United States Environmental Protection Agency
Region 5
Waste, Pesticides, and Toxics Division

Risk Management Strategy for Corrective Action Projects

EPA Region 5 RCRA Program

MAY 2005

NOTICE

The procedures described in this U.S. EPA Region 5 **Risk Management Strategy for Corrective Action Projects** are provided as guidance and recommendations primarily for Project Managers in the RCRA Corrective Action program. It is intended to apply to RCRA corrective action investigations and remedial decisions on sites/facilities for which Region 5 is the lead agency.

This Strategy does not create any new regulatory compliance requirements and does not supersede any applicable Federal or state statutory or regulatory requirements. The Strategy does not impose legally binding requirements on EPA, the states, or regulated entities. Region 5 may decide that the Strategy is not applicable at a particular site/facility or part of a site/facility due to specific circumstances. The Strategy should be used in conjunction with formal corrective action agreements that apply at a site/facility, such as a permit, unilateral order, consent order, voluntary agreement, etc.

The Strategy is based in part on several U.S. EPA technical guidance and policy documents which Region 5 has incorporated into the Strategy. All decisions regarding corrective action at a particular site/facility will be made based on the applicable statutes and regulations.

Interested parties are free to raise questions about the appropriateness of any recommendation or policy in the Strategy with respect to a particular site/facility. After reviewing such questions, Region 5 will consider whether or not the recommendations in the Strategy are appropriate to apply.

The Strategy may be revised and updated at any time to reflect the Region's experience in implementing the Strategy or in response to questions and comments received from the States, regulated entities, and the public.

CONTENTS

Page

Acronyms v

Chapter 1: Introduction..... 1

Section 1: Requirements and challenges of the RCRA Corrective Action program
Section 2: Reforms in the RCRA Corrective Action Program
Section 3: Decision-making Based on Risk Management
Section 4: When are risk management decisions made?

Chapter 2: What is the Purpose of the Region 5 RCRA Risk Management Strategy? 5

Section 1: What are the responsibilities of the RCRA Project Manager?
Section 2: Are there other participants who could contribute to risk management decisions?

Chapter 3: Starting down the road to Risk Management decisions - the Conceptual Site Model ... 7
Section 1: Facility Profile
Section 2: Physical Profile
Section 3: Release Profile
Section 4: Land Use and Exposure Profile
Section 5: Ecological Profile
Section 6: Risk Management Profile

Chapter 4: Applying "Priority Factors" for Making Risk Management Decisions 11

Section 1: Phase 1 - Initiate Site Characterization and Risk-Based Ranking 11

1.1: Land Use Decisions
1.2: Groundwater Use and Groundwater Classification
1.3: Data Quality Objectives
1.4: Human Health Risk-Based Screening
1.5: What is Risk Screening?
1.6: Which environmental media, receptors, and land uses are appropriate to consider for risk-based screening?
1.7: Are there land uses and receptors for which risk screening should not be applied?
1.8: What risk ranking categories should be used?
1.9: When should the risk-based screening be initiated?
1.10: How should the risk-based screening be carried out?
1.11: Ecological Risk-Based Screening
1.12: Which environmental media, receptors, and land uses are appropriate to consider for ecological risk-based screening?
1.13: Are there land uses and receptors for which ecological risk screening should not be applied?

Page

1.14: When should the ecological risk-based screening be initiated?

Section 2: Phase 2 - Complete the Site Characterization and Risk Evaluation 25

2.1: Address the high risk release locations
2.2: Select and plan Interim Measures
2.3: Site-specific risk assessment
2.4: Ecological risk assessment
2.5: Risk Evaluation Report

Section 3: Phase 3 - Remedy Selection to Achieve Site-wide Risk Management Goals 32

3.1: Human Health Risk Goals
3.2: Ecological Risk Management Goals
3.3: Source Control
3.4: Removal / Reduction
3.5: Engineered Controls
3.6: Monitored Natural Attenuation of Chemical Contaminants
3.7: Institutional Controls
3.8: Risk Management Plan

Chapter 5: Relationship between the Risk Management Strategy and State RCRA Corrective Action Authority 48

Attachment 1: Criteria for determining compliance with Toxic Substances Control Act (TSCA) regulations at a RCRA site found to have PCB contamination..... 50

Attachment 2: Region 5 RCRA program policy on the use of occupational standards for evaluating concentrations of chemical constituents in indoor air 54

Attachment 3: EPA's Expectations for Final Corrective Action Remedies..... 55

EXHIBIT 1: Performing risk-based screening of surface soil data 58

EXHIBIT 2: Performing risk-based screening of groundwater and surface water data..... 60

ACRONYMS

ANPR - *Advanced Notice of Proposed Rulemaking*
AOC - Area of Concern
BTSC - Brownfields Technology Support Center (EPA)
CMS - Corrective Measures Study
CSGWPP - Comprehensive State Ground Water Protection Program
CSM - Conceptual Site Mode
CWA - *Clean Water Act*
DAF - Dilution-Attenuation Factor
DERA - Detailed Ecological Risk Assessment
DQO - Data Quality Objective
EI - Environmental Indicator
ESL - Ecological Screening Level
GPRA - *Government Performance and Results Act*
HI - Hazard Index
HQ - Hazard Quotient
IC - Institutional Control
IEUBK - Integrated Exposure Uptake Biokinetic Model
IM - Interim Measure
J&E - Johnson and Ettinger
MCL - Maximum Contaminant Level
MNA - Monitored Natural Attenuation
MOU - Memorandum of Understanding
NAPL - Non-Aqueous Phase Liquid
NCP - *National Oil and Hazardous Substances Pollution Contingency Plan*
NHANES - *NATIONAL HEALTH AND NUTRITION EVALUATION SURVEY*
ORD - Office of Research and Development (EPA)
OSHA - Occupational Safety and Health Administration
OSWER - Office of Solid Waste and Emergency Response (EPA)
PBT - Persistent and Bioaccumulative Toxic
PCB - Polychlorinated Biphenyl
PCOC - Potential Contaminant of Concern
PEL - Permissible Exposure Limit
PERA - Preliminary Ecological Risk Assessment
PM - Project Manager
PRG - Preliminary Remediation Goal
QAPP - Quality Assurance Project Plan
RCRA - *Resource Conservation and Recovery Act*
RFI - RCRA Facility Investigation
RP - Responsible Party
SERA - Screening Ecological Risk Assessment
SWMU - Solid Waste Management Unit
TEQ - Toxic Equivalence
TSCA - *Toxic Substances Control Act*
UCL - Upper Confidence Level
WPTD - Waste, Pesticides and Toxics Division

CHAPTER 1: Introduction

Section 1: Requirements and challenges of the RCRA Corrective Action program

When the Resource Conservation and Recovery Act (RCRA) was enacted in 1976 and regulations went into effect in 1980, thousands of industrial facilities that handle hazardous waste became subject to new federal regulations. The RCRA regulatory structure with its emphasis on “cradle to grave” management of waste has helped ensure that hazardous waste generated from ongoing industrial operations is properly managed and does not contribute to a future generation of toxic waste sites. Important regulations were put in place for the proper handling and disposal of hazardous waste and for imposing permit compliance requirements on facilities that generate, store, treat, and dispose hazardous waste.

In addition to waste handling and permit requirements, the Hazardous and Solid Waste Amendments of 1984 gave EPA the authority to impose corrective action requirements for solid waste management units (SWMUs) and other areas of concern (AOCs) at facilities where a hazardous waste treatment, storage or disposal unit was operated after 1980. More than 5000 facilities were estimated to be subject to RCRA corrective action authority. Many of these facilities had existing soil and groundwater contamination resulting from historical waste management practices. The degree of investigation and corrective action necessary to protect human health and the environment varies significantly across these facilities. Some facilities were recognized as requiring no remediation or only minor action, while many were found to be as complex and highly contaminated as any Superfund site.

Over the last decade, general consensus was reached among Congress, the EPA, state agencies, facility owners, and concerned citizens that the pace and progress of RCRA remediation decisions must be increased and streamlined. In reviewing the program, EPA and other stakeholders identified several factors that were impeding timely and cost-effective remediation. In some instances, RCRA site investigations and remedial decisions were perceived as being hampered by an emphasis on process steps and a lack of clarity in remedial objectives. An additional complication is the actual or perceived impediments to site remediation created by the application of certain RCRA requirements, such as the land disposal restrictions, minimum technological requirements, and permit application and review.

Section 2: Reforms in the RCRA Corrective Action Program

In an effort to address the key impediments to timely site investigation and remediation, EPA announced an initiative called the “RCRA Cleanup Reforms.” The purpose of the reforms is to enhance RCRA program flexibility and spur progress toward faster and more efficient site investigation and remedial decisions. The key reforms are:

- Foster maximum use of program flexibility and practical approaches through training and outreach, and by issuing new results-oriented site investigation and remedial guidance containing more clearly defined objectives.

- Promote the guidance for program flexibility and streamlined remedial approaches that EPA described in the “*Advanced Notice of Proposed Rulemaking*” (*ANPR*) on corrective action at RCRA regulated facilities.

- Promote and implement Environmental Indicator (EI) determinations at RCRA sites. EPA has established two short-term EI goals for the RCRA Corrective Action program. These goals were developed in response to the *Government Performance and Results Act* (*GPRA*) and apply to RCRA facilities that EPA and the states have identified as high priority sites. The purpose of short-term EI goals is to provide evidence that the current conditions at a RCRA site are not causing significant human health risks. The goals require that by the end of 2005, EPA and the states will document that 95 percent of approximately 1700 RCRA facilities will have "current human exposures under control,"

and 70 percent of these facilities will have "migration of contaminated groundwater under control." The long-term goal of the program is to achieve final remediation at all RCRA corrective action facilities.

- Promote “results-based” approaches for RCRA corrective action. EPA will favor and accept results-based approaches that emphasize outcomes and eliminate reliance on unnecessary process steps. Results-based approaches should be accepted in order to meet the GPRA goals and to move facilities toward the ultimate goal of achieving final remediation. Results-based approaches include setting clearly understood cleanup standards, providing procedural flexibility in how goals are met, inviting innovative technical approaches, and allowing facility owners to undertake cleanup action with reduced agency oversight when appropriate. Under such approaches, owners focus on environmental results and the most technologically efficient means of achieving them while still being held fully accountable.

- Promote the RCRA Brownfields Initiative (1998). The goal of the Initiative is to encourage the reuse of potential RCRA Brownfields so that the affected land better serves the needs of the community either through more productive commercial or residential development or as greenspace /recreational space. (A potential RCRA Brownfield is a RCRA facility or portion of a RCRA facility that is not actively managed or not in full use, and where there is redevelopment potential. For most of these sites, reuse or redevelopment has been slowed due to factors such as: real or perceived concerns about actual or potential chemical contamination, legal liability for new property owners, and RCRA cleanup requirements.)

  Preparing Brownfield sites for productive reuse through corrective action requires the integration of many elements - financial issues, community involvement, liability considerations, risk assessment. The cleanup strategy must integrate the concept of risk management into the overall redevelopment process. The risk assessment will be affected by the planned reuse of the property. Since cleanup strategies will vary from site to site, the challenge is to clean up sites in accordance with redevelopment goals in a way that benefits communities and local economies. Meeting this challenge for land reuse is Agency policy as articulated in various guidance documents and memos.

  EPA’s Land Revitalization Initiative is sponsored by OSWER. Region 5 has a Land Revitalization Team (including a Team Leader, a Superfund Brownfields coordinator, and a RCRA Brownfields coordinator) which is available to assist with strategies for working with communities on the non-technical issues, such as how to include local interests in redevelopment/reuse strategies. For technical information, EPA-ORD maintains a Brownfields Technology Support Center (BTSC). The BTSC can provide information about specific technologies or types of technologies for use during site investigation and cleanup activities. Included are field-based measurement techniques, off-site analytical techniques, and innovative or conventional techniques for cleaning up contaminated soil or groundwater at a site. The BTSC can identify applicable technologies and provide brief analyses of their potential advantages and limitations in light of site-specific features and needs.

Key references:

RCRA Cleanup Reforms: Faster, Focused, More Flexible Cleanups (EPA530-F-99-018; July 1999) http://www.epa.gov/osw

RCRA Cleanup Reforms - Reforms II: Fostering Creative Solutions (EPA 530-F-01-001; Jan. 2001) http://www.epa.gov/osw

Approaches and Tailored Oversight Guidance for Facilities Subject to Corrective Action Under Subtitle C of the Resource Conservation and Recovery Act (EPA 530-R-03-012; Sept. 2003)

http://www.epa.gov/epaoswer/hazwaste/ca/resource/guidance/gen_ca/reslt-bse.pdf

Advance Notice of Proposed Rulemaking: Corrective Action for Releases from Solid Waste Management Units at Hazardous Waste Management Facilities (Fed. Reg. 61: 19432, May 1, 1996). http://www.epa.gov/docs/fedrgstr/EPA-WASTE/1996/May/Day-01/pr-547.pdf

Partial Withdrawal of the May 1, 1996 Rulemaking Proposal. (Fed Reg.64, 54604, October 7, 1999). http://www.epa.gov/fedrgstr/EPA-WASTE/1999/October/Day-07/f26070.htm

Government Performance and Results Act (http://www.epa.gov/ocfo/planning/gpra.htm)

Interim Final Guidance for RCRA Corrective Action Environmental Indicators (Feb. 1996) http://www.epa.gov/epaoswer/correctiveaction/eis/ei_guida.pdf

RCRA Brownfields Overview (http://www.epa.gov/swerosps/rcrabf/overview.htm)

Brownfields Technology Support Center (http://www.brownfieldstsc.org)

Section 3: Decision-making Based on Risk Management

In the previous section, EPA's *ANPR* for corrective action was mentioned as a major item under the RCRA reforms initiative. After publishing the *ANPR*, the Agency later decided not to rely heavily on the rulemaking process for corrective action, but designated the *ANPR* as "the primary corrective action implementation guidance." In the *ANPR*, EPA outlined a few basic operating principles that it believed should be implemented to accomplish flexible and results-based corrective action. The principles were referred to as the "Program Management Philosophy" for implementing corrective action. The major principles are:

- **Corrective action decisions should be based on risks to human health and the environment. Remedial decisions for a site are now recognized fundamentally as risk management decisions.** EPA, the states, and facility owners will be making decisions to eliminate risks, control exposure, and reduce potential future risk. The risk management decisions will cover human health risks and risks and threats to the environment. Risks to the environment will be addressed through ecological risk assessment which can include analysis and protection of wildlife, natural habitats, and environmental resources (e.g., watersheds, surface water, and sediments).

- Interim actions and stabilization to reduce or prevent chemical releases are also risk management decisions. Finding, stabilizing, and controlling existing sources of chemical releases should be the early focus of a site investigation project.

- The site investigations should focus on how to get meaningful results. The purpose of the program should be to stabilize releases, cleanup releases, and reduce or eliminate risks in a timely manner. The program implementers should focus on getting results rather than fulfilling standardized process steps.

Section 4: When are risk management decisions made?

As a result of the implementation of the *ANPR* and the *RCRA Cleanup Reforms*, the major application points for risk management decisions during the corrective action for a site are:

- EI determinations - to meet the Region 5 RCRA program commitments under the GPRA; these determinations formally apply only to the current site conditions and primarily for human health risks. Ecological risk evaluation applies if contaminated groundwater is discharging to surface water.

- Decisions to perform interim actions or take stabilization measures - actions to reduce or prevent significant chemical releases from a source of waste or to prevent significant potential chemical migration from one environmental media to another. These decisions could be made at any time during the site investigation process.

- Final remedial decisions - the final decisions that apply to an entire site. These are the decisions that apply to current conditions and also address reasonably foreseeable future conditions. These decisions address remediation of both human health risk & ecological risk/ecological damage. They are referred to as final remedial decisions even if implementation of the decisions occurs in multiple phases.

CHAPTER 2: What is the Purpose of the Region 5 RCRA Risk Management Strategy?

EPA's national program goals and the emphasis on promoting program flexibility and results-based approaches for conducting corrective action projects were outlined above. The concept that all important site remedial decisions are risk management decisions were also introduced. Based on these ideas, the Region 5 RCRA program decided to develop a single guidance that would be suitable as an approach for making risk management decisions at any RCRA corrective action site. Consequently, the objectives of this Strategy are:

- To provide a unified guidance and a "coaching tool" that a Project Manager (PM) can follow to design a site investigation and compile the critical site related information that will allow for timely and transparent risk management decisions.

- To assist a PM in collecting and organizing the essential information needed to recommend appropriate risk management decisions.

- To recommend a practical sequence or time-line of site investigation activities which will support efficient risk management decisions;

- To explain the fundamental risk management policies and preferences that the Region 5 RCRA program will apply for making risk management decisions.

The primary application of the Strategy is for RCRA corrective action sites. However, it is anticipated that parts of the Strategy could be useful for other personnel in the Waste, Pesticides and Toxics Division (WPTD) who make decisions that fall in the category of risk management. This would include project managers and staff in the Underground Storage Tank program and the Toxics Program.

It should be noted that this Strategy does not provide in-depth technical details for how to perform the site investigation and data collection and does not eliminate the need to refer to and use the EPA technical guidance that already exists.

Section 1: What are the responsibilities of the RCRA Project Manager?

For RCRA corrective action projects in Region 5, the site PM takes a lead role in oversight of a project by reviewing plans and making recommendations to the RCRA Corrective Action Program Manager on major site decisions, including how the site investigation should be conducted and what site-specific interim and final remedial decisions should be made. The major PM responsibilities include:

- Defining the scope of the corrective action project needed for a specific site to fulfill the original enforcement order, permit, or consent agreement;

- Setting up internal "briefing" meeting(s) with other EPA staff to introduce the project and start defining project information needs; lining up technical support from other Region 5 staff as needed (e.g., analytical chemist/QA specialist; risk assessment specialists; hydrogeologist; public affairs specialist)

- Setting up meeting(s) with the facility owner/operator who is the Responsible Party (RP) for the site; explaining EPA's needs and requirements for making site decisions; leading discussions with the RP to define project information needs and the time line for proceeding (as a follow-up to the original order or permit);

- Providing oversight on the RP's site investigation and the technical reports that document the

progress of the investigation;

- Providing oversight on the RP's conduct of the required public participation activities for the site; determining the level of public interest in the site and recommending additional voluntary public participation activities by the RP;

- Responding to citizen questions about RCRA regulations and the site investigation;

- Filling out site EI forms or reviewing EI forms submitted by an RP.

- Presenting alternatives and recommendations on the following important site activities and decisions: a) public participation activities that should be undertaken by EPA (e.g., fact sheets, information meetings; health agency consultations); b) EI decisions; c) Interim Measures decisions; and d) final remedial decisions and the Statement of Basis for a site. The RCRA Corrective Action Program Manager will evaluate the alternatives, the PM's recommendations and make site decisions, including how the site investigation should be conducted, what site-specific interim measures are needed and the basis for the final risk management determination.

- Providing oversight on the RP's implementation of the Interim Measures decisions and the final remedial decisions for the site.

Section 2: Are there other participants who could contribute to risk management decisions?

EPA guidance and practice recommend that the PM and the Program Managers should accept or seek input from a number of additional sources as part of the process of risk management decision making. These sources could be regarded as participants in the risk management decision process but not as the decision maker for the corrective action. The following groups or entities should be regarded as the most appropriate participants:

- The RP - in particular, the "on-site" project manager who is the RP's representative; this individual promotes the interests of the RP in the overall project; provides direct management of the RP's site investigation; explains the RP's future land use plans and economic interests in the site; explains and promotes the RP's favored options for remedial decisions at the site;

- The public - in particular citizens living in the vicinity of a site under investigation. Citizens can influence a site investigation by: providing additional information on site operational history and possible chemical release locations; providing additional information on local land uses, groundwater well locations, and potential chemical exposure scenarios; expressing concern over the completeness or limitations of the RP's investigation.

- Government agencies (state, local, other Federal agencies, other EPA programs) and non-governmental organizations. These agencies and organizations may provide information that the PM and RP should consider in planning and implementing the site corrective action. They may have significant interest or information regarding: a) the current and future use(s) of the land and groundwater at a specific RCRA site or the areas surrounding the site; b) the nature of releases or environmental conditions of the site or adjacent sites that may have impacted a RCRA site; c) regulatory requirements needed to implement remedies - including establishing, monitoring, and enforcing institutional controls; d) the presence of threatened or endangered species or critical habitats; and e) remedial options which could be perceived as having an influence that goes beyond the site boundaries. The typical list of entities includes: the State environmental agencies or health departments; the EPA Superfund program; the State and Federal fisheries and natural resource agencies; the U.S. Army Corps of Engineers; local municipalities; regional planning authorities; and environmental organizations.

CHAPTER 3:

Starting down the road to Risk Management decisions - the Conceptual Site Model (CSM)

In the *ANPR* for corrective action, EPA stated that site investigations and remedy decisions are most successful when based on a "conceptual site model." A CSM is a multi-dimensional picture of site conditions that conveys what is known about the chemical contaminant sources, contaminant release and transport mechanisms, chemical fate and transport pathways, chemical exposure pathways and exposure scenarios; and ultimately, the quantitative estimation of health and ecological risks.

The CSM is based on information available at any time and will evolve as new information becomes available. It should be used as a starting point for identifying known and potential contaminant source locations, for deciding where the analytical sampling of media should be performed to test for contaminant releases, and to make logical deductions on how and where contaminant releases could migrate. The initial version of the CSM can often be drawn from the traditional RCRA Facility Assessment and its supporting material. At the beginning stage, the CSM should be used to compile all relevant site information and to begin identifying the scope of the subsequent site sampling and characterization investigation. The CSM should be documented by focused written descriptions of site conditions (e.g., adapted from the RCRA Facility Assessment) and supported by visual documentation such as maps, diagrams, and data tables.

After the CSM is initiated, the PM and the RP should discuss the relevance and quantity of additional information to be included as the site investigation proceeds. Six categories of information should be included as the CSM is developed. **It is not necessary for the PM and the RP to regard each category as requiring a new formal written document. Rather, it is expected that the categories and the recommended information in each category should serve as placeholders or "check lists" to cover the information and analysis that the site investigation needs to accomplish.**

The recommended categories are:

Section 1: Facility Profile

The facility profile should provide information on potential source areas and identify buildings or process structures that could affect sampling decisions for the site investigation. The locations of facility structures and their links to chemical handling processes are important in identifying contaminants of potential concern that will need to be addressed in the Data Quality Objectives and the risk evaluation. The location of property boundaries can be important for evaluating land use determinations.

The facility profile should describe all important existing man-made features on the site, including: facility buildings; chemical process areas; solid waste management units (SWMUs); property boundaries; and historical features that are no longer present but may have impacted historical releases (e.g., demolished process buildings, storage tank locations; earth-filled trenches).

Section 2: Physical Profile

The physical profile should concentrate on the important environmental setting information that is applicable even if detailed data on the chemical releases are not yet available. The physical profile information will be integrated later with information from the release profile to describe the behavior of contaminants in the environment. The initial development of the physical profile will begin with some

preliminary understanding of the environmental setting. Data gaps can than be identified and used to design future investigations.

The physical profile describes the factors that may affect releases, fate and transport, and receptors, including:

- topographical features, such as hills, gradients, surface vegetation or pavement
- surface geology including soil types and parameters, outcrops, and faulting
- subsurface geology including stratigraphy, continuity, and connectivity
- hydrogeologic information identifying the water-bearing zones, hydrologic parameters, and impermeable strata
- soil boring and monitoring well logs and locations
- surface water features such as drainage routes, surface water bodies, wetlands, and watershed parameters and characteristics

Section 3: Release Profile

A Release Profile will be developed over time as information is obtained. At the beginning of the CSM, the release profile may consist only of the potential source locations. As the CSM undergoes development, the profile should contain site-specific information on release locations and characteristics. The contaminant migration and fate and transport aspects of the release profile should be integrated with the geologic and hydrogeologic information developed for the physical profile.

The release profile should describe the nature of the contaminants in the environment, including the following:

- identification of potential source locations and source materials;
- identification of contaminants of potential concern;
- source locations where a release has been confirmed;
- soil sampling and groundwater monitoring well locations;
- delineation of the area of contamination;
- analytical sampling data on the concentration of contaminants of concern in a release;
- migration routes and mechanisms;
- rationale for selecting fate and transport models and results of the modeling;

Section 4: Land Use and Exposure Profile

The PM and the RP should begin by evaluating the types of land use and determining beneficial resources on and around the facility. In addition, information on potential receptors locations (such as surface water bodies, water wells, and residences) should be incorporated. For example, the identification of surface water bodies at locations in the assessment area indicates the potential for exposure from drinking water, water recreation, and fishing consumption. Receptor information also can be important in demonstrating potentially complete or incomplete exposure pathways for the risk

evaluation.

In the risk evaluation, the land use information is reviewed to determine the applicable exposure scenarios for the facility and surrounding off-site properties. The determination of appropriate exposure scenarios is also addressed. After this review is completed, the applicable exposure scenarios should be incorporated into the CSM. If on-site or off-site land use changes, the land use profile and CSM should reflect those changes.

The land use and exposure profile consists of information used to identify and evaluate the applicable exposure scenarios and receptor locations, including:

- land use on-site at the facility and off-site in nearby adjacent properties, emphasizing specific uses (industrial/production, non-production open land, single-family homes, wood lands, park lands, agriculture, etc.)
- beneficial resource determination (groundwater classification, natural resources, wetlands, etc.)
- resource use locations (water supply wells, surface water intakes, etc.)
- significant off-site landmark types and receptor locations (schools, hospitals, daycare centers)
- applicable exposure scenarios (residential, industrial, recreational, farming, etc.)
- applicable exposure pathways identifying the specific sources, release and migration mechanisms, exposure media, exposure routes, and receptors

Section 5: Ecological Profile

The ecological profile consists of information concerning the physical relationship between the developed and undeveloped portions of the site, the use and level of disturbance of the undeveloped property, and the type of ecological receptors present in relation to completed exposure pathways. The information captured in the ecological profile will be critical in completing the ecological risk-based screening and the site-specific ecological evaluation.

The following information should be included in the ecological exposure profile (some applicable information may already be available from other CSM profiles):

- description of the undeveloped property zones on-site and adjacent to the site, including but not limited to - sensitive environmental areas (federal/state parks and protected areas) habitat types (wetland, grass land, forest, pond, stream, etc.), primary ecological uses, degree and nature of historical disturbances, locations of drainage ditches, creeks, and landfill areas
- description of site receptors in relation to habitat type, including but not limited to - endangered or protected species, mammals, migratory and native birds, fish, etc.)
- description of relationship of releases to potential habitat areas - suspected or known contaminants of concern, media contaminated, sampling data summary, potential or likely routes of migration or exposure of potential receptors

Section 6: Risk Management Profile

The risk management profile summarizes and illustrates the ultimate outcomes of the site investigation. It

will summarize the relationship between the human health and ecological risk evaluations, the EPA risk management goals, and the selected risk management decisions/remedies. During the development of the preliminary CSM, this profile will serve as a placeholder. As the facility progresses through the site investigation, the information contained in the risk management profile will be augmented and refined and will ultimately explain the specific risk management decisions that were made for the site.

The risk management profile should include the following:

- summary of the risk evaluations for human health and ecology
- summary of the chemical release situations that require risk management actions and remedies
- summary of the selected remedies and how they accomplish the required risk management

The following references provide guidance and more detailed information that can be consulted for developing a CSM, including useful data "fill-in" sheets and a case study that illustrates the development of a CSM.

Key References:

Region 6 Corrective Action Strategy (Nov. 2000)
www.epa.gov/earth1r6/6pd/rcra_c/pd-o/riskman.htm

Soil Screening Guidance: User's Guide (U.S. EPA Publication 9355.4-23; April 1996)
http://www.epa.gov/superfund/resources/soil/index.htm#user

Soil Screening Guidance: Technical Background Document (U.S. EPA Publication EPA/540/R-95/128; May 1996) http://www.epa.gov/superfund/resources/soil/toc.htm

CHAPTER 4: Applying "Priority Factors" for Making Risk Management Decisions

Chapter 3 described the EPA concept that a CSM should be developed to summarize all of the important information concerning chemical releases, chemical migration and transport, risk evaluation to receptors, and risk management remedies. However, the construction of a full CSM could appear to be daunting and complicated task, and a plan for developing a CSM was not described.

The Region 5 RCRA program believes that the information needed to complete the CSM and for making risk management decisions can be obtained by applying a reasonable set of "Priority Factors." The Priority Factors represent the major information sources, evaluation exercises, and policy preferences that should be applied to a site investigation. The results of applying these factors can be incorporated directly into the CSM. In addition, the Priority Factors can be utilized by the PM and/or the RP in an approximate sequence that will benefit accomplishing the site investigation and the risk management decision-making for any site.

Some of the Priority Factors also contain the risk management policy preferences that the R5 RCRA program will apply to accomplish certain risk management decisions for a site.

Section 1: Phase 1 - Initiate Site Characterization and Risk-Based Ranking

The Priority Factors designated as Phase 1 should be applied to accomplish the initial or preliminary site investigation and to identify all of the high risk chemical release situations that need immediate or expedited attention.

1.1: Land Use Decisions

Both the ANPR and Superfund program guidance have recognized current and future land use as important early decision points that will affect the ultimate risk management decisions for a site. Land use decisions are of fundamental importance because they affect the risk evaluation to be performed for the site and the risk management decisions about the contaminant cleanup goals and the levels of residual contaminants that can be left in place. Early in the site investigation, the PM should develop a preliminary land use summary that could be subject to change after further discussion with the RP.

The basic technical information that is needed for making land use determinations was already summarized above in Chapter 3 under the heading "Land Use and Exposure Profile." In addition to the technical information needed for the CSM, the following factors about land use should be considered or reviewed since they could affect the risk evaluation procedures and could entail professional judgment on the part of the PM.

- The fundamental concept is that the Region 5 RCRA program will recognize that RCRA sites have been historically industrial and that many sites will remain industrial. For many RCRA sites where the prevailing evidence is that the current industrial use will be continued by the existing owner/operator, the decision to accept the RP's claim that future land use will be industrial is relatively straightforward.
- An RP's assertion that land use will remain industrial will likely trigger the need for land use institutional controls and/or land use covenants that will need to be imposed on the RP's property through deed notices, State authorized deed restrictions, a Region 5 enforcement order/permit condition or some combination of these mechanisms.

- For many historically industrial sites, the future land use situation may change because of economic conditions and/or property taxation. RPs may want to convert existing facilities into multiple land parcels for sale to new owners, lease to new users, or donation to a municipality or non-profit organization for recreational use or ecological habitat. EPA encourages these decisions which result in redevelopment and revitalization of property as part of the RCRA Cleanup Reforms. In some cases, the redevelopment of the property may be a driving force for the RP to conduct the site investigation. For these situations, the claims and assertions about future land use should be carefully reviewed.
- For many large industrial sites, a single future land use designation may not be warranted. For example, parts of a facility not historically used for industrial operation (e.g., set back lands) may not be logical to consider as only for future industrial use. PMs should raise questions about considering alternate future uses such as residential, commercial, recreational, and ecological habitat. And RPs should be encouraged to seek the widest range of future uses consistent with EPA's promotion of redevelopment and revitalization. Therefore, the PM should collect and review a wide range of information for the site - historical land uses, the RP's economic interest and stated plans for the site, and local land use plans and trends.

Key Reference:

Land Use in the CERCLA Remedy Selection Process (OSWER Directive 9355.7-04, May 25, 1995)
http://www.epa.gov/swerffrr/documents/land_use_cercla_remedy.htm

1.2: Groundwater Use and Groundwater Classification

The fundamental Agency policy is to maintain and/or restore groundwater to its highest beneficial uses wherever practical, within a time frame that is reasonable given the particular circumstances at a RCRA site. The understanding of groundwater uses and the potential for a groundwater use classification at a site is another early decision point that can affect the ultimate risk management decisions for a site.

EPA's primary objective is to restore currently used and reasonably expected sources of drinking water, as well as groundwater closely connected hydraulically to surface waters, whenever such restorations are practicable and attainable. Determining current and reasonably expected uses of groundwater at a facility is important for assessing the risks posed by groundwater contamination on-site and off-site, determining appropriate remedial objectives, and setting appropriate cleanup levels when groundwater restoration is an objective. Alternatively, a determination that groundwater is not a drinking water source (currently or in the reasonably expected future) or that restoration is not practical will generally result in groundwater remedial objectives which address other uses and exposures that could occur (e.g., agricultural uses, recharge to usable groundwater, groundwater-surface water interface transfer). EPA recognizes that groundwater use designations can enhance flexibility for groundwater cleanups while still protecting human health and the environment.

Groundwater use designation is the determination and identification of the reasonably expected current and future uses of groundwater at a site and adjacent to a site. The groundwater use designation needs to define whether the groundwater is a current or potential source of drinking water, or whether it has value other than drinking water. The following activities are important to consider for establishing the groundwater use designation for a site. Since they do not require the collection of extensive analytical data on groundwater contamination or quality, they can be considered early in the site investigation.

- Determine if groundwater is a current or reasonably expected future source of drinking water at the site based on the current and future land uses for the site; consult the land use decision information if necessary; determine if a groundwater aquifer(s) capable of supporting a drinking water supply is located beneath the site or in reasonable proximity to the site.

- Determine if groundwater migration from the site could be expected to impact local groundwater currently used as drinking water or reasonably expected to be used as drinking water; to verify local groundwater use, consider the need to locate current groundwater well users through historical well logs/records and through actual confirmatory location surveys and local interviews;

- To assist in making designations for off-site groundwater use, confer with the applicable State environmental agency and/or natural resource agency; Determine if the state has placed a formal groundwater use designation in the vicinity of the facility - such as a determination that groundwater is within a designated non-drinking water aquifer; EPA will generally defer to a state groundwater use designation when it is part of an EPA-endorsed Comprehensive State Groundwater Protection Program (CSGWPP).

- In the absence of an EPA-endorsed CSGWPP, the PM should determine if the state has an alternate designation for local groundwater which considers the same factors listed in the CSGWPP guidance (EPA 1992). If EPA has the lead role in implementing corrective action and a State designation system is not available or is not adequately protective based on the CSGWPP guidance, then PMs should consider using EPA's classification. EPA's groundwater classification system for site-specific groundwater use designations is found in "Guidelines for Groundwater Classification under the EPA Ground-Water Protection Strategy" (EPA 1986). These guidelines describe three classes of groundwater that represent resource values to society: Class I is groundwater that is an irreplaceable source of drinking water and/or ecologically vital; Class II is groundwater currently used or potentially usable as a source of drinking water; and Class III includes groundwater that is not a current or potential source of drinking water.

- If a non-drinking water use designation is determined to be valid for the site groundwater, alternative use designations for the groundwater should still be identified; at a facility-specific level, there may be uses of groundwater or potential exposures to contaminants from groundwater that might not be considered in a State-wide groundwater use designation. Alternative uses for groundwater on-site could include product manufacturing (e.g., cooling water, cleaning water); alternative uses for groundwater off-site could include crop irrigation and gardening.

Key References:

Handbook of Groundwater Protection and Cleanup Policies for RCRA Corrective Action (EPA/530/R-04-030; April 2004)
http://www.epa.gov/epaoswer/hazwaste/ca/resource/guidance/gw/gwhandbk/gwhndbk.htm

The Role of CSGWPPs in EPA Remediation Programs (OSWER Directive 9283.1-09; April 1997)
http://www.epa.gov/superfund/resources/csgwpp/roledesc.htm

Final Comprehensive State Groundwater Protection Program Guidance (EPA/100/R-93/001; 1992)
http://www.epa.gov/correctiveaction/resource/guidance/gw/csgwpp.htm

Guidelines for Ground-Water Classification under the EPA Ground-Water Protection Strategy (EPA 1986). http://www.epa.gov/correctiveaction/resource/guidance/gw/gwclass.htm

1.3: Data Quality Objectives

One of the key objectives of the Release Profile of the CSM is the collection of appropriate and relevant data on chemical releases that will be evaluated through risk-based screening and through site-specific risk assessments.

Data Quality Objectives (DQOs) are qualitative and quantitative statements about the types of analytical data that will need to be collected at the site, the types of decisions to be made with data, and the level of

sensitivity that must be obtained to use the data (i.e., detection limits, reporting limits). DQOs should be used to ensure that environmental data are scientifically valid, defensible, and of an appropriate level of quality given the intended use of the data.

Site investigations can be expedited considerably when DQOs are carefully established during project planning. For example, if the objective of an initial investigation is to define a geographic area of gross contamination, a DQO for this investigation may include accepting a relatively high method detection limit provided by a cost-effective field screening technology for analysis of samples. In contrast, if the objective is to determine if chemical contamination is present in groundwater used as drinking water, the DQO should specify a very low method detection limit.

In the Region 5 RCRA program, DQOs should be established in the Quality Assurance Project Plan (QAPP) for the site investigation. The QAPP is a document for which Region 5 and the RP will both be signatories, and it may be the only document in the site investigation for which EPA gives formal signature approval before final risk management and remedial decisions are made for a site. The RCRA program has issued a formal guidance for how an acceptable QAPP should be written (see reference below).

The following is a summary of the fundamental needs to be established in the DQO/QAPP process so that data obtained in the site investigation will be suitable for risk evaluation and risk management decisions.

- Identify SWMUs and Areas of Concern (AOCs) on which the sampling effort will be focused. This information is usually drawn from the Preliminary Site Assessment, the RFA, or other documents assembled by the PM and the RP.

- For most site investigations, sample data will need to be collected for both human health and ecological risk evaluation. The QAPP should recognize and explain differences in sample locations, types of media, and sample depths needed to collect site data for both types of applications.

- Identify the chemical constituents to be sampled at each SWMU/AOC and in each environmental medium (e.g., soil, groundwater, sediment, surface water) suspected to be of concern at the start of the project. These chemicals are often referred to as the Potential Contaminants of Concern (PCOC) since they will be chemicals which contribute to human health and ecological risk. The QAPP should contain a rationale for how the PCOC list was derived based primarily on the knowledge of facility operations and/or the documented history of chemical releases at the site. If knowledge of the facility history is minimal or highly uncertain, the QAPP should show that an expanded list of PCOCs was selected to cover the potential risk concerns.

- Provide DQO statements and/or Decision Rules (e.g., “if-then” statements) to explain how the collected data will be used to make decisions about the significance of chemical releases and actions to be taken if the releases are found to be significant. The applicable DQOs should address how the data on chemical constituent concentrations would be used for risk-based screening.

- Identify the analytical reporting limits that must be achieved so that the data for PCOCs will be sensitive enough to use for risk-based screening and site-specific risk assessments. For human health risk evaluation, the Region 5 RCRA program recommends that the Region 9 Preliminary Remediation Goals (PRGs) and the Maximum Contaminant Levels (MCLs) be used to establish the appropriately sensitive reporting levels. For ecological evaluation, the Region 5 Ecological Screening Levels should be employed to establish the appropriately sensitive reporting levels.

- Provide a plan for background sampling if site-specific SWMU/AOCs sample concentration data will be compared to site-specific background sample concentration data. According to RCRA policy, only data on naturally-occurring inorganics should be compared to site-specific background data.

In addition to the fundamental needs described above, specific risk management and/or analytical concerns exist for the following 3 constituents:

Lead - when lead releases are expected at a site based on historic industrial operations or based on preliminary/historical analytical data, the DQOs for soil should always call for sampling in the shallow surface soil (typically the upper 3 inches of surface soil). This is because exposure to shallow surface soils is expected to be the predominant pathway for lead intake by children in residential land use and by adults in industrial land use.

Polychlorinated Biphenyls (PCBs) - Almost any industrial site that was in operation prior to 1978 may have used equipment that contained PCBs, usually in an oil, but possibly also in other forms. PCBs were mainly used in the following equipment or materials:

- electrical equipment, particularly transformers, capacitors, and voltage regulators;
- hydraulic equipment, particularly any hydraulic system used in operations involving die casting, forging, extruding, a foundry, and a furnace, or other operations involving high temperatures or fire risks;
- heat transfer systems; and investment casting waxes.
- waste oils (i.e., waste oil drums, tanks, or storage areas) and foundry sands, generated or involving the above uses.

If any of the above equipment or materials were used at a site, the site investigation should include the possibility of releases or spills of PCBs, and the DQOs should include sampling for PCBs in waste materials, soils, and sediments. If PCBs are actually detected at a site, see Attachment 1 to view the criteria for determining if compliance with Toxic Substances Control Act (TSCA) regulations will be required at the site. TSCA regulations can apply to the site investigation procedures, the waste handling/disposal procedures, and the remedial cleanup goals for the site. In addition, it should be noted that the Region 5 RCRA program will confer with the Region 5 TSCA program (Toxics Program Section) to identify the TSCA requirements that apply at a RCRA site.

Polychlorinated Dibenzodioxins and Polychlorinated Dibenzofurans (Dioxins)

Dioxins would usually be constituents of concern only at sites that have specific current or historical operations. These are likely to be sites where the following activities occurred: combustion of hazardous and nonhazardous waste in incinerators and boilers; open burning of waste; wood treatment facilities using chlorinated phenols; manufacturing of certain chlorinated pesticides (e.g., 2,4-D; 2,4,5-T); paper and pulp mills. If dioxins are suspected as potential constituents of concern, EPA guidance calls for application of analytical procedures that will allow for detection and quantitation of the full range of toxic congeners needed to evaluate the potential risk from the mixture of congeners expected from locations where dioxin releases might have occurred. The DQOs for dioxin should include sampling for dioxins in waste materials, soils, and sediments.

Key References:

Regional Policy for Development of Quality Assurance Project Plans (QAPP; EPA-Region 5 Waste, Pesticides and Toxics Division; *May 1998)* http://www.epa.gov/reg5rcra/ca/qapp.htm

Data Quality Objectives Process for Hazardous Waste Site Investigations (QA/G-4HW; January 2000) http://www.epa.gov/quality/qa_docs.html

Guidance for the Data Quality Objectives Process (QA/G-4; August 2000) http://www.epa.gov/quality/qa_docs.html

Preliminary Remediation Goals (U.S. EPA - Region 9; 2004) http://www.epa.gov/region09/waste/sfund/prg/index.htm

Region 5 RCRA Corrective Action: Ecological Screening Levels (EPA-Region 5 Waste, Pesticides and Toxics Division) http://www.epa.gov/reg5rcra/ca/edql.htm

1.4: Human Health Risk-Based Screening

The RCRA program recognizes that important time savings and sometimes cost savings can be realized by ranking chemical releases from a site according to their apparent level of risk. Then, additional effort on site characterization can be focused on the locations and constituents that represent the most significant potential health risks. This would include both current risks and future risks based on the expected uses of the site. By converse, locations and constituents that exhibit very low or insignificant risks can become candidates for elimination from further characterization.

When a suitable QAPP is developed and sensitive analytical sampling is performed at a site, it should be possible to identify high risk release areas and their associated constituents by conducting risk-based screening.

1.5: What is Risk Screening ?

Risk screening is an exercise in which measured site-specific concentrations of chemicals are compared to pre-determined chemical concentrations which correspond to known levels of health risk. A pre-determined chemical concentration is derived from exposure parameters and chemical toxicity factors which are combined to "back-calculate" the chemical concentration which corresponds to a known risk level. The exposure parameters are selected to represent a specific exposure scenario that is plausible at a site (e.g., residential land use, industrial land use, drinking water consumption). The chemical toxicity factor is derived from EPA's analysis of the dose-response characteristics of the chemical in an experimental system or from epidemiological data in humans.

The primary use of risk-based screening levels is to identify the lower bound of the risk spectrum, namely, chemical concentration levels below which EPA believes there is no concern for further action provided that the appropriate exposure scenario is applied. In addition, the comparison of site concentrations to screening levels can also be used to identify the upper end of the risk spectrum, namely, chemical concentrations which EPA believes would require further study including remedial action. Consequently, risk-based screening can be used as a tool to expedite the identification of contaminants and exposure locations/areas of both low and high risk concern.

1.6: Which environmental media, receptors, and land uses are appropriate to consider for risk- based screening ?

Surface Soil - As described in the *Soil Screening Guidance*, surface soil screening evaluation should reflect the actual nature of surface soil exposure expected at a site. Consequently, the Region 5 RCRA program makes the following recommendations:

- Industrial land use - the receptor is a full-time facility worker who contacts surface soil on every work day at the location in question. The assumed exposure pathways are incidental soil ingestion, inhalation of volatile chemicals and particulates, and dermal contact. The sampling plan and the depth for surface soil screening should normally be limited to the top 6 inches of soil. (Note: A trespasser on industrial property may also be screened under the full-time facility worker scenario only if the trespasser is assumed to be exposed to contaminants in surface soils from the same SWMUs and AOCs to which the worker has contact.)

- Residential land use - the receptor is a full-time resident who contacts surface soil on a daily basis at the location in question. The assumed exposure pathways are incidental soil ingestion, inhalation of volatile chemicals and particulates, and dermal contact. The sampling plan and the depth for surface soil screening should normally be limited to the top 3 inches of soil.

Subsurface Soil

- The assumed exposure pathway is migration or leaching of subsurface soil chemical constituents to underlying groundwater. The exposure scenario is the consumption of groundwater as drinking water by a resident receptor. Consequently, this screening process is commonly referred to as the "Migration to Groundwater Pathway" or the "Protection of Groundwater Pathway." As described in the *Soil Screening Guidance*, chemical constituents that can be screened by this pathway are limited to those expected to have a significant potential for migration in the soil column.

Groundwater

- The receptor is a full-time resident who consumes groundwater as drinking water. For risk-based screening, this exposure assumption is applied anywhere that screening is performed (i.e., at any monitoring well location or any place within a groundwater plume).

Indoor Air

- The assumed exposure pathway is the migration of volatile chemicals from underlying contaminated groundwater and/or soil gas into homes and buildings. The migration process is usually referred to as "vapor intrusion." As described in the OSWER guidance, the process is limited to chemical constituents that have a significant capacity for upward migration through the soil column (see reference below).

- Industrial land use - the receptor is a full-time facility worker who is exposed to contaminants on every work day by inhalation at an existing building or at a future building located above the groundwater/soil gas contamination. (NOTE: For vapor intrusion into industrial buildings, the EPA has no applicable risk-based screening levels; for Environmental Indicator determinations, EPA has made a policy decision that OSHA indoor air concentration limits can be applied as screening levels for the vapor intrusion pathway. For a more detailed explanation for how the Region 5 RCRA program will recognize the use of OSHA compliance limits, see Attachment 2).

- Residential land use - the receptor is a full-time resident who is exposed to contaminants on a daily basis by inhalation at an existing residence (or a residential use location) above the contaminated groundwater/soil gas.

Sediment

- The assumed exposure pathway is that a worker or resident has occasional (non-daily) contact with surface sediments. The screening level assumption is that the daily surface soil direct contact scenario for residential land use (described above) can be used as a suitable surrogate for direct contact with surface sediments (i.e., incidental ingestion, dermal contact, and vapor/particle inhalation).

Key References:

Soil Screening Guidance: User's Guide (U.S. EPA Publication 9355.4-23; April 1996)
http://www.epa.gov/superfund/resources/soil/index.htm#user*Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance)* (OSWER ; November 2002) http://www.epa.gov/epaoswer/hazwaste/ca/eis/vapor.htm

1.7: Are there land uses and receptors for which risk screening should not be applied ?

Based on historical experience with site investigations and risk assessments, several potential exposure pathways and exposure scenarios have been identified which the EPA believes are not suitable for applying risk-based screening. Most of these situations involve cases where standard conservative exposure factors cannot be assigned or the exposure scenarios are too complicated for the purpose of back-calculating a suitable screening level. They include the following situations:

- Agricultural land use where food consumption pathways are actually occurring or are reasonably possible on contaminated land;
- Food consumption pathways from recreational use (e.g., fishing and hunting), especially where indirect exposure to persistent and bioaccumulative toxics could occur through contaminated sediments, soil, and plants (e.g., harvesting fish from a contaminated water body; harvesting game animals that have contact with contaminated soil or sediments);
- Potential "trespasser" exposure to contaminants on industrial property by activities other than surface soil contact at known SWMUs or AOCs. Such activities would include: contact with on-site contaminated sediments and surface water; consumption of or contact with contaminated groundwater; harvesting fish from a contaminated water body; harvesting game animals that have contact with contaminated soil or sediments;
- Most "recreational" land use situations because they cannot obviously be accounted for by using default industrial or residential land use exposure parameters as a surrogate;
- Future soil excavation/construction situations; these could vary widely in time duration and exposure frequency and include contact with soil and groundwater.
- Groundwater concentrations that are estimated using a groundwater transport model; this is because the modeled concentration is not an actual measurement of contaminant levels.

All of these situations need to be addressed in a site-specific risk assessment where site- specific exposure factors and parameters are assigned for each scenario.

Key Reference:

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual; Part A (EPA/540/1-89/002; Dec. 1989) http://www.epa.gov/superfund/programs/risk/ragsa/index.htm

1.8: What risk ranking categories should be used ?

In order to characterize health risks, the EPA separates potential risks into those from cancer-causing chemicals and those from toxic chemicals not known to induce cancer. The risk from toxic chemicals is normally referred to as a "hazard."

EPA treats cancer induction as a process which has no threshold dose, meaning that some level of health risk is caused at any dose level. Therefore, cancer risk for a specific chemical is estimated as a probability derived from:

$$\text{Cancer Risk} = (\text{Intake Dose}) \times (\text{Cancer Potency})$$

Cancer risk is expressed as a probability such as 3E-05 (i.e., 3×10^{-5}; or "3 chances per 100,000 individuals"). As a policy, EPA generally regards cancer risks at or below 1E-06 (1 in a million) to be levels that do not require further concern (also called a *"de minimus"* risk level).

EPA treats the induction of toxicity as a process with a threshold dose, meaning that a specific dose

would need to be reached before actual adverse toxic effects would be expected. EPA assigns chemicals a Reference Dose or Reference Concentration below which no adverse health effects would be expected even on long-term exposure. Therefore, a Hazard Quotient (HQ) for a specific chemical is a quantity derived from the direct comparison of the intake dose to the Reference Dose:

Hazard Quotient = (Intake Dose) ÷ (Reference Dose)

As a policy, EPA generally regards Hazard Quotients at or below 1.0 to be levels that do not require further concern.

In addition, for the purpose of obtaining a screening level estimate of cancer risk and hazard from exposure to multiple chemicals by the same individual, EPA estimates cumulative cancer risk and cumulative hazard quotient (called a "Hazard Index") as the sums of the individual cancer risks and individual quotients, respectively.

Consequently, for evaluating chemical releases in a site investigation, the categorization of risk significance should be based on the following rationale:

- Chemical constituent levels considered to be of "No Further Concern";

  Cancer Risk - All individual constituents at concentrations below a cancer risk level of 1E-06 and cumulative cancer risk not exceeding 1E-06; [1]

  Hazard Index - All individual constituents at a concentration below an HQ of 1.0 and cumulative Hazard Index for multiple constituents also below 1.0; [2]

  Response action - no additional sampling or risk evaluation should be necessary when the sampling was conducted in accordance with the Quality Assurance Plan. The location and constituents of the sampling may be proposed for a No Further Action determination.

- Chemical constituent levels that may need further evaluation.

  Cancer Risk - One or more individual constituents at a concentration between a cancer risk level of 1E-06 to 1E-04 and cumulative cancer risk level between 1E-06 and 1E-04;

[1] For the purpose of risk screening, the chemical constituent concentrations corresponding to a cancer risk of 1E-06 will be the Preliminary Remediation Goal (PRG) concentrations for the cancer endpoint developed in the EPA Region 9 PRG Tables. See Section 1.10 for additional information.

[2] For the purpose of risk screening, the chemical constituent concentrations corresponding to a Hazard Quotient of 1.0 will be the Preliminary Remediation Goal (PRG) concentrations for the non-cancer endpoint developed in the EPA Region 9 PRG Tables. See Section 1.10 for additional information.

Hazard Index - One or more individual constituents at a concentration above an HQ of 1.0 with a cumulative Hazard Index for multiple constituents not exceeding 2;

Response action - require further evaluation through additional sampling for constituent(s) that exceed an HQ of 1.0; the release location may be associated with a "hot spot" of chemical contamination; the PM may decide that the release location is not fully characterized and may need additional sampling in horizontal or vertical directions;

- Chemical constituent levels that are high risk

Cancer Risk - One or more individual constituents at a concentration above a cancer risk level of 1E-04 or a cumulative cancer risk level above 1E-04;

Hazard Index - One or more individual constituents at a concentration above an HQ of 2.0 or a cumulative Hazard Index above 4.0

Response action - elevate the location for expedited further evaluation and/or direct remedial response:

The PM should conclude that the extent of release from the location is not fully characterized and needs additional sampling in horizontal or vertical directions to more fully characterize the nature and extent of contamination;

The release location may be associated with a "hot spot" of chemical contamination;

The release location is a candidate for causing significant constituent migration to other media; the location should be regarded as: a candidate location for source control measures; a candidate for Interim Measures; a situation which would prevent positive EI determinations;

1.9: When should the risk-based screening be initiated ?

Risk screening should usually begin at the completion of the first round or Phase I of the sampling plan spelled out in the QAPP and other project work plans. Screening may be initiated as data become available at each release location under study (SWMU or AOC).

Soil: Based on information found in the Soil Screening Guidance and other Agency guidance, the Region 5 RCRA program is recommending the following procedures to accomplish the sampling needs for risk-based screening:
Surface soil

- A minimum of 8 surface soil sample results that meet QA requirements are needed to begin risk screening of areas not larger than 0.5 acre under residential or industrial land use; SWMUs and AOCs suspected of having release areas much larger than a 0.5 acre should be subdivided into 0.5 acre parcels for which a minimum of 8 samples should be obtained. An area of 0.5 acre should be regarded as the generic unit area/lot size for risk-based screening unless reliable site-specific information indicates that a different lot size is appropriate to apply at a specific site (e.g., existing local residential lot sizes are significantly above or below 0.5 acre). [3]

[3] These recommendations are based on information from the EPA ***Soil Screening Guidance***. The sample size of 8 is a necessary minimum number of random discrete (non-composited) samples needed to conduct a valid direct comparison of each sample's constituent concentrations to risk-based screening concentrations. This is the sample size corresponding to only 5% probability that the actual mean constituent concentrations of the samples will

- The above recommendation for a minimum of 8 surface soil samples per unit area is a generic starting point for application to the risk screening exercise. This frequency represents a balance between the need to reduce uncertainty in risk management decisions (by collecting additional data) with the objective of early identification and action at high priority areas. The acceptable sample density could be affected by site-specific factors. For example, unit-specific characteristics including the variability of waste(s) managed, how chemicals were managed, and any physical alterations to the unit that would affect contaminant distribution could dictate a higher, or lower, sampling frequency. Units for which preliminary or historical information indicates that contamination is relatively homogeneous may require less sampling than units with potentially highly variable or highly uncertain chemical distributions in soil. An RP may present rationale for the PM's consideration for an alternate sampling frequency if supported by site-specific conditions.

- Because of the relatively small sample sizes normally encountered in risk screening of multiple SWMUs and AOCs, the maximum detected concentration of each constituent should be used for the comparison to the screening level concentration during the risk-based ranking exercise for Phase 1 of the site investigation. It is recommended that statistical analysis of the data should be deferred to Phase 2 of the site investigation after a larger number of sample results become available or after the necessary data is obtained to answer concerns about the extent of contamination. (See Section 2)

Subsurface soil

- A minimum of 3 soil borings should be obtained from the area of highest known or suspected contaminant impact within a SWMU or AOC. In each boring, soil samples from appropriate depth intervals (e.g., 2 feet) should be collected and analyzed until the maximum depth to be sampled is reached (e.g., depth to water table; depth to bedrock).

- In each soil boring, the maximum and mean concentration of each constituent within the soil segments should be found by reviewing the data;

Groundwater: Because of the higher potential for migration of contaminants in groundwater and the difficulty in linking groundwater contamination with potential source locations, chemical constituent concentration data from each groundwater well should be compared to the screening level concentration. Data from multiple wells should not be combined to derive a mean concentration unless a clear rationale can be offered.

Key Reference:

Soil Screening Guidance: User's Guide (U.S. EPA Publication 9355.4-23; April 1996)
http://www.epa.gov/superfund/resources/soil/index.htm#user

---

not exceed 2x the risk-based screening concentrations. An area of 0.5 acre was recommended as the default suburban residential lot size.

1.10: How should the risk-based screening be carried out ?

Surface Soil

A procedure for performing the risk-based screening of surface soil data is outlined in Exhibit 1. The procedure utilizes the EPA Region 9 PRG values as risk-based screening concentrations.

For each constituent, the procedure will determine if the measured site concentration exceeds: a 1E-06 risk level, a 1E-04 risk level, and/or an HQ of 1.0.

In addition, the use of the procedure will allow for calculation of a cumulative screening level cancer risk and a cumulative screening level hazard index for the multiple constituents present at a given location (i.e.,. SWMU or AOC).

Subsurface soil

A set of generic or default screening levels for the soil-to-groundwater migration pathway can be found in Appendix A of the *Soil Screening Guidance: Technical Background Document* (http://www.epa.gov/superfund/resources/soil/toc.htm). Table A-1 of Appendix A has a list of constituents for which EPA determined that adequate physical/chemical data on migration potential was available to develop a conservative screening level for the soil-to-groundwater migration pathway.

To conduct the screening procedure, locate the maximum subsurface soil concentration for each detected chemical constituent in each soil boring from the available data for a given SWMU or AOC. If the chemical constituent is listed in Table A-1, compare the maximum concentration from each soil boring to the value listed under the column labeled “Generic Migration to Groundwater - 20 DAF”. (Note: 20 DAF refers to a Dilution Attenuation Factor of 20. This means that contaminants migrating in soil leachate are expected to be diluted by a factor of 20 when entering groundwater. EPA determined that this was a reasonable and conservative dilution factor to apply for a screening level evaluation).

Groundwater and Surface Water

A procedure for performing the risk-based screening of groundwater/surface water data is outlined in Exhibit 2. The procedure utilizes the EPA Region 9 PRG values and the EPA Maximum Contaminant Levels (MCLs) as risk-based screening concentrations.

For each constituent, the procedure will determine if the site concentration exceeds: the published MCL value, a 1E-06 risk level, a 1E-04 risk level, or an HQ of 1.0.

In addition, the use of the procedure will allow for calculation of a cumulative screening level cancer risk and a cumulative screening level hazard index for the multiple constituents present at a given groundwater or surface water location.

It should be noted that the use of surface water as drinking water is the only surface water exposure pathway that can be evaluated through risk-based screening. It is appropriate to apply MCL values for risk-based screening of surface water used as drinking water. Other human uses of surface water (e.g., consumption of fish, recreational use) cannot be addressed through risk-based screening. They need to be addressed through site-specific risk assessment (Section 2.3).

Indoor Air

- Current Industrial Land Use:

As explained in Section 1.6, the EPA does not have risk-based screening levels for indoor air in the industrial use environment. For on-site industrial buildings determined to be subject to OSHA compliance, Region 5 will recognize the OSHA-Permissible Exposure Limits (PELs) as acceptable indoor air screening level concentrations for EI determinations. The OSHA-PEL values can be downloaded from the following web site: <http://www.osha.gov/SLTC/pel/>

The following should be regarded as additional needs and requirements for applying indoor air screening using OSHA-PEL values:

- Application of OSHA-PEL values for screening indoor air concentrations for on-site buildings is an option to be exercised by the RP; the RCRA program may request the RP to provide evidence that the on-site building(s) is regulated under OSHA for the contaminants of concern.

- In order to apply OSHA-PEL values, the RP will need to run the Johnson and Ettinger (J&E) Model as described in current EPA guidance. The J&E Model allows indoor air concentrations to be estimated starting from chemical constituent concentration data for on-site groundwater or soil gas. The RP must provide suitable documentation to show that it can make appropriate use of the J&E Model in a manner that fits the specific site application including the use of appropriate building characteristics.

- Future Industrial Land Use and Residential Land Use:

The EPA guidance for evaluating vapor intrusion to indoor air is found in the document "DRAFT GUIDANCE FOR EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY FROM GROUNDWATER AND SOILS." (http://www.epa.gov/correctiveaction/eis/vapor/complete.pdf). This is a guidance which provides a step-wise protocol for determining if vapor intrusion has the potential to be a "complete" exposure pathway at a site. If application of the protocol shows that vapor intrusion cannot be a complete pathway, then it may be eliminated from further concern.

The guidance provides risk-based screening levels for evaluating whether migration of constituents from contaminated groundwater could cause unacceptable long-term indoor air concentrations (Tables 1 - 3; http://www.epa.gov/epaoswer/hazwaste/ca/eis/vapor.htm). Consequently, the screening levels actually apply to groundwater concentrations. For each chemical, screening levels are provided for 3 risk levels (1E-06, 1E-05, and 1E-04) or for a hazard quotient of 1.0 (whichever is lower). Consequently, a user can determine where a specific chemical fits within the risk ranking categories described in Section 1.8. The risk screening model uses several conservative assumptions for estimating the migration of chemicals from groundwater to indoor air. Because of the uncertainties inherent in this modeling, it is not recommended that the screening levels should be used to estimate cumulative cancer risk levels or hazard index levels at the present time.

Key References:

Preliminary Remediation Goals (U.S. EPA - Region 9; 2004)
http://www.epa.gov/region09/waste/sfund/prg/index.htm

Soil Screening Guidance: Technical Background Document; Appendix A (U.S. EPA Publication EPA/540/R-95/128; May 1996) http://www.epa.gov/superfund/resources/soil/toc.htm

Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance; Tables 1-3) (OSWER; November 2002)
http://www.epa.gov/epaoswer/hazwaste/ca/eis/vapor.htm

Safety and Health Topics: Permissible Exposure Limits (PELs) (U.S. Department of Labor; Occupational Safety & Health Administration; 2003) http://www.osha.gov/SLTC/pel/

Johnson and Ettinger (1991) Model for Subsurface Vapor Intrusion into Buildings (U.S. EPA; Superfund Risk Assessment) http://www.epa.gov/superfund/programs/risk/airmodel/johnson_ettinger.htm

Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance) (*APPENDIX G: CONSIDERATIONS FOR THE USE OF THE JOHNSON AND ETTINGER VAPOR INTRUSION MODEL)*
(OSWER; November 2002) http://www.epa.gov/epaoswer/hazwaste/ca/eis/vapor.htm

1.11: Ecological Risk-Based Screening

As with human health risk, the RCRA program recognizes that important time savings and sometimes cost savings can be realized by ranking chemical releases from a site according to their apparent level of risk. Then, additional effort on site characterization can be focused on the locations and constituents that represent the most significant potential ecological risks - both current risks and future risks based on the expected uses of the site. By converse, locations and constituents that exhibit very low or insignificant risks can become candidates for elimination from further characterization.

When a suitable QAPP and sensitive analytical sampling are performed at a site, it should be possible to identify high risk release areas and their associated constituents by conducting ecological risk-based screening.

Ecological risks should initially be evaluated through a screening ecological risk assessment (SERA) process. A SERA is ideally conducted early in the RCRA site investigation schedule. This process begins with the identification of goals, such as the environmental values to be protected, and the ecological endpoints to be measured. Endpoints should define both the valued ecological entity (e.g., specific species, resource, habitat type) at the site and a characteristic of the entity to protect (e.g., reproductive success, survival, areal extent). A SERA most often consists of a desktop effort which compares measured concentrations in environmental media against conservative ecological screening values. If the comparison to screening level concentrations identifies potential risks, a more detailed study is conducted. The detailed study would focus only on those specific stressors (e.g. chemicals) and species identified in the SERA as presenting a risk concern. In some cases, further analysis of risk is necessary later in the site investigation process. Alternatively, a site-specific assessment may be included in the Corrective Measures Study or during later stages when final remedial goals are developed. (The site-specific ecological risk assessment process is described in more detail in Section 2.4)

1.12: Which environmental media, receptors, and land uses are appropriate to consider for ecological risk-based screening ?

Surface Soil - The EPA's national guidance on ecological soil screening should be followed (*Guidance for Developing Ecological Soil Screening Levels*; 2003). This guidance published acceptable soil screening levels for 9 constituents frequently encountered during hazardous waste site investigations (Aluminum, Antimony, Barium, Beryllium, Cadmium, Cobalt, Iron, Lead, and Dieldrin). Several additional constituents will be added to the above guidance in the future and the selected screening levels will become nationally applicable levels. For constituents not on the above list, the Region 5 RCRA program's *Ecological Screening Levels* should be applied. The actual depth for appropriate soil sampling and screening will be distinct for each site based on the likely receptor species and the naturally occurring soil horizons. The general expectation is that samples for surface soil screening should not exceed a depth of 2 feet below ground surface.

Subsurface Soil - The EPA guidance is the same as above for surface soil, except that the appropriate depth for sampling will depend on site-specific information on the likely receptor species.

Surface Water - The level of protection and the appropriate screening levels need to follow established beneficial uses as addressed in EPA's *Water Quality Criteria* (2002). In addition, individual Region 5

state water quality standards should also be considered as applicable screening levels.

Sediment - the objective is to protect species in aquatic communities with a particular focus on organisms associated directly with sediments. Consequently, the chemical contaminants of major concern in sediment will be persistent and bioaccumulative toxics (PBTs). Where the sediment PBTs could be part of a food web, an evaluation needs to be made for terrestrial species that consume aquatic life. A Region 5 ecologist should be consulted to determine if appropriate chemical-specific screening levels are available for application to sediments at a specific site.

Air - A level of protection has not been established, but some direction is available in EPA guidance (see references below). Screening levels for a few chemicals in air can be found in the Region 5 *Ecological Screening Levels* tables.

1.13: Are there land uses and receptors for which ecological risk screening should not be applied ?

Based on EPA guidelines, ecological risk concerns and risk screening should apply only to wild plants and wild animals. Consequently, ecological risk concerns should not be applied to agricultural crops, domestic pets, and animals raised as livestock. Risk screening should also not be applied to artificially maintained landscapes that are recognized as being constructed solely for human uses (e.g., recreational fields, ballparks). An exception arises if the artificial landscape creates an attraction for wildlife.

1.14: When should the ecological risk-based screening be initiated ?

Risk screening should usually begin at the completion of the first round or Phase I of the sampling plan spelled out in the QAPP and other project work plans. Screening may be initiated as data become available at each release location under study (SWMU or AOC).

No required or specific sampling needs for ecological risk-based screening can be identified other than those available in the EPA ecological risk assessment guidance documents (see references below). For example, a specific default exposure unit area (e.g., 0.5 acres) for soil sampling cannot be recommended because the exposure area for a wildlife species depends on the particular “home range” that the species needs for food consumption and protective cover.

Key references:

Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments - Interim Final (EPA540-R-97-006; OSWER 9285.7-25; June 1997) http://www.epa.gov/superfund/programs/risk/ecorisk/ecorisk.htm

Guidelines for Ecological Risk Assessment (Final; Risk Assessment Forum; EPA/630/R-95/002F; April 1998) http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=12460

Guidance for Developing Ecological Soil Screening Levels (Eco-SSLs) (OSWER Directive 9285.7-55; Nov. 2003) http://www.epa.gov/superfund/programs/risk/ecorisk/ecossl.htm

FACT SHEET: ECOLOGICAL RISK ASSESSMENT IN THE RCRA PROGRAM (EPA-Region 5 Waste, Pesticides and Toxics Division; Jan. 2000) http://www.epa.gov/reg5rcra/ca/guidance.htm

Region 5 RCRA Corrective Action: Ecological Screening Levels (EPA-Region 5 Waste, Pesticides and Toxics Division) http://www.epa.gov/reg5rcra/ca/edql.htm

Section 2: Phase 2 - Complete the Site Characterization and Risk Evaluation

The Priority Factors designated as Phase 2 should be applied to address site contaminant releases that need a rapid response, and to complete the contaminant characterization and risk evaluation for the entire site.

2.1: Address the High Risk Release Locations

By this point in the investigation, after the Phase 1 priority factors have been applied, the release locations of highest concern should be identified. The high risk release locations identified by the risk-based screening (Section 1.10) should be elevated for direct and/or expedited remedial responses. The following are decisions and actions that should be applied to address the high risk release locations (i.e., SWMUs and AOCs).

For soil:

- The concentration levels in the release are a verified problem, but the location likely is not fully characterized; additional sampling is needed in horizontal and/or vertical directions to more fully characterize the nature and extent of contamination;

- analytical results from additional constituent sampling should be compared to human health risk-based screening levels; continue the sampling effort until new concentration data for all constituents fall below the high risk screening level.

- original sample locations with high constituent concentrations may be associated with one or more "hot spots" of contamination; consider sampling in horizontal and/or vertical directions around the known hot spots until subsequent sample concentrations are determined to fall below the high risk screening level.

- evaluate whether the original source of release (e.g., landfill, lagoon, holding pond, tank) could be a continuing release point for contaminants to soil; If yes - source control will be needed to eliminate the source or to place a release barrier around the source (e.g., excavation, capping, capture trench);

- the possibility that the release location could cause significant migration to other media should be considered; consider soil-to-groundwater migration and soil runoff/erosion to surface water as prime migration problems; new or additional groundwater monitoring should be considered at and downgradient of the release location;

- the location should be considered as: a candidate location for source control measures; a candidate for Interim Measures; a situation which would prevent positive EI determinations;

For Groundwater:

- Additional monitoring is needed in horizontal or vertical directions to more fully characterize the nature and extent of contamination; analytical results of additional sampling should be compared to human health risk-based screening levels; continue sampling in horizontal and/or vertical directions until concentrations for all constituents fall below the "high risk" screening level.

- Need to question whether groundwater contaminant migration is "under control" at the location of concern; Determine if contaminated groundwater could be located in a "perched zone" or in an upper aquifer with no significant potential for migration.

- Additional monitoring may be needed to track migration of contaminated groundwater and to determine if contaminated groundwater is moving in a plume; consultation with hydrogeologist and more study of groundwater flow characteristics may be needed for the location.

- The migration outcomes of most concern are: migration to a drinking water aquifer; migration of groundwater off-site to locations not under control of the RP; migration of groundwater to a surface water body (i.e., groundwater-to-surface water interface).

- If significant evidence for contaminant migration under control cannot be obtained in a reasonable time, then the groundwater plume should become a candidate for Source Control in the remedy selection process or could become a candidate for Interim Measures (see below).

- If contaminant concentrations in groundwater indicate that vapor intrusion cannot be eliminated as a potential complete exposure pathway by the screening procedures recommended in the EPA guidance (Section 1.10) , then additional work to address the pathway will be required. The additional work could include site-specific vapor migration modeling, soil gas sampling, sub-slab sampling, indoor air sampling, or a combination of these approaches. The recommendations in the EPA guidance should be used as a starting point for planning additional work.

2.2: Select and Plan Interim Measures

Interim Measures (IMs) are actions and responses needed for situations of such high concern for risk management/risk reduction that they need to be addressed before the final remedy decisions for the site are selected and announced. IMs are actions that go above and beyond additional sampling of constituents. Some of the candidate situations are described above. They fall under the following general categories:

- The presence of contamination or the physical state of contamination threaten actual or potential contamination of drinking water supplies or sensitive ecosystems;

- A hazardous contamination situation exists that is a potential source for release or is a threat to health or the environment, and EPA perceives that a long time will be needed to develop and implement a permanent final remedy;

- The presence of hazardous waste and/or hazardous constituents in unstable containers or stored in unreliable containment that poses a threat of release; significant risks of fire, explosion or sudden release from hazardous wastes or hazardous constituents stored in unstable or unreliable containers;

- Groundwater is currently contaminated at significant concentrations levels near the boundaries of a site such that off-site migration is imminent; off-site groundwater is already contaminated by constituents that originated from on-site groundwater sources.

- Groundwater is currently contaminated at significant concentration levels and suitable near-term actions could be taken to bring the migration under control;

- A contaminant source continues to be a significant release point for contaminants to soil; and/or a soil contaminant location continues to be a significant release point for migration of contaminants to groundwater;

- The presence of Non-Aqueous Phase Liquids (NAPLs) or “free product” contamination; NAPLs are identifiable contaminant sources which should be candidates for recovery/remediation;

The following are brief examples of actions that could be taken as part of IM decisions:

- installation of a pump-and-treat system to directly reduce contaminant levels in groundwater;

- installation of a soil vapor extraction system to collect and treat volatile contaminants in soil gas;

- construction of cut-off walls as containment structures designed to prevent the migration of groundwater from or into a source area. By preventing the migration of groundwater, cut-off walls may minimize or prevent impacts from contaminants in groundwater. Common types of cut-off walls include slurry trenches, sheet piling barriers, and grouted barriers.

- construction of hydraulic containment barriers usually consisting of trenches, sumps, drains, and wells designed to reverse localized groundwater flow gradients in such a manner as to reduce or prevent the migration of contaminated groundwater. By preventing groundwater migration, hydraulic containment barriers may minimize or prevent impacts from contaminants in groundwater.

- clay caps and synthetic caps designed as protective covers to prevent the infiltration of precipitation and surface water into a waste or contaminated media. The prevention of precipitation infiltration can reduce leachate generation, the migration of contaminants in the subsurface soil and to groundwater, and contaminant transport via erosion and surface water. Caps can also reduce vapor emissions from waste and contaminated media, and prevent direct contact with waste or contaminated soil.

An additional consideration is that the RCRA program preference is that the outcome of IM actions should be essentially equivalent to what would be achieved if the action were taken after "final remedy" selection. As stated in the *ANPR*, "Generally, interim actions should be compatible with, or a component of, the final remedy." In other words, the RCRA preference is that the technical or engineering part of an IM action would not need to be re-visited in the final remedy selection. Ideally, the only part of an IM to be addressed in the final remedy selection should be administrative requirements (e.g., future land use restriction or land use covenant).
Key References:

Advance Notice of Proposed Rulemaking: Corrective Action for Releases from Solid Waste Management Units at Hazardous Waste Management Facilities (Fed. Reg. 61: 19432, May 1, 1996).
http://www.epa.gov/docs/fedrgstr/EPA-WASTE/1996/May/Day-01/pr-547.pdf

RCRA Corrective Action Plan (Final); (OSWER Directive 9902.3-2A; May 1994)http://www.epa.gov/correctiveaction/resource/guidance/gen_ca/rcracap.pdf

2.3: Site-specific risk assessment

In previous Sections, the evaluation and ranking of health risks at a site were based on essentially standardized or default procedures that could be used for risk-based screening and risk ranking. At many sites, additional evaluation of health risk will need to be performed for situations or for exposure scenarios that do not lend themselves to the application of standard or default assumptions. Several of the situations requiring a site-specific risk evaluation were described in Section 1.7: "Are there land uses and receptors for which risk screening should not be applied ?" (The PM should review Section 1.7 to determine if any of the exposure scenarios described there apply to the site under investigation.)

An additional situation for which site-specific risk evaluation is often proposed is for a SWMU/AOC that is perceived as having an original risk ranking that represents a significant overestimate of the actual risk. The concept is that the application of additional site-specific risk evaluation could lead to a decision that the SWMU/AOC should be moved to a lower risk category. The information needed to justify the investment of additional time and resources for these situations would usually be submitted by the RP and would entail one or both of the following:

- A significant amount of analytical sampling data is available (or will become available) so that statistical analysis can be used to generate alternative exposure point concentrations for chemical constituents that will be lower than those employed for the original risk-based screening exercise (i.e., the Phase 1 risk screening). The EPA guidance on Exposure Point Concentrations should be

consulted for performing data analysis tests to determine if a statistically derived mean value can be used (e.g., the 95% UCL of the mean; see reference below). A PM should normally consult a Region 5 statistician before embarking on a statistical analysis or reviewing a proposal from an RP on using statistical analysis.

- Reliable and current site-specific information is available which shows that one or more of the exposure factors or exposure parameters employed in the risk-based screening is a significant overestimate of the actual situation at the site.

Consideration of Background in Risk Assessment

A site-specific risk assessment is conducted to characterize the current and potential threats to human health posed by hazardous substances and chemical constituents at a site. EPA's *Risk Assessment Guidance for Superfund* (*RAGS*; 1989) provides general guidance for selecting chemicals of concern and considering background concentrations. In *RAGS*, EPA cautioned that eliminating chemical constituents from risk evaluation based on background (because chemical concentrations are below background levels or are attributable to background sources) could result in the loss of important risk information for potentially exposed persons, even though the cleanup decision may or may not eliminate the source of risk caused by the background levels.

In light of more recent EPA guidance for risk-based screening (EPA, 1996) and risk characterization (EPA 1995), the current EPA policy recommends a baseline risk assessment approach that retains constituents that exceed risk-based screening concentrations (EPA 2002). This approach calls for addressing site-specific background issues at the end of the risk assessment, in the Risk Characterization step. Specifically, the chemical constituents with high background concentrations should be discussed in the risk characterization, and if data are available, the contribution of the background concentration levels to the site-related concentration levels should be distinguished. Chemical constituents that have both release-related and background-related sources should be included in the risk assessment. When concentrations of naturally-occurring substances (e.g., metals; inorganics) at a site exceed risk-based screening levels, that information should be discussed qualitatively in the risk characterization. To summarize:

- The constituents retained in the quantitative risk assessment should include those with concentrations that exceed risk-based screening levels.

- The Risk Characterization should include a discussion of elevated background concentrations of chemical constituents and their contribution to site risks.

This general approach is preferred in order to:

- Encourage national consistency in this area;

- Present a more thorough picture of risks associated with hazardous chemical constituents at a site;

- Prevent the inadvertent omission of potentially release-related hazardous chemical constituents from the risk assessment**.**

This approach is consistent with the *Policy for Risk Characterization* which calls for fully and clearly characterizing risks (EPA, 1995). Risks identified during the baseline risk assessment should be clearly presented and communicated for risk managers and for the public.

Key References:

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation Manual; Part A

(EPA/540/1-89/002; Dec. 1989) http://www.epa.gov/superfund/programs/risk/ragsa/index.htm

Soil Screening Guidance: User's Guide (U.S. EPA Publication 9355.4-23; April 1996)
http://www.epa.gov/superfund/resources/soil/index.htm#user

Guidance for Risk Characterization (Science Policy Council; Feb. 1995)
http://epa.gov/osa/spc/htm/rcguide.htm

Risk Characterization Handbook (Science Policy Council; Dec. 2000)
http://epa.gov/osa/spc/htm/2riskchr.htm

CALCULATING UPPER CONFIDENCE LIMITS FOR EXPOSURE POINT CONCENTRATIONS AT HAZARDOUS WASTE SITES (OSWER Directive 9285.6-10; December 2002)
http://www.epa.gov/superfund/programs/risk/tooltrad.htm

Role of Background in the CERCLA Cleanup Program (OSWER Directive 9285.6-07P; April 26, 2002)http://www.epa.gov/superfund/programs/risk/bkgpol_jan01.pdf

2.4: Ecological risk assessment

Corrective action remedies selected under RCRA must be protective for both the environment and human health. Therefore, some form of ecological assessment will be necessary at all RCRA sites. This would involve application of the ecological risk-based screening exercise described earlier (Section 1.12) as well as a more formal site-specific ecological risk assessment.

EPA guidance defines ecological risk assessment as a "process that evaluates the likelihood that adverse ecological effects are occurring or may occur as a result of exposure to one or more stressors." Environmental stressors include any physical, chemical or biological entity that can induce responses such as sublethal chronic effects, death of organisms, or loss of ecosystem functions.

An ecological risk assessment evaluates the potential adverse effects that chemical contamination has on the plants and animals that make up ecosystems. The risk assessment estimates the likelihood that adverse ecological effects (e.g. mortality, diminished growth, reproductive failure) will occur as a result of releases of hazardous wastes at a site. The risk assessment process provides a way to develop and analyze scientific information, assumptions, and uncertainties so that they are relevant to environmental decisions.

When conducted at an industrial facility, the ecological risk assessment process can be used to identify and characterize current and potential threats to the environment from a hazardous substance release, to prioritize data collection activities, to identify vulnerable and valued ecological resources, to evaluate the ecological impacts of alternative remediation strategies, and to establish clean-up levels protective of the natural resources at risk.

The following are examples of why ecological risk assessment is important and has different needs from a human health risk assessment:

- Ecological Screening Levels (ESLs) are often derived from adverse health or population effects on the animal and plant species most sensitive to the effects of a given chemical constituent. Many sites will have constituent levels that exceed these sensitive ESLs. Based on readily obtainable local/regional survey data and site-specific information, it may be possible to conclude that a highly sensitive species is not present at the site and is not likely to frequent the site in the future. Alternative species could be proposed as the focus of the ecological evaluation.

- The locations on a site that are important for evaluating ecological species and eco-habitats are often

different than the locations used to evaluate human health risk. The environmental media most important for ecological evaluation are usually also different from those that dominate human health risk, with eco-risk tending to be dominated by contaminant levels in surface water, sediment, and soil rather than groundwater. Consequently, the site locations for sampling environmental media to evaluate ecological risk will likely differ from those needed to evaluate human health risk.

- In certain situations, especially where non-residential land use is applicable, remedial and cleanup goals for ecological receptors may be more stringent (i.e., lower) than those needed for human health protection. Therefore, ecological exposure pathways could be the driving force for remedial decisions at major geographic areas of a RCRA site.

- The presence of sensitive species and sensitive environments that may require special protection or special consideration needs to be evaluated. Examples could include the presence of threatened and endangered species or habitats and locations recognized as having a special ecological concern (e.g., proximity to Great Lakes habitats or designated nature preserves). (Additional examples are found in Exhibit 1-1 of the ecological guidance for Superfund; see reference below). Completion of an evaluation for sensitive species and habitats will demonstrate compliance with the *National Environmental Policy Act* of 1969 (NEPA) and the *Endangered Species Act* (ESA).

The Region 5 RCRA policy for conducting ecological risk assessment is outlined in the guidance *Region 5: Ecological Risk Assessment Guidance for RCRA Corrective Action*. This guidance describes what an ecological risk assessment should cover and what approaches should be taken to streamline the ecological risk assessment effort by applying a "tiered" approach that is consistent with EPA's national guidance.

Ecological risk assessment can range from simple to complex and qualitative to quantitative depending upon the site under investigation and the tier of the assessment itself. Region 5 recommends that the ecological risk assessment effort should be partitioned into three tiers of effort. Each successive tier requires more detailed and quantitative data collection, analysis, and evaluation than the preceding tier, in order to determine the degree of risk. These three tiers are referred to as the screening ecological risk assessment (SERA), preliminary ecological risk assessment (PERA), and detailed ecological risk assessment (DERA).

Ecological risk assessment is an iterative process where at the culmination of each tier, a decision is made on whether to conduct more work at the current tier, to progress to the next tier, or to terminate the process. As the ecological risk assessment progresses from one tier to another, the assessment becomes more quantitative, the base of information increases, the precision increases, and the allocation of resources increases.

Key References:

Ecological Risk Assessment Guidance for Superfund: Process for Designing and Conducting Ecological Risk Assessments - Interim Final (EPA540-R-97-006; OSWER 9285.7-25; June 1997) http://www.epa.gov/superfund/programs/risk/ecorisk/ecorisk.htm

Region 5: Ecological Risk Assessment Guidance for RCRA Corrective Action (Interim Draft; U.S. EPA-Region 5; Waste Management Division; Office of RCRA; October 1994)

Region 5 RCRA Corrective Action: *Ecological Screening Levels* (EPA-Region 5 Waste, Pesticides and Toxics Division) http://www.epa.gov/reg5rcra/ca/edql.htm

2.5: Risk Evaluation Report

At this point in the site investigation, the nature and extent of releases from the facility have been

characterized and the PM should have available the following information and analysis: a) the identification of the High Risk Release Locations; b) the plans and/or decisions about source control measures and Interim Measures; c) a site-specific human health risk assessment, if needed; and d) a site-specific ecological risk assessment.

The RP should now generate a Risk Evaluation Report. The Report should draw from information that likely is already available in other existing documents (e.g., site investigation reports; human health and ecological risk assessments; IM Work Plans), and may be included as an attachment to these reports. It does not need to provide a new technical evaluation of the data. At a minimum, the Report should contain the following information:

- The results from the Risk-Based screening exercises on each SWMU/AOC or sampling location; a summary of which SWMUs/AOCs were recommended for: "no further action"; recommended for further sampling and study; recommended for further sampling and source control or IMs; recommended for evaluation in the site-specific risk assessment. For projects being conducted under traditional orders - this information would likely be provided in the Phase I RFI Report. For Streamlined Orders - this information would be included in the Investigation Report. For Voluntary Agreements - this information would be provided in the Final Corrective Measures Proposal. Facilities conducting corrective actions under Voluntary Agreements may wish to submit the investigation results in phases prior to submission of the Final Corrective Measures Proposal to keep EPA informed of interim measures activities.

- The results from conducting site-specific human health risk assessment. The summary should include a description of human exposure scenarios that were evaluated, the relationship between the exposure scenario at specific SWMUs/AOCs, and the quantitative cancer risk and hazard index estimates. For projects being conducted under traditional orders - this information would likely be provided in the Phase II RFI Report. For Streamlined Orders - this information would be included in the Investigation Report. For Voluntary Agreements - this information would be provided in the Final Corrective Measures Proposal.

- A summary of the information to needed to support the CA 725 EI decision of "Current Human Exposures Under Control." The RP should consider attaching the completed draft CA 725 forms. For projects being conducted under traditional orders, this information would likely be provided in the Phase I and Phase II RFI Reports. For Streamlined Orders and Voluntary Agreements, this information would be included in the Environmental Indicator Report.

- A summary of the information needed to support the CA 750 EI decision of "Migration of Contaminated Groundwater Under Control." The RP should consider attaching the completed draft CA 750 forms. For projects being conducted under traditional orders - this information would likely be provided in the Phase I and Phase II RFI Reports. For Streamlined Orders and Voluntary Agreements - this information would be included in the Environmental Indicator Report.

- A summary of the results from conducting the site-specific ecological risk assessment. The summary should include a description of the major results from each Tier of the assessment and their relationship to specific SWMUs, AOCs, and sampling locations; for projects being conducted under traditional orders - this information would likely be provided in the Phase II RFI Reports. For Streamlined Orders - this information would generally be included in the Investigation Report. For Voluntary Agreements - this information would generally be included in the Final Corrective Measures Proposal.

Section 3: Phase 3 - Remedy Selection to Achieve Site-wide Risk Management Goals

After a PM decides that the site characterization is completed, the evaluation of the complete risk management options for the site can begin. This has historically been referred to as the "Remedy

Selection Process."

The Remedy Selection Process can be defined as the combination of residual risk goals, source controls, technical/engineering remediation goals and institutional controls that the PM determines will achieve long-range risk management for the entire site.

The Priority Factors designated as Phase 3 should be applied to put in place the remedies to accomplish risk management goals for the site.

EPA has issued a number of criteria and guidance documents for evaluating remedial alternatives. For example, the *National Contingency Plan* (*NCP*) outlines nine criteria that should used for evaluating remedial alternatives to ensure that important considerations are factored into the selection. The 1996 *ANPR* also lists criteria which are very similar to those presented in the *NCP*. EPA also has issued other guidance documents that clarify or expand on the remedy selection framework presented in the *NCP* and the *ANPR*.

For the RCRA program, Region 5 has compiled the recommended criteria into a formal list titled: "Expectations for Final Corrective Action Remedies" (Attachment 3). This list is divided into the Fundamental Expectations, Remedy Selection Criteria, and Balancing Criteria that are recommended for evaluating remedial alternatives. PMs and other stakeholders can review this list at any time to understand EPA's fundamental approach for remedy selection. This list was reviewed to select specific priority factors that should cover the major risk management decisions a PM would encounter as part of selecting remedies for a site.

3.1: Human Health Risk Goals

The EPA has established preferences for the level of health risk for chemical constituents left in place (residual risk) in a medium that can be the source of current and/or future exposure.

Cancer Risk

Under current EPA policy as interpreted from the *NCP* and Superfund guidance, the Agency has established a policy that residual cancer risks in an exposure medium (soil, groundwater, and surface water) can be considered acceptable when the cumulative (multi-chemical) cancer risk is within the range of 1E-06 to 1E-04. The Agency has stated its preference that remedial decisions will be targeted to the lower end of this risk range. Ultimately, the specific EPA program responsible for making decisions will decide where within the acceptable range the residual cancer risk goal will be established for a given site or a specific location within a site.

To further clarify the understanding of residual risk goals for sites under its jurisdiction, the Region 5 RCRA program establishes the following policy preferences:

A) When setting the risk-based remediation goals for individual chemicals, the Region 5 program will use the 1E-06 risk level as the starting point for the protection goal. This is consistent with the EPA preference to achieve remediation at the lower end of the risk range, and is also consistent with the concept that the 1E-06 risk level should be used as the "point of departure" for setting chemical-specific remediation goals.

B) The individual chemical cancer risk goal may then be revised to a different level within the acceptable risk range based on consideration of the following primary categories of factors outlined in the *National Contingency Plan* and other EPA guidance.

   Exposure factors - including the reliability and conservativeness of the selected exposure parameters to estimate the risks; the potential for exposure from multiple pathways at the site; population

sensitivity, including the potential for exposure to children and the elderly; balance between the need to achieve protection for individual chemical exposure and the need to achieve acceptable multiple chemical exposure; the site-specific background levels of contaminants.

Uncertainty factors - including the level of uncertainty in the dose-response assessment of a specific chemical and the toxicity factors employed in the risk assessment; reliability and verification of fate and transport models used to estimate Exposure Point Concentrations; level of uncertainty in the assumptions for future land use and future groundwater use;

Technical factors - including the actual amount and density of analytical sampling data and the frequency of sampling in areas of known contamination; the actual chemical-specific detection/reporting limits achieved in the site investigation; the presence of matrix interferences in sampling for specific chemicals; the level of confidence to establish reliable and enforceable long-term exposure controls for contaminants left in place.

C) The preferences and factors described above apply to the development of the risk-based remediation goals at any RCRA site. They do not take into account the additional criteria of cost and technical practicability. These criteria would be evaluated through additional site-specific studies such as the traditional Corrective Measures Study (CMS) and the Corrective Measures Implementation Plan (CMIP). Consequently, the risk-based remediation goals can be viewed as the starting point for focusing the additional studies needed for the CMS and CMIP.

Residual soil contaminants - the goal is that residual cumulative cancer risk for multiple chemicals should not exceed 1E-04. For setting the risk-based remediation goals for individual chemicals, the preferences and factors described above should be used.

Residual groundwater contaminants - for carcinogenic constituents which have final MCL values, the goal is that the MCL should not be exceeded; for all other carcinogenic constituents, the goal is that the residual cumulative cancer risk for multiple chemicals should not exceed 1E-04. For setting the risk-based remediation goals for individual chemicals not having a final MCL, the preferences and factors described above should be used.

Surface water used as drinking water - for carcinogenic constituents which have final MCL values, the goal is that the MCL should not be exceeded; for all other carcinogenic constituents, the goal is that the residual cumulative cancer risk for multiple chemicals should not exceed 1E-04. For setting the risk-based remediation goals for individual chemicals not having a final MCL, the preferences and factors described above should be used.

Surface water not used as drinking water - for uses other than drinking water, EPA has established values known as “Recommended Water Quality Criteria”. These criteria are numeric values that protect human health from the harmful effects of pollutants in ambient water. Under section 304(a) of the *Clean Water Act* (CWA), water quality criteria are based solely on data and scientific judgments about the relationship between pollutant concentrations and environmental and human health effects; they do not consider economic or social impacts. The criteria also serve as guidance to the states and authorized tribes in adopting water quality standards in support of the CWA. They also provide guidance to EPA when it promulgates Federal regulations under the CWA. They are not regulations in themselves and do not impose legally binding requirements on EPA, states, authorized tribes or the public. There are currently approximately 80 numeric criteria available for specific chemicals. These are recommended water concentrations for specific constituents that should not be exceeded in order to provide human health protection for additional contaminant exposures through surface water (e.g., recreational use, consumption of fish and shellfish).

Non-cancer toxic hazard

For constituents regarded as non-carcinogenic, the EPA policy is that for each residual contaminant, the hazard quotient should not exceed a level of 1.0. In addition, for multiple contaminants that express their threshold toxic effect on the same target organ or by the same mechanism of action, the cumulative (i.e., additive) hazard quotients should not exceed a level of 1.0. (The additive hazard quotients are referred to as a Hazard Index.)

To further clarify and streamline the understanding of residual hazard goals for sites under its jurisdiction, the Region 5 RCRA program establishes the following policy preferences:

Residual soil contaminants - the goal is the same as described in the paragraph above.

Residual groundwater contaminants - for non-carcinogenic constituents which have final MCL values, the goal is that the MCL should not be exceeded; for all other hazardous constituents, the goal is that the hazard quotient for each constituent should not exceed a level of 1.0.; In addition, for multiple contaminants that express their threshold toxic effect on the same target organ or by the same mechanism of action, the cumulative (i.e., additive) hazard quotients should not exceed a level of 1.0.

Surface water used as drinking water - for non-carcinogenic constituents which have final MCL values, the goal is that the MCL should not be exceeded; for all other hazardous constituents, the goal is that the hazard quotient for each constituent should not exceed a level of 1.0.; In addition, for multiple contaminants that express their threshold toxic effect on the same target organ or by the same mechanism of action, the cumulative (i.e., additive) hazard quotients should not exceed a level of 1.0.
Surface water not used as drinking water - for uses other than drinking water, EPA has established values known as Recommended Water Quality Criteria. These criteria are numeric values that protect human health from the harmful effects of pollutants in ambient water. Under section 304(a) of the *Clean Water Act* (CWA), water quality criteria are based solely on data and scientific judgments about the relationship between pollutant concentrations and environmental and human health effects; they do not consider economic or social impacts. The criteria also serve as guidance to the states and authorized tribes in adopting water quality standards in support of the CWA. They also provide guidance to EPA when it promulgates Federal regulations under the CWA. They are not regulations in themselves and do not impose legally binding requirements on EPA, states, authorized tribes or the public. There are currently approximately 80 numeric criteria available for specific chemicals. These are recommended water concentrations for specific constituents that should not be exceeded in order to provide human health protection for additional contaminant exposures through surface water (e.g., recreational use, consumption of fish and shellfish).

Risk goals for contaminated sediments

In 2002, EPA issued *Principles for Managing Contaminated Sediment Risks at Hazardous Waste Sites* (OSWER Directive 9285.6-08). This Directive outlines 11 principles to assist site managers in making scientifically sound and nationally consistent risk management decisions at contaminated sediment sites. Plans to remediate, dispose, and manage contaminated sediments can be very complex and involve the interests of the RP, public stakeholders, and government resource trustees (e.g., Federal and state fisheries and natural resource agencies). The Directive recommends consultation with the Corrective Action Branch of the Office of Solid Waste where proposed plans for actions on sediments for an entire site will address more than 10,000 cubic yards or five acres of contaminated sediment.

Risk goals for specific constituents

Certain constituents present special challenges during the selection of risk goals because of factors related to potential toxicity, regulatory requirements, background levels, or specific Agency policy. Constituents for which these factors are likely to be encountered are described below.

Lead

For potential exposures to lead, the Agency has not assigned either a cancer slope factor or a Reference Dose. Therefore, a cancer risk level or Hazard Quotient cannot be established for lead when it is encountered at a RCRA site, and the contribution of lead to cumulative cancer risk or cumulative Hazard Index also cannot be determined. Consequently, a risk-based residual limit for lead must be established separately from other constituents.

For hazardous waste cleanup sites and other situations where exposure to lead in soil could be encountered, the stated goal of the Agency is: "... OSWER will attempt to limit exposure to soil lead levels such that a typical (or hypothetical) child or group of similarly exposed children would have an estimated risk of no more than 5% exceeding the 10 ug lead/dl blood lead level. This 10 ug/dl [micrograms/deciliter] blood lead level is based upon analyses conducted by the Centers for Disease Control and EPA that associate blood lead levels of 10 ug/dl and higher with health effects in children; however, this blood lead level is below a level that would trigger medical intervention." This is the strategy employed as part of determining a soil remediation goal for lead at hazardous waste sites (e.g., Superfund, RCRA, Brownfields).
To evaluate health risk from lead, the Agency uses a quantitative model that correlates potential adverse health effects with lead intake levels and predicted blood lead levels following absorption (Integrated Exposure Uptake Biokinetic Model; IEUBK). Numerous studies on adverse health effects from lead have shown that children are a highly sensitive receptor because of the effects of lead on the developing neurological system.

For lead exposure in the residential land use setting, young children (age 6 to 84 months) are known to be the sensitive receptor. Based on running the IEUBK Model and taking into account reasonable background levels of lead in other media (e.g., air, water, diet), the Agency has recommended that a soil lead level of 400 mg/kg (400 ppm) can be adopted as an acceptable remedial goal for soil in the residential use setting.

For lead exposure in the non-residential land use setting (e.g., industrial use, commercial use), the exposed receptor is assumed to be an adult worker, and the sensitive receptor is a developing fetus being carried by a pregnant female. For this situation, the Agency has developed an Adult Lead Model which accounts for lead intake by an adult and transfer of lead to a developing fetus. Based on the most recent Agency analysis, data on baseline blood lead levels in women of child-bearing age were derived from the NHANES III national study. The data were further analyzed by geographic quadrants and ethnic groups. The recommendation is that the combined data on ethnic groups in a specific quadrant (e.g., Midwest) should be used since the future worker population at most sites is likely to be heterogenous and could consist of several ethnic groups. For the Midwest quadrant (including all Region 5 States), use of the NHANES data in the Adult Lead Model resulted in calculation of a protective risk-based goal of 1100 mg/kg. Consequently, a soil lead remedial goal of 1100 mg/kg (1100 ppm) is recommended as an acceptable goal for soil in the non-residential use setting where only adult workers would be the expected exposure group.

Arsenic

For arsenic in soils, a problem often encountered at Midwestern sites is that naturally-occurring arsenic background concentration levels actually exceed the calculated risk-based screening levels. For example, the Illinois EPA reports that the statewide arsenic background soil concentrations at sites unimpacted by industry show a mean concentration of 6.7 mg/kg with a range of 0.35-24 mg/kg. This mean and upper range both exceed the concentration corresponding to the 1E-05 cancer risk screening level for the typical residential and industrial land use scenarios. Consequently, arsenic will often be retained as a constituent of concern at RCRA sites based on measured background levels. When final remedial concentration goals are selected for arsenic, a comparison to the naturally-occurring

background levels of arsenic at the site will often need to be evaluated.

PCBs

As stated earlier in Section 1.3, PCBs may be encountered as contaminants of concern at many RCRA sites because of historical industrial activities. At some of these sites, the PCB contamination may trigger the need to comply with TSCA regulations that could apply to both the site investigation and to remedial requirements for the site. The remedial requirements could include specific numerical cleanup levels for future industrial use or future residential use, or the option to base cleanup goals on a site-specific risk assessment in certain cases. An explanation of the site remedial requirements under TSCA regulations is presented in Attachment 1.

In addition, it should be noted that the Region 5 RCRA program will confer with the Region 5 TSCA program (Toxics Program Section) to identify the TSCA requirements that apply at a RCRA site and to ensure that compliance with TSCA requirements will be achieved through the remedial decisions.

Dioxin

As stated earlier in Section 1.3, the detection of dioxins in soil as a site related constituent is likely to be encountered at sites where specific industrial or waste treatment practices occurred. Because the EPA has not completed and released its comprehensive exposure, toxicology and dose-response analysis of dioxin (the "Dioxin Reassessment"), the EPA has established interim goals for the remediation of dioxin in soils at sites which are investigated under Superfund and RCRA. The interim goals are presented in the OSWER Directive "Approach for Addressing Dioxin in Soil at CERCLA and RCRA Sites."

The Directive establishes recommended remedial goals for dioxin in soil under residential and industrial land use. For current and future residential land use, the recommended remedial goal in soil is 1 ug/kg TEQ (1 ppb TEQ), where TEQ refers to the "Toxic Equivalents" for the mixture of toxic congeners. For current and future industrial land use, the recommended remedial goal in soil is a starting point of 5 ug/kg TEQ (5 ppb TEQ) with a range that should not exceed 20 ug/kg TEQ (20 ppb TEQ).

The Directive addresses only direct contact to contaminated soil. Consequently, the actual site risks and potential remedial goals for other exposure media (e.g., sediment, food crops, fish) and other exposure scenarios (crop consumption, fish consumption) would be need to be developed through a site-specific risk assessment.

Comparison of site-related constituent concentrations to naturally-occurring background levels

The importance of conducting sampling for evaluating the levels of naturally-occurring constituents at a site was described earlier (Sections 1.3 and 2.3). EPA's preference is that the health risks from the site-specific background concentrations should be calculated and understood in comparison to the risks from the site-related chemical releases. EPA will also consider any additional supporting evidence that the measured background levels are naturally-occurring or are regional background levels that were not impacted by the site-specific industrial activities.

Generally, the RCRA program will not set cleanup goal concentrations for site releases (SWMUs/AOCs) that are lower than the concentrations found for natural background levels at the site. For example, in cases where a risk-based cleanup goal (e.g., 1E-05 cancer risk) for a chemical constituent would be below the site-specific background concentrations, the cleanup goal may be established based on the background level. Consequently, the RCRA program will not require remediation of naturally-occurring metals to levels below the site-specific background of naturally-occurring metals.

Key References:

NATIONAL OIL AND HAZARDOUS SUBSTANCES POLLUTION CONTINGENCY PLAN: Remedial investigation/feasibility study and selection of remedy (Code of Federal Regulations; TITLE 40 - PROTECTION OF ENVIRONMENT; CHAPTER I - ENVIRONMENTAL PROTECTION AGENCY; PART 300; Subpart E - Hazardous Substance Response; Sec. 300.430)
http://homer.ornl.gov/oepa/guidance/cercla/siteclosure/document.cfm?type=ncp&sh=31646&len=15175

Role of the Baseline Risk Assessment in Superfund Remedy Selection Decisions (OSWER Directive 9355.0-30; April 22, 1991) www.epa.gov/superfund/programs/risk/baseline.pdf

Compilation of National Recommended Water Quality Criteria (Office of Water; Dec. 2003)
http://www.epa.gov/waterscience/standards/wqcriteria.html

Principles for Managing Contaminated Sediment Risks at Hazardous Waste Sites (OSWER Directive 9285.6-08; February 12, 2002) www.epa.gov/superfund/resources/remedy/pdf/92-85608-s.pdf

Draft Contaminated Sediment Remediation Guidance for Hazardous Waste Sites;
www.epa.gov/superfund/resources/sediment/guidance.htm

Clarification to the 1994 Revised Interim Soil Lead (Pb) Guidance for CERCLA Sites and RCRA Corrective Action Facilities (OSWER Directive (9200.4-27P; August 1998)
http://www.epa.gov/superfund/programs/lead/products/oswer98.pdf

Reference Manual: Documentation of Updates for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) Windows Version (EPA 540-K-01-007; OSWER 9285.7-44; May 2002)
http://www.epa.gov/superfund/programs/lead/products.htm

Recommendations of the Technical Review Workgroup for Lead for an Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil (EPA-540-R-03-001; OSWER 9285.7-54; Jan. 2003)
http://www.epa.gov/superfund/programs/lead/products.htm

BLOOD LEAD CONCENTRATIONS OF U.S. ADULT FEMALES: SUMMARY STATISTICS FROM PHASES 1 AND 2 OF THE NATIONAL HEALTH AND NUTRITION EVALUATION SURVEY (NHANES III) (OSWER #9285.7-52; March 2002)
http://www.epa.gov/superfund/programs/lead/products.htm#guidance

Adult Lead Methodology Frequently Asked Questions (EPA-OSWER; Technical Review Work Group for Lead; April 2004) http://www.epa.gov/superfund/programs/lead/almfaq.htm

Approach for Addressing Dioxin in Soil at CERCLA and RCRA Sites (OSWER Directive 9200.4-26; April 13, 1998)

Role of Background in the CERCLA Cleanup Program (OSWER Directive 9285.6-07P; April 26, 2002)
http://www.epa.gov/superfund/programs/risk/bkgpol_jan01.pdf

3.2: Ecological Risk Management Goals

Establishing remediation goals for ecological receptors is considerably more difficult than establishing such goals for the protection of human health due to the scarcity of broadly applicable and quantifiable toxicological data for wildlife species. Remedial exposure levels are best established on a site-specific basis because of the large variation in the kinds and numbers of receptor species present at sites, the differences in their susceptibility to contaminants, and the tremendous variation in environmental bioavailability of many contaminants in different media.

Since ecological receptors at sites exist within a larger ecosystem context, remedies selected for

protection of these receptors should also assure protection of the ecosystem components upon which they depend or which they support. Except at a few very large sites, RCRA and Superfund risk assessments typically do not address effects on entire ecosystems, but normally gather effects data on individuals in order to predict or postulate potential effects on local wildlife, fish, invertebrate, and plant populations and communities that occur or that could occur in specific habitats at sites (e.g., wetland, floodplain, stream, estuary, grassland, etc.). Ecological risk assessments incorporate a wide range of tests and studies to either directly estimate community effects (e.g., benthic species diversity) or indirectly predict local population-level effects (e.g., toxicity tests on individual species), both of which can contribute to estimating ecological risk. RCRA remedial actions generally should not be designed to protect organisms on an individual basis, but to protect local populations and communities of biota. (An exception is legally designated protected resources, such as listed or candidate threatened and endangered species that could be exposed to site releases). Contaminant levels that are expected to protect local populations and communities can be estimated by extrapolating from effects on individuals and groups of individuals using a lines-of-evidence approach.

For establishing remedial goals, the PM should consult with an ecological risk assessor to address the following four questions, which highlight fundamental ecological risk assessment and risk management concerns:

A. What ecological receptors should be protected?

EPA guidance provides information on identifying and selecting assessment endpoints for evaluating the ecological risk to biotic receptors at sites. An assessment endpoint is defined as: “an explicit expression of the environmental value that is to be protected.” RCRA risk assessments use site-specific assessment endpoints that address chemical-specific potential adverse effects to local populations and communities of plants and animals (e.g., reductions in populations of fish-eating birds, or reductions in survival, reproduction or species diversity of indigenous benthic communities). The number of necessary assessment endpoints depends on the number and type of contaminated habitats at the site. Risk assessment measures (i.e., measures of effect, measures of exposure, measures of ecosystem and receptor characteristics) should then be selected based on site-specific conditions and used to infer effects on the local population or community of concern. Examples might include: toxicity test results, tissue concentrations, and physical-chemical measurements related to fate and transport of the contaminants.

B. Is there an unacceptable ecological risk at the site?

Unless the ecological impacts are readily apparent (e.g., no vegetation will grow on the contaminated portion of the site or no benthic organisms exist in the sediment downstream from the release), site-specific biological data should be developed in order to determine if there are unacceptable risks. The baseline risk assessment may include site-specific toxicity tests with test organisms that address the assessment endpoints selected for the site. These readily available test organisms are considered surrogates for the actual species exposed. The ecological risk assessor can identify the tests and species most appropriate for the site. Other techniques to estimate the magnitude and severity of risks may include modeling to predict food-chain transfer and secondary toxicity of bioaccumulative chemicals to upper trophic level receptors, the measurement of tissue concentrations, the performance of species diversity studies (e.g., Rapid Bioassessment Protocols), and in-situ bioassays (e.g., caged fish/bivalves). Through the use of field studies and/or toxicity tests, several types of data may be developed to provide supporting information for a lines-of-evidence approach to characterizing site risks. This approach is far superior to using single studies or tests or measurements to determine whether or not the observed or predicted risk is unacceptable.

If studies or tests performed with site soil, sediment, or water demonstrate or predict serious adverse effects (e.g., increased mortality, diminished growth, impaired reproduction, etc.) on the selected assessment endpoints as compared to tests conducted at an appropriate reference site or using reference media, there is usually sufficient evidence to assume that unacceptable adverse effects have already occurred or may occur at the site.

Sufficient information should be collected in the ecological risk assessment to allow the risk assessor to

make a decision about: (a) causality between levels of contamination and effects; (b) whether the observed or predicted adverse effect on the site's local population or community is of sufficient magnitude, severity, areal extent, and duration that they will not be able to recover and/or maintain themselves in a healthy state; and (c) whether these effects appear to exceed the natural changes in the components typical of similar non-site-impacted habitats (i.e., reference areas). The information gathered in the ecological risk assessment should provide a clear and concise estimate of overall risk to the site under review.

C. Will the cleanup cause more ecological harm than the current site contamination?

Whether or not to clean up a site based on ecological risk can be a difficult decision at some sites. When evaluating remedial alternatives, the *NCP* highlights the importance of considering both the short-term and long-term effects of the various alternatives, including the no action alternative. Even though an ecological risk assessment may demonstrate that adverse ecological effects have occurred or are expected to occur, it may not be in the best interest of the overall environment to actively remediate the site. At some sites, especially those that have rare or very sensitive habitats, removal or *in-situ* treatment of the contamination may cause more long-term ecological harm than leaving it in place.

The likelihood of the response alternatives to achieve success and the time frame for a biological community to fully recover should be considered in remedy selection. Although most receptors and habitats can recover from physical disturbances, risk managers should carefully weigh both the short- and long-term ecological effects of active remediation alternatives and passive alternatives when selecting a final response. This does not mean that there is a preference for passive remediation; all reasonable alternatives should be considered. For example, the resilience and high productivity of many aquatic communities would allow for aggressive remediation; whereas the removal of bottomland hardwood forest communities in an area in which they cannot be restored due to water management problems would argue against extensive action in all but the most highly contaminated areas.

D. What cleanup levels are protective?

When a decision is made that a response action should be taken at a site based on unacceptable ecological risk, the risk manager selects chemical-specific cleanup levels that are acceptable. These would be levels that provide adequate protection of the ecological receptors as determined from the selected assessment endpoints. Appropriate cleanup levels can be identified by using the same toxicity tests, population or community-level studies, or bioaccumulation models that were used to determine if there was an unacceptable ecological risk. Sufficient testing and interpretation should be performed at various site locations to quantify the relationship between chemical concentrations and effects. The data can then be used to establish a concentration and response gradient to define the concentration that represents an acceptable (i.e., protective) level of risk. At some relatively small sites, however, it may be more cost effective to remove, treat, or contain all contamination rather than to generate a concentration and response gradient.

An additional difficulty is the determination of the acceptable level of adverse effects for the receptors to be protected (e.g., what percent reduction in fish survival or in benthic species diversity is no longer protective?) There is no “magic” number that can be used. The acceptable level will be dependent on the assessment endpoints selected and the risk assessment measures used, including the chemical and biological data gathered from the range of contaminated locations. While it may be desirable to identify a standard numerical level of risk reduction that is protective, it is impracticable to do this for each possible species that could be exposed. For that reason, surrogate measures or representative species are used to evaluate the ecological risks to the assessment endpoints at the site. The acceptable level of adverse effects should be discussed and understood by the PM and risk assessor.

Key Reference:

Ecological Risk Assessment and Risk Management Principles for Superfund Sites (OSWER Directive 9285.7-28P; Oct. 1999).

3.3: Source Control

Source Control was previously mentioned as a situation to address under High Risk Releases (Section 2.1). When final remedies are ready to be selected, the need for additional source controls not covered under High Risk Releases should be considered. At least three situations are recognized where additional source control activity could be recommended:

- Source control at a SWMUs or AOCs which did not have High Risk Releases but have releases for which the PM may want to set risk-based remedial goals. In this case, the original source continues to be a release point for chemical constituents if left in place; the PM should consider permanent source control or source removal to prevent the need for long-term chemical monitoring as the remedial solution;

- Remediation of free phase chemical or NAPLs even where groundwater is not expected to be highly mobile or to be prime candidate for drinking water source; EPA regards free products and NAPLs as sources for future chemical migration and for degradation of groundwater resource quality;

- Removal or elimination of sources which prevent land from being converted or revitalized to a better or more ideal future condition including enhancement of ecological quality and habitat;

3.4: Removal/Reduction

Removal/Reduction is the process of accomplishing the Residual Risk Goals through the direct elimination or reduction of risk reduction by excavation and removal of chemical constituents and/or reduction of concentrations by waste treatment *in-situ*. The following are recommended procedures that would be employed to enhance appropriate removal/reduction decisions:

- Develop or calculate the chemical-specific cleanup goals that will be needed to meet the Residual Risk Goals at each SWMU or AOC that needs action; the chemical-specific cleanup goals can be determined from the original PRG values used for risk-based screening (Section 1.10) and by taking into account the desired cancer risk and Hazard Index goals. For exposure scenarios not covered through risk-based screening, the chemical-specific cleanup goals will need to be determined by utilizing the results of the site-specific risk assessments (RCRA risk assessors and ecologists can be consulted for assistance in interpreting and utilizing the results of site-specific risk assessments);

- For many locations, the problem will be dominated by a few “risk driving” chemicals; For soils and sediments - the removal/reduction plan can often focus on the risk drivers; establish the risk-based cleanup goal for the risk driving chemical(s); if reduction of risk driving chemicals is accomplished, the cumulative risk and Hazard Index goals will be satisfied; For groundwater - set a cleanup goal at the MCL for each chemical possessing an MCL; for chemicals not possessing an MCL, the chemical-specific cleanup goals will need to be determined by utilizing the results of the site-specific risk assessments (RCRA risk assessors and ecologists can be consulted for assistance in interpreting and utilizing the results of site-specific risk assessments);

- Conduct additional sampling of soil or sediments at SWMUs or AOCs if necessary to establish the starting geographic boundaries (lateral and vertical) over which the initial removal action should occur. Develop confirmatory sampling plans for excavated areas to determine if clean-up goals are achieved or if excavation needs to continue. Some options to consider:

    - ♦ allow statistical analysis of data in excavation zones and accept a mean chemical concentration not exceeding the chemical-specific target cleanup goal as long as the highest

concentration does not exceed some specific multiple of the cleanup goal (e.g., 2x of cleanup goal).

- ♦ the depth of excavation should be linked to the risk-based management goal; all excavations should be planned on basis of future exposure to contaminated surface soil; excavation should account for other likely future activities at site (e.g., gardening, parking lot construction; building excavation); all excavations should be planned to the depth needed to protect the migration to groundwater pathway;

3.5: Engineered Controls

Engineered Controls are physical structures or barriers designed to minimize or prevent exposure when contaminants are left in place. They can also be used to prevent the migration of chemical contaminants to locations where unacceptable exposure might occur. They do not accomplish reduction of chemical contaminant concentrations except through natural attention over time.

Three categories of engineered controls that are commonly regarded as useful risk management options are: caps, cut-off walls, and hydraulic containment barriers. They were previously described as examples of Interim Measures (Section 2.2). For selection of these controls as final remedies, the following factors should be considered:

- Why is an engineered control a necessary or desirable alternative to contaminant removal? EPA's stated preference is that contaminant sources and contaminant migration should be addressed through direct contaminant removal or direct reduction of contaminant concentrations. Consequently, the selection of engineered controls should be accompanied by further analysis to show that controls are suitable options after evaluating important factors such as technical practicability, implementation time, and total cost over time.

- These control methods may appear to be less costly for initial application, but may need to be operated and maintained over a long time period. Successful implementation may also need continued environmental sampling to demonstrate effectiveness.
- These controls usually also require placing institutional controls on the property to ensure that the engineered control remains in place; institutional controls may need to remain in place for a very long time if combined with natural attenuation (example - natural attenuation of volatile and semi-volatile contaminants in soil and groundwater).

- Implementation and maintenance of the engineering control may affect the attractiveness and revitalization options of the property.

3.6: Monitored Natural Attenuation of Chemical Contaminants

The term "monitored natural attenuation" (MNA) refers to the reliance on natural processes that can lead to the reduction in concentration or mobility of chemical constituents. Within the context of a site remediation approach, the objective of MNA is to achieve site-specific remediation objectives within a time frame that is reasonable compared to that expected from the application of other more active methods. The natural attenuation processes that are at work in such a remediation approach include a variety of physical, chemical, or biological processes that, under favorable conditions, can act without human intervention to reduce the mass, toxicity, mobility, volume, or concentration of contaminants in groundwater and soil.

These *in-situ* processes include biodegradation; dispersion; dilution; sorption; volatilization; radioactive decay; and chemical or biological stabilization, transformation, or destruction of contaminants. When deciding to rely on natural attenuation processes for site remediation, EPA prefers those processes that degrade or destroy contaminants. Also, EPA generally expects that MNA will only be appropriate for

sites that have a low potential for contaminant migration.

Natural attenuation processes are typically occurring at all sites, but to varying degrees of effectiveness depending on the types and concentrations of contaminants present and the physical, chemical, and biological characteristics of the soil and groundwater. Natural attenuation processes may reduce the potential risk posed by site contaminants in three ways:

(1) Transformation of a contaminant(s) to a less toxic form through destructive processes such as biodegradation or non-biological transformations;

(2) Reduction of contaminant concentrations such that potential exposure levels may be reduced;

(3) Reduction of contaminant mobility and bioavailability through sorption onto the soil or rock matrix.

Where conditions are favorable, natural attenuation processes may reduce contaminant mass or concentration at sufficiently rapid rates to be integrated into a soil or groundwater remedy for a site. After source control measures are put in place, natural attenuation may be sufficiently effective to achieve remediation objectives at some sites without the aid of other traditional active remedial measures. However, EPA's expectation is that MNA will be used in conjunction with active remediation measures. For example, active remedial measures should be applied in areas with high concentrations of contaminants while MNA could be used for low concentration areas; or MNA could be used as a follow-up to active remedial measures.

EPA does not view MNA to be a "no action" remedy, but rather considers it to be a means of addressing contamination under a limited set of site circumstances where its use meets the applicable statutory and regulatory requirements. MNA is not a "presumptive" or "default" remediation alternative, but rather should be evaluated and compared to other viable remediation methods (including innovative technologies) during the study phases leading to the selection of a remedy. The decision to implement MNA should include a comprehensive site characterization, risk assessment where appropriate, and measures to control sources.

For practical guidance in making a decision on whether MNA should be adopted as an appropriate remedy at a site, the PM should evaluate the following criteria and recommendations:

Appropriate Situations Where MNA May Be Considered

- The RP can demonstrate that MNA would be able to achieve groundwater or soil cleanup objectives such as the need to reduce contaminant concentrations to the acceptable risk-based goals (e.g., MCLs; chemical-specific risk limits);
- Measures for source control of the original groundwater or soil contamination are already in place;
- The dominant natural attenuation processes would cause degradation or destruction of contaminants as opposed to those processes that merely dilute contamination or prevent its movement;
- The groundwater contaminant plume(s) is already stable or shrinking in extent;
- The estimated time frame to meet cleanup levels is reasonable considering factors such as the desired groundwater use and the time frames required for other remedies; and the time frame is comparable to that which could be achieved through active remediation;
- The MNA remedy would be used in conjunction with an active remedial system or as a follow-up measure to active remediation.

Evaluation of the MNA Proposal

A three-tiered approach to evaluating MNA as a potential remedy is recommended. In this approach, successively more detailed information is collected as necessary to provide a specified level of confidence on the estimates of attenuation rates and the remediation time frame. These three tiers of site-specific information are:

(1) Historical groundwater and/or soil chemistry data that demonstrate a clear and meaningful trend of decreasing contaminant mass and/or concentration over time at appropriate monitoring or sampling points. (In the case of a groundwater plume, decreasing concentrations should not be solely the result of plume migration. In the case of inorganic contaminants, the primary attenuating mechanism should also be understood.)

(2) Hydrogeologic and geochemical data that can be used to demonstrate or deduce the type(s) of natural attenuation processes active at the site, and the rate at which such processes will reduce contaminant concentrations to required levels. For example, characterization data may be used to quantify the rates of contaminant sorption, dilution, or volatilization, or to demonstrate and quantify the rates of biological degradation processes occurring at the site.

(3) Data from field or microcosm studies (conducted in or with actual contaminated site media) can directly demonstrate the occurrence of a particular natural attenuation process at the site and its ability to degrade the contaminants of concern (typically used to demonstrate biological degradation processes only).

The decision to move to successive tiers of information should be made as follows:
If historical data are not of sufficient quality and duration to support the requirements of Tier Number 1, move onto Tier Number 2 and obtain data to characterize the nature and rates of natural attenuation processes at the site; If these data are also inadequate or inconclusive, move onto Tier Number 3 and conduct the microcosm studies.

Contingency Remedies

- EPA recommends that RPs and regulators should consider the need for identifying one or more contingency remedies; A contingency remedy (or contingency plan) is a cleanup approach specified in a remedy decision document that functions as a “backup” remedy in the event that the selected MNA remedy fails to perform as anticipated;

- Contingency remedies are especially appropriate for an MNA remedy that is selected based primarily on predictive analyses or predictive models rather than documented analytical data demonstrating trends of decreasing contaminant concentrations.

Monitoring Period

The MNA remedy should include conditions requiring the collection of constituent concentration data until groundwater cleanup level goals are met at the point of compliance; Usually, monitoring would be continued for some specified additional time period (e.g., 1-3 years) to demonstrate that concentration levels are stable and remain below the cleanup goals.

Key Reference:

Use of Monitored Natural Attenuation at Superfund, RCRA Corrective Action, and Underground Storage Tank Sites (Final) (OSWER Directive D9200.4-17; April 1999)
http://www.epa.gov/swerust1/directiv/d9200417.htm

3.7: Institutional Controls

Institutional Controls (ICs) are restrictions on the use of land, water, and other resources that are used to limit or prevent human activity that could result in exposure to environmental media containing chemical contaminants. They are used most appropriately as an adjunct or supplement to other more direct risk management and risk reduction options such as source control and engineered controls. ICs should not be regarded as a substitute for active remedial efforts that will that prepare a site for the highest level of beneficial reuse and revitalization. Consequently, EPA believes that ICs will seldom serve as the sole remedy at a site.

ICs should be evaluated in the same level of detail as other remedy components because they are considered to be response actions under Superfund and RCRA. ICs should be evaluated by the same balancing criteria recommended when considering other remedial decisions for a RCRA site.

When is the placement of an IC a necessity?

The need for an IC can be driven by both the need to prevent potential exposure and to protect another remedy option. The general requirement is: If any remedial option calls for leaving waste in place and unrestricted land use and unlimited exposure should not be allowed, an IC should be placed as a remedy to ensure that unacceptable exposure from residual contamination does not occur. Typical situations that would call for placement of an IC would include the following:

- The RP elects to conduct risk screening, site-specific risk assessment and/or contaminant remediation based on future industrial land use rather than evaluating or remediating contaminants for future residential land use;

- Groundwater will remain contaminated above drinking water standards and/or acceptable risk concentrations for residential water consumption so that use of groundwater as a drinking water source must be prevented.

- Remedy options that leave residual wastes on-site including capping waste in place, construction of containment facilities, and natural attenuation and long-term pumping-and-treatment of groundwater.

What are the types of ICs that could be applicable to the Region 5 RCRA Program?

The following types are recognized as being potential candidates for use as ICs in RCRA corrective action remedies:

- *Informational Devices:* Informational devices provide information or notification. Common examples include State registries of contaminated properties, deed notices, and advisories. Informational devices themselves may often be non-enforceable. For example, deed notices are a common form of institutional control because they effectively inform future owners about the residual contamination and any use restrictions imposed on the facility. However, deed notices, like most informational devices, have no legal force to limit or control land use or activities; they serve only as a notice function and should not be relied upon as the sole institutional control at a site.

- *Governmental Controls:* Governmental controls are usually implemented and enforced by a State or local government and are based on State or local authorities that restrict property use. Specific examples include restrictions on the use of land and water, zoning restrictions, ordinances, building permits or other permit requirements. Governmental controls can be useful in controlling potential exposure. However, their effectiveness is dependent on enforcement by a third party (i.e., state or local government) and the controls can be changed or terminated at any time without the involvement of EPA. Consequently, for corrective action projects where Region 5 is the lead Agency, these

controls should not be used as the sole institutional control.

- *Proprietary Controls*: Proprietary controls have their basis in private property law. There are numerous controls within this category, including easements and covenants. Controls under this category are unique in that they create legal property interests. In other words, proprietary controls involve legal instruments placed in the chain of title for the property that convey a property interest from the owner (grantor) to a second party (grantee) for the purpose of limiting the use or imposing restrictions on land and/or water. An example of this type of control is an easement to provide access rights to inspect and monitor. The principal benefit of this type of control is that it can be made to "run with the land". It is binding on subsequent purchasers of the property (successors in title) and transferable, which may make it more reliable in the long-term than other types of institutional controls.

  Generally, proprietary controls are advisable when the restrictions on activities are intended to be long-term or permanent, or when other controls are deemed unreliable. EPA's authority to acquire proprietary controls at a site could become a complicated situation. Consequently, the PM should consult with a Regional attorney to evaluate whether EPA has the authority to acquire proprietary controls.

- *Enforcement Actions with Institutional Control Components*: EPA administrative orders and judicial consent decrees may be used to require and ensure long-term compliance with institutional controls. These enforcement documents can be used where the landowner agrees to limit or allow certain long-term site activities. Although frequently used, certain limitations should be addressed. For example, most enforcement actions do not "run with the land". This means that the restrictions in the enforceable order/decree are only binding on the signatories. There are often provisions requiring notification to EPA prior to a property transfer in these agreements. However, the property restrictions themselves are not automatically transferred at the time of the property transaction. This limitation may be addressed by having either the prior land owner remain responsible to EPA for continued performance and adherence to the institutional control, or by imposing a separate order negotiated with the subsequent purchaser.

Does the Region 5 RCRA Program have a policy for how ICs should be selected?

Based on considerable review of the types of available ICs and the potential effectiveness of ICs to serve as remedies, the Region 5 RCRA program has developed the following policy preferences for how ICs should be selected and implemented:

- ICs should be selected only where the Region believes they will be effective and enforceable, both in the short-term against the current facility owner/operator and in the long-term against potential future property owners. To enhance the over-all effectiveness of institutional controls, project managers should consider "layering" controls (i.e., using multiple types of ICs) to provide overlapping assurances of protection from future contaminant exposure.

- To ensure compliance with an IC, a facility owner/operator must agree to a written enforceable order which contains the specific requirements for the IC and binds the owner/operator to notify subsequent property owners of the IC and the obligation to maintain the requirements of the IC after the property transfer.

- EPA generally will ensure federal enforceability of the owner/operator's commitment to maintain and operate the selected IC through the use of consent orders and/or judicial consent decrees. Depending upon site specific conditions, EPA may use its consent order authority under Sections 3008(h) or 7003 of RCRA or Section 106(a) of CERCLA. There are other statutory sections such as Section 311 of the Clean Water Act which may also apply depending on the nature of the hazards posed at the facility. For facility owners/operators with a permit or an approved closure/post-closure

plan, EPA will require them to enter into a consent order separate and apart from the permit and/or closure/post-closure permit. Similarly, owner/operators subject to voluntary agreements would have to enter into a consent order for the component of the remedy which relies upon ICs.

More details on the enforceable consent order and the specific requirements it needs to contain can be found in the Region 5 guidance document listed below.

Key Reference:

Use of Institutional Controls in the RCRA Corrective Action Program (EPA-Region 5; Waste, Pesticides, and Toxics Division; March 2000)

3.8: Risk Management Plan

At this point in the site investigation, the PM should have received a set of proposed remedies from the RP for review. For Voluntary and Streamlined Orders, this information would generally be included in the Final Corrective Measures Proposal. For projects being conducted under traditional 3008(h) Orders, this information would be included in the Corrective Measures Study. The proposed remedies submitted by the RP should be the culmination of the site investigation work performed under the traditional RCRA correction action activities such as the RFI and the CMS. The scope of the Plan should be discussed with the RP to reach consensus on what it should contain. The proposed remedies would normally be reviewed by and commented on by the PM, which would result in a set of acceptable remedies. The Plan should focus on an explanation of the proposed remedies and not on re-evaluation of existing site data. Ideally, the Plan should provide the following information that will directly assist the PM to convey the proposed site decisions to RCRA Program Managers and the public:

- Describe each remedial action proposed to be performed or put in place to eliminate risk or reduce risk to acceptable levels; the Plan should identify specific site locations (SWMUs, AOCs), specific media (soil, groundwater, sediments), and specific chemical constituents that will be addressed by a remedy; Explain whether the remedy is needed to address human health risk and/or ecological risk;

- Explain how each proposed remedial option will achieve EPA's remedial expectations. EPA's expectations are as follows and are explained in more detail in Attachment 3 of this document:

  - To use treatment to address principle threat wastes.
  - To return groundwaters to their maximum beneficial use.
  - To use engineering controls for low-level threats.
  - To use institutional controls.
  - To control or eliminate sources.
  - To consider innovative technologies.
  - To use a combination of methods to achieve protection.

- Evaluate each proposed remedy using EPA's Remedy Threshold and Balancing Criteria. EPA's criteria are as follows and are explained in more detail in Attachment 3 of this document:

  - Threshold Criteria: - Protect Human Health and the Environment
    - Attain Media Cleanup Standards
    - Control Sources to reduce or eliminate further releases

  - Balancing Criteria: - Long-term reliability and effectiveness
    - Reduction of toxicity, mobility, or volume of wastes
    - Short-term effectiveness
    - Implementability
    - Cost

- Community and State Acceptance

- Identify remedies that require long-term technical monitoring or maintenance to accomplish the risk management goal (e.g., continued groundwater monitoring to demonstrate migration under control); describe the criteria used to decide when the long-term technical remedy achieves the risk management goal;

- Describe the approximate schedule or time line for implementing the remedies;

- Identify any remedies already put in place at the site (e.g., IMs, source controls) and explain how they accomplished a risk management goal(s); Explain any significant additional actions needed to complete the remedies (e.g., addition of an IC);

- Provide a recommendation for the preferred remedy or combination of technologies evaluated that will achieve EPA's remedial expectations and effectively provide a long-term solution which achieves the project goals.

CHAPTER 5:

Relationship between the Risk Management Strategy and State RCRA Corrective Action Authority

By regulatory design and historical practice, the States have become primary implementers of many provisions of the Federal RCRA program. In some states, nearly all of the Federal RCRA provisions have been delegated to State authority. In EPA Region 5, all 6 States have been granted authority to implement a large portion of Federal RCRA Corrective Action program.

The granting of authority means that the EPA determined that a State could implement a RCRA corrective action program that provides for site investigations and site remedial decisions which would provide for remedies and protections to land and water that would be equivalent to remedies provided by the Federal program. In addition, the States may decide to implement standards or additional requirements which could be interpreted as making the State RCRA program more "stringent" than the federal program. The States must apply their own environmental law making authority in order to create these additional requirements and standards.

Because of the large number of RCRA sites that must be addressed, the administrative need exists to conduct RCRA corrective action under both Federal and State authority. As expected, certain problems have been identified in achieving consistency and efficiency when several different agencies try to

administer the same basic program. Therefore, Region 5 and several States have entered into Memorandums of Understanding (MOUs) to help define the roles of the agencies in implementing RCRA corrective action and to avoid administrative and legal conflicts between the agencies. MOUs are non-binding documents which may be modified or rescinded by the discretion of one or both parties.

Because of the apparent "dual" authorities to implement RCRA corrective action, questions and concerns have surfaced about the legal and practical relationship between Federal and State corrective action programs. A major concern is that RPs may perceive that two distinct sets of corrective action regulations apply to the same investigation. The RPs do not want to be required to conduct a separate investigation to satisfy each agency (i.e., "be required to serve two masters"), and do not want to be placed in the position of having one agency's decisions called into question by a second agency (i.e.,"be caught in double jeopardy").

After reviewing its MOUs with the states and considering the need to expedite corrective action in a clear and transparent manner, the Region 5 RCRA program will adopt the following working relationship to avoid the problems described above and to expedite decision-making:

- When a State is the lead regulatory agency for a corrective action site project, the State will essentially be the implementer of the federal RCRA program. Region 5 will recognize the authority of the State to oversee site investigations and to make final decisions on site remediation. Region 5 will provide comment and technical assistance to the particular state on the corrective action project if requested.

- When Region 5 is the lead regulatory agency for a corrective action site project, Region 5 becomes the implementer of the State RCRA program for the State in which the project is located. Region 5 expects that States will recognize the authority of Region 5 to oversee site investigations, to exercise its professional judgment in implementing the state's corrective action program, and to make final decisions on site remediation.

As a complement to the above points, Region 5 will make significant efforts to understand each State's corrective action program requirements (legal and policy), and to identify significant differences between the state and federal programs. This will include participation in training programs, workshops, and active technical exchanges between project managers, program managers and other staff. When developing risk management decisions for a site, Region 5 will review State requirements and State standards that would be reasonable to apply to the federal decisions. Region 5 will make clear where specific State requirements and/or State standards are being applied in its decisions. However, Region 5 will still apply its own professional judgment in making decisions and will favor accomplishing performance goals over the application of specific processes.

ATTACHMENT 1:

Criteria for determining compliance with Toxic Substances Control Act (TSCA) regulations at a RCRA site found to have PCB contamination

RCRA sites found to be contaminated with PCBs must be remediated in a manner that satisfies requirements of the Federal PCB regulations under TSCA at 40 CFR Part 761, particularly 761.50(b)(3) and 761.61(a) thru (c). An important consideration for the applicability of the PCB regulations is the source of the PCBs at the site, and both the date and concentration of the original release or spill of the PCBs. In some cases, depending on the date and concentration of the original release or spill and the current concentration of PCBs found at the site, remediation may not be required.

If the PCBs at the site are the result of a regulated release or spill, specific information should be submitted to the Region in the form of a notification or application which needs to include the following types of information: sampling data (i.e., characterization of PCBs in environmental media and cleanup verification); cleanup levels; engineering and institutional controls for PCBs remaining on site; and off-site disposal procedures for remediation waste;

Part 1: Site Investigation Phase

PCB Concentration Considerations (In-situ and Source)

The source of the release or spill of PCBs is an important consideration to determine if and how any PCB contamination as the site will or should be remediated. These regulatory considerations are discussed below along with a table which summarizes the considerations.

If the source concentration of the original release or spill was < 50 ppm (< 50 mg/kg) PCBs, regardless of the date of release, or if the release occurred before April 18, 1978, regardless of the concentration at time of release, the site is not required to be remediated under TSCA. The release can be characterized and remediated under RCRA, as described earlier in Section 3 and Section 4 of this Risk Management Strategy. If the release occurred before April 18, 1978 and the concentrations of PCBs found at the site are ≥50 ppm, cleanup is not required if the responsible party can demonstrate that the PCBs do not present an unreasonable risk to human health or the environment.

For sites that have PCB contamination resulting from a release or spill that occurred prior to April 18, 1978, off-site disposal of any PCB contaminated material can be based on its "as found" concentration, with the exception that PCB contaminated material with concentrations ≥50 ppm may be disposed of in a hazardous waste (RCRA C) landfill if a notification or application as described below under **"Notification and/or Application Requirement"** is submitted to the Region.

If the source of the original release or spill was ≥50 ppm PCBs and the release occurred on or after April 18, 1978, regardless of the concentration of PCBs found at the site, the site must be remediated in accordance with the Federal PCB regulations, as described below under **"Remedial Decision Phase**."

If the date or concentration of the original release or spill is not known, it must be assumed that the PCBs are regulated and are required to be remediated. In other words, the assumption must be made that the source was ≥50 ppm and the release occurred on or after April 18, 1978.

April 18, 1978 is used since that is the effective date of the *PCB Disposal and Marking Rule*, when releases of PCBs became regulated. (There are actually two applicable dates and concentrations, April 18, 1978, and July 2, 1979, and 50 ppm and 500 ppm. However, only one date and concentration, the most conservative combination, are provided here to avoid confusion.)

Date of release	Source concentration	As found concentration	Cleanup required under TSCA?	Comment
before April 18, 1978	any concentration (above or below 50 ppm)	< 50 ppm	No	See 761.50(b)(3)(i) and definition of PCB remediation waste (761.3)
before April 18, 1978	any concentration (above or below 50 ppm)	≥50 ppm	Possible, depending on an evaluation of the risk of releases of PCBs from the site. If the site cannot demonstrate that there is no unreasonable risk, than the PCBs should be cleaned up.	See 761.50(b)(3)(ii). The Region 5 PCB program typically requests the responsible party to demonstrate that there is no unreasonable risk for leaving the PCBs at the site.

on or after April 18, 1978	< 50 ppm	< 50 ppm	No	See definition of PCB remediation waste (761.3).
on or after April 18, 1978	≥50 ppm	≥50 ppm	Yes	Remediate per 761.61 (a),(b), or (c).

Site Investigation and Characterization

If PCBs are known, assumed, or expected to be at a site, the site must be investigated to determine the extent of the contamination. The Federal PCB regulations include guidance for characterization sampling. It is essentially a 10 foot grid. Some compositing of samples can be conducted. The guidance is at 40 CFR 761 Subpart N. However, the use of this guidance is not specifically required and other characterization sampling procedures, such as any characterization sampling guidance developed and used by the RCRA, Superfund, or Brownfields programs can be used.

Notification and/or Application Requirements

For almost all PCB sites being cleaned up under the PCB regulations, a notification or application should be submitted to the Region. Specifically, if a site is remediating the PCB contamination under the self-implementing option or risk-based option identified below, a notification or application should be submitted to the Region which includes the following 5 elements (see 40 CFR 761.61(a)(3)):

A) Description of the nature of contamination (soils, concrete, etc.);
B) Summary of characterization sampling procedures and results;
C) Map showing location and extent of contamination with sample sites noted;
D) Cleanup and disposal plan;
E) Certification on location of sampling information;

In addition to the above information, if a risk assessment is being used to determine the cleanup levels at a site, the risk-assessment or any other information needed to demonstrate that there is no unreasonable risk from the PCBs should also be submitted to the Region.

Part 2: Remedial Decision Phase

There are several options for remediating PCBs in accordance with the Federal PCB regulations: self-implementing, performance based disposal, risk-based, coordinated approval (see, respectively 761.61(a), 761.61(b), and 761.61(c), and 761.77). These options are discussed below, in order of what is most likely to be used, not in order of when they appear in the regulations.

Self-implementing On-site Cleanup and Disposal of PCB Remediation Waste

PCBs may be remediated following specific cleanup, sampling, disposal, and control methods in accordance with the PCB regulations for the self-implementing on-site cleanup and disposal of PCB remediation waste. Self-implementing remediation of PCBs can be considered as an “approval by Rule”, since if the specific requirements are followed, a written approval is not required.

For self-implementing PCB remediation, a notification must be submitted to the Region which includes the information specified in the 5 elements listed above. The notification must be submitted at least 30 days before remediation is to begin. Thirty (30) days after submitting the notification, if it is considered complete, the responsible party may consider it approved.

The actual remediation is based on future occupancy of the area with the PCB contamination. If the area

is going to be occupied for 6.7 hours or more per week, it is considered a high-occupancy area. If the area is going to be occupied for less than 6.7 hours per week, it is a low-occupancy area.

For high occupancy areas, the responsible party has two options: 1) cleanup all the PCBs to 1 ppm, or 2) cleanup all the PCBs to 10 ppm and cover the PCBs with a cap. A notice to the deed is required if the option of cleaning to 10 ppm and covering with a cap is used.

For low occupancy areas, the responsible party has three options: 1) cleanup all the PCBs to 25 ppm; 2) cleanup all the PCBs to 50 ppm and place a fence around and mark the PCB area; or 3) cleanup all the PCBs to 100 ppm and cover the PCBs with a cap. A notice to the deed is required if any of the low occupancy area options are used.

Specific verification sampling procedures must be followed (see 40 CFR 761 Subpart O). In summary, it involves the use of a 5 foot grid. Compositing up to 9 samples is allowed.

Non-liquid remediation waste with any concentration of PCBs may be sent to a hazardous waste (RCRA C) landfill and non-liquid remediation waste with less than 50 ppm PCBs may be sent to a municipal or non-municipal non-hazardous waste (RCRA D) landfill.

The self-implementing remediation of PCBs does not apply to sites where the PCB contamination is in sediments, groundwaters or surface waters, grazing lands, or vegetable gardens, sewers, or drinking water source or distribution systems. If the PCB contamination is in any of these situations, the PCBs must be remediated following the risk-based approval or performance-based disposal options described below.

Risk-based Disposal Approval

If a proposal to cleanup, sample, dispose, or store PCB remediation waste is not provided for in other parts of the PCB regulations, such as the regulations for self-implementing remediation of PCBs (as described above), the activity may be approved if the responsible party demonstrates that it does not present an unreasonable risk to human health or the environment. Such approvals are referred to as risk-based approvals and are provided for in the PCB regulations at 40 CFR 761.61(c).

The demonstration that an activity does not present an unreasonable risk is similar to and essentially the same as the process followed by the RCRA program. The responsible party can eliminate the potential for exposure by removing the PCBs to a level that does not present an unreasonable risk; or alternatively, reduce the potential for exposure by using engineering and institutional controls.

An application or work plan for a risk-based disposal approval must be submitted and must include, at a minimum, the information specified above under **Notification and/or Application Requirements**. It must also include any addition information needed to demonstrate that the planned approach to remediate the PCBs will not present an unreasonable risk. The procedures in the Risk Management Strategy that are normally used by the RCRA program to evaluate risk may also be used to demonstrate that the PCBs will not present an unreasonable risk.

The approvals must be issued in writing and be signed by the Division Director of WPTD. The authority to issue TSCA risk-based disposal approvals has been delegated to the WPTD Division Director. So, a RCRA corrective action document signed by the WPTD Division Director may also be considered a TSCA risk-based approval. The approval document should specify the PCB activity being approved (cleanup, sampling, disposal, storage), include any conditions needed for that activity, and note that the document is a TSCA risk-based approval in accordance with 40 CFR 761.61(c).

Coordinated Approval

The PCB regulations also provide an option for the remediation of PCBs to be considered satisfied if the remediation was conducted in accordance with a decision document, such as a permit or consent order or agreement, issued by EPA, including by RCRA, which addresses the remediation of PCBs. If such a document has been issued, a written TSCA Coordinated Approval may be issued and will satisfy requirements of the Federal PCB regulations for remediation of the PCBs. The written TSCA Coordinated Approval may simply be a letter signed by the WPTD Division Director, which references the PCB remediation requirements in the decision document.

In evaluating the actual requirements to remediate the site, the cleanup objectives established by the RCRA program, for instance, using the procedures in Section 3 and Section 4 of this Risk Management Strategy, may also be acceptable for the remediation of PCBs.

For a TSCA Coordinated Approval for the remediation of PCBs, the responsible party must submit the following information:

- A request for a coordinated approval;
- The name, organization, and telephone number of the contact person for the RCRA waste management authority;
- A copy of the relevant waste management document (if the Region does not already have a copy of the document);
- And a certificate that the person(s) who owns the site is aware of and will adhere to any applicable PCB record keeping and reporting requirements.

Performance-based Disposal

A responsible party may also remediate all the PCBs at the site without obtaining any approval from the Region. If a responsible party remediates all the PCB contamination at the site down to a concentration of 1 ppm, and disposes of the remediation waste and cleanup material as regulated PCB waste in an approved PCB incinerator or PCB landfill, no notification or application needs to be submitted to EPA, and no approval needs to be obtained from EPA under the PCB regulations. The remediation and disposal of PCBs following these requirements is known as performance-based disposal [40 CFR 761.61(b)].

ATTACHMENT 2:

Region 5 RCRA program policy on the use of occupational standards for evaluating concentrations of chemical constituents in indoor air

The following outlines the current Region 5 RCRA policy for recognizing OSHA compliance limits as risk-based screening concentrations for indoor air. This policy will apply unless and until the U.S. EPA announces an Agency-wide policy on how OSHA compliance should be applied to RCRA corrective action projects.

1. For Environmental Indicator determinations (i.e., CA 725 - Current Human Exposures Under Control and CA 750 - Migration of Contaminated Groundwater Under Control), the Region 5 RCRA program will recognize the use of OSHA Permissible Exposure Limits (PELs) as appropriate health based screening levels for indoor air within on-site industrial buildings. This recognition will apply to buildings under the direct control of the Responsible Party (RP) (owner/operator). This recognition is based on a policy adopted by the Office of Solid Waste at EPA Headquarters. If the site also contains a

building(s) which is not obviously industrial (e.g., cafeteria, day-care center, commercial space) or not obviously under the control of the RP, then Region 5 may request the RP to provide evidence that the building(s) is regulated under OSHA for the contaminants of concern.

2. For site remedial decisions beyond the EI determinations (e.g., RFI determinations; CMS requirements; Statement of Basis), OSHA PELs will not be recognized as the appropriate health based screening levels for indoor air within any on-site industrial buildings. EPA's risk-based screening levels for exposure to air contaminants will be applied according to the document titled: "DRAFT GUIDANCE FOR EVALUATING THE VAPOR INTRUSION TO INDOOR AIR PATHWAY FROM GROUNDWATER AND SOILS" (http://www.epa.gov/correctiveaction/eis/vapor/complete.pdf). The RP may apply this guidance to demonstrate that vapor intrusion to indoor air is not a complete exposure pathway for an on-site building(s). If vapor intrusion of all applicable contaminants cannot be eliminated as a pathway of concern by the screening procedures recommended in the guidance, then additional work to address the pathway will be required.

3. For off-site buildings (i.e., buildings not under control of the RP), OSHA PEL values will not be recognized as appropriate health based screening levels for indoor air for EI determinations or for subsequent remedial decisions. EPA's risk-based screening levels for exposure to air contaminants will be applied according to the guidance given above. However, the RP may apply this guidance in an effort to demonstrate that vapor intrusion to indoor air at the off-site building(s) or location(s) in question is not a complete exposure pathway. If vapor intrusion cannot be eliminated as a pathway of concern by the screening procedures recommended in the guidance, then additional work to address the pathway will be required.

ATTACHMENT 3:

EPA's Expectations for Final Corrective Action Remedies

These expectations were taken from the May 1, 1996, *Advance Notice of Proposed Rulemaking* (*ANPR*) (61 FR 19432). Many of these expectations were first articulated in the discussion of remedy selection at CERCLA sites in the *National Oil and Hazardous Substances Pollution Contingency Plan* (*NCP*) (40 CFR 430(a)(1)). CERCLA and RCRA corrective action criteria address the same types of considerations and should generally result in similar remedies when applied to similar site-specific conditions.

1. EPA expects to use treatment to address the principal threats posed by a site whenever practicable and cost effective[4]. Contamination that represents principal threats for which treatment is most likely

[4] The term "cost-effective" does not necessarily mean least costly.

to be appropriate includes contamination that is highly toxic, is highly mobile, or cannot be reliably contained, and that would present a significant risk to human health and the environment should exposure occur.

Helpful References:

- *A Guide to Principal Threat and Low Level Wastes (OSWER Directive 9380.3-06FS, November 1991)*
- *The Role of Cost in the Superfund Remedy Selection Process (EPA 540/F-96/018, September 1996)*

2. EPA expects to return usable groundwaters to their maximum beneficial uses wherever practicable, within a time frame that is reasonable given the particular circumstances of the site. When restoration of groundwater is not practicable, EPA expects to prevent or minimize further migration of the plume, prevent exposure to the contaminated groundwater and evaluate further risk reduction. EPA also expects to control or eliminate surface and subsurface sources or effects of groundwater contamination.

   Helpful References:

   - *Region 5 RCRA Subtitle C Corrective Action Risk Assessment Guidance (1998)*
   - *Corrective Action for Releases from Hazardous Waste Management Units; Proposed Rule (Federal Register, May 1, 1996)*
   - *Guidance for Evaluating the Technical Impracticability for Ground-Water Restoration, (Directive 9234.2-25, September, 1993).*

3. EPA expects to use engineering controls, such as containment, for wastes and contaminated media which can be reliably contained, pose relatively low long-term threats, or for which treatment is impracticable.

4. EPA expects to use a combination of methods (e.g., treatment, engineering and institutional controls), as appropriate, to achieve protection of human health and the environment.

5. EPA expects to use institutional controls such as groundwater and land use restrictions primarily to supplement engineering controls as appropriate for short- and long-term management to prevent or limit exposure to hazardous wastes and constituents. EPA does not expect that institutional controls will often be the sole remedial action.
6. EPA expects to consider using innovative technology when such technology offers the potential for comparable or superior treatment performance or implementability, less adverse impact, or lower costs for acceptable levels of performance when compared to more conventional technologies.

7. EPA expects to remediate contaminated soils as necessary to prevent or limit direct exposure of human and environmental receptors and prevent the transfer of unacceptable concentrations of contaminants (e.g., via leaching, runoff or airborne emissions) from soils and subsurface soils to other media.

With regard to media cleanup standards, EPA's risk reduction goal is to reduce the threat from carcinogenic contaminants such that for any medium, the excess risk of cancer to an individual would be between 10^{-6} to 10^{-4}. For non-carcinogens, the hazard index should generally not exceed 1. EPA's preference is to select remedies that are at the more protective end of the risk range. Therefore, 10^{-6} should be used as the point of departure when determining site-specific cleanup standards. Final cleanup standards should consider factors such as exposure frequency, receptor or ecosystem sensitivity, uncertainty, or technical limitations.

Remedy Selection Criteria

The 1996 *ANPR* reaffirmed the appropriateness of the remedy selection criteria proposed in 1990. (*61 FR 19449, May 1, 1996*). A summary of the remedy selection criteria is included in this section along with

references that provide additional information. Another helpful reference is the National Contingency Plan. RCRA and CERCLA remedy selection criteria are similar and the National Contingency Plan and its preamble explain the criteria in greater detail.

Remedies will be evaluated in two phases. During the first phase, potential remedies are screened against the following threshold criteria. Remedies must:

3. Protect human health and the environment.
4. Attain media cleanup standards (e.g., state cleanup standards)
5. Control the source(s) of releases so as to reduce or eliminate, to the extent practicable, further releases of hazardous wastes (including hazardous constituents) that might pose threats to human health and the environment.
6. Comply with applicable standards for waste management (e.g. Clean Air Act & Clean Water Act emissions limitations, hazardous waste storage & transportation regulations, etc.)

Balancing Criteria

Remedies that meet the threshold criteria are then compared to the following balancing criteria:

1. Long term reliability and effectiveness. This pertains to the risk remaining at the facility after completion of a remedial action. It considers:
   (a) the level of threat posed by hazardous constituents remaining in place and the adequacy and reliability of any engineering or institutional controls to manage those risks, and
   (b) the risk associated with treatment residuals compared to the risk associated with untreated waste.

2. Reduction of toxicity, mobility, or volume of wastes. This pertains to the preference for remedies which, wherever practicable, involve treatment that permanently and significantly reduce the toxicity, mobility, or volume of wastes that pose principal threats. (*See also: "A Guide to Principal Threat and Low Level Wastes" (OSWER Directive 9380.3-06FS, November 1991)*

1. Short-term effectiveness. This criterion evaluates the effects of the remedial alternatives on human health and the environment during their implementation. It considers factors such as:
   (b) dust from excavation
   (c) transportation of hazardous materials
   (d) air quality impacts
   (e) potential impacts to the environment from remedy construction and implementation and the reliability of mitigation measures to prevent or reduce impacts.

4. Implementability. This addresses the technical and administrative feasibility of implementing an alternative and the availability of services and materials.

5. Cost. Cost effectiveness is determined by comparing the costs and overall effectiveness of alternatives to determine whether the costs are proportional to the effectiveness achieved. Criteria used to evaluate cost effectiveness include long-term effectiveness and permanence, reduction of toxicity, mobility, or volume through treatment, and short-term effectiveness. *(See also: The Role of Cost in the Superfund Remedy Selection Process (EPA 540-F-96-018, September 1996)*

6. Community acceptance. EPA encourages public involvement activities beyond the formal requirements found in the regulations, especially when it fosters an early and open dialogue with potentially affected parties. Efforts should be taken to involve interested parties in activities throughout the corrective action process, instead of only at junctures specified in the regulations. Public participation can also be very beneficial when provided at the initiation of corrective action,

the selection of significant interim measures (as appropriate), prior to remedy proposal, and at the completion of corrective action. *(See also: RCRA Public Involvement Manual, EPA530-R-93-006, September 1993)*

7. State acceptance. State acceptance of the proposed action should be a very important consideration in EPA's actions. Frequent coordination with State agencies that have an interest in the action is highly recommended.

EXHIBIT 1: Performing risk-based screening of surface soil data
(Refer to Chapter 4; Sec 1.10)

The following is a general procedure for conducting the risk-based screening of surface soil sampling data.

1) Set your Internet browser to: <http://www.epa.gov/region09/waste/sfund/prg/index.htm>
Open the Web site titled: "Region 9: Superfund - Preliminary Remediation Goals"

Bullet links #1- #4 contains very useful background information on PRG values and how they are calculated.

2) To view the chemical-specific PRG values for surface soil screening, scroll down the home page and open the bullet link titled:
Soil Calculations. This is a Table of PRG values for the Residential Land Use and Industrial Land Use scenarios. The PRG values have soil concentration units (i.e., mg/kg).

3) For each chemical constituent of interest, the PRG values should be located from the following columns:

RESIDENTIAL SOIL
Cancer Risk = 1E-06 Chronic HQ = 1
combined combined

INDUSTRIAL SOIL
Cancer Risk = 1E-06 Chronic HQ = 1
combined combined

For example, for the chemical Aldrin, the corresponding values are:

RESIDENTIAL SOIL
Cancer Risk = 1E-06 Chronic HQ = 1
combined combined
2.9E-02 mg/kg 1.8E+00 mg/kg

INDUSTRIAL SOIL
Cancer Risk = 1E-06 Chronic HQ = 1
combined combined
1.0E-01 mg/kg 1.8E+01 mg/kg

(NOTE: Some chemicals do not have listed Cancer Risk PRG values; and some chemicals do not have listed HQ = 1 PRG values)

4) To calculate the PRG value corresponding to a Cancer Risk = 1E-04, multiply the PRG value for Cancer Risk = 1E-06 by a factor of 100

For example, for the chemical Aldrin, the corresponding PRG values for Cancer Risk = 1E-04 are:

RESIDENTIAL SOIL
Cancer Risk = 1E-04 is: 2.9E-02 mg/kg x 100 = 2.9E+00 mg/kg

INDUSTRIAL SOIL
Cancer Risk = 1E-04 is: 1.0E-01 mg/kg x 100 = 1.0E+01 mg/kg

5) Collect all the sample analytical data for surface soil at each SWMU or AOC that is ready for screening. Label each SWMU/AOC with a simple letter/number combination (e.g., S01, S02 , A01, A02, etc.) Find and flag the maximum detected concentration (MAX) of each chemical constituent in each SWMU/AOC.

6) Start comparing the MAX concentration of each chemical constituent to its corresponding PRG values (as identified in Step #3 and Step #4 above) to determine the risk ranking of the chemical. For example, suppose the MAX concentration of Aldrin at a SWMU is 2.1 mg/kg. For the Residential Use scenario, this means that the MAX concentration is higher than the Cancer Risk = 1E-06 PRG (2.9E-02 mg/kg) but lower than the Cancer Risk = 1E-04 PRG (2.9E+00 mg/kg). The MAX concentration is also greater than the HQ =1 PRG (1.8E+00 mg/kg).

7) Calculate the "Screening Level Cancer Risk" and the "Screening Level HQ" corresponding to the MAX concentration. These values are calculated as follows:

Screening Level Cancer Risk = [(MAX) ÷ (PRG for Cancer Risk of 1E-04)] x (1E-04)

For example, for the Aldrin case cited in Step #6 above:

Screening Level Cancer Risk = [(2.1 mg/kg) ÷ (2.9 mg/kg)] x (1E-04) = 7.2E-05

Screening Level HQ = (MAX) ÷ (PRG for HQ = 1)

For example, for the Aldrin case cited in Step #6 above:

Screening Level HQ = (2.1 mg/kg) ÷ (1.8 mg/kg) = 1.2

8) If the SWMU/AOC contains additional chemical constituents for screening, repeat Step #3 through Step #7 above for each chemical.

9) Then calculate a "Cumulative Screening Level Cancer Risk" by summing all the Screening Level Cancer Risk values for each chemical constituent; and calculate a "Cumulative Screening Level HQ" by summing all the Screening Level HQ values for each chemical constituent.

To obtain additional assistance with risk-based screening, contact a human health risk assessment specialist from the WPTD-RCRA program.

EXHIBIT 2: Performing risk-based screening of groundwater and surface water data (Refer to Chapter 4; Sec 1.10)

The following is a general procedure for conducting the risk-based screening of groundwater/surface water sampling data**.**

1) Set your Internet browser to: < http://www.epa.gov/region09/waste/sfund/prg/index.htm >
Open the Web site titled: "Region 9: Superfund - Preliminary Remediation Goals"

Bullet links #1- #4 contains very useful background information on PRG values and how they are calculated.

2) To view the chemical-specific PRG values for groundwater and surface water screening, scroll down the home page and open the bullet link titled:
Air - Water Calculations. This is a Table of PRG values for the Residential Use of groundwater or surface water. The PRG values have water concentration units (i.e., ug/Liter).

3) For each chemical constituent of interest, the PRG values should be located from the following columns:

TAP WATER	
Cancer Risk = 1E-06	Chronic HQ = 1
combined	combined

For example, for the chemical Aldrin, the corresponding values are:

TAP WATER	
Cancer Risk = 1E-06	Chronic HQ = 1
combined	combined
4.0E-03 ug/L	1.1E+00 ug/L

(NOTE: Some chemicals do not have a listed Cancer Risk PRG value; and some chemicals do not have a listed HQ = 1 PRG value)

4) To calculate the PRG value corresponding to a Cancer Risk = 1E-04, multiply the PRG value for Cancer Risk = 1E-06 by a factor of 100

For example, for the chemical Aldrin, the corresponding PRG value for Cancer Risk = 1E-04 is:

TAP WATER
Cancer Risk = 1E-04 is: 4.0E-03 ug/L x 100 = 4.0E-01 ug/L

5) Collect all the sample analytical data for groundwater or surface water at each SWMU or AOC that is ready for screening. Label each SWMU/AOC with a simple letter/number combination (e.g., S01, S02, A01, A02, etc.) Find and flag the maximum detected concentration (MAX) of each chemical constituent in each SWMU/AOC.

6) Start comparing the MAX concentration of each chemical constituent to its corresponding PRG values (as identified in Step #3 and Step #4 above) to determine the risk ranking of the chemical. For example, suppose the MAX groundwater concentration of Aldrin at a SWMU is 6.0E-01 ug/L. This means that the MAX concentration is higher than the Cancer Risk = 1E-06 PRG (4.0E-03 ug/L) and higher than the Cancer Risk = 1E-04 PRG (4.0E-01 ug/L). The MAX concentration is lower than the HQ =1 PRG (1.1E+00 ug/L).

7) Calculate the "Screening Level Cancer Risk" and the "Screening Level HQ" corresponding to the MAX concentration. These values are calculated as follows:

Screening Level Cancer Risk = [(MAX) ÷ (PRG for Cancer Risk of 1E-04)] x (1E-04)

For example, for the Aldrin case cited in Step #6 above:

Screening Level Cancer Risk = [(6.0E-01 ug/L) ÷ (4.0E-01 ug/L)] x (1E-04) = 1.5E-04

Screening Level HQ = (MAX) ÷ (PRG for HQ = 1)

For example, for the Aldrin case cited in Step #6 above:

Screening Level HQ = (6.0E-01 ug/L) ÷ (1.1E+00 ug/L) = 0.6

8) If the SWMU/AOC contains additional chemical constituents for screening, repeat Steps #3 through #7 above for each chemical.

9) Then calculate a "Cumulative Screening Level Cancer Risk" by summing all the Screening Level Cancer Risk values for each chemical constituent; and calculate a "Cumulative Screening Level HQ" by summing all the Screening Level HQ values for each chemical constituent.

10) To screen the groundwater and surface data against EPA's Maximum Contaminant Levels (MCLs), set your Internet browser to:
< http://www.epa.gov/safewater/mcl.html#mcls >
Open the web site titled: "List of Drinking Water Contaminants & MCLs"

11) Locate each chemical in your data set which has a listed MCL value (Note: only about 45 chemicals commonly detected at Superfund or RCRA sites have a published MCL value.)

12) Compare the MAX concentration of each chemical constituent with its corresponding MCL value to determine if the MAX concentration exceeds the MCL. (Note: MCL values on the web site are listed in units of mg/L. To convert to ug/L, multiply the listed value by a factor of 1000.)

To obtain additional assistance with risk-based screening, contact a human health risk assessment specialist from the WPTD-RCRA program.

Filename: Final Risk Management Strategy doc_v6_Apr05.doc
Directory: E:\New Web Design\cars\carsinfo
Template: C:\Documents and Settings\moliver\Application Data\Microsoft\Templates\Normal.dot
Title:
Subject:
Author: epauser
Keywords:
Comments:
Creation Date: 5/23/2005 9:26:00 AM
Change Number: 3
Last Saved On: 5/23/2005 4:40:00 PM
Last Saved By: Government User
Total Editing Time: 12 Minutes
Last Printed On: 6/23/2005 4:23:00 PM
As of Last Complete Printing
Number of Pages: 67
Number of Words: 31,333 (approx.)
Number of Characters: 178,602 (approx.)