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GUIDELINES FOR DEVELOPING RISK-BASED CLEANUP LEVELS AT RCRA SITES IN REGION 10

Prepared for

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ACRONYMS AND ABBREVIATIONS

AAC	Alaska Administrative Code
CERCLA	Comprehensive Environmental Response, Compensation and Liability Act
CFR	Code of Federal Regulations
DEQ	Oregon Department of Environmental Quality
DDE	dichlorodiphenyltrichloroethene
DDT	dichlorodiphenyltrichloroethane
EPA	U.S. Environmental Protection Agency
FR	Federal Register
FY	fiscal year
g	grams
HEAST	Health Effects Assessment Summary Tables
IRIS	Integrated Risk Information System
L	liters
LC_{50}	lethal concentration to 50 percent of the organisms
LOAEL	lowest-observed-adverse-effect-level
m^3	cubic meters
MCL	maximum contaminant level
mg/kg-day	milligrams per kilogram per day
µg/L	micrograms per liter
NOAEL	no-observed-adverse-effect-level
OSWER	Office of Solid Waste and Emergency Response
PCB	polychlorinated biphenyl
ppm	parts per million
RCRA	Resource Conservation and Recovery Act
RDX	hexahydro-1,3,5-trinitro-1,3,5-triazine
RFI	RCRA facility investigation
USC	United States Code
WAC	Washington Administrative Code

GLOSSARY

Action levels: Health-based and environment-based contaminant levels for environmental media (i.e., soil, groundwater, surface water, air) determined by EPA to be indicators for protection of human health and the environment. If contamination exceeding these action levels is identified during a RCRA facility investigation, EPA or an authorized state agency must decide if further analysis is required. Action levels, if exceeded, typically trigger a corrective measures study.

Acute effects: Adverse human or ecological impacts caused by very short-term exposure to contaminants.

Bioaccumulation: The process by which substances that are very slowly metabolized or excreted increase in concentration in living organisms as they breathe contaminated air, drink contaminated water, or eat contaminated food.

Bioconcentration: The ratio of a contaminant concentration in living tissue to its concentration in a specific environmental medium.

Biomagnification: The process by which concentration of a substance increases as it is ingested by smaller organisms that are eaten in turn by larger organisms, thereby moving up the food chain.

Bio-uptake: A process in plants in which water and minerals from the soil are absorbed and incorporated within the plant. Contaminants (especially ones that are highly soluble in water) may also be absorbed and incorporated by plants through this process.

Chlorotic (vegetation): A condition of green plants seen as a yellowing disease of the green parts of the plants.

Chronic effects: Adverse human or ecological impacts caused by long-term exposure to contaminants.

Cleanup levels: The contaminant concentrations to which a contaminated environmental medium (e.g., soil, groundwater, surface water, air) must be cleaned or remediated, in order to adequately protect human health and the environment. Although similar to action levels, cleanup levels differ in the following ways:

- EPA or an authorized state establishes cleanup levels on a site-by-site basis during the remedy selection process
- The current and reasonably expected future uses of the site may be taken into account when establishing the cleanup levels

Concentration response evaluation: The process of characterizing the relationship between the concentration of a contaminant in an exposure medium (such as air or water) and the incidence of response in the exposed population.

Dose-response evaluation: The process of quantitatively evaluating toxicity information and characterizing the relationship between the dose of a contaminant received and the incidence of adverse health effects in the exposed population.

Ecological endpoint: A physical, chemical, or biological parameter that is characteristic of an organism, population, or ecosystem and is potentially affected by contaminants. Endpoints may include effects on individual organisms, communities, and ecosystems (e.g., reduced larvae production in a particular species, reduction of key populations, or disruption of community structure in an ecosystem).

Ecosystem: The integrated and interdependent populations of species along with their remains and the minerals, chemicals, water, and atmosphere on which they depend for sustenance and shelter.

Exposure pathways: The various ways a contaminant in a given medium can come into contact with a receptor. For example, possible exposure pathways for contaminated soil include ingestion of the soil, inhalation of the soil as dust, inhalation of volatile organics emanating from the soil, and dermal contact with the soil.

Exposure route: The way an environmental contaminant can enter an organism. The three primary routes are ingestion, inhalation, and dermal contact.

Hazard index: An estimate of the risk associated with a specified exposure to a noncarcinogenic contaminant, expressed as the ratio of a substance exposure level over a specified time period to a reference dose for that substance derived from a similar exposure.

Indicator species: A species whose life history is well understood and whose condition or health is selected to be representative of the health of a larger ecosystem.

Linearized multistage model: One of a number of mathematical models and procedures used to extrapolate from carcinogenic responses observed at high doses to responses expected at low doses.

Mutagen: Any substance that can cause a change in genetic material.

Receptor: An organism (human, plant, or animal) that is potentially exposed to chemical contamination from a site.

Reference dose: An estimate (with uncertainty spanning an order of magnitude or greater) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to carry no appreciable risk of deleterious effects during a lifetime.

Slope factor: A plausible upper-bound estimate of the probability of an individual developing cancer as a result of a lifetime of exposure to a particular level of a potential carcinogen.

Systemic toxicant: A chemical that produces adverse health effects distant from the point of contact through absorption and distribution in the body.

Threshold: The exposure level of a chemical at which a physiological effect begins to be evident.

Toxicity value: A numerical expression of a dose-response relationship for a particular substance. The most common toxicity values used in EPA risk assessments are reference doses (for noncarcinogenic effects) and slope factors (for carcinogenic effects).

EXECUTIVE SUMMARY

This guidance document provides procedures for developing human and ecological health-based cleanup levels for contaminated sites undergoing corrective action and clean closure under the Resource Conservation and Recovery Act (RCRA). The procedures are presented in a step-by-step approach intended for use by U.S. Environmental Protection Agency (EPA) permit writers and regulatory compliance officials. The analysis presented here will enable RCRA site managers to identify sites for which federal or state promulgated action levels may be used as cleanup criteria, versus sites requiring exposure-based risk calculations to address site-specific problems. This document also describes situations that are likely to require expert technical assistance. Application of these procedures is intended for RCRA sites where hazardous waste or hazardous constituents have been released and where contaminated environmental media (that is, soil, surface water, sediment, groundwater, or air) and contaminant concentrations have been identified by means of environmental sampling and analysis.

Using the step-by-step process presented in this document for developing cleanup levels, regulatory personnel should be prepared to answer the following questions for a contaminated site undergoing corrective action and clean closure under RCRA:

- Are all receptors and pathways likely to be affected by site contamination identified?
- Are promulgated standards or criteria available for use as cleanup levels?
- Can action levels published in 55 FR 30865-30867 (proposed Subpart S Appendix A) be used as cleanup levels? (These can be used only if the potential receptors are human.)
- Must cleanup levels be calculated using published reference doses and slope factors?
- Must cleanup levels be adjusted to account for multiple contaminants or multiple exposure pathways?
- Is there a potential ecological problem at the site requiring special consideration during the cleanup level determination and evaluation?

This document provides equations for calculating cleanup levels when there are no promulgated standards for contaminants of concern. In addition, references are provided for state standards and protocols that should be used or considered for use in developing cleanup levels. These guidelines recommend consultation with human health risk assessment specialists and ecologists for the more complex, technical aspects of the assessment process.

1.0 INTRODUCTION

This guidance document provides procedures for developing human and ecological health-based cleanup levels for contaminated sites undergoing corrective action and clean closure under the Resource Conservation and Recovery Act (RCRA). The procedures are presented in a step-by-step approach intended for use by U.S. Environmental Protection Agency (EPA) permit writers and regulatory compliance officials. The analysis presented here will enable RCRA site managers to identify sites for which promulgated action levels (described in detail in Sections 2.3 and 3.3) may be used as cleanup criteria, versus sites requiring exposure-based risk calculations to address site-specific problems. This document also describes the situations that are likely to require expert technical assistance. Application of these procedures is intended for RCRA sites where hazardous waste or hazardous constituents have been released and where contaminated environmental media (that is, soil, surface water, sediment, groundwater, or air) and contaminant concentrations have been identified by means of environmental sampling and analysis.

This approach is intended to be consistent with the Comprehensive Environmental Response, Compensation and Liability Act (CERCLA), known as Superfund. Where RCRA guidelines and proposed rules do not specify procedures, Superfund guidance is used.

This guidance document is a companion document to *Northwest RCRA Corrective Action Strategy* (EPA 1990b), and also complements *RCRA Facility Investigation (RFI) Guidance* (EPA 1989b).

This document is organized into two main parts: Section 2 focuses on developing cleanup levels protective of human health, and Section 3 focuses on developing cleanup levels protective of ecological species and systems.

1.1 HUMAN HEALTH AND ECOLOGICAL RISK ASSESSMENTS: AN OVERVIEW

Human health and ecological risk assessments as described in Chapter 8 of the RCRA facility investigation guidance (EPA 1989b) are conducted in two steps: identification of potential exposure pathways, and comparison of site contaminant concentrations with human health and ecological criteria (action levels). Action levels for carcinogens are set as concentrations associated with an excess upper bound lifetime cancer risk of 1×10^{-6} due to continuous constant lifetime exposure.

Under the RCRA corrective action process, an action level is the contaminant concentration that triggers an investigation such as a corrective measures study. Examples of action levels include but are not limited to the following:

•	Groundwater	Maximum contaminant levels (MCLs)
•	Soil	Concentrations listed in 55 FR 30865-30867, Appendix A (proposed Subpart S), July 27, 1990
•	Surface water	MCLs for drinking water; water quality criteria for multiple water uses
•	Air	Concentrations listed in 55 FR 30865-30867, Appendix A (proposed Subpart S), July 27, 1990

Often the cleanup level is set at the action level, because action levels are calculated to be health-protective. Cleanup levels may be less stringent than action levels, if it can be demonstrated that the higher cleanup level concentrations are protective of human health and the environment. Cleanup levels may be more stringent than action levels if there are multiple contaminants at a site or multiple exposure pathways for an individual chemical. Also, state regulations may be more restrictive than action levels.

In order to clean-close a facility or part of a facility, it must be demonstrated that the cleanup levels are protective of human health and the environment or that they do not exceed background contaminant levels.

If action levels are not available or are not sufficiently protective, risk-based cleanup levels can be calculated for a contaminated site once contaminants of concern, contaminated media, and important exposure pathways are identified. These calculations incorporate toxicity values and exposure assumptions to derive an acceptable concentration for each contaminant in each environmental medium.

An example of an action level that may not be sufficiently protective is the MCL for benzene, which is 5 micrograms per liter (μg/L). The excess lifetime cancer risk calculated for residential ingestion of water contaminated with 5 μg/L benzene is 8×10^{-6}, which is above the target risk level of 1×10^{-6}. The health-based concentration for benzene is 1 μg/L (calculated using the equation presented in Appendix 1). It may be appropriate to set the cleanup level at the lower risk-based level, depending on site-specific conditions. In some cases the acceptable risk-based level may be lower than the analytical detection limit, and it may be necessary to select a value other than the risk-based level for cleanup.

1.2 SETTING RISK-BASED CLEANUP LEVELS : THE DUAL PROCESS

Both human and ecological health should be considered when calculating cleanup levels at a site. Cleanup levels are always calculated to be protective of human health. Cleanup levels based on ecological health need to be determined if specific exposure pathways and ecological receptors are identified at a site. The procedures for calculating cleanup levels based on human risk assessment are different from those used for calculating cleanup levels based on ecological risk assessment. Both procedures should be applied at each site; the processes can be conducted either simultaneously or sequentially.

A quantitative approach to deriving human health-based cleanup levels is presented here, while the approach to developing ecological risk-based cleanup levels is qualitative. For human health risk assessment, numerical standards are used and calculations are performed to yield specific contaminant concentrations in each environmental medium. In ecological risk assessment, the many site-specific conditions and impacts resulting from the complex interrelationships among chemicals taken up by the ecological receptors are weighed and assessed in a series of judgements on the relative risks. In this way, one or more contaminant-medium-receptor pathways are identified as the greatest threats to ecological health at a site. An ecologically based cleanup level is determined for each contaminant in each medium by weighing considerations of technical feasibility and the economic, social, and ecological value of species at risk.

Figure 1 shows the dual process of developing cleanup levels for a RCRA site. The left-hand side of the flowchart is specific to human health-based cleanup levels, and the right-hand side shows the steps in developing cleanup levels based on ecological assessment.

Before either process is begun, contaminants of concern at a site must be identified. The list of site contaminant concentrations should be produced from RCRA facility investigation reports, corrective measures study reports, sampling reports, or monitoring reports.

Once site contaminants are identified, the first step in the human health risk assessment is identification of exposure pathways. If state or federal criteria or standards have been promulgated for an identified exposure pathway and contaminant of concern, these criteria can be used as cleanup levels. If no promulgated criteria exist for a specific contaminant or

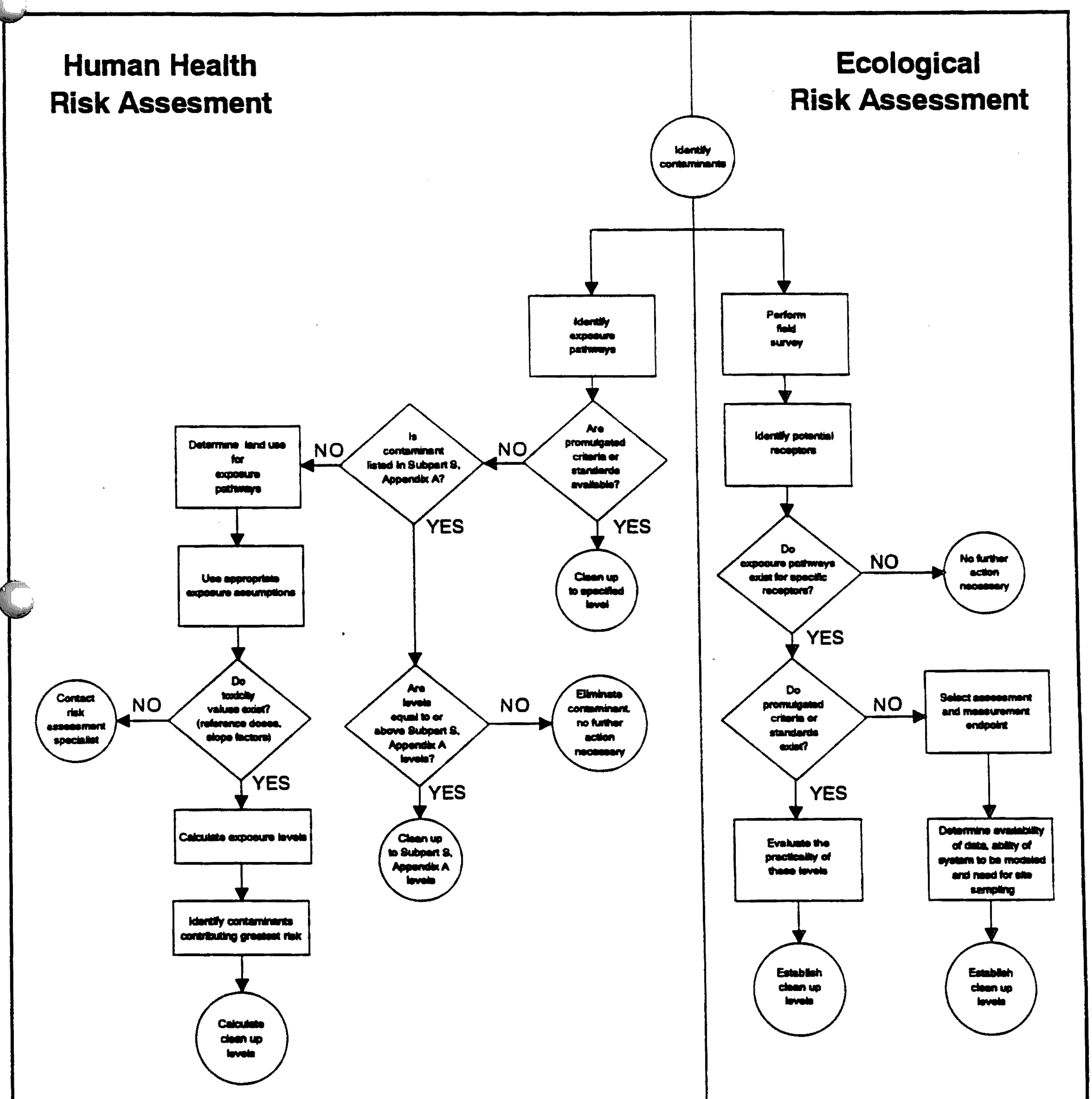

Figure 1. Overview of RCRA Clean-Up Level Development

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pathway, Appendix A of Subpart S should be consulted. If the site contaminant concentration is above concentrations listed in Appendix A, Subpart S, the values listed in Appendix A of Subpart S should be used as cleanup levels. It should be noted that Subpart S action levels are based on residential land use assumptions. If the contaminant is not given in the Subpart S, Appendix A table, then land use should be determined for a site. If industrial land use assumptions are appropriate for use in developing cleanup levels, then Subpart S assumptions are not applicable. Once land use is determined, appropriate exposure assumptions should be made and combined with toxicity criteria to calculate risk-based concentrations. If cleanup levels are to be developed based on industrial land use, then exposure assumptions found in the "Standard Default Exposure Factors" can be used (EPA 1991b). If no toxicity criteria exist, a risk assessor should be consulted. If toxicity criteria exist and there are numerous contaminants of concern at a site, then contaminants contributing the greatest risk can be determined and cleanup levels can be calculated for these contaminants.

Once contaminants are identified, a field survey is conducted and potential receptors are identified. Next it is determined whether exposure pathways exist for specific receptors. If not, there is no need to calculate ecologically based cleanup levels for the site. If exposure pathways are identified for specific receptors, then it should be determined whether promulgated criteria or standards exist for the contaminant of concern in the appropriate medium. If criteria have been established, then these criteria should be considered as cleanup levels. If not, it is likely that consultation with an ecologist will be needed to assist with defining assessment and measurement endpoints and determining whether adequate data are available, whether the system can be modeled, and whether on-site sampling is needed. Once all the necessary data are collected and evaluated, cleanup levels can be decided upon. Some sites will only require calculation of human health risk-based cleanup levels. However, for sites requiring development of both types of cleanup levels, the two levels should be compared and the more stringent of the two adopted as the cleanup level.

2.0 CLEANUP LEVELS BASED ON HUMAN HEALTH RISK ASSESSMENT

This section describes the steps to follow when developing cleanup levels based on human health risk assessment. The main elements of the procedure are:

- Identification of exposure pathways
- Identification of available promulgated criteria or standards
- Use of Subpart S Appendix A
- Use of risk-based cleanup calculations

Once preliminary cleanup levels have been derived, they can be adjusted to account for multiple contaminants and multiple pathways, as needed.

2.1 IDENTIFICATION OF EXPOSURE PATHWAYS

It is important to identify the complete exposure pathways and important receptors at a site so that health-based cleanup levels that are protective of all potential receptors can be developed.

Table 1 summarizes potential exposure pathways for human receptors at a typical site. Exposure pathways are identified within each pertinent exposure scenario. There are several exposure scenarios that may be applicable at a given facility. Those most commonly evaluated are the industrial and residential exposure scenarios. The residential scenario is the more conservative of the two (i.e., it results in more protective cleanup levels). Agricultural and recreational scenarios may be important depending upon facility location and identification of the most exposed individual. Most often the residential or industrial exposure scenario is used for developing cleanup levels. However, if the individual subject to the greatest exposure to site-related contaminants is the recreational user of a nearby stream or lake, then a recreational scenario may be sufficiently protective.

The pathways listed in Table 1 should be evaluated to identify the contaminated media for which cleanup levels should be developed. At some sites, a small fraction of the potential exposure pathways may be relevant. At other sites, all pathways listed may be important. Cleanup levels should be determined for a specific medium, such as soil, rather than for each individual exposure pathway. For soils, it is important to consider the potential for contaminants in soil to reach groundwater. Some contaminants are relatively immobile, such as inorganic contaminants (e.g., lead, cadmium) and will not be likely to pose a significant threat to

TABLE 1

POTENTIAL EXPOSURE PATHWAYS FOR HUMAN RECEPTORS[a]

Contaminated Medium	Exposure Scenario	Potential Exposure Pathway	Important for Calculation of Cleanup Levels?
Groundwater	Residential/agricultural use as potable water	Ingestion of water	Yes
		Inhalation of volatiles	Yes, if volatiles present
		Dermal contact with water	Yes, for organic contaminants of concern
		Transfer to food crops or livestock and subsequent ingestion	Site-specific determination
	Industrial use as potable water	Ingestion of water	Yes
		Inhalation of volatiles	Site-specific determination
		Dermal contact with water	Site-specific determination
Surface water and sediment	Residential/agricultural or industrial use as potable water	Ingestion of water	Yes
		Inhalation of volatiles	Yes, if volatiles present
		Dermal contact with water	Yes, for organic contaminants of concern
		Transfer to food crops or livestock and subsequent ingestion	Site-specific determination
	Recreational use or subsistence fishing	Consumption of fish and seafood	Site-specific determination
	Recreational use or trespasser	Ingestion of water	Site-specific determination
		Dermal contact with water	Site-specific determination
		Ingestion of sediment	Site-specific determination
		Dermal contact with sediment	Site-specific determination

TABLE 1 (continued)

Contaminated Medium	Exposure Scenario	Potential Exposure Pathway	Important for Calculation of Cleanup Levels?
Soil	Residential or agricultural	Incidental soil ingestion	Yes
		Dermal contact with soil	Yes
		Inhalation of particulates/volatiles from soil	Yes
		Consumption of produce, meat, milk	Site-specific determination
		Soil as potential source to groundwater	Site-specific determination
	Industrial	Soil ingestion	Yes
		Dermal contact with soil	Yes
		Inhalation of particulates/volatiles from soil	Yes
		Soil as potential source to groundwater	Site-specific
Air	Residential or agricultural	Inhalation of particulates/volatiles from stack or other emissions	Site-specific determination
	Industrial	Inhalation of particulates/volatiles from stack or other emissions	Site-specific determination

a Modified from EPA (1991d)

groundwater quality. Other contaminants, such as the organics benzene and trichloroethylene, are relatively soluble in water and much more mobile and likely to move from the soil to the groundwater. The cleanup level calculated for each medium should include consideration of all pathways that contribute to exposure or risk. For example, the cleanup levels for soil should be developed using all possible exposure routes for soil that are appropriate at a site (e.g., ingestion, dermal contact, inhalation of soil as dust particles).

There are three primary routes by which toxic agents can enter the body:

- Ingestion of contaminated water and food (e.g., fruits, vegetables, fish, shellfish), and incidental ingestion of soil
- Inhalation of vapors or dust
- Dermal contact with water or soil

For an exposure pathway to be considered important or complete at a site, there must be a receptor that is exposed to contamination via this pathway. A receptor is any organism that may be exposed to the contamination. In this section, receptor refers to any human (e.g., trespasser, schoolchild, area resident) who might be exposed to site-related contaminants by one or more pathways.

When developing cleanup levels for air, the most exposed individual outside the facility boundary should be considered. For clean closure of a waste unit, it is assumed that the most exposed individual is at the boundary of the unit. For cleanups under the corrective action process, the most exposed individual is identified on a site-specific basis. Air concentration should be measured at the location of the human receptor who is subject to the greatest exposure.

Equations are presented in Appendix 1 for use in calculating cleanup levels based on residential exposures. If other exposure scenarios such as industrial, agricultural, or recreational are used to calculate cleanup levels, Region 10 risk assessment guidance (EPA 1991d) and *Risk Assessment Guidance for Superfund* (EPA 1989c) should be consulted for the appropriate equations.

2.2 IDENTIFICATION OF PROMULGATED CRITERIA AND STANDARDS

When developing cleanup levels for a site, the site manager must take into consideration promulgated federal and state standards or criteria for environmental media contaminated by site activities. Currently, federal standards exist for drinking water supplies and surface water bodies (marine and freshwater).

MCLs have been established for a number of inorganic and organic chemicals in drinking water supplies. These concentrations should not be exceeded in groundwater or in surface water unless there are compelling scientific reasons to accept such exceedances.

At this time, the other promulgated federal criteria are the national ambient air quality standards for key pollutants and the ambient water quality criteria. Concentrations are established for surface waters. Standards exist for protection of human health from ingestion of contaminants in water and fish, and for protection of human health from fish ingestion only. These water quality criteria are provided for protection of aquatic life also.

An example of promulgated state criteria is found in the Washington Model Toxics Control Act (WAC 173-340), which establishes cleanup levels for groundwater and soil. In Oregon, the Department of Environmental Quality cleanup policy establishes background concentrations as target cleanup levels for RCRA facilities when feasible.

Information on specific state standards and criteria is available through the following agencies:

Alaska Department of Environmental Conservation Juneau, Alaska	907-563-6529
Idaho Department of Health and Welfare, Division of the Environment Boise, Idaho	208-334-0550
Oregon Department of Environmental Quality Portland, Oregon	503-229-5696
Washington Department of Ecology Olympia, Washington	206-459-6000

2.3 CLEANUP LEVELS FOR CONTAMINANTS LACKING CRITERIA AND STANDARDS

If there are no promulgated criteria or standards (as outlined above) for the chemical of concern, then the procedures described in this section should be followed. This section explains when to use the Subpart S Appendix A action levels as cleanup levels, and when health-based cleanup levels should be calculated. It may be necessary to adjust both types of cleanup levels to account for multiple contaminants or multiple exposure pathways, as well as the potential for soil contaminants to leach to groundwater, as explained at the end of this section.

2.3.1 Use of Subpart S Appendix A Action Levels as Cleanup Levels

If a contaminant is listed in Subpart S Appendix A, a concentration-based screening can be performed as follows:

1) Determine the site contaminant concentration in the specific medium.

2) Compare the site concentration to the value listed in Subpart S Appendix A. If the concentration is below that listed in Subpart S Appendix A, then eliminate the contaminant from consideration for cleanup. If the concentration is equal to or greater than that listed, then use the Subpart S Appendix A value as the cleanup level.

3) Read Sections 2.4 and 2.5 below to determine if adjustments to the cleanup levels are needed for multiple contaminants or multiple pathways.

If the contaminant is not listed in Subpart S Appendix A, then cleanup levels should be calculated as described in Section 2.3.2 below.

2.3.2 Calculation of Health-Based Cleanup Levels

If no promulgated criteria or standards are available, and if the contaminant is not listed in Subpart S Appendix A, then health-based cleanup levels must be calculated. This section explains land use classification, standard assumptions (federal, regional, and state), and critical toxicity values that must be used in the calculations. In addition, guidance is provided for identifying the contaminants posing the greatest health threats, in order to focus the cleanup efforts.

2.3.2.1 Classification of Land Use

The evaluation of a site to determine appropriate cleanup levels is based in part upon the appropriate land use scenario. Depending on assumptions regarding future site uses, either a residential scenario or an industrial scenario is typically chosen. A residential scenario results in more conservative (i.e., more protective) cleanup levels, because it is assumed that adults and children live or will live on the site and are or will be exposed to contaminants 24 hours a day. In the industrial scenario, exposure is assumed only for adults and only during working hours. The residential scenario is usually used for calculating cleanup levels. An example of a possible exception is for sites in Washington that fulfill the industrial criteria listed in the Model Toxics Control Act cleanup regulation. The residential scenario should be used if workers or owners and their families live on-site at an industrial facility, or if future use of the property might include residential use.

A site may be considered industrial for cleanup of soil in Washington if it meets all of the following requirements of the Model Toxics Control Act cleanup regulation:

- The site is zoned or otherwise officially designated for industrial use
- The site is currently used for industrial purposes or has a history of use for industrial purposes
- Adjacent properties are currently used for industrial purposes or are designated for industrial use
- The site is expected to be used for industrial purposes for the foreseeable future because of site zoning, statutory or regulatory restrictions, comprehensive plans, adjacent land use, and other relevant factors

If the site meets the requirements for industrial classification, then the risk-based cleanup level may be based on 10^{-5} excess lifetime cancer risk instead of 10^{-6} (for soil contamination by carcinogenic contaminants only).

Determination of cleanup levels for groundwater, surface water, and air is the same for all sites regardless of land use classification as industrial or residential for soil cleanup. Groundwater and surface water are always cleaned up to target levels such as MCLs or drinking water standards unless there are extenuating site-specific circumstances.

If the air pathway is a significant exposure pathway for a site, cleanup levels are calculated for a specific location depending on the type of cleanup planned. For clean closure it is assumed that the most exposed individual is at the unit boundary, and air contaminant concentrations must be equal to or below the health-based level at the unit boundary. Under the corrective action process, the most exposed individual is identified on a site-specific basis and may be someone living across the street from the facility, a worker living on the site, or a resident a mile away, depending on site characteristics.

2.3.2.2 Use of Appropriate Exposure Assumptions

The exposure assumptions used in this document to calculate cleanup levels are found in Appendices D and E of the proposed Subpart S rule (EPA 1990a). These exposure assumptions were developed to address human health concerns, and are consistent with current federal and Region 10 CERCLA guidance. These exposure assumptions are based on residential exposure assumptions and should be used in calculations at most sites.

For sites that can be cleaned up based on industrial exposure assumptions, the industrial exposure assumptions provided in EPA (1991b), Standard Default Exposure Factors, should be used in cleanup level calculations.

2.3.2.3 Use of Critical Toxicity Values

Critical toxicity values are reference doses and slope factors that are used frequently in risk assessments. Reference doses are used to evaluate the noncarcinogenic toxic effects of chemicals; slope factors are used to evaluate the carcinogenic effects of chemicals.

2.3.2.3.1 Toxicity Values for Noncarcinogens

The reference dose for a specific chemical, expressed in units of milligrams per kilogram per day (mg/kg-day), represents an estimated intake rate that is unlikely to produce measurable adverse effects over a lifetime of exposure. The reference dose is usually based on the relationship between the dose of a noncarcinogen and the occurrence of systemic toxic effects in experimental animals or humans. It is a specific assumption of this method that there is a threshold intake rate below which toxic effects do not occur. Generally, a no-observed-adverse-effect-level (NOAEL) or dose is divided by uncertainty factors to derive a reference dose that is intended to protect the most sensitive members of the population.

The uncertainty factors are usually multiples of 10, with each factor representing a specific area of uncertainty inherent in extrapolation from the available data. Uncertainty factors are used to account for the following:

- Variation in the general population (intended to protect sensitive subpopulations such as children and the elderly)
- Extrapolation from animal data to humans
- Derivation of a NOAEL from a subchronic study rather than a chronic study
- Use of a lowest-observed-adverse-effect-level (LOAEL) rather than a NOAEL

Once a reference dose for a chemical is verified by EPA, it is used to evaluate long-term noncarcinogenic risks at a site. This reference dose is compared with the expected site dose (calculated using the procedure described in Appendix 1) to determine whether chronic effects might occur. Chronic effects are those adverse health effects that result from long-term exposure to relatively low levels of a substance. A hazard index is calculated to determine if noncarcinogenic toxic effects may be of concern based on an estimated exposure level or dose. The hazard index expresses the likelihood that exposure will result in noncarcinogenic toxic effects. It is the ratio of an exposure level to a reference dose. A hazard index of 1.0 or less indicates that long-term exposure to the chemical is not likely to cause an adverse health effect. Hazard indices are not probabilistic estimates of risk, however.

2.3.2.3.2 Toxicity Values for Carcinogens

For chemicals classified by EPA as potential human carcinogens, risk is evaluated differently, because noncarcinogenic and carcinogenic effects are believed to have entirely different mechanisms of action. Typically, animal carcinogenicity studies are conducted using relatively high doses. To evaluate the probability of developing cancer at the lower doses more frequently encountered in the environment, the linearized multistage model is used. This mathematical model expresses excess cancer risk as a function of exposure. The model is based on the assumption that even a single, low-dose exposure to a carcinogen may result in cancer. In other words, it is assumed that there is no threshold dose for carcinogens.

Using the linearized multistage model, the 95th percentile confidence limit of the slope from the dose-response curve is calculated. The dose-response curve is generated by graphically plotting response against dose. The slope of the dose-response curve defines the steepness of the curve. The linearized multistage model assumes that a line drawn through the dose-response data points rises at a rate or steepness that is likely to overestimate rather than underestimate the true rate or steepness of the dose-response curve. This slope factor, expressed in units of $(mg/kg\text{-}day)^{-1}$, provides a health-protective estimate of the probability of cancer developing from exposure over a lifetime. By definition, there is only a 5 percent chance that the probability of developing cancer is higher.

To calculate the cancer risk associated with exposure to a contaminant at a site, the dose from a given exposure route first must be estimated. Then the estimated dose is multiplied by the chemical-specific slope factor to derive the estimated risk. Cancer risk is expressed as the chance of an individual in a population developing cancer, e.g., one in a million or $1x10^{-6}$.

EPA assigns weight-of-evidence classifications to potential carcinogens. Under this system, a chemical is classified in one of six groups, defined as follows:

- Group A - chemicals for which sufficient data exist to support a causal association between exposure to the agent and cancer in humans
- Group B1 - chemicals for which there is limited evidence of carcinogenicity from human exposure studies but sufficient evidence of carcinogenicity from animal studies
- Group B2 - chemicals for which there is inadequate evidence of carcinogenicity from human exposure studies but sufficient evidence of carcinogenicity from animal studies
- Group C - chemicals for which there is limited evidence of carcinogenicity from animal studies
- Group D - chemicals for which the carcinogenicity data base is inadequate
- Group E - chemicals exhibiting no evidence of a carcinogenic response in humans or animals

The reference doses or slope factors used to calculate cleanup levels are available from the EPA Integrated Risk Information System (IRIS), a computer data base (EPA 1991c). Reference doses or slope factors not available from IRIS may be listed in the most recent EPA *Health Effects Assessment Summary Tables* (HEAST) (EPA 1991a), which are updated quarterly. If there is no reference dose or slope factor listed for a chemical, the following EPA offices may be consulted:

Health and Environmental
Assessment Section
Region 10 EPA
ES-098
1200 Sixth Avenue
Seattle, Washington
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2.3.2.4 Identification of Contaminants Presenting the Greatest Health Risks

It should be determined whether only a few or many contaminants pose the primary threat. Chemicals that contribute a small percentage of the overall threat as determined by a risk-based screening process should be eliminated. The screening process is outlined below. This process was developed by Region 10 EPA to address multiple contaminants at CERCLA sites.

1) List maximum concentration of each contaminant in each medium

2) Calculate risk-based concentrations for each contaminant, as described in Appendix 1 of this document

3) Eliminate a contaminant from screening if the maximum concentration in water is:

   $\leq 10^{-6}$ cancer risk screening value, or
   ≤ 0.1 hazard index screening value

4) Eliminate a contaminant from screening if the maximum concentration in soil is:

   $\leq 10^{-7}$ cancer risk screening value, or
   ≤ 0.1 hazard index screening value

5) Include remaining contaminants for further consideration in calculating cleanup levels

As stated in Step 2 above, the screening level should be determined using the equations provided in Appendix 1. As indicated in Step 3, the default screening level at which carcinogenic contaminants can be eliminated is based on 10^{-6} risk in groundwater. Step 4 shows that for soil, contaminants with concentrations exceeding 10^{-7} risk should be included for further consideration in calculating cleanup levels for a site. This lower risk factor is used because additional pathways such as dermal contact and inhalation are not taken into account in the calculations and could result in significantly higher exposures for some chemicals. For noncarcinogens, because multiple pathways and multiple contaminants may result in cumulative effects, the screening concentration should be based on a hazard index of 0.1, rather than 1.0, which is the usual level of concern.

It can be assumed that if no single sample maximum value exceeds a concentration representing a human health risk concern, total exposure to the contaminant is not of concern.

Six inorganic constituents that are not associated with toxicity to humans under normal circumstances are aluminum, calcium, iron, magnesium, potassium, and sodium. No quantitative toxicity information is available for these elements from EPA sources, and they can generally be eliminated from consideration during development of cleanup levels.

Additional contaminant characteristics to be considered (in consultation with a risk assessor) include the following:

- Persistence
- Mobility (including potential for soil contaminants to leach to groundwater)
- Natural background concentration
- Frequency of detection
- Degradation products
- Bioaccumulation characteristics
- Treatability

If after screening it is found that more than one or two contaminants contribute to the health threat, then cleanup levels must be adjusted to take multiple contaminants into consideration (see Section 2.4 and Appendix 1).

2.3.2.5 Calculation of Cleanup Levels

Cleanup levels should be calculated using the equations provided in Appendix 1. As an example, assume that RDX (hexahydro-1,3,5-trinitro-1,3,5-triazine), an ordnance or munitions compound, is the contaminant of concern in groundwater and that ingestion of groundwater is the only pathway to be considered. RDX is not listed in Subpart S Appendix A. Consulting the IRIS data base (EPA 1991c) or HEAST (EPA 1991a), it is found that RDX has toxicity values for both toxic noncarcinogenic and carcinogenic effects. The slope factor is 0.11 $(\text{mg/kg-day})^{-1}$, and the oral reference dose is 0.003 mg/kg-day.

Using the equations presented in Appendix 1, the following cleanup levels can be calculated for carcinogenic and noncarcinogenic effects of RDX in groundwater.

2.3.2.5.1 Carcinogenic Effects

The equation for calculating health-based cleanup levels in water is:

$$C_w = [R \times 70 \text{ kg} \times 70 \text{ yr}]/[CSF \times 2L/\text{day} \times 70 \text{ yr}]$$

(See Appendix 1 for an explanation of the individual terms in the equation).

Substituting the appropriate values for R and CSF, the equation becomes

$$C_w = [10^{-6} \times 70 \text{ kg} \times 70 \text{ yr}]/[0.11 \text{ (mg/kg-day)}^{-1} \times 2\text{L/day} \times 70 \text{ yr}]$$

and the risk-based cleanup level is

$$C_w = 3.2 \times 10^{-4} \text{ mg/L or } 0.32\ \mu\text{g/L}$$

2.3.2.5.2 Noncarcinogenic Effects

The equation for calculating health-based cleanup levels in water for noncarcinogenic effects is:

$$C_w = [\text{reference dose} \times 70 \text{ kg}]/[2\text{L/day}]$$

Substituting the appropriate value for the reference dose, the equation becomes

$$C_w = [0.003 \text{ mg/kg-day} \times 70 \text{ kg}]/[2 \text{ L/day}]$$

and the risk-based cleanup level is

$$C_w = 0.11 \text{ mg/L or } 110\ \mu\text{g/L}$$

The cleanup level calculated based on carcinogenic effects is lower and therefore more stringent than that based on noncarcinogenic effects. In such cases, the more stringent cleanup level should be selected as the more health-protective level.

Appendix 1 contains the equations for other exposure routes and media.

2.4 ADJUSTMENT OF CLEANUP LEVELS FOR MULTIPLE CONTAMINANTS

Risks from contaminants having carcinogenic effects are assumed to be additive. If there are 3 to 10 carcinogenic contaminants remaining after the risk-based screening process, then the target risk level should be 10^{-7} risk from each chemical (use 10^{-7} instead of 10^{-6} for R in the equations given in Appendix 1). Hazard indices from contaminants having systemic toxic effects are also assumed to be additive. If there are 3 to 10 noncarcinogenic contaminants remaining after the risk-based screening process, then the target risk level is adjusted to 0.1 rather than 1.0 (i.e., divide the calculated contaminant concentration [C_a, C_g, C_w] by 10).

If more than 10 contaminants remain after risk-based screening, then a risk assessor should be consulted for assistance in adjusting cleanup levels to take all the contaminants into consideration.

2.5 ADJUSTMENT OF CLEANUP LEVELS FOR MULTIPLE PATHWAYS

If there are multiple exposure pathways, cleanup levels should be adjusted to be protective against potential exposure by more than one pathway. The cleanup levels for individual contaminants obtained from Subpart S Appendix A, or derived by methods given in Appendix 1, should be divided by two if there are two exposure pathways. If there are three exposure pathways for a given medium at a site, divide by three, and so on.

The potential for contaminants to leach from soil into groundwater and the subsequent degradation of groundwater should be taken into consideration when developing cleanup levels. Cleanup levels developed on the basis of soil ingestion only may not be low enough to protect the groundwater from degradation. Currently there is no specific guidance for quantifying or estimating risks to groundwater from contaminated soil. However, EPA headquarters is investigating various modeling approaches to address this issue.

2.6 RESULT OF HUMAN HEALTH-BASED ANALYSIS

Once the human health risk assessment process and the step-by-step process for developing cleanup levels are understood, regulatory officials should be prepared to answer the following questions regarding a contaminated site undergoing corrective action or clean closure under RCRA:

- Have receptors and pathways that are likely to be affected by site contamination been identified?
- Are promulgated federal or state criteria or standards available?
- Can action levels published in Subpart S Appendix A be used as cleanup levels?
- Must cleanup levels be calculated using published reference doses and slope factors?
- Must cleanup levels be adjusted to account for multiple contaminants or multiple exposure pathways?

Risk-based cleanup levels are associated with varied levels of uncertainty, depending on many factors (e.g., confidence that land use assumptions are correct). If residential land use assumptions were used to develop cleanup levels, then the cleanup levels may be more protective than they need to be if the site is an industrial facility. The toxicity values (slope factors and reference doses) used in calculations are associated with a number of uncertainties. These include the following:

- Animal studies are used to develop human toxicity criteria
- Chronic effects are often extrapolated from subchronic or acute studies
- Sensitive subpopulations (such as children or the elderly) may not have been considered

Other sources of uncertainty stem from how the cleanup levels are calculated. For example, cleanup levels in soil are derived based on the ingestion route of exposure. This may not be protective enough if the inhalation or dermal contact routes of exposure are important pathways for the chemicals of concern.

Additional uncertainty for soil cleanup levels is associated with whether or not the soil contaminants will leach to groundwater. Risk-based cleanup levels may not be low enough to protect against this occurrence.

3.0 CLEANUP LEVELS BASED ON ECOLOGICAL RISK ASSESSMENT

This section follows the steps outlined in the flowchart under cleanup levels based on ecological assessment (Figure 1). The first steps are performance of a field survey and identification of potential receptors. The next step is to identify exposure pathways for specific receptors. If no pathways exist at a site, it is not necessary to develop cleanup goals based on ecological assessment. If exposure pathways do exist for specific receptors at or near a site, then the next step is determining whether federal or state standards or criteria exist for the exposure pathway or medium. Laws and regulations containing promulgated standards in Region 10 are listed in Section 3.3. If there are criteria or standards for a contaminant of concern, these criteria may be used as cleanup levels, if appropriate. EPA has developed and promulgated specific ambient water quality criteria for protection of aquatic life in surface waters (EPA 1986b). General guidelines are provided for evaluating the ecological health-protectiveness and practicality of the standards.

If there are no promulgated criteria or standards (such as water quality criteria) for the contaminants of concern, consultation with an ecologist may be needed to define ecological assessment and measurement endpoints for the site and to determine if data are available for the identified endpoints. If sufficient data are not available, the ecologist can assist in determining whether the potentially impacted system can be modeled using existing site information, or whether additional sampling and ecological assays will be needed before the ecological effects of site contamination can be assessed.

Because of the complexity of variables involved in identifying appropriate ecological receptors and contaminant concentrations that may cause harm to them, a quantitative analysis of ecological risk, similar to the approach to human health risk, is not available. Therefore, the ecological factors are generally incorporated qualitatively rather than quantitatively into the development of cleanup levels.

The following sections describe in detail the steps to follow and questions to be asked when examining the potential ecological impact of site contamination.

3.1 PERFORMANCE OF FIELD SURVEY AND IDENTIFICATION OF POTENTIAL RECEPTORS

The field survey can be performed at the same time as the field inspection. The purpose of the survey is to confirm the presence of potentially affected biota and determine whether symptoms of environmental damage are apparent. Visible signs of environmental contamination and degradation should be recorded. Potential receptors should be noted. Plant and animal species, plant and animal communities, or entire ecosystems may be classified as ecological receptors. These receptors can be identified with the aid of information from local, state, and federal agencies and published species lists. The following questions should be answered during this portion of the process:

Is there obvious evidence of environmental degradation that may be related to site contamination?

Such evidence may include the following:

- Stained, barren soils
- Chlorotic (i.e., yellowed, discolored) or other signs of stressed vegetation
- Unusually thick layer of leaves or other detritus (i.e., dead vegetation)
- Dead or unhealthy organisms near sites of contamination in amounts above normal (e.g., dead fish on the shores of lakes or streams)
- Visible or other sensory evidence of chemical contamination (e.g., oily film or foam on surface water, chemical odor from water or soils)
- Reports by employees or neighbors of unusual environmental occurrences (e.g., dead birds, dying trees, absence of usual visitor or resident species, unusual behavior exhibited by animals)

If any of these conditions is evident, then an ecologist should be consulted to assist with incorporating these environmental factors into the development of cleanup levels.

Are there threatened or endangered species that are likely to be exposed to site contaminants?

To identify species that are threatened or endangered, 50 CFR 17.11 and 17.12 (U.S. Fish and Wildlife Service List of Endangered and Threatened Wildlife and Plants) may be consulted.

To identify critical habitats (necessary for breeding, feeding, nesting, and sustaining life) for endangered or threatened species, the U.S. Fish and Wildlife Service may be consulted. Published information is available on location of critical habitats. Additionally, The Nature Conservancy maintains a data base for identification of critical wildlife habitats in specific regions.

If there are endangered or threatened species that depend on the site as critical habitat, the following laws and regulations apply:

- Endangered Species Act of 1973 (16 USC 1531 et seq.)
- 50 CFR Part 200
- 50 CFR Part 402
- Fish and Wildlife Coordination Act (16 USC 661 et seq.)

Can animals and plants be identified in contaminated areas of the ecosystem?

Once contaminated areas are identified at a site, the organisms (receptors) that nest, feed, grow, reproduce, or otherwise come in contact with the contaminated areas can be identified.

Information on geographical distribution of fish and wildlife may be obtained from many sources including the following:

- U.S. Forest Service
- U.S. Bureau of Land Management
- U.S. Soil Conservation Service
- U.S. Fish and Wildlife Service
- Biologists at local universities, park services, and state agencies

The completed field survey should provide information necessary for determining whether there is currently ecological damage as a result of site contamination or whether there are potential ecological receptors. If no ecological receptors are identified, cleanup levels derived to protect human health should be used. If potential ecological receptors are identified, then the steps outlined below should be followed to develop cleanup levels that are protective against ecological impacts.

3.2 IDENTIFICATION OF EXPOSURE PATHWAYS FOR SPECIFIC RECEPTORS

The effect of any contaminant on an ecological receptor is highly dependent on both the receptor and the chemical properties of the contaminant.

When a contaminant enters an ecosystem it may reach a receptor by various exposure pathways depending on the organism, the contaminant, and the ecosystem. For example, water-soluble contaminants such as metals that are found in soils are frequently taken up by plants. These contaminated plants can then pose risks to both ecological and human receptors. Common ecological exposure pathways are shown in Table 2. Depending on the contaminant and the contaminated medium, one or all of the pathways listed in the table might exist at a site.

Before the effects of a contaminant on a receptor organism can be evaluated, it is necessary to know the quantity of the chemical reaching the receptor, which depends on characteristics of the contaminant, the organism, and the environment. The following questions should be answered during this portion of the process:

Which organisms are exposed to contaminants from the site, and what are the significant routes of exposure?

Appendix 2 provides two examples of hypothetical sites that have several potential ecological exposure pathways and ecological receptors. Potentially important exposure pathways for specific receptors at a hypothetical landfill site include:

- Vegetation growing in contaminated soil
- Fish swimming in a nearby stream
- Other aquatic organisms in contact with sediments and surface water in the stream
- Terrestrial animals feeding on aquatic organisms
- Terrestrial animals in contact with stream water
- Biota in the wetland ecosystem
- Birds feeding and nesting in the area

Once important pathways and receptors that may be in contact with contaminants are identified, it is possible to identify the environmental media that require cleanup to protect the environment from further degradation. For example, if fish in a nearby stream might be affected by site contaminants in the water, it may be important to clean up contaminated surface water. If vegetation is growing in contaminated soil, then the soil requires cleanup to levels that are protective of vegetation or the organisms likely to depend on the vegetation for food.

TABLE 2

PRIMARY EXPOSURE PATHWAYS FOR ECOLOGICAL RECEPTORS

Receptor	Inhalation/ Respiration	Ingestion Food/Water	Dermal/ Ambient Contact
Animals			
Mammals		x	
Birds		x	
Amphibians		x	
Reptiles		x	
Insects		x	x
Other invertebrates	x		x
Finfish	x	x	x
Mollusks	x	x	
Crustaceans	x	x	
Plants			x
Terrestrial plants		x*	
Aquatic plants		x*	

*Bio-uptake

At this point it may be evident that there are no likely ecological receptors or that there is no pathway for exposure. In that case it will not be necessary to go further in the process. Cleanup levels based on human health risk are expected to be sufficiently protective in these instances.

If ecological exposure pathways are likely to exist for site contaminants, then the following questions should be answered with respect to the specific contaminants of concern.

Are the contaminants of concern at the site mobile in the environment (i.e., are they soluble and likely to migrate)?

Mobile contaminants that tend to migrate off-site have greater potential for reaching more environmental receptors. To determine the mobility of specific contaminants, the following resources may be consulted:

- Vershueren, Karel, 1983. *Handbook of Environmental Data on Organic Chemicals.* 2nd edition. Van Nostrand Reinhold Co.
- Kabata-Pendias, A. and H. Pendias, 1984. *Trace Elements in Soils and Plants.* CRC Press.

Mobile receptors within an ecosystem can spread contamination from the site as well. Herbivores (i.e., plant eaters) such as deer and mice may eat contaminated vegetation, then drop contaminated feces off-site. Birds may carry contaminated vegetation off-site for nesting. Predators eating contaminated prey may spread contamination through excretory channels.

Do the contaminants of concern bioaccumulate or biomagnify?

Bioaccumulation is the process by which a substance is concentrated in a certain organism or tissue. The extent and nature of exposure is affected by the tendency of an organism to bioaccumulate the chemical and by the kind of tissue in which the chemical is stored. *Bioconcentration* is expressed as the ratio of the contaminant concentration in tissue to the concentration in a specific medium, and is a way to measure bioaccumulation. Contaminants that bioaccumulate may have increased potential to cause toxicity in a receptor organism or in a receptor that feeds on that organism. The following references may be helpful in determining the bioaccumulation potential of individual contaminants:

- Vershueren, Karel, 1983. *Handbook of Environmental Data on Organic Chemicals*. 2nd edition. Van Nostrand Reinhold Co.

- Kabata-Pendias, A. and H. Pendias, 1984. *Trace Elements in Soils and Plants*. CRC Press.

Biomagnification is the process in which a substance moves up the food chain, being ingested by small organisms that are eaten in turn by larger organisms. The substance becomes increasingly concentrated as it moves up the chain. Contaminants that biomagnify may not cause impacts on the original receptor (such as algae that absorb contaminants in a pond) but may have serious impacts on predator species at the top of the food chain (such as birds that eat fish that eat algae). The following example illustrates biomagnification in the food chain. In a Dutch elm disease control program, the pesticide DDT (dichlorodiphenyltrichloroethane) was applied as a 6 percent (i.e., 6 parts per hundred) suspension in water. Directly after treatment, leaves had a DDT residue of 183-283 parts per million (ppm), underlying soil had 1-18 ppm, and leaves falling in autumn had 20-30 ppm. Earthworms eating the fallen leaves had DDT residues of 120 ppm, and robins dying from eating earthworms contained residues in the brain in excess of 340 ppm.

If there are potentially affected ecological receptors, and the contaminants at a site are expected to bioaccumulate or biomagnify in the receptors, adjustments in cleanup levels may be needed. The types of contaminants that are likely to bioaccumulate or biomagnify are usually highly lipophilic [such as DDT, polychlorinated biphenyls (PCBs), and dioxins] or highly stable (like DDT, PCBs, and metals). A few parts per million of PCBs in sediments can move up the food chain through zooplankton, fish, and marine birds, with resulting concentrations of several parts per thousand in the marine birds.

Are the contaminants degraded or transformed into other toxic compounds in the ecosystem?

Biotic and abiotic reactions in the environment can greatly impact the toxicity of many contaminants. For example, ethylene glycol (i.e., antifreeze) and cyanide can both be oxidized to form innocuous breakdown products. Chromium VI, under specific environmental circumstances, is reduced to the less toxic chromium III. Other products, however, can become more persistent or toxic when released in the environment. Elemental mercury can be converted to methyl mercury by microbial methylation in sediments. Methyl mercury is fat-soluble and readily bioaccumulates, biomagnifying from plankton to fish, to fish-eating birds. Fish may carry high body burdens of mercury with minimal observable effects. Higher predators, such as birds and mammals, would be at greater risk. Overall, methylation of inorganic compounds, such as mercury, may lower the acute toxicity (when compared to the inorganic salt), but the ecological risk is increased because of the tendency of the methylated compound to bioaccumulate. The pesticide DDT is converted to DDE (dichlorodiphenyltrichloroethene); it is DDE, not DDT, that is the primary cause of eggshell thinning and resultant mortality of certain bird species. Depending on site contaminants and their potential breakdown products, additional sampling may be required or cleanup levels might require adjustment to account for more toxic breakdown products.

Are the contaminants distributed in specific zones of the ecosystem?

Contaminant disposal locations are important factors in identifying the impacted environmental receptors at a site. Ecosystems are divided into vertical and horizontal zones that vary in biotic and abiotic components. The distribution of a contaminant is an important factor in identifying the affected organism and exposure pathways. For example, a contaminant deposited on soil can affect soil microorganisms, soil invertebrates, vegetation, and decomposition processes, while a contaminant deposited on the forest canopy (i.e., treetops) affects vegetative growth and tree dwellers.

In another example, a chemical of high molecular weight and low water solubility such as PCBs deposited in an aquatic habitat where they would tend to sink to the bottom and partition into the sediments poses less threat to organisms near the surface than to bottom dwellers.

Are the contaminants indirectly toxic to the receptors?

A contaminant may not be directly toxic to an organism through ingestion or exposure but may alter the normal state of the ecosystem, causing conditions that may be toxic to receptors. For example, contaminants that raise or lower pH levels can render nutrients unavailable to plants. Contaminants in a water supply might have low toxicity for fish but might reduce free oxygen thus killing fish by suffocation rather than poisoning.

The following references may be helpful in estimating the toxicity of chemicals to ecological receptors:

- Lyman, W.J., et al., 1982. *Handbook of Chemical Property Estimation Methods.* McGraw-Hill Book Company.
- EPA, 1986b. *Superfund Public Health Evaluation Manual.* EPA 540/1-86/060. OSWER Directive 9285.4-1. U.S. Environmental Protection Agency. October 1986.
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- Vershueren, Karel, 1983. *Handbook of Environmental Data on Organic Chemicals.* 2nd edition. Van Nostrand Reinhold Co.

The enzymatic, metabolic, and reproductive systems of ecological receptors may react to contaminants very differently than do the systems of human receptors. In addition, since some organisms spend all their time in contaminated sediments, respiring and absorbing contaminants, even low concentrations of certain contaminants can have severe ecological effects. Ecological effects vary greatly depending on contaminants of concern and ecological receptors. Review of relevant literature and available guidance is essential in accurately identifying potential effects.

3.3 IDENTIFICATION OF PROMULGATED CRITERIA AND STANDARDS

The next step in the process is determining whether promulgated criteria or standards exist for the contaminants in the medium of concern.

Are any promulgated environmental standards applicable to contaminants found at the site?

Federal and state environmental agencies have established regulatory standards for contaminants in air, water, and soil. Laws and regulations that provide cleanup levels are listed below:

Federal Regulations (administered by EPA)

40 CFR 61	Provides regulations on national emission standards for hazardous pollutants
40 CFR 50	Provides regulations on national primary and secondary ambient air quality standards
Clean Water Act Section 304	Establishes water quality standards under Section 303 of the Clean Water Act
EPA 440/5-86-001	Provides quality criteria for water, May 1, 1986, updated September 7, 1990
CERCLA Section 121(d)(2)(B)(1)	Requires that determination of federal water quality criteria be based on designated or potential use of the media affected, the purposes of the criteria, and current information

State Regulations in Region 10

Alaska (administered by Alaska Department of Environmental Conservation)

18AAC50	Alaska air quality control regulations
18AAC70	Alaska water quality standards

Idaho (administered by Idaho Department of Health and Welfare, Division of the Environment)

Title 1, Chapter 2	Idaho water quality standards and waste water treatment requirements

Oregon (administered by Oregon Department of Environmental Quality)

Oregon air control pollution laws Title 7 of the revised statutes: Oregon air pollution control regulations	Oregon Administrative Rules, Chapter 340 -- Division 31 -- ambient air quality standards
Oregon water pollution control regulations	Oregon Administrative Rules, Chapter 340 -- Division 40 -- groundwater quality protection Division 41 -- water quality standards
Oregon solid waste regulations	Oregon Administrative Rules, Chapter 340 -- Division 120 -- hazardous substance remedial action rules

Washington (administered by Washington Department of Ecology)

WAC 173-470	Ambient air quality standard for particulate matter
WAC 173-474	Ambient air quality standard for sulfur oxides
WAC 173-475	Ambient air quality standards for carbon monoxide, ozone, nitrogen dioxide
WAC 173-480	Ambient air quality standard for radionuclides
WAC 173-481	Ambient air quality standard for fluorides
WAC 173-201	Washington water quality standards
WAC 173-200	Washington groundwater quality standards
WAC 173-204	Sediment management standards

WAC 173-340	Model Toxics Control Act
WAC 173-340-720	Groundwater cleanup standards
WAC 173-340-730	Surface water cleanup standards
WAC 173-340-740	Soil cleanup standards
WAC 173-340-750	Industrial soil cleanup standards
WAC 173-340-760	Cleanup standards to protect air quality
WAC 173-340-770	Sediment cleanup standards
WAC 173-303	Washington dangerous waste regulations

Once specific criteria or standards that could apply to contaminated media at a site are identified, these criteria should be evaluated in terms of practical cleanup considerations. It may not be technically possible to meet a particular cleanup criterion. For example, the chronic ambient freshwater criterion for dieldrin is 0.0019 μg/L, which is an order of magnitude lower than the current analytical method detection limit. Other considerations include economic concerns and social importance or relevance of the ecological receptor.

3.4 CLEANUP LEVELS FOR CONTAMINANTS LACKING CRITERIA AND STANDARDS

EPA has developed and promulgated specific ambient water quality criteria for protection of aquatic life in surface waters (EPA 1986b) that represent protective concentrations of common contaminants. In addition, EPA has several guidance documents available for developing water quality criteria based on toxicity studies (EPA 1985).

Water quality criteria have been developed based on results of bioassays using invertebrates such as *Daphnia* and fish such as fathead minnows. Criteria for certain compounds have also been developed by organizations other than EPA. For example, Oak Ridge National Laboratory has developed water quality criteria for ordnance compounds such as trinitrotoluene and dinitrotoluene (ORNL 1987). These documents can be consulted to develop cleanup levels in surface waters.

There has also been extensive work on potentially toxic effects from contaminated sediments. The state of Washington recently developed marine sediment quality standards for several contaminants of concern (WAC 173-204). These standards are based on results of bioassays and calculated apparent-effects-thresholds (i.e., sediment contaminant concentrations above which statistically significant biological effects are always expected). The U.S. Army Corps of Engineers and EPA both require toxicity testing of dredged sediments prior to disposal. Results of those studies may be useful for determining toxic effects on ecological receptors in contaminated sediments.

Thus, for marine and fresh surface waters and for marine sediments, a great volume of data exists for assessing potential toxic effects and subsequently developing cleanup levels protective of ecological receptors. Thorough literature searches may be necessary to identify and interpret these data and their relevance to ecologically based cleanups.

Unfortunately, similar volumes of data are not available for contaminated soils and freshwater sediments. Specific risk-based soil and freshwater sediment values for ecological receptors have not been developed. Limited bioassay data are available, however, based on earthworm testing, root elongation, and bioassay testing of soil extracts. At this time, there are no readily available models for determining contaminant uptake from soils by ecological receptors. Developing health-based soil cleanup levels for terrestrial receptors is, therefore, a difficult and challenging task associated with a high degree of uncertainty, and one that will likely require a good deal of professional judgement.

3.5 SELECTION OF ASSESSMENT AND MEASUREMENT ENDPOINTS

If no standards or criteria are promulgated for the contaminants of concern in the media of concern, completion of the ecological risk assessment requires the identification of ecological endpoints suitable for measurement. Ecological endpoints are physical or biological parameters characteristic of the ecosystem that can be affected by contaminants.

Assessment endpoints are formal expressions of the environmental values to be protected. They are the environmental characteristics which, if significantly affected, would indicate a need for cleanup. An example would be primary productivity of an ecosystem. Assessment endpoints are considered along with political, legal, economic, and ethical values to arrive at cleanup levels and plans for cleanup.

A *measurement endpoint* is a quantitative expression of an observed or measured effect of the hazard; it is a measurable environmental characteristic that is related to the characteristic chosen as an assessment endpoint. For example, if the assessment endpoint is identified as being decreased abundance of fish, an LC_{50} toxicity test (lethal concentration to 50 percent of the organisms) can be conducted with leachate or contaminated sediment to relate environmental concentrations with potential ecological effects. Sometimes the assessment endpoint and the measurement endpoint are the same. For example, if the assessment endpoint for a waste site is decreased abundance of green sunfish in a stream adjoining the site, then abundance of the sunfish can be measured and related to abundance in reference sites. However, because some potential assessment endpoints are not observable or measurable, and because assessments are often limited to using available standard data, measurement endpoints are often surrogates for assessment endpoints. For example, if the assessment endpoint is reduced production of green sunfish in the stream due to toxic effects of leachate from a landfill, productivity cannot be measured in the time allotted to a typical field survey, and toxic effects cannot be reliably separated in the field from other effects on productivity. In that case, use of toxicity test endpoints is appropriate. Toxicity test endpoints are typically standard EPA test endpoints such as fathead minnow LC_{50} for the leachate contaminants. When the measurement endpoint is not the same as the assessment endpoint, a model is used to express the relationship between the two.

A literature search may be necessary to determine if available site data and published ecological data provide an adequate data base to assess ecological impacts and, consequently, develop cleanup levels. If insufficient information exists, an ecologist can assist with determining whether the site ecosystem can be modeled with available site information to develop cleanup levels. If the system cannot be modeled, additional sampling may be needed in order to develop cleanup levels.

Developing cleanup levels to protect ecological receptors is not as straightforward as developing human health-based cleanup levels. However, guidelines exist for developing ecologically based cleanup levels that use data from toxicity tests such as aquatic, soil, and sediment bioassays (EPA 1988b).

3.6 RESULT OF ECOLOGICAL RISK-BASED ANALYSIS

If an ecological problem exists at a site, special consideration must be given to the cleanup level determination and evaluation. The cleanup level must be evaluated for its protectiveness of the appropriate ecological receptors. However, the process of developing ecologically based cleanup levels is more complex than that of developing human health-based cleanup levels.

Once the process outlined in Section 3 of this document is understood, a site manager should be prepared to determine whether the presence of ecological receptors at the site will require lower detection limits and additional sampling. If additional sampling is needed, it is critical to have a well-designed study that focuses on specific endpoints and quantitative cleanup criteria.

At the completion of the process for developing cleanup levels based on ecological assessment, regulatory officials in consultation with ecologists should be prepared to answer the following questions for a contaminated site undergoing corrective action or closure under RCRA:

- Are there signs of environmental contamination or degradation at the site?
- Are there potential ecological receptors, especially endangered or threatened species, at or near the site?
- Are there exposure pathways for site contaminants to reach ecological receptors?
- Do site contaminants pose a toxic hazard to receptors (i.e., are contaminants directly or indirectly toxic; will they bioconcentrate or biomagnify)?
- Can promulgated standards or criteria be used as cleanup levels?
- Must ecological endpoints be defined for the site?
- Does an adequate data base exist to assess ecological impacts?
- Can the ecosystem be modeled?
- Is further site sampling needed?

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APPENDIX 1

CALCULATING RISK-BASED CONCENTRATIONS

CALCULATING RISK-BASED CONCENTRATIONS

Risk-based concentrations can be calculated for individual chemicals using the following exposure assumptions and equations, which were adapted from Appendices D and E of 40 CFR 264, 265, 270, and 271, *Corrective Action for Solid Waste Management Units at Hazardous Waste Management Facilities*, Proposed Rule (July 27, 1990). These assumptions and equations are used to estimate risks from residential exposures. If industrial, recreational, or agricultural exposures are expected to be a more reasonable basis for cleanup levels, then EPA's Risk Assessment Guidance for Superfund, Volume I, Human Health Evaluation Manual, Part A (EPA 1989c) and the Standard Default Exposure Factors (EPA 1991b) should be consulted.

EXPOSURE ASSUMPTIONS

1. In deriving cleanup levels for hazardous constituents in groundwater, assume a water intake of 2 liters/day for a 70-kg adult for a 70-year lifetime exposure period.

2. In deriving cleanup levels for hazardous constituents in air, assume an air intake of 20 cubic meters/day for a 70-kg adult for a 70-year lifetime exposure period.

3. In deriving cleanup levels for hazardous constituents in soil that are known or suspected carcinogens, assume a soil intake of 0.1 gram/day for a 70-kg adult for a 70-year lifetime exposure period.

4. In deriving cleanup levels for hazardous constituents in soil, for constituents other than known or suspected carcinogens, assume a soil intake of 0.2 gram/day for a 16-kg child for a 5-year exposure period (age 1-6).

5. In deriving cleanup levels for hazardous constituents in surface water designated by the state for use as a drinking water source, assume a water intake of 2 liters/day for a 70-kg adult for a 70-year lifetime exposure period, unless intake of aquatic organisms is also of concern. If intake of aquatic organisms is of concern, ambient water quality criteria should be used. If criteria do not exist for the contaminant of concern, then risk assessment specialists should be consulted for more detailed calculations.

EQUATIONS FOR CALCULATING RISK-BASED CONCENTRATIONS

Independent calculations are performed to derive risk-based contaminant concentrations for noncarcinogens and carcinogens. For a contaminant that has both noncarcinogenic and carcinogenic effects (that is, it has both a reference dose and a slope factor), cleanup levels should be calculated for both types of effects, and the more health-protective cleanup level should be used.

EQUATIONS FOR NONCARCINOGENIC CONTAMINANT EFFECTS

For systemic toxicants (i.e., noncarcinogens), the following general equation should be used to calculate risk-based concentrations:

$$C_m = [\text{reference dose} \times W]/I \qquad (1)$$

Where

C_m =	risk-based concentration in medium (units are medium-dependent)
reference dose =	chemical-specific reference dose (mg/kg-day)
W =	body weight (kg)
I =	intake assumption (units are medium-dependent)

This general equation can be used to calculate cleanup levels in air, soil, and water. The specific equations are listed in order:

For noncarcinogens in air:

$$C_a = [\text{reference dose} \times 1{,}000\ \mu g/mg \times 70\ kg]/[20\ m^3/day] \qquad (2)$$

Where

C_a =	risk-based concentration in air ($\mu g/m^3$)
reference dose =	chemical-specific reference dose (mg/kg-day)
W =	70-kg adult
I =	20 m^3/day

For noncarcinogens in soil:

$$C_s = [\text{reference dose} \times 16\ \text{kg}]/[0.2\ \text{g/day} \times 0.001\ \text{kg/g}] \quad (3)$$

Where

C_s =	risk-based concentration in soil (mg/kg)
reference dose =	chemical-specific reference dose (mg/kg-day)
W =	16 kg (5-year-old child)
I =	0.2 g/day

For noncarcinogens in water:

$$C_w = [\text{reference dose} \times 70\ \text{kg}]/[2\ \text{L/day}] \quad (4)$$

Where

C_w =	risk-based concentration in water (mg/L)
reference dose =	chemical-specific reference dose
W =	70-kg adult
I =	2 L/day

In order to take into account multiple noncarcinogenic contaminants in an individual pathway, divide the cleanup level obtained using the above equations by the number of contaminants. For example, if there are five soil contaminants, then first calculate the cleanup level for each contaminant using equation (3) above. Then divide each cleanup level by 5 to derive a cleanup level that does not exceed a combined hazard index of 1.0 for soil ingestion.

EQUATIONS FOR CARCINOGENIC CONTAMINANT EFFECTS

For carcinogens, the following general equation should be used to calculate risk-based concentrations:

$$C_m = [R \times W \times LT]/[CSF \times I \times ED] \quad (5)$$

Where

C_m =	risk-based concentration in medium (units are medium-dependent)
R =	assumed risk level (dimensionless)(10^{-6} target risk level)
W =	body weight (kg)
LT =	assumed lifetime (years)
CSF =	chemical-specific cancer slope factor
I =	intake assumption (units are medium-dependent)
ED =	exposure duration (years)

This general equation is modified to calculate risk-based cleanup levels in air, soil, and water as follows:

For carcinogens in air:

$$C_a = [R \times 1{,}000 \mu g/mg \times 70\ yr \times 70\ kg]/[CSF \times 20\ m^3/day \times 70\ yr] \quad (6)$$

Where

C_a =	risk-based concentration in air ($\mu g/m^3$)
R =	10^{-6} or 10^{-5}
W =	70-kg adult
LT =	70-year lifetime
CSF =	chemical-specific cancer slope factor
I =	20 m^3/day
ED =	70-year exposure duration

For carcinogens in soil:

$$C_s = [R \times 70\ kg \times 70\ yr]/[CSF \times 0.1\ g/day \times 0.001\ kg/g \times 70\ yr] \quad (7)$$

Where

C_s =	risk-based concentration in soil (mg/kg)
R =	10^{-6} or 10^{-5}
W =	70-kg adult
LT =	70-year lifetime
CSF =	chemical-specific cancer slope factor
I =	0.1 g/day
ED =	70-year exposure duration

For carcinogens in water:

$$C_w = [R \times 70\ kg \times 70\ yr]/[CSF \times 2\ L/day \times 70\ yr] \quad (8)$$

Where

C_w =	risk-based concentration in water (mg/L)
R =	10^{-6}
W =	70-kg adult
LT =	70-year lifetime
CSF =	chemical-specific cancer slope factor
I =	2 L/day
ED =	70-year exposure duration

In order to take into account multiple carcinogenic contaminants in an individual pathway, the above equations can be modified by substituting an adjusted target risk level (R). If R = 10^{-7} instead of 10^{-6}, the resulting cleanup levels will yield an overall target risk of 10^{-6} if there are 10 or fewer chemicals. Cleanup levels are still calculated for individual contaminants, but these individual contaminant levels are adjusted to account for the presence of multiple contaminants. This adjustment can be made in the same way for all three of the above equations.

APPENDIX 2

IDENTIFYING EXPOSURE PATHWAYS
TWO EXAMPLE SITES

IDENTIFYING EXPOSURE PATHWAYS: TWO EXAMPLE SITES

To illustrate the identification of exposure pathways and receptors, two examples of typical sites are described below.

EXAMPLE No. 1: MILL SITE

This hypothetical mill, located on the banks of a major river, historically allowed effluent from dye processes to discharge directly to the river. The site has extensive soil contamination, and contaminated groundwater beneath the site discharges into the river. Sediment sampling in the river adjacent to the site has shown contamination. Baseball playing fields are located on the northeast portion of the site property, several residences are located near the site, and a park is proposed for development along the river near the site.

The potential exposure pathways and receptors likely to be of concern at the mill site are identified by evaluating the information provided in Table 1 (on page 7) and reviewing the land uses and other features of the site and vicinity:

Potential Human Exposure Pathways at the Site

- Incidental ingestion of soil
- Dermal contact with soil
- Inhalation of contaminated dust particles in the air
- Ingestion of groundwater
- Recreational contact with the river
- Ingestion of contaminated fish from the river

Potential Ecological Exposure Pathways at the Site

- Contact with contaminated soils
- Contact with contaminated surface water and sediments in the river
- Ingestion of contaminated surface water and sediments in the river
- Inhalation of contaminated dust particles in the air
- Ingestion of contaminated soil

- Ingestion of contaminated vegetation
- Ingestion of contaminated prey

Potential Human Receptors at the Site

- Children playing in yards, playgrounds, or schools in the vicinity of the site coming into contact with the site soil
- Nearby residents or site workers who could inhale dust generated by disturbed soils on the site
- Nearby residents or site workers using groundwater or surface water as drinking water
- Recreational users of the river (for fishing, boating, or swimming) who contact contaminated water or sediments or eat fish caught in the river

Potential Ecological Receptors at the Site

- Fish, amphibians, insects, and invertebrates in the river ingesting and respiring in contaminated sediments and water
- Plants growing in contaminated soil or water
- Birds and other animals eating fish and drinking from the river
- Herbivores consuming contaminated vegetation
- Benthic organisms contacting contaminated sediments and water in the river
- Predators consuming contaminated prey

EXAMPLE No. 2: HYPOTHETICAL LANDFILL SITE

Potential exposure pathways at a hypothetical municipal landfill located near a residential development, a public school, and a stream are illustrated in Figure 2-1. Typical sources of contamination at landfills include emissions to air, leaching to groundwater, and subsurface gas formation and migration.

The following potential exposure pathways and receptors of concern at the hypothetical landfill site are:

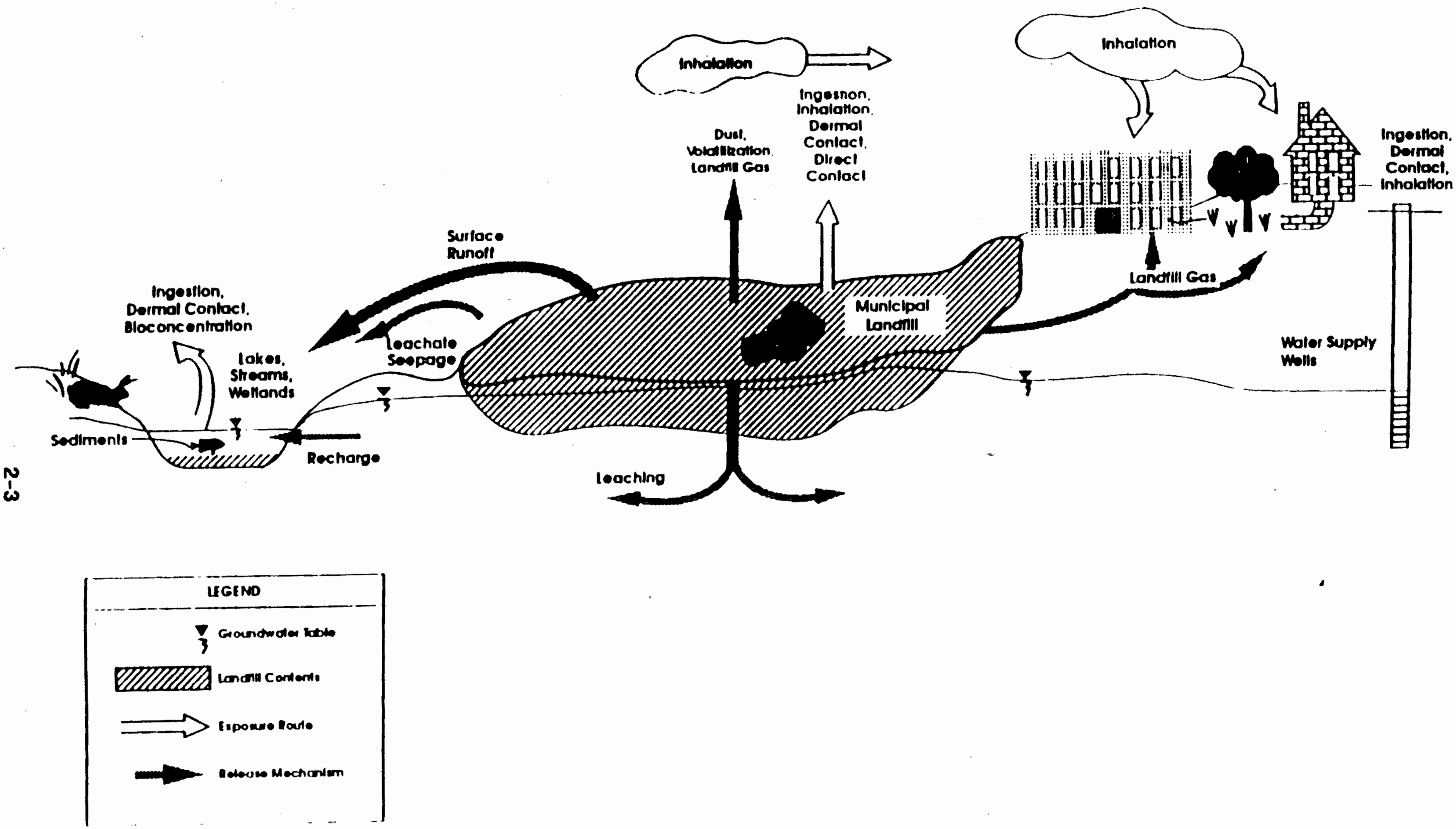

FIGURE 2-1

SCHEMATIC DIAGRAM OF HYPOTHETICAL LANDFILL SITE

Potential Human Exposure Pathways at the Site

- Inhalation of contaminated dust particles in the air
- Inhalation of volatile contaminants in vapors and gases
- Ingestion of groundwater
- Recreational contact with the nearby stream
- Ingestion of contaminated fish from the nearby stream

Potential Ecological Exposure Pathways at the Site

- Inhalation of contaminated dust particles in the air
- Inhalation of volatile contaminants in vapors and gases
- Ingestion of contaminated surface water
- Contact with contaminated sediments and surface water in the stream
- Ingestion of contaminated vegetation
- Ingestion of contaminated prey

Potential Human Receptors at the Site

- Children at the school inhaling contaminants
- Nearby residents inhaling contaminants in air and ingesting and inhaling contaminants in drinking water
- Recreational users of the nearby stream for wading, swimming, or fishing

Potential Ecological Receptors at the Site

- Vegetation growing in contaminated soil
- Fish swimming in the stream
- Other aquatic organisms in contact with sediments and surface water in the stream
- Terrestrial animals in contact with stream water
- Terrestrial animals feeding on aquatic organisms
- Biota in the wetland ecosystem

The hypothetical landfill shown in Figure 2-1 illustrates multiple exposure pathways. At this site, groundwater that is a source for domestic wells is contaminated with volatile organic compounds. In a residential setting an individual using water from a contaminated well could be exposed to these volatile contaminants by three pathways:

- Ingestion of contaminated water
- Inhalation of volatile contaminants during showering and other household activities
- Dermal contact with contaminated water during showering and other household activities

A risk assessment specialist can assist in determining the significance of the potential exposure pathways and the need for adjustment of the cleanup levels to account for multiple pathways.