section 2.8.4) to identify areas needing particular attention.

Risk-based PRGs are associated with varied levels of uncertainty, depending on many factors (e.g., confidence that anticipated future land use is correct). To place risk-based PRGs that have been developed for a site in proper perspective, an assessment of the uncertainties associated with the concentrations should be conducted. This assessment is similar to the uncertainty assessment conducted during the baseline risk assessment (see RAGS/HHEM Part A, especially Chapters 6, 7, and 8). In fact, much of the uncertainty assessment conducted for a site's baseline risk assessment will be directly applicable to the uncertainty assessment of the risk-based PRGs.

In general, each component of risk-based PRGs discussed in this chapter — from media of potential concern to target risk level — should be examined, and the major areas of uncertainty highlighted. For example, the uncertainty associated with the selected future land use should be discussed. Furthermore, the accuracy of the technical models used (e.g., for volatilization of contaminants from soil) to reflect site-specific conditions (present and future) should be discussed. If site-specific exposure assumptions have been made, it is particularly important to document the data supporting those assumptions and to assess their relevance for potentially exposed populations.

As the chemical- and medium-specific PRGs are developed, many assumptions regarding the RME individual(s) are incorporated. Although PRGs are believed to be fully protective for the RME individual(s), the proximity of other nearby sources of exposure (e.g., other CERCLA sites, RCRA facilities, naturally occurring background contamination) and/or the existence of the same contaminants in multiple media or of multiple chemicals affecting the same population(s), may lead to a situation where, even after attainment of all PRGs, protectiveness is not clearly achieved (e.g., cumulative risks may fall outside the risk range). The more likely it is that multiple contaminants, pathways, operable units, or other sources of toxicants will affect the RME individual(s), the more likely it will be that protectiveness is not achieved. This likelihood should be addressed when identifying uncertainties.

2.8.3 OTHER CONSIDERATIONS IN MODIFYING PRGs

The NCP preamble and rule state that factors related to exposure, technical limitations, and uncertainty should be considered when modifying PRGs (see next two boxes) and setting final remediation levels.

While the final remedial action objectives must satisfy the original "threshold criteria" of protection of human health and the environment and compliance with ARARs, the factors in the "balancing and modifying criteria" (listed in Section 1.3.2) also are considered in the detailed analysis for choosing among remedial alternatives. In cases where the alternative that represents the best balance of factors is not able to attain cancer risks within the risk range or an HI of 1, institutional controls may be used to supplement treatment and/or containment-based remedial action to ensure protection of human health and the environment.

NCP PREAMBLE: EXPOSURE, TECHNICAL, AND UNCERTAINTY FACTORS
(55 *Federal Register* 8717, March 8, 1990)

"Preliminary remediation goals ... may be revised ... based on the consideration of appropriate factors including, but not limited to: exposure factors, uncertainty factors, and technical factors. Included under exposure factors are: cumulative effect of multiple contaminants, the potential for human exposure from other pathways at the site, population sensitivities, potential impacts on environmental receptors, and cross-media impacts of alternatives. Factors related to uncertainty may include: the reliability of alternatives, the weight of scientific evidence concerning exposures and individual and cumulative health effects, and the reliability of exposure data. Technical factors may include: detection/quantification limits for contaminants, technical limitations to remediation, the ability to monitor and control movement of contaminants, and background levels of contaminants. The final selection of the appropriate risk level is made when the remedy is selected based on the balancing of criteria...."

NCP RULE: EXPOSURE, TECHNICAL, AND UNCERTAINTY FACTORS
(40 CFR 300.430(e)(2)(i))

"(i)...Remediation goals...shall be developed by considering the following:

"(A) Applicable or relevant and appropriate requirements...and the following factors:

"(*1*) For systemic toxicants, acceptable exposure levels...;

"(*2*) For known or suspected carcinogens, acceptable exposure levels...;

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

"(*4*) Factors related to uncertainty; and

"(*5*) Other pertinent information."

Note that in the absence of ARARs, the 10^{-6} cancer risk "point of departure" is used as a starting point for analysis of remedial alternatives, which reflects EPA's preference for managing risks at the more protective end of the risk range, other things being equal. Use of "point of departure" target risks in this guidance does not reflect a presumption that the final remedial action should attain such goals. (See NCP preamble, 55 *Federal Register* 8718-9.)

2.8.4 POST-REMEDY ASSESSMENT

To ensure that protective conditions exist after the remedy achieves all individual remediation levels set out in the ROD, there generally will be a site-wide evaluation conducted following completion of a site's final operable unit (e.g., during the five-year review). This site-wide evaluation should adequately characterize the residual contaminant levels and ensure that the post-remedy cumulative site risk is protective. More detailed guidance on the post-remedy assessment of site "protectiveness" is currently under development by EPA.