Nov 2000

General

REGION 6
CORRECTIVE ACTION STRATEGY

GUIDE FOR PILOT PROJECTS

Prepared by

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November 2000

NOTICE

The procedures set forth in the U.S. EPA Region 6 November 2000 Corrective Action Strategy (CAS) are provided as guidance for the implementation of pilot projects for corrective action at sites with releases of hazardous constituents. Region 6 EPA intends to identify and conduct pilot projects at specific facilities in conjunction with state agencies to help in the further development of this strategy and EPA Region 6 intends to limit, at this time, use of the CAS to EPA and/or state-lead pilot projects. These pilot projects are intended to demonstrate the degree that corrective action can be accelerated through a streamlined process. This guide is not intended to supercede any applicable state statutory or regulatory requirements. This guide should be used in conjunction with a formal agreement, such as a permit, order, letter agreement, etc.

This guidance is based in part on policies referred to in the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), published on March 8, 1990 (*55 Federal Register* 8666) and the Advanced Notice for Proposed Rulemaking (ANPR) Subpart S, published on May 1, 1996 (61 *Federal Register* 19432).

The CAS provides guidance to the Region 6, U.S. Environmental Protection Agency (EPA) and the states in Region 6 as one possible method/process to implement RCRA corrective action. The CAS is meant to supplement not to replace previous guidance issued by the Agency regarding RCRA corrective action. It also provides guidance to the public and to the regulated community on how EPA, Region 6 may exercise its discretion in implementing its regulations. The CAS does not substitute for EPA regulations, nor a regulation itself. Thus, it does not impose legally binding requirements on EPA, the states, or regulated entities, and may not apply to a particular situation based on specific circumstances of the facility.

EPA Region 6 does not recommend this approach be used at facilities with a history of past noncompliance or one not interested in aggressively implementing corrective action. All decisions regarding correction action at a particular facility will be made based on the applicable statutes and regulations. Therefore, interested persons are free to raise questions and objections about the appropriateness of any recommendation in the CAS with respect to a particular facility, and EPA Region 6 will consider whether or not the recommendations in the CAS are appropriate.

The CAS is meant to be a living document to be updated and changed based on EPAs, the states, regulated entities, and the public experience in implementing it and as circumstances warrant.

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1.1 PURPOSE AND SCOPE OF THE CORRECTIVE ACTION STRATEGY

The U.S. Environmental Protection Agency (EPA) Region 6 has developed a corrective action strategy (CAS) to accelerate corrective action at Resource Conservation and Recovery Act (RCRA) facilities. This document was developed as guidance to help regulators and facilities make meaningful progress with corrective action at RCRA sites. The two primary objectives of this guide are to prioritize corrective action at facilities, and streamline corrective action administrative procedures, resulting in the protection of human health and the environment.

Although the CAS was developed for the RCRA program, its purpose is consistent with the cleanup principals and goals of other waste cleanup programs. Therefore, this guide may be useful to other persons engaged in cleaning up storage tanks, voluntary cleanup programs and Brownfields programs.

This guide describes a risk management strategy that, can be implemented during any phase of corrective action, introduces the use of a risk-based screen that prioritizes releases at a facility to better focus time and money on releases that pose a significant and unacceptable risk, and provides guidance for its implementation. EPA contemplates that the value of this guide will be demonstrated through EPA and/or state pilot projects.

The CAS is a performance-based approach that emphasizes results over process. Using the data quality objective process, investigations begin with the endpoint in mind. Use of existing and new

site-specific information is encouraged. Performance standards are established at the beginning of the corrective action process, allowing for more focused implementation. Releases are screened to determine the priority of corrective action, and remedial alternatives are selected on the basis of their ability to achieve and maintain the established performance standards, resulting in protection of human health and the environment.

The guide was designed as a tool for all stakeholders (EPA, states, facilities, and the public) involved in site remediation activities, and was meant to complement, not supersede, existing Federal, state, and local regulations.

The traditional RCRA corrective action process and reports (i.e., RCRA Facility Investigations (RFIs), Corrective Measure Studies (CMSs), Corrective Measure Implementation (CMI), etc.) are not elements of the CAS. However, the use of information and reports from the current process, if available, is encouraged. EPA Region 6's objective is to provide an alternative approach to corrective action by using the flexibilities available under the RCRA statute, and in existing state and Federal remediation guidance.

1.2 EVOLUTION OF THE CORRECTIVE ACTION PROCESS

The EPA and state regulatory agencies have made significant efforts in implementing corrective action under RCRA. Considerable progress is being made to eliminate pathways of exposure from industrial hazardous waste under current programs, however, final corrective action has only taken place at a fraction of facilities.

The corrective action program is now driven by two environmental indicators (EIs): the control of current human exposure, and the control of the migration of contaminated ground water (Government Performance and Results Act (GPRA) of 1993). EPA included the indicators as performance objectives to be achieved by 2005 for all high-priority RCRA facilities. The performance objectives are to control current human exposure to hazardous contamination at 95 percent of the high-priority RCRA facilities and, control the migration of contaminated ground water at 70 percent of the high-priority RCRA facilities

(GAO 1997). These goals will provide clear measures of the progress achieved in RCRA corrective action, and will also assess the level of protection to human health and for ground water resources that has been achieved from the implementation of numerous interim measures and stabilization actions.

> ***RCRA Corrective Action Environmental Indicator Codes (CA725/CA750)***
>
> In an effort to accelerate corrective action at RCRA facilities, the GPRA has set a goal of having 95% of the high priority facilities to have current human exposures controlled, and 70% to have the migration of contaminated ground water controlled by the year 2005. These goals will provide a measurement of the progress of corrective action for all RCRA facilities and will be represented by the following environmental indicators: CA 725 for Current Human Exposures Controlled, and CA 750 for Migration of Contaminated Ground water Controlled. These codes will be entered into the RCRA Information System (RCRIS) database by EPA and the states when RCRA facilities have reached these goals.

Meeting these performance objectives for GPRA may be difficult or impossible unless corrective action is accelerated. As in most programs, EPA's fundamental goal of the corrective action program is to control or reduce risks to human health and the environment. Risk-based prioritization can be used to ensure that corrective action activities are promptly initiated and fully protective, when evaluated against reasonable current and future land use and exposure assumptions at a given facility. Therefore, the CAS was developed to help EPA and the states meet the performance objectives established in response to the mandates of the GPRA, and to promote realistic strategies to assist in meeting the RCRA program's ultimate goal of achieving final remedial action.

The following sections summarize the evolution of the corrective action process under RCRA and address the factors affecting progress under the traditional corrective action approach. Also addressed are initiatives that EPA, states, and industry have taken to streamline corrective action through the design and implementation of various risk-based approaches.

1.2.1 Traditional Approach for RCRA Permitting

EPA's traditional corrective action approach is based on interpretation of applicable statutes, regulations, the detailed requirements set forth in 1990 in the proposed Subpart S regulations (55 *Federal Register* 30798), and the more recent Advanced Notice for Proposed Rulemaking (ANPR) Subpart S, published on May 1, 1996 (61 *Federal Register* 19432). Although EPA has not made the majority of the proposed requirements final, they serve as guidance for the corrective action program and have had a significant influence in the development of the CAS. The corrective action process as described in the RCRA Corrective Action Plan (CAP), OSWER Directive 9902.3-2A, May 1994, is structured around several elements common to most cleanup activities. In the first phase, RCRA facility assessment (RFA), EPA or the authorized state assesses the facility to identify releases and determine the need for corrective action. In the second phase, RCRA facility investigation (RFI), the facility conducts a more detailed investigation to determine the nature and extent of contaminants released to ground water, surface water, air, and soil. This phase can be complex and lengthy and is conducted under EPA or state review and monitoring. If remedial action is needed, a third phase, corrective measures study (CMS), is started. During this phase, the facility conducts a study, which when completed, describes the advantages, disadvantages, and costs of various cleanup options. The EPA then solicits public comments on the preferred option and selects a final method. In the fourth phase, corrective measures implementation (CMI), the facility implements the selected remedy and is required to design, construct, operate, maintain, and monitor it (GAO 1997).

Regulators and industry have focused historically on facility cleanups in a fragmented manner, in which each unit with a potential release was investigated and evaluated equally and independently. In these instances, corrective action for each release proceeded based on the individual characteristics of the particular release, and resources were not expended based on risk. Because of this approach, facilities were reluctant to spend limited resources on investigations and cleanup they considered unimportant and unwarranted based on risk. As a result, many facilities have not adequately investigated areas that pose real threats to human health and the environment because investigations and cleanup focused on all releases.

Although the 1996 APR. proposal outlines areas of flexibility in corrective action and emphasizes site-specific analyses, the process still is largely implemented through the traditional structured approach (i.e., RFA, RFI, CMS, and CMI).

1.2.2 Risk-Based Approaches Under Permit Programs

EPA, states, and industry recently have undertaken initiatives to streamline the corrective action process and make cleanup decisions based on an acceptable level of risk to human health and the environment, rather than focusing efforts on returning sites to pristine conditions. These recent risk-based initiatives are an improvement over the traditional approach, but generally focus only on the risk associated with releases and the cleanup levels required to be protective.

In most cases, the states and EPA developed risk-based approaches based on soil cleanup standards or soil screening levels, which focused on the protection against direct contact with soil (soil ingestion, dermal contact, and inhalation) and the protection of ground water from contaminants leaching through and from contaminated soil. Soil screening levels are generally used to screen releases at all sites regardless of site conditions or dynamics, and often use conservative assumptions and methodologies to offset non-site specific physical and exposure parameters (for example, screening levels are derived assuming that the exposure point is proximal to the source area, regardless of the location of the receptor). Screening risk assessment models also use conservative assumptions such as these to simplify and expedite risk evaluation, but usually at the cost of overestimating risk.

Other new tiered risk-based approaches were developed to better define site risks based on the complexity of the release, the amount of information available or required to characterize risk, and a balance of cost for evaluation versus cleanup (TNRCC 1999, IEPA 1997). The tiered approaches provide some additional flexibility for the facility in assessing site risks based on actual site conditions, but they do not streamline the overall corrective action process.

1.3 RISK MANAGEMENT USING THE CAS

EPA Region 6 developed the CAS to expedite the implementation of corrective action based on risk management to protect human health and the environment. The CAS is a performance-based approach that emphasizes results over process, and recommends evaluating risks to receptors posed by contaminants from known releases. Using the data quality objective process, investigations begin with the endpoint in mind. The CAS allows and encourages the use of existing and new site-specific information throughout the

process. It establishes performance standards in three key areas that will govern corrective action at a facility. The performance standards are established at the beginning of the process, rather than during the RFI/CMS phases under the traditional approach, to allow earlier implementation of corrective action, and to allow facilities to better plan response actions and estimate costs. Remedial alternatives are selected on the basis of their ability to achieve and maintain the performance standards.

One of the primary objectives of the CAS is to help regulators and facilities prioritize those releases that pose the most significant risks to achieve greater protectiveness. The CAS advocates the use of the risk-based priority screen (Screen), as a tool to prioritize releases of contaminants to soil and ground water. Use of the Screen will facilitate risk management and should lower the cost of implementing the corrective action process by identifying the significant releases that warrant immediate attention. Facilities may then opt to use more resource intensive approaches (e.g., site-specific risk assessment) to more closely examine risks from other releases, if necessary, to refine the remedial action objectives.

Figure 1-1 illustrates the philosophical concept of the CAS, that there is no one specific path through it. The administrative authority focuses on whether the established performance standards are met, ultimately achieving the primary goal of RCRA, to protect human health and the environment. Figure 1-1 does not illustrate how a facility proceeds through the CAS, but shows the options and flexibility available to evaluate risks at a site. Figure 2-1 (Chapter 2) illustrates how a facility would apply the various elements of the CAS.

1.4 ORGANIZATION OF THE DOCUMENT

The remainder of this document is organized into 6 chapters. Chapter 2 describes the CAS in greater detail and identifies the steps for implementing the CAS, such as establishing performance standards and the deliverables necessary for documenting progress. Chapter 3 addresses data quality objectives for site characterization, the development and use of a conceptual site model to define data needs, and data quality considerations for existing data. Chapter 4 describes the human health risk-based screen used to prioritize corrective action. Chapter 5 addresses the site-specific risk assessment process and how it is used in the CAS. Chapter 6 describes the process of evaluating remedial alternatives to

address unacceptable risk. Chapter 7 addresses monitoring requirements and remedial performance to ensure protection of human health and the environment.

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Chapter 2	Overview of the Corrective Action Strategy
Chapter 3	Data Quality Objectives and Data Types
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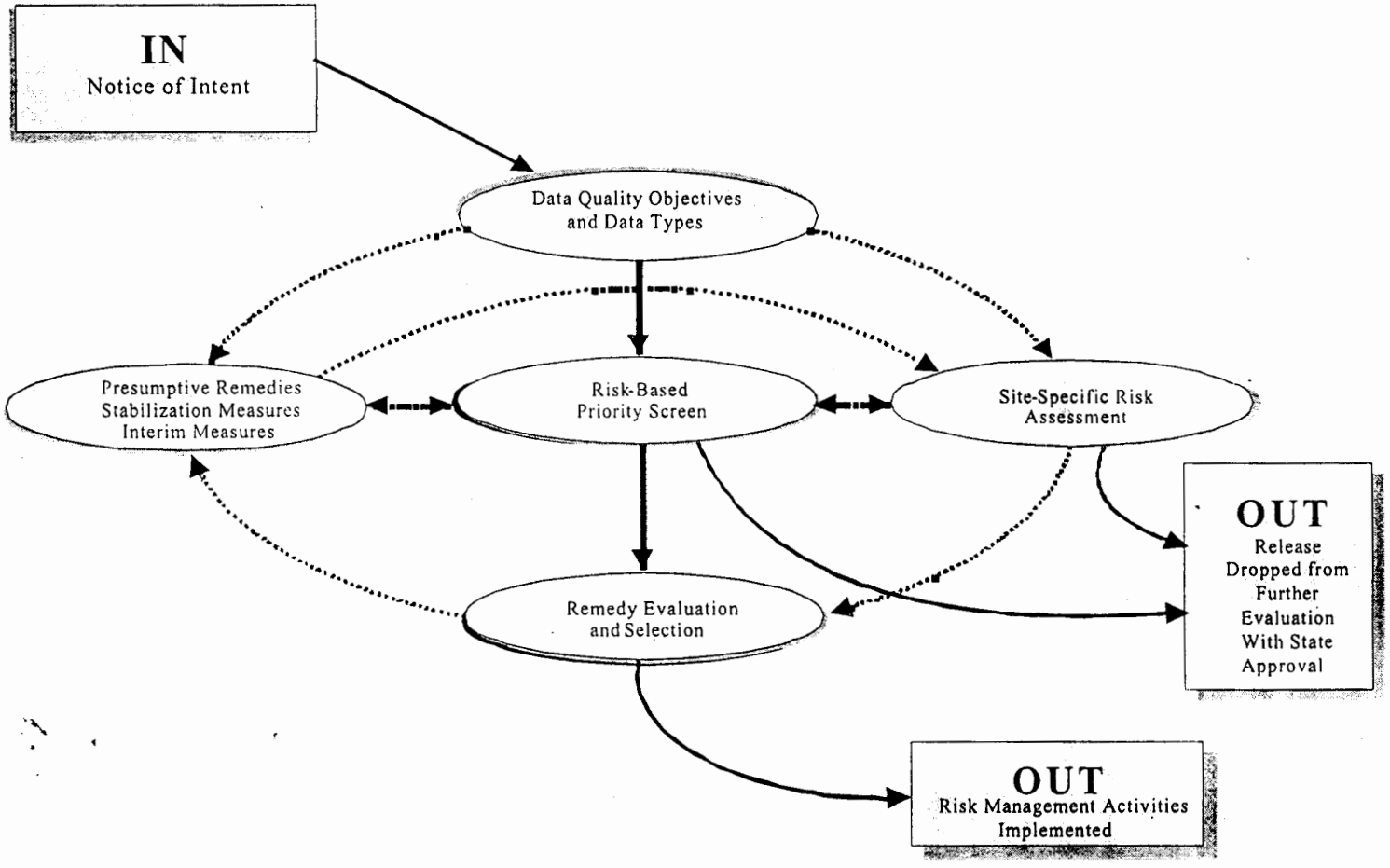
Appendix C	Innovative Site Assessment Techniques
Appendix D	Risk-Based Priority Screening Bright-Line Tables (BLTs)
Appendix E	Ecological Exclusion Criteria Worksheet & Ecological Assessment Checklist

Figure 1-1

Corrective Action Strategy Philosophy



2.0 OVERVIEW OF THE CORRECTIVE ACTION STRATEGY

This chapter describes . . .

Elements of the CAS
Performance standards
Responsibilities of the facility and administrative authority
Implementing the CAS and the administrative process

2.1 KEY ELEMENTS OF THE CAS

The steps in this chapter describe a flexible approach to corrective action. The CAS is initiated by individual facilities or the administrative authority recognizing the need for correction action. Key elements in this approach are establishing performance standards at the beginning of the process; developing data quality objectives and data types (including the conceptual site model); using a high-priority/low-priority risk-based screen; performing a site-specific risk assessment, if warranted; and evaluating, selecting, and monitoring performance of the remedy. The end result of the CAS process is a facility-specific prioritized plan for releases that pose highest risk to human health and the environment.

There is an overriding goal of the CAS:

To protect human health and the environment

To accomplish this goal, performance standards should be established at the beginning of the corrective action process. Through the application of the performance standards, the facility and administrative authority determine whether a release must be addressed through corrective action, and whether implemented corrective actions are protective of human health and the environment.

2.2 PERFORMANCE STANDARDS

The EPA's expectations for the outcome of corrective action at a facility are established in the

CAS by three performance standards. The performance standards are not new; however, the CAS ensures that they are applied consistently at an early stage of the corrective action process. Fixed performance standards established at the beginning of the CAS should streamline the corrective action process more than all other policy considerations by focusing activities toward a specific endpoint and allowing facilities to anticipate corrective action costs. These performance standards combine existing policy and regulatory requirements with a risk-based goal of protectiveness.

The three CAS performance standards are:

1. **Source Control Performance Standard:** Source control refers to the control of materials that include or contain hazardous wastes or hazardous constituents, that act as a reservoir for migration of contamination to soil, sediment, ground water, surface water, or air, or as a source for direct exposure. Sources are not always stationary, but can migrate from a landfill or surface impoundment where contamination originally was released. Contaminated ground water plumes are not generally considered a source material, although non-aqueous phase liquids (NAPL) in the ground water generally would be viewed as source material (Rules of Thumb for Superfund Remedy Selection, 1997).

2. **Statutory and Regulatory Performance Standard:** Statutes and regulations may dictate media-specific contaminant levels that must be achieved, such as maximum contaminant levels (MCLs) in drinking water. These requirements may be specified in Federal, state, and local laws and regulations.

3. **Final Risk Goal Performance Standard:** The final risk goal is the level of protection to be achieved and maintained by the facility. The final risk goal is established by the administrative authority based on land use, special subpopulations, contaminant concentrations based on acceptable risk, location at which the levels are measured, and the remediation time frame.

Source Control

EPA's continuing emphasis on source control reflects the Agency's strong preference for remedies that are protective in the long term. For ground water, source control is critical to returning our nation's contaminated ground waters to their maximum beneficial uses in a reasonable time frame, and to ensuring that uncontaminated ground water is available for future generations. Controlling sources of contamination is also consistent with the Agency's long-standing policies dealing with pollution prevention; it is generally easier to deal with the contamination at the source than to clean up wide-spread contamination.

The facility needs to determine if source material is present. Removal, containment, treatment, or a

combination of the three, should be evaluated on a case-by-case basis and balanced against factors such as effectiveness, implementability and cost. Controlling source material is predominating in the CAS, and must be addressed to ensure protectiveness over time. Prioritization as outlined in Chapter 4 does not mean avoidance of controlling source materials.

Applicable statutory and regulatory requirements (Federal, state, and local) will be identified at the beginning of the CAS and may become a performance standard for the facility (e.g., an MCL).

Of all of the performance standards, the final risk goal is the only one that will be based purely on site-specific issues, such as release and receptor characteristics, land use, and beneficial resources. One final risk goal may apply to the entire facility, but it is more likely that different releases will require different final risk goals due to variations in location of releases, land use, proximity of receptors, etc. Generally, cleanup standards range from a $1x10^{-4}$ to $1x10^{-6}$ excess lifetime cancer risk from exposure to carcinogenic hazardous constituents and a 1.0 hazard quotient for exposure to non-carcinogens. The final risk goal should be developed on sound risk assessment methodologies, such as EPA's Superfund risk assessment guidance (*Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation manual (Part A); EPA/540/1-89/002*).

The facility should not interpret that the order in which the performance standards are listed above suggests that one performance standard takes priority over the others. The EPA expects that all applicable performance standards will be achieved by the facility.

The objective of the risk-based priority screen described in Chapter 4 is to prioritize releases to determine those that require either immediate response or further evaluation from those that are a lower risk or long-term threat. Remedial alternatives for corrective action are then selected on the basis of their ability to achieve and maintain the performance standards.

2.3 RESPONSIBILITIES OF THE FACILITY AND ADMINISTRATIVE AUTHORITY

For the CAS to be effective, the responsibilities of the facility and the administrative authority must be clear. The facility proposes performance standards to the administrative authority for approval.

The facility should justify the proposed performance standards through evaluation and documentation of land use, ground water designation (current and reasonably expected future use), types of receptors present, and exposure pathways, etc. The administrative authority will then approve the performance standards proposed by the facility or establish the final risk goals that it determines are adequate based on a technical evaluation of the information provided by the facility, as well as other information available to the administrative authority.

The responsibilities of the facility and administrative authority are as follows:

The facility has the responsibility to achieve and maintain the performance standards as established by the administrative authority. In doing so, the facility may use any of the tools provided in the CAS.

The administrative authority has the responsibility to ensure that the actions undertaken by the facility are protective of human health and the environment, as established by performance standards. The administrative authority should also provide technical assistance to the facility and the public.

2.4 STEPS FOR IMPLEMENTING THE CAS

The following sections provide the facility and the administrative authority with a road map for implementing the CAS. Figure 2-1 illustrates the process of how a facility should proceed through the CAS.

2.4.1 Beginning the CAS

To begin a CAS pilot project, a facility should submit to the administrative authority a notice of its intention to conduct corrective action using the CAS. EPA and/or state will review the notice of intent and respond whether a Federal and/or state pilot project should be initiated.

2.4.1.1 Notice of Intent

The notice of intent need not be longer than a few of pages and should state the following in a concise manner:

commitment to conduct corrective action under a formal agreement

request to conduct corrective action using the CAS

general information regarding site location

general information regarding the facility's operational history

general discussion on how the facility will proceed through the CAS

brief description of proposed performance standards for corrective action

request for a scoping meeting between the facility and the administrative authority

2.4.1.2 Scoping Meeting

The scoping meeting should serve as the first CAS milestone where the facility and administrative authority identify expectations concerning the CAS implementation. The meeting may need to be scheduled over the course of a few days, depending on the complexity of the site. The purpose for the meeting is to bring the administrative authority and facility representatives together early in the process so that an agreement on land use, ground water classification and expectations for cleanup goals can be discussed. At the scoping meeting, the facility should present the following:

preliminary conceptual site model

discussions on history of corrective action at the facility, including investigations conducted, risk evaluations or risk assessments, interim measures/stabilizations and final remedies implemented

discussion on how the facility plans to use the CAS to meet its corrective action obligations, including permitting and compliance issues

proposed performance standards for the facility with justification, and potential risk management approaches

Public Participation

The CAS promotes the early and continued involvement of stakeholders in site remediation activities. This would include the development of site-specific performance standards, discussions on future land use, designation of beneficial ground water uses, significant interim measures, and probable cleanup concentrations. The CAS encourages states to implement their own established procedures as long as they provide public participation opportunities at key decision-making stages in the process (e.g., during agreement on performance standards, remedy proposals, and closeout). Additional information on public participation can be found in Appendix A of the CAS and EPA's RCRA Public Participation Manual, September 1996. (EPA530-R-96-007).

communication strategy (i.e., how the facility and administrative authority will share information about the site - progress reports, conference calls, routine meetings, etc.)

site-specific concerns (i.e., sensitive environments or special subpopulations)

need for interim measures or stabilization activities, if necessary

schedule for submittal of the CAS Work Plan and proposed schedule for conducting and completing CAS elements, including public participation

It is suggested that the scoping meeting be held at the facility for the following reasons:

the facility can demonstrate the accuracy of the information contained in the preliminary conceptual site model in support of the proposed performance standards using all existing in-house data

the administrative authority can confirm firsthand the information contained in the preliminary conceptual site model, aiding in the approval of the performance standards

Following the scoping meeting, the administrative authority may either approve the performance standards proposed by the facility or establish performance standards that the administrative authority deems necessary to protect human health and the environment. Since approved performance standards may become the final cleanup goals for the facility, it is recommended that public participation be considered at this time. Should an impasse occur between the facility and the administrative authority regarding the performance standards, the administrative authority may consider mechanisms for implementing corrective action other than the CAS.

2.4.2 CAS Work Plan

The facility should prepare a CAS Work Plan that describes the activities the facility intends to conduct during CAS implementation.

The CAS Work Plan should be based on the conclusions of the scoping meeting as well as any significant input from public participation and should include, but not be limited to, the following:

performance standards for each release area with supporting facility-specific information

releases and potential releases listed and described (information regarding historical

corrective action activities need only be included if final remedy approval is needed or if releases require further investigation)

data quality objectives needed for achieving performance standards, including data quality project plans and sampling and analysis plans

proposed or planned release characterization activities, including, but not limited to:

- evaluating existing data and determining whether additional data are necessary

- conducting any necessary investigation and data collection (sampling analysis plan and quality assurance project plan), including process for identifying additional data gaps and data collection until adequate data is available

- implementing interim measures or stabilization of releases, if warranted

- revising the conceptual site model to reflect the new or updated information

describing how the facility intends to proceed through the CAS

scheduling of all facility activities for conducting and completing the CAS

The facility should submit the CAS Work Plan to the administrative authority to maintain the formal corrective action documentation record, but approval of the CAS Work Plan by the administrative authority may not be required. For larger facilities or facilities that have complex geology or site conditions, however, the administrative authority or the facility may request that the CAS Work Plan be approved. The CAS Work Plan should also provide any and all data necessary to demonstrate that the proposed performance standards are sufficient to protect human health and the

Interim/Stabilization Measures

The overall goal of interim/stabilization measures is to control or abate threats to human health and/or the environment from releases. With stabilization, the rate of corrective action may be increased by focusing on near term actions to control or abate threats to human health and/or the environment from releases and minimize the further spread of contamination while long-term remedies are pursued. Stabilization actions can increase the overall level of environmental protection by implementing a greater number of actions across many facilities rather than following the more traditional process of pursuing comprehensive final remedies at only a few facilities. (ANPR, 1996) Sufficient information about the contaminants and the facility's environmental setting must be known for stabilization to be a viable option. Stabilization can include source control, contaminated media cleanup, ground water containment, and/or limiting exposure to contamination. (RCRA CAP, 1994) If the contamination problem at a facility is small or simple (e.g., a small soil contamination problem), then excavation and removal by interim/stabilization measures may be the best option.

environment and that planned characterization activities are sufficient to support the performance standards.

2.4.3 Evaluating and Prioritizing Impacts From Releases

Under the CAS, impacts to human health and the environment may be evaluated through the use of risk-based screening of releases to soil and ground water specific to commercial/industrial facilities and land uses, and through site-specific risk assessment. Ecological risk is addressed indirectly through an exclusion worksheet that allows a facility to exclude ecologically insignificant portions of a site from further evaluation and also provides an assessment checklist for areas that require further examination (Appendix E).

2.4.3.1 Risk-Based Priority Screen

In order to quickly prioritize releases of contaminants that pose higher risk to human health and the environment, the CAS includes a risk-based priority screen (Screen) that consists of high-priority and low-priority bright-line (look-up) tables (BLTs). The CAS screening process is described in greater detail in Chapter 4.

The Screen is an integral component of the CAS. The primary objective of the Screen is to identify releases at the facility that pose the highest risk or threat (using the high-priority BLT) from contaminants in soil and ground water, and to allow the administrative authority and facilities to focus on achieving maximum risk reduction in a reasonable time frame. Another objective of the Screen (using the low-priority BLT) is to allow facilities to identify releases that pose minimal risk from contaminants in soil and ground water. Thus the releases are of no current Federal concern and may be de-emphasized in the corrective action workload. However, for these *de minibus* releases to be considered for no further actions (NFA), state concurrence is necessary.

The Screen incorporates release characterization requirements and land use determinations specific to industrial/commercial facilities using realistic receptors and relevant points of exposure. The degree of impact at the points of exposure then can be quickly evaluated using the high-priority and low-priority

BLTs. EPA Region 6 suggests that all facilities initially use the Screen to evaluate their releases as this is the fastest and most cost-effective way to evaluate relative site risk. Use of the Screen may eliminate the need to carry each release through completion of a site-specific risk assessment.

Results of the Screen will allow a facility to prioritize corrective action efforts and resource utilization by differentiating releases that are a high risk or high threat and require expeditious evaluation or remedial response from releases that are lower risk or long-term threats. The lower priority releases, however, may warrant further evaluation to determine if any additional action is necessary.

2.4.3.2 Site-Specific Risk Assessment

The CAS includes a site-specific risk assessment component to further define impacts from releases where necessary. The site-specific risk assessment can aid in evaluating potential risks not considered in the Screen or more precisely define ecological risks. Specifically, facilities have greater flexibility to evaluate contaminant fate and transport, re-evaluate exposure scenarios that were not previously or adequately covered in the Screen, exclude certain pathways from consideration, and evaluate contaminants of potential concern concentrations in background media. The site-specific risk assessment process is described in greater detail in Chapter 5.

2.4.3.3 Ecological Exclusion Screening

EPA Region 6 is providing an Ecological Exclusion Criteria Worksheet and Ecological Assessment Checklist to help facilities and the administrative authority determine whether or not further ecological evaluation is necessary at an affected property where corrective action is being pursued.

Ecological screening under the CAS is a relatively simple process. Use of the exclusion criteria worksheet, general information about the facility, its operation, physical site characteristics, ecological habitats and receptors will help identify incomplete or insignificant exposure pathways that exist at the affected property, thus eliminating the need for further ecological evaluation at these areas. If an area cannot be excluded from further ecological evaluation, additional information about ecological areas can be obtained using the assessment checklist to assist in further ecological risk evaluations. Appendix E is the

single location in the CAS that contains information (exclusion worksheet, assessment checklist, and risk assessment references) concerning the evaluation of ecological areas.

2.4.3.4 Risk Evaluation Report

The facility should prepare a Risk Evaluation Report that describes the activities the facility conducted for release characterization, as described in the CAS Work Plan, and the evaluation of impacts and prioritization of these releases. The Risk Evaluation Report is submitted to the administrative authority as documentation of site risks but is not approved unless required by the administrative authority.

The Risk Evaluation Report should include, but not be limited to, the following:

- documentation of release characterization activities and results
- documentation of the exposure scenario evaluation
- documentation of the results of the Screen
- identification of release sites that will require further risk evaluation along with a schedule for implementation
- documentation of any interim measures/stabilizations implemented during the course or as a result of the release characterization
- presentation of the results of any previously conducted risk assessments
- proposed revisions to performance standards, if warranted

The Risk Evaluation Report is a summary report that documents whether releases are actionable. The Risk Evaluation Report should concisely summarize the relevant data for risk decision making and should not be a compilation of all data collected during the course of all corrective action activities. With the submission of this report, the facility should be able to attach the forms for the environmental indicators (CA725/750) in a completed format.

EPA Region 6 suggests that the Risk Evaluation Report be submitted to the administrative authority after the initial Screen evaluation to document the differentiation between the releases that are a

high risk or high threat from releases that are lower risk or long-term threats. At the time that other releases (those that don't lend themselves to the Screen because of media impacted or when impacts need to be more precisely defined) are evaluated through a site-specific risk assessment, the Risk Evaluation Report should be updated to reflect the current information.

If data collection and release characterization reveal new information that may have an effect on the performance standards that were agreed upon with the administrative authority (e.g., change in land use, difference in expected receptors and/or exposure, or other differences in site conditions), the facility will need to notify and meet with the administrative authority to discuss making adjustments to the performance standards.

2.4.4 Managing Risk (Remedy Evaluation, Selection, and Performance)

This section provides guidelines and tools for evaluating actions to mitigate risks from releases. The tools for risk management include remedial technologies, engineering controls, and institutional controls. The process of selecting cleanup tools for risk management is simplified by focusing on meeting the performance standards that were established earlier.

2.4.4.1 Risk Management Plan

After the facility has determined which releases do not meet the performance standards (i.e., source control, statutory/regulatory requirements, final risk goal) as established by the administrative authority, it should evaluate and propose appropriate risk management activity(ies). When the facility has developed a course of action to achieve and maintain the performance standard, a Risk Management Plan should be prepared to describe and justify the facility's intended actions that will ensure protection of human health and the environment. Because the administrative authority is responsible for ensuring that the actions undertaken by the facility are protective of human health and the environment, as established by performance standards, the administrative authority should review and approve the Risk Management Plan.

The Risk Management Plan should describe and justify risk management activities for releases that failed the high-priority BLT, releases that failed to meet the performance standards, and other releases that

the facility chooses to address in the near term. In addition, releases that pose a lower risk or a long-term threat should be identified in the Risk Management Plan along with a schedule for their evaluation.

The approval process for the Risk Management Plan likely will be similar to that used currently for approving corrective action reports and should be designed in accordance with all current and applicable laws and regulations, including public participation. The facility should begin implementation of the plan upon approval by the administrative authority.

The Risk Management Plan should include, but not be limited to, the following:

planned risk management activity - Describe and justify determinations that risk can be managed, and/or reduced to acceptable levels. The activity or remedial action used to manage or reduce risk for each release should be specifically identified and described in the plan (e.g., demonstrate that site-specific pathways are incomplete, re-evaluate exposure based on site specific parameters, show that monitoring wells are needed to ensure that a ground water plume is not migrating at an unacceptable rate, etc.).

performance monitoring - Identify specific criteria (such as land use changes, fate and transport model verification and constructed remedy performance) that will be evaluated to demonstrate that the risk management activity implemented will remain protective. Establish a schedule for periodic performance review (such as monitoring data summaries, possibly including graphical and statistical analyses) to demonstrate that the implemented activities are consistently achieving and maintaining desired results. Establish a mechanism to re-evaluate risk management activities in the event the implemented action does not achieve and maintain the performance standards.

presentation of the conceptual site model supporting the Risk Management Plan - Identify the location of releases that did not meet the performance standards and that are addressed by a risk management activity. Identify the contaminant of concern concentrations in media after implementation of the risk management activity, including concentrations that are representative of the long-term fate and transport of residual contaminants of concern. Identify exposure pathways affected by a risk management activity and the performance monitoring locations.

schedule for implementation (and for additional risk evaluation as described in the revised Risk Evaluation Report) in accordance with all current laws and regulations

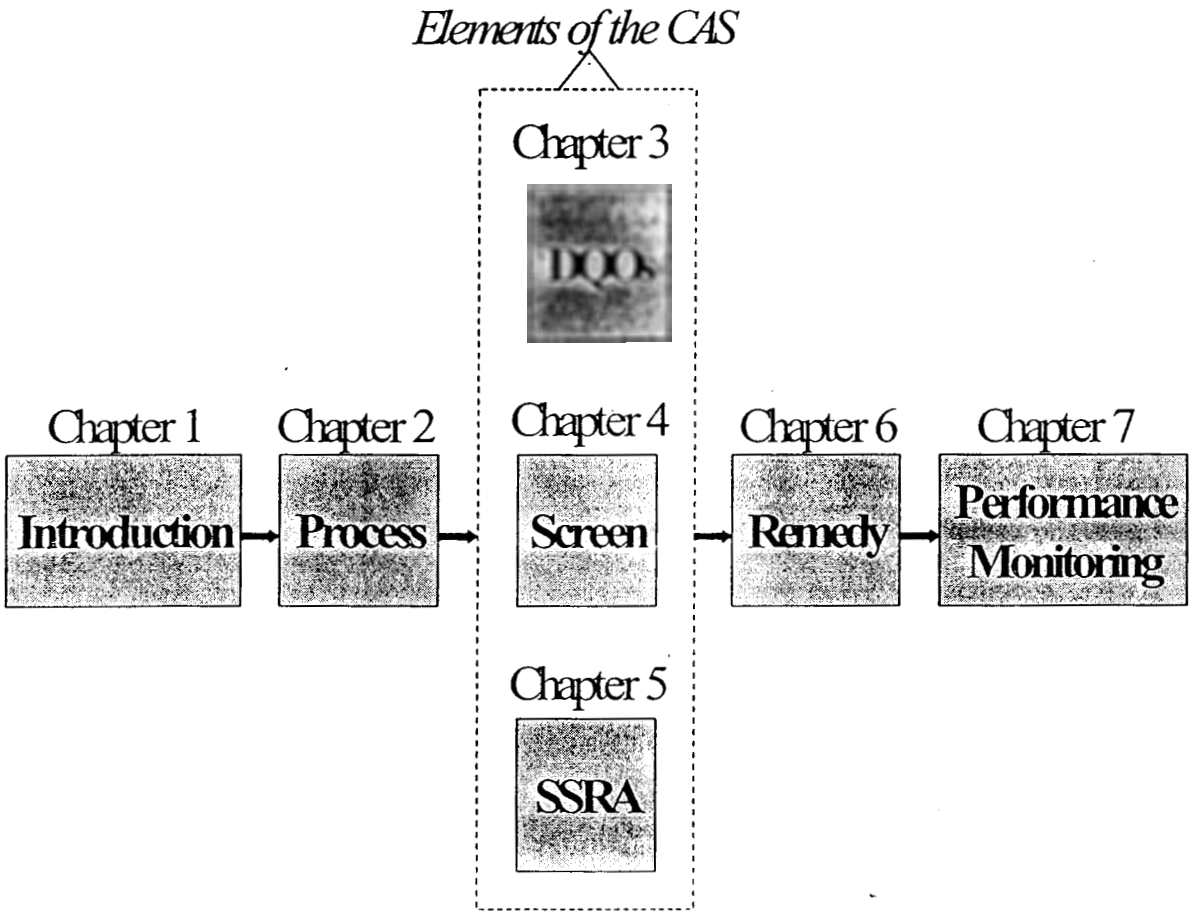
references to supporting documentation

2.5 COMPLETING THE CAS

The Risk Management Plan, as approved by the administrative authority, should contain all elements and activities necessary to achieve compliance with the performance standards. Therefore, the CAS should be complete when all activities specified in the approved Risk Management Plan have been implemented, and the performance standards have been achieved and are being maintained, including appropriate monitoring and performance review activities.

Figure 2-1

Correction Action Strategy Process



DQO - Data Quality Objective

SSRA - Site Specific Risk Assessment

3.0 DATA QUALITY OBJECTIVES AND DATA TYPES

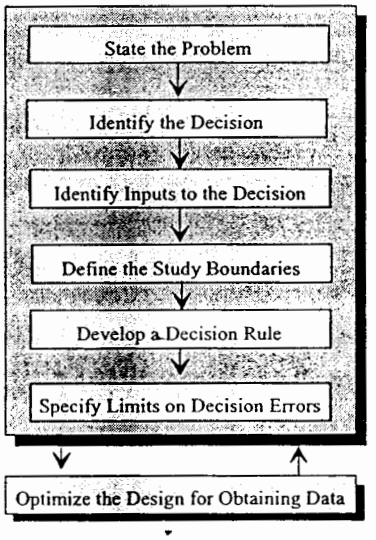
This chapter describes . . .

Importance of establishing DQOs for site characterization
Use of a conceptual site model to define data needs
Elements of a conceptual site model
Data quality considerations for the strategy

3.1 ESTABLISHING DQO'S FOR SITE CHARACTERIZATION

This chapter provides general guidance for establishing data quality objectives (DQOs), building a conceptual site model (CSM), and using specific data quality considerations to implement the CAS. One of the key objectives of the CAS is the use of appropriate and relevant data to evaluate releases using the Screen or a site-specific risk assessment. Therefore, data should not be collected or compiled until the end use of the data is known. When the end use or quality is not considered, too much data can be as detrimental as too little, and the wrong kind of information can be useless and as significant a problem as the lack of data.

FIGURE 3-1
THE DATA QUALITY OBJECTIVE PROCESS



DQOs are qualitative and quantitative statements that specify the quality of the data required to support remedy decisions. The DQO process is illustrated on Figure 3-1. The DQO approach is not limited to laboratory quality control criteria for sample analysis (precision, accuracy, representativeness, completeness, and

comparability). DQOs are determined based on the end use of the data to be collected, and the DQO development process should be integrated into project planning and refined throughout the CAS implementation. The EPA has developed guidance regarding establishing DQOs:

> *Guidance for the Data Quality Assessment, Practical Methods for Data Analysis.* QA97 Version EPA QA/G-9. January 1998.
>
> *Guidance for the Data Quality Objectives Process.* EPA QA/G-4. September 1994.
>
> *Data Quality Objectives for Remedial Response Activities.* EPA/540/G87-003 March 1987.

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. Furthermore, 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 an area of gross contamination, a DQO for this investigation may include a higher method detection limit provided by a cost-effective field screening technology for analysis of samples. In contrast, a very low method detection limit would be an appropriate DQO to determine if contamination is present in ground water used as drinking water.

Traditionally, environmental investigations have used the development of quality assurance project plans (QAPP) to specify DQOs and quality control protocols. QAPPs are valuable tools for facilities and administrative authorities in providing direction and requirements to ensure that the data obtained is usable for the intended objectives. The EPA has developed extensive QAPP guidance under various programs, and the following guidance documents should be consulted in the DQO process:

> *Guidance on Quality Assurance Project Plans.* EPA QA/G-5 February 1998.
>
> *EPA Requirements for Quality Assurance Project Plans for Environmental Data Operations.* August 1994.
>
> *Interim EPA Data Requirements for Quality Assurance Project Plans.* EPA Region 6, Office of Quality Assurance. May 1994.

The CAS Work Plan (Section 2.4.2) is required to have DQO's that are developed to support the performance standard for each release, therefore, the QAPP should be included in the CAS Work Plan.

3.2 CONCEPTUAL SITE MODEL

Investigations and remedy implementation are often most successful when based on a CSM; therefore, the first critical step in implementing the CAS is the development of a CSM. A CSM is a three-dimensional "picture" of site conditions at a discrete point in time (a snapshot) that conveys what is known or suspected about the facility, releases, release mechanisms, contaminant fate and transport, exposure pathways, potential receptors, and risks. The CSM does not have to be based on a mathematical or computer model, although these tools often help to visualize current information and predict future conditions. The CSM should be documented by written descriptions of site conditions and supported by maps, cross sections, analytical data, site diagrams that illustrate actual or potential receptors, and any other descriptive, graphical, or tabular illustrations necessary to present site conditions.

Quality EI Determinations

Environmental indicator (EI) determinations are a reflection of the current conditions at a facility from a site-wide perspective. Information used to make these determinations should be both complete and accurate. The CAS presents the use of a comprehensive conceptual site model (composed of 6 profiles) and the use of the DQO process in data collection and evaluation.
The CSM will provide a complete picture of the current conditions at the facility for both indicators. The DQO process will ensure that quality data will be used, thus raising the level of confidence for the "yes" determinations on CA725/CA750 for a facility.

The preliminary CSM should be built based on existing site data and should be developed before initiating any field activities. It should also be used to aid in the scoping of future investigations. Facilities that have not conducted field investigations can develop a CSM by making use of process knowledge, current and historical waste management operations, aerial photographs, topographic maps, land use maps, and published information on local and regional climate, soils, geology, hydrogeology and ecology (such as physical characterization of the facility).

The CSM, along with the DQO process, can be used to identify data gaps in current site knowledge and focus future investigative activities for making risk-based decisions. The CSM is dynamic and should be tested and refined from the initial stages of the CAS, to the point at which the site has been remediated

and no longer presents unacceptable risks to human health and the environment. Additional information on the development and use of the CSM is available in *Soil Screening Guidance: Users Guide* (EPA 1996) and the *Guidance for Evaluating the Technical Impracticability of Ground-Water Restoration* (EPA 1993).

When preparing a CSM, the facility should decide the scope, quantity, and relevance of the information to be included, balancing the need to present a complete model that documents site conditions and justifies risk management actions with the need to limit the information on that necessary to perform risk-based screening. The facility may solicit advice from the administrative authority regarding the scope of information to be presented. The CSM should present all relevant aspects, or profiles, of site conditions. The six profiles to be addressed in the CSM are: facility profile, land use and exposure profile, physical profile, release profile, ecological profile and risk management profile. These profiles and their corresponding data elements are described in the following subsections. During initial development of the CSM, each profile serves as a placeholder in the preliminary CSM, as all relevant information may not be available for all profiles. However, as a facility progresses through the CAS, additional information will become available and should be used to update the CSM and complete each profile.

Appendix B contains additional information including a case study that may be useful when developing and presenting a CSM.

3.2.1 Facility Profile

The facility profile describes the various manmade features present on or near the site, including:

- facility structures
- process areas
- solid waste management units (SWMUs)
- property boundaries
- historical features that are no longer present but may have impacted actual or potential releases

The facility profile may provide information on potential source areas and identify buildings or process structures that may affect characterization or remedy implementation. The locations of facility structures and process areas relative to a release are important in identifying contaminants of potential concern for the Screen or site-specific risk assessment. The location of property boundaries also can be important in land use determinations.

3.2.2 Land Use and Exposure Profile

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 the facility and adjacent properties, emphasizing specific uses (single-family homes, agriculture, etc.)
- beneficial resource determination (ground water classification, natural resources, wetlands, etc.)
- resource use locations (water supply wells, surface water intakes, etc.)
- subpopulation types and locations (schools, hospitals, daycare centers, etc.)
- 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

To develop the land use and exposure profile, the facility should begin by evaluating the types of land use and determining beneficial resources on and around the facility. In addition, information on potential receptors (such as surface water bodies, water wells, and residences) should be incorporated into the CSM for each release. For example, the identification of surface water bodies at locations in the assessment area indicates the potential for exposure from ingestion of fish and possibly drinking water sources. Receptor information also can be important in demonstrating potentially complete or incomplete exposure pathways for the Screen or site-specific risk assessment.

In the Screen, the land use information is evaluated to determine the applicable exposure scenarios for the facility and surrounding properties. The determinations of appropriate exposure scenarios also are addressed. After this evaluation is complete, the applicable exposure scenarios should be incorporated into the CSM. If onsite or offsite land use changes, the land use profile and CSM should reflect those changes.

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

- description of the developed property on the site, including but not limited to, structures, process areas, waste management units, property boundaries, and historical uses (reference to a facility map)
- description of the undeveloped property on the site, including but not limited to, sensitive environmental areas (Federal or state parks or protected areas) habitat type (wetland, grassy area, forested, pond, stream, etc.), primary use, degree and nature of disturbance, ornamental areas, drainage ditches, creeks, and landfill areas (reference to a facility map)
- description of site receptors in relation to habitat type, including but not limited to, endangered or protected species, mammals, birds, fish, etc)
- description of relationship of releases to potential habitat areas, contaminants of potential concern present or suspected, media contaminated, sampling data summary, potential or likely routes of migration or exposure of potential receptors, etc.

The information captured in the ecological profile will be critical in completing the Ecological Exclusion Criteria Worksheet and Ecological Assessment Checklist (Appendix E). The exclusion worksheet was developed to help facilities and the administrative authority identify incomplete or insignificant exposure pathways that exist at the affected property, thus eliminating the need for a formal Ecological Risk Assessment (ERA).

3.2.4 Physical Profile

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 water features such as drainage routes, surface water bodies, wetlands, and watershed parameters and characteristics

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

The physical profile should concentrate on the environmental setting information in the absence of a release. The physical profile information will generally be integrated 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 then can be identified and used to design future investigations.

3.2.5 Release Profile

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

identification of source materials

identification of contaminants of potential concern and contaminants of concern, as appropriate

potential source locations

source locations where a release has been confirmed

soil sampling and monitoring well locations

delineation of the area of contamination

distribution and magnitude contaminants of potential concern and contaminants of concern in a release

migration routes and mechanisms

fate and transport modeling results

As with the other profiles, the release profile will be developed over time as information is obtained. At the beginning of the CAS, the release profile may consist of the potential source locations, but at the completion of the CAS, it should contain site-specific information on release 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; this information can also aid in the development of the performance monitoring for risk management activities implemented under the CAS.

3.2.6 Risk Management Profile

The risk management profile illustrates the relationship between releases and risks. It also illustrates how the release-risk relationship can be altered by implementing risk management activities. The risk management profile can include the following:

summary of risks

impact of a risk management activity on release and exposure characteristics

performance monitoring locations and media

contingency plans in the event performance monitoring criteria are exceeded

The risk management profile will represent the risks and risk consequences of the selected risk management activity(ies). This profile also can provide a basis for determining appropriate performance monitoring locations and establishing contingency plans to ensure protectiveness. During the development of the preliminary CSM, the profile may serve as a placeholder. As the facility progresses through the

CAS, the information contained in the risk management profile will be augmented and refined and will ultimately demonstrate how facility risk will be managed.

3.3 DATA QUALITY CONSIDERATIONS FOR THE CAS

This section describes data quality considerations in developing DQOs for use in the CAS for the identification of contaminants of potential concern, data reporting limits, use of existing information, data collection, and release characterization techniques.

3.3.1 Identification of Contaminants of Potential Concern

Contaminants of potential concern (COPCs) are constituents (including transformation or daughter products and companion products) likely to be present in media affected by a release. The COPC evaluation process will involve screening the initial COPCs based on the findings of release characterization activities. COPCs should be identified through existing information regarding the process, product, or waste from which the release originated, and by characterization of the release. The two-step process listed below should be followed.

Step 1. Evaluate the types of products or waste handled at the source from which the release originated.

For example, if a potential source area is a permitted waste pile that historically managed materials that included nitroaromatic compounds, the list of COPCs should include nitroaromatic compounds. If a storm water basin is a potential source area, the list of COPCs should include all known and potential compounds based on the industrial activity in the area that drains into the storm water basin (i.e., raw feed materials, finished products, waste by-products). In cases where the site history is incomplete or the quality of information is uncertain, laboratory analyses should include a broader spectrum of compounds to characterize the release. The range of COPCs may be reduced if available information indicates that certain compounds or classes of compounds (halogenated volatile organic compounds, polychlorinated biphenyls, etc.) consistently are absent from the source and release media.

Step 2. Evaluate COPCs that may be of concern due to other site-specific factors such as community and regulatory issues.

The community or regulatory authority may be concerned about specific chemicals or analytes not identified during Step 1.

If it can be determined that the chemical or analyte may not be present, documentation should reflect this fact. The process of identifying COPCs will provide the information necessary to conclude that the facility has not overlooked a chemical or analyte which may pose a risk at the point of exposure. The initial list of COPCs can be refined during and after release characterization to more accurately reflect any constituent(s) that may be present in the release.

3.3.2 Data Reporting Limits

The data reporting limits for the CAS are the minimum detection or quantitation limits for the laboratory or field analyses for the environmental data set collected. The data reporting limits should be:

based on the intended use of the data, as determined during the development of the DQOs for sample/data collection

established prior to the collection of samples and confirmed that the chosen analytical method can achieve the limits

achieve most stringent (precision, accuracy, etc.) need of the data

Example 1: The data reporting limit for Contaminant Z in soil based on the DQOs is 10 mg/kg. Three analytical methods can be used to confirm the presence of Contaminant Z. The methods are equal except for the following minimum quantification limits: Method I reliably can quantify Contaminant Z to 25 mg/kg, Method II to 5 mg/kg, and Method III to 0.01 mg/kg. Method I would not be acceptable because resulting data may not provide a minimum quantification that ensures detection of Contaminant Z at levels that meet the DQOs. Methods II and III both would be acceptable because the reporting limit would meet the DQOs. As a result, factors such as the cost and time of conducting the analysis could be used as a basis for the final selection between Methods II and III.

Example 2: At Facility A, samples will be collected from a suspected source area having high concentrations of several contaminants. The analytical method detection limit may have to be adjusted for the high concentrations of contaminants (resulting in a sample quantitation limit) from samples collected from the source material. Therefore, the detection limits for the analytes may be too high to generate an accurate list of COPCs or to define the boundary of the release to any meaningful risk concentration. The data reporting limits for the samples collected to define the boundary of the source material then will call for a more precise analytical method to detect lower concentrations of contaminants and to generate a list of COPCs.

Example 3: An industrial facility uses approximately 60 percent of its property for its industrial operations and the remaining property is undeveloped. The facility, with the approval of the administrative authority, has opted to separate the industrial use property from the undeveloped property. Therefore, the industrial operation portion of the facility will be remediated to meet an industrial land use scenario, and the undeveloped property will be remediated to meet a residential land use scenario. The administrative authority has agreed that based on site-specific conditions, the facility's industrial land use property should achieve a final risk goal of 1×10^{-4}, and the facility's residential land use property should achieve a final risk goal of 1×10^{-5}. The data reporting limits will, therefore, be different for sample/data collection on the industrial land use property (the 1×10^{-4} contaminant concentration can be detected) than for the sample/data collection on the residential land use (the 1×10^{-5} contaminant concentration can be detected).

3.3.3 Quality Considerations for Existing Data

When the potential use of existing data during implementation of the CAS is evaluated, the data quality should be characterized and its relevance established based on present objectives, DQOs and other applicable requirements for collection of new data. The use of historical or existing data should not be limited only to information collected under the direction and oversight of the administrative authority. Before this information can be considered useable for risk management activities, the following factors should be reviewed:

Objectives: What were the objectives of the original data collection and are they consistent with the DQOs of the current characterization activities? Data needs likely would be significantly different if historical data were collected to establish that a release occurred versus the data needs for characterization of associated risk and hazard for a receptor population based on contact with impacted environmental media.

Relevance: Are the historical data relevant given current site conditions? Data collected from a unit that has been remediated or has undergone an interim measure (i.e.,

excavation, removal action and backfill) may not be relevant for establishing protective concentrations under current site conditions. What changes have occurred at the facility since historical data were collected? Will contaminant-specific factors, site conditions, and time impact the reliability of historical data to make it questionable for current assessment?

Quality: Were adequate quality assurance/quality control (QA/QC) procedures in place at the time of sampling, and if so, did the program meet the objectives? Were QA/QC procedures consistent with current practices? Were the methods and analyses used to generate the data capable of achieving the DQOs required by the CAS? Is the documentation sufficient to adequately reconstruct the sampling procedures and associated information (locations, depths, and analytical detection limits)? Can the limitations which affect usability be adequately defined?

Confirmation: Upon review, are the historical data valid or is confirmatory sampling necessary to establish relevance and data quality?

The historical data review should determine if the data is valid, if confirmatory sampling to validate historical data is needed, if the data are valid for limited purposes (such as confirmation of a release), and/or if the data is not usable.

General guidelines for the use of existing or historical data, based on data quality or limitations, are listed below:

data of questionable or unknown quality

- may be used to establish a release has occurred
- may be useful in planning sampling location and analytical approaches for new data collection activities
- may be used in the initial identification of COPCs and potential exposure pathways
- may be used in developing a preliminary conceptual site model
- should not be used to identify COPCs for use in a risk assessment
- should not be used to eliminate a release from consideration
- should not be used to eliminate or restrict new sampling activities

- S should not be used to support critical risk management decisions
- S should not be used in the determination of exposure concentrations

data verified by confirmatory sampling at identical locations, using comparable sampling and analytical methods

- S may be used to establish representativeness, comparability, and completeness between historical and new data
- S may be used to provide information in evaluating contaminant fate and transport over time
- S may be used to establish the relevance of historical data to current site conditions

data meeting quality criteria and relevance specific to the objectives and other requirements for collecting new data as proposed by the CAS

- S may be used in lieu of new data to support critical risk management decisions

3.3.4 Quality Considerations For New Data Collection

The facility should consider the following issues when developing DQOs for the collection of new data:

Selected sampling and analytical methods should ensure analysis for, and detection of, COPCs at or below the contaminant-specific data reporting limits. If COPCs cannot be identified based on historical data, a broad suite of analytical methods (e.g., analysis of total metals, organic constituents, pesticides, etc.) should be used.

Sampling locations should be selected within each medium at probable locations of a release to ensure that all media impacted by the release are identified. Media properties, conditions, and contaminant behavior in the media should be considered to ensure that the data collected are representative, reproducible, and complete.

3.3.5 Release Characterization Techniques

Release characterization techniques are those methods and activities used to collect current information about site conditions so that COPCs can be identified, and impacts can be evaluated. Release

characterization can include collection and analysis of environmental media samples; remote sensing and non-invasive procedures to estimate physical properties of the site, or potential release areas predicated on historical land use (aerial photographs indicating specific historical operations); and other field measurements to obtain data for purposes such as ground water modeling.

The facility should identify the techniques to be used for release characterization when planning field activities. While administrative approval of the CAS Work Plan may not be required, the facility is expected to communicate its characterization plans with stakeholders. The administrative authority can assist the facility by providing expertise, particularly in identifying new and emerging technologies for site characterization.

In recent years, emerging innovative site assessment techniques were recognized for providing physical and release characterization data in a cost effective and timely manner compared to the collection of traditional enforcement quality (Level III or IV) data (EPA 1991). Innovative site assessment techniques often consist of minimally invasive sampling methods such as direct push technologies, and on-site analytical equipment such as field test kits, portable x-ray fluorescence, gas chromatograph/mass spectrometers, and mobile laboratories. Appropriate sampling and analytical techniques (innovative or traditional) for release characterization are those that are capable of reliably obtaining data that meet qualitative and quantitative DQOs established for the site.

When selecting innovative site assessment techniques for release characterization, the intended use of the data should be considered so appropriate data reporting limits are established. Discussions with laboratory or technical staff may facilitate the selection of the methodologies necessary to achieve the appropriate data reporting limits.

If several techniques can achieve established DQOs for site characterization, factors such as cost effectiveness, time efficiency, ease of use, and site-specific conditions should be considered when the selecting the techniques. Appendix C lists references and web links that provide comparative information on many different site assessment techniques and methods based on data quality, cost, efficiency, and other parameters.

The facility may choose to develop a sampling and analysis program that uses innovative site assessment approaches that may or may not achieve DQOs to supplement high quality analytical data. Combining sampling and analysis techniques in this manner can provide significant savings of time and money without sacrificing data quality, provided the facility implements adequate control parameters. However, critical decisions can be based only on data that meet DQOs.

4.0 RISK-BASED PRIORITY SCREEN - HUMAN HEALTH

This chapter describes . . .

Human health risk evaluation
- Background and purpose of the risk-based prioritization process
- Overview of the risk-based prioritization process
- Conducting the Screen (comparison to bright-line tables)
- Using the Screen to prioritize releases

4.1 BACKGROUND AND PURPOSE OF THE RISK-BASED PRIORITIZATION PROCESS

The CAS presents a simplified approach to prioritize corrective action at a facility through the use of a risk-based priority screen (Screen). The primary objective is to quickly identify the highest risk releases at a facility and to focus limited corrective action resources (time and money) on these areas in order to obtain the maximum risk reduction in the shortest time frame. This approach puts a high priority on addressing the most significant risks at a facility first and is consistent with achieving EPA's Environmental Indicator (EI) goals for the protection of human health and the control of ground water (EPA RCRIS database CA725/CA750 codes).

The Screen is made up of two separate bright-line (look-up) tables (BLTs), each with a separate objective (Appendix D). The first table, the high-priority BLT, is used to help differentiate releases at a facility that have the highest relative risk and warrant immediate expenditure of resources (to ensure the protection of human health) from releases that pose a lower risk or long term threat and can be considered a lower priority. The second table, the low-priority BLT, is used to further subdivide the lower priority sites into those that may warrant additional evaluation from those associated with *de minimus* risk, and therefore designated as no current Federal concern (NCFC). See Figure 4-1.

4.1.1 High-priority BLT - a table of chemical-specific, human health screening values which separate releases into two groups requiring action or further evaluation:

Releases to Address Now - those chemical concentrations in environmental media that pose the highest risk and require immediate evaluation or remedial response to ensure protection of human health (i.e., individual chemical concentrations indicative of a target cancer risk in excess of 1×10^{-4} or a hazard quotient of 10).

Releases to be evaluated under the low-priority BLT - those chemical concentrations in environmental media which do not exceed screening levels presented in the high-priority BLT; these should then be evaluated under the low-priority BLT.

4.1.2 Low-priority BLT - a table of chemical-specific, human health screening values which further subdivide the low risk releases at facilities into those which could pose an unacceptable risk or threat and may warrant further evaluation from those that are considered NCFC:

Releases that May Warrant Further Evaluation - those chemical concentrations in environmental media which do not exhibit the highest potential risks by exceeding the high-priority BLT screening values, but which exceed the low-priority BLT screening values. Releases in this category are assumed to have site-related risks or hazards generally within the National Oil and Hazardous Substances Contingency Plan risk range of 1×10^{-4} to 1×10^{-6} for carcinogens or exceed a hazard index of 1.0 for non-carcinogens.

Releases considered as NCFC - those chemical concentrations in environmental media which do not exceed the low-priority BLT screening values (1×10^{-6} for carcinogens and a hazard index of 1.0 for non-carcinogens) may be proposed to the administrative authority for a no further action (NFA) determination. The administrative authority will make final NFA determinations.

In order to further prioritize releases that may "Warrant Further Evaluation," it is necessary to evaluate them for potential cumulative contaminant risk that could exceed 1×10^{-4} for carcinogens and a hazard index of 10 for non-carcinogens. Sites that have multiple contaminants that exceed these risks or hazards should also be categorized as high-priority or "Address Now"sites for immediate consideration. Step 6 in Conducting the Screen below provides a simple algorithm for calculating the cumulative risk or hazard for these releases.

In the event that a facility does not have releases that are in the high-priority or "Address Now" category, their corrective action efforts should shift to evaluating the low-priority category releases to determine if they meet the performance standards for the facility.

Figure 4-1

Results of the Risk Priority Screen

PRIORITY	HIGH Address Now	LOW Releases that Warrant Further Evaluation	No Current Federal Concern (NCFC) (or NFA with AA Approval)
RISK **Human Health** **Cancer**	$> 10^{-4}$	10^{-4} to 10^{-6}	$< 10^{-6}$
Hazard	> 10	1 to 10	< 1
Exceed Ecological Exclusion Criteria		YES	NO
RESPONSE OPTIONS	Risk Assessment Remedial Action	Confirm if Human Health and/or Ecological Issues Exist	*DeMinimus* Risk None

** **Note:** This is a relative categorization. A facility should address its highest priority areas in the most timely manner practicable. If a facility encompasses only low priority releases as defined under the CAS, corrective action, as necessary, should be advanced at the relative highest priority release areas.

The high-priority and low-priority BLTs are maintained by EPA and can be found on the EPA Region 6 web site at http://www.epa.gov/earth1r6/6pd/rcra_c/pd-o/riskman.htm as well as in Appendix- D.

4.2 OVERVIEW OF THE RISK-BASED PRIORITY SCREEN

The following section describes the major elements of the risk-based priority screen (Screen).

4.2.1 Land Use and Receptors

The accurate classification of current and future land use at a facility is essential in order to identify the kinds of human receptors that may be present and the types of activities in which they are likely to engage. This identification goes beyond simply designating a category of land use (e.g., residential, industrial or agricultural). Risk from contamination at a site is a function of the specific activities that receptors are assumed to undertake and the exposures to contaminants that are associated with those activities. The activities can vary considerably, even across sites that fall within the same land use category; thus, it is critical that the assumptions regarding receptor activities accurately reflect the land use and exposure profiles presented within the CSM.

The Screen emphasizes the use of current land use conditions when evaluating exposures at commercial/industrial facilities because for most of these facilities, current land use is assumed to continue into the foreseeable future. If a different land use has been planned or may be reasonably anticipated for the facility (or a portion of the facility), then this future land use should be evaluated during the CAS screening process. The two primary land use categories in the CAS screening process are non-residential and residential. However, if other land use categories exist (e.g., agricultural or recreational), then any evaluation of risk from these exposure scenarios can be assessed by using the Screen (if they are sufficiently conservative for the land use and receptors involved) or should be addressed through a site-specific risk assessment. Caution is recommended when using the Screen in an evaluation of land uses other than those upon which the BLT

Ecological Risks

The CAS prioritizes action first for all releases that present a risk to human health. This prioritization is not intended to ignore or dismiss any environmental risks which may be present at a site. In fact, failure to address environmental impacts in a timely fashion may result in the growth or compounding of possible ecological damage at the site. The CAS contains an Ecological Exclusion Criteria Worksheet and Ecological Assessment Checklist to help determine if significant habitat and/or receptors, are present at a facility and assess the need for a more thorough ecological assessment (See Appendix E). These tools are simply aids and do not substitute for the judgement or requirements of the administrative authority or natural resource trustees who may be responsible for the site.

screening values were based, because each of the land use categories is associated with a specific and potentially unique set of exposure assumptions.

> Non-residential land use - encompasses commercial/industrial site uses. Under the CAS screening process, the receptors for the commercial/industrial scenario are limited to generic on-site workers (indoor workers and outdoor workers). There is no requirement under this land use category to evaluate exposure to members of the public. Access to industrial facilities is generally restricted (workers often being the only receptors), and even though the public may have access to commercial sites (e.g., customers, delivery people, etc.), BLT screening values that are protective of workers are assumed be protective of a customer who visits the site on an infrequent basis.
>
> Residential land use - encompasses evaluation of adult and child receptors with regard to on-site contaminants associated with known or potential future residential use of the property or parts of the property. In addition, off-site residential receptors may be considered when construction activities at a site may impact off-site areas with fugitive dust and/or volatile emissions. Off-site receptors also should be evaluated when contamination from the site has migrated off-site to a residential land use setting from soil or ground water.

If a future commercial/industrial land use is likely to involve substantial exposure to the public (i.e., where the current or future use involves housing, education, and/or care of children, the elderly, or other sensitive sub-populations), the exposure should be evaluated under the residential risk screening scenario in the BLTs if the assumptions are sufficiently similar.

4.2.2 Exposure Scenarios and Exposure Pathways

The exposure scenarios included in both the high-priority and low-priority BLTs are routinely associated with activities found at and around facilities undergoing corrective action. A facility is not required to evaluate environmental data against all of the exposure scenarios established in the BLTs. This comparison should be limited to the receptors and pathways that exist or potentially exist at the facility based on current land use and reasonable future land use assumptions (e.g., ambient air or ingestion of ground water or surface water would not be evaluated where contaminants are not present or pathways are incomplete or not expected to be complete).

The focus for most facilities will be on current land use, because most cleanups at industrial facilities will be based on industrial exposure assumptions (assuming the current land use continues into the foreseeable future). Institutional controls may be required to ensure that environmental conditions are protective of human health and the environment over the long term, but should not be assumed to be in place at the time the CAS screening process. If exposure scenarios specific to a site are not covered in the BLTs and are not sufficiently similar to one of the default scenarios presented in the BLTs (such as sensitive sub-population receptors: day care centers or convalescent centers, etc.), the facility should consider evaluating the receptors under a site-specific risk assessment in order to adequately characterize their exposure (Chapter 5).

The high-priority and the low-priority BLTs include three generic exposure scenarios: commercial/industrial indoor and outdoor workers, and residential receptors. The list of pathways included for each scenario is not exhaustive but represents those that typically account for the majority of risk at a typical site. Because of this, it is important for a facility to compare the land use and exposure profile (Section 3.2.2) from the site-specific CSM with the assumptions and limitations associated with each applicable exposure scenario as quantified in the BLTs to identify whether they are sufficiently similar to support a defensible comparison. If significant differences are readily apparent, detailed assessments may be necessary (i.e., a site-specific risk assessment).

The potential exposure scenarios and exposure pathways included in the Screen are outlined below. Additional information on the chemicals evaluated, exposure parameters, and exposure pathways used in the BLTs are detailed in Appendix D.

> Residential receptor - incidental soil ingestion, inhalation of particulate and/or volatiles, dermal contact with soil, and ground water or surface water through ingestion and inhalation (includes uses as household water)
>
> Outdoor worker - incidental soil ingestion, dermal contact with soil and inhalation of particulate and/or volatiles
>
> Indoor worker - incidental ingestion of contaminated dust from outdoor soils, and inhalation of dust and/or volatiles from outdoor soils

There is a high level of uncertainty surrounding the hazards associated with skin contact with soils. Therefore, comparisons to the dermal exposure pathway are limited to the following chemicals: arsenic, cadmium, chlordane, 2,4-D, DDT, lindane, PAHs, pentachlorophenol, PCBs, and dioxin.

Where volatile contaminants are present in soil or ground water under or near an existing structure, consideration should be given to the inhalation of volatiles for indoor air exposure in a site-specific risk assessment.

Screening values for ground water that is a current or reasonably expected future source of drinking water are included in the BLTs. If an aquifer is determined to be a current or reasonably expected future source of drinking water and concentrations of contaminants exceed the screening values in the high-priority BLT (which are maximum contaminant levels (MCLs), maximum contaminant level goals (MCLGs), or other risk-based concentrations), then the release is considered to be a high priority for corrective action. Facilities should consult with state and local authorities on the designated use and classification of underlying ground water to determine whether the water bearing unit beneath or adjacent to the facility is a potential drinking water source or has another designated beneficial use. The state will make the determination as to what level the aquifer is to be protected. If the state has not made a determination on the use of the aquifer, then the facility should consult with the state on using the EPA aquifer classification designation. If an aquifer is not a drinking water resource, does not have any other beneficial resource attributes, does not impact indoor air, does not contaminate surface water, or does not contaminate a drinking water aquifer, then the level of protection

Ground Water Use Designation

EPA prefers to rely on states to develop ground water use designations and will generally defer to a state's designation of ground water classification and use. These designations may be part of an EPA-endorsed Comprehensive State Ground water Protection Program (CSGWPP) that provides for facility-specific decisions or may rely on an alternate state ground water use designation system and/or Federal ground water guidelines. EPA has an expectation to return usable ground waters to their beneficial uses where practicable, within a time frame that is reasonable given the particular circumstances of the facility. When restoration of ground water to beneficial uses is not practicable, EPA has an expectation of a facility to prevent or minimize further migration of the plume, prevent exposure to the contaminated ground water, and evaluate further risk reduction. Additional information can be found in Chapter 7, Appendix A and at http://www.epa.gov/correctiveaction.

(e.g., MCL or alternate concentration limit (ACL)) to be met at or within the facility boundary will be determined in consultation with the administrative authority.

4.3 CONDUCTING THE RISK-BASED PRIORITY SCREEN

There are seven steps involved in evaluating releases against the BLTs:

Step 1. Compile risk relevant data from the site-specific CSM

Development of a site-specific CSM is the first step in the CAS screening process at a facility. The CSM is a comprehensive three-dimensional representation of the facility that documents current site conditions. It initially is developed from existing facility data, but should be revised continually as new site investigations produce updated and more accurate information. It identifies and characterizes the distribution of contaminant concentrations across the facility, release mechanisms, fate and transport/migration routes, complete or potentially complete exposure pathways and receptors of concern.

Chapter 3 of the CAS describes the development of a CSM. There are six profiles used in the CAS to build a CSM, two of which are specific to the Screen: land use and exposure profile (Section 3.2.2, consisting of information used to identify and evaluate applicable exposure scenarios and receptor locations); and the release profile (Section 3.2.5, consisting of information used to confirm whether a release has occurred, defining the exposure area and identifying COPCs and their distribution and magnitude).

Step 2. Verify that the exposure assumptions and scenarios in the CSM are consistent with (and comparable to) the assumptions upon which the BLTs are based

The next step in the CAS screening process is to compare the complete or potentially complete exposure scenarios presented in the CSM to the generic exposure assumptions used to develop screening values presented in the BLTs. The exposure scenarios included in the BLTs routinely are associated with the types of activities found at and around facilities. The facility is not required to evaluate all of the receptors, rather, this analysis is limited to the receptors that exist or may potentially exist at the facility based on current land use and reasonable future land use assumptions. This comparison is designed to determine whether the releases, exposure pathways, and receptors of concern outlined in the site-specific

CSM are sufficiently similar to the generic exposure scenarios used in the BLTs to allow a defensible screening comparison. If the basic exposure pathways are not sufficiently similar (whether through omission of a complete exposure pathway, or receptor population, or whether an exposure parameter used in the BLTs tends to underestimate exposure), use of the Screen is not appropriate and the facility should evaluate the release areas through a site-specific risk assessment.

Step 3. Evaluate existing data set to determine if it is adequate for use in the CAS screening process and then determine additional data collection needs, if necessary

Areas that are unlikely to be contaminated based on historical documentation of the location, storage, handling, or disposal of hazardous materials at a facility may be eliminated from further evaluation at this stage after consultation with the administrative authority. The necessity for collecting confirmation samples in these areas will depend upon the level of confidence in historical information concerning the potential release site(s).

In order to use the BLTs, existing data should be sufficient to adequately characterize the release as described in Chapter 3 (Section 3.3.3) under the DQO process. Existing data also may be used to identify data gaps and focus data collection needs.

A sampling and analysis plan should be developed (as part of the CAS Work Plan) before any new sampling activities are initiated to ensure that the data collected will fill data gaps and are of sufficient quality and quantity, based on the intended use of the data. The sampling approach should be designed to reflect the data needs specific to the complete or potentially complete exposure pathways identified in the CSM. The types of receptors identified in the CAS and the site-specific CSM vary in terms rate of contact and sources. For example, while indirect exposures associated with inhalation of volatiles from subsurface contamination may impact all receptors located on-site, direct contact to subsurface contamination may be limited to outdoor workers conducting excavation activities.

In addition, the facility also should consider the collection of information on site-specific soil characteristics (e.g., soil texture, dry bulk density, organic carbon content, pH, etc.) during sampling. The information may provide an additional level of accuracy at the site-specific risk assessment stage, if it

becomes necessary. Chapter 3 (Section 3.3.4) under the DQO process provides more information on quality considerations for the collection of new data.

Step 4. Collect and analyze additional samples, if necessary

Analytical results for individual chemicals, if the quality is sufficient, will be compared to screening values presented in the BLTs. Analytical results help define the nature, extent, and rate of migration of contaminants from a release. Upon receipt of these data, the assumptions (e.g., exposure assumptions) outlined in the site-specific CSM should be reviewed to ensure that they still are valid, and include any additional components indicated by the most recent results.

Collection and evaluation of soil characteristic data also should be considered. The information can assist in the assessment of inhalation of volatiles, and fate and transport considerations at the site-specific risk assessment stage, if necessary.

Step 5. Identify appropriate site receptors and exposure pathway(s) for comparison to the BLTs

Determine which, if any, of the receptors and exposure pathways presented in the BLTs are appropriate for comparison against site chemical release results based on the presence or absence of contamination in a given media. Certain exposure pathways presented in the BLTs may be eliminated from consideration when the pathway is not complete or reasonably expected to be complete. An example would be where the ground water pathway would not be evaluated when ground water is not considered a current or future drinking water source.

Step 6. Compare release data against BLT values for site-specific receptors

After the appropriate BLTs screening values have been identified, they are compared to the measured concentrations of contaminants. At this point, it is important to again review the CSM to confirm the actual site data that were evaluated or collected during the CAS screening process ensuring that the BLT screening values are applicable to the site (Figure 4-1).

Generally, for most new and existing data sets, the 95th percent upper confidence limit (UCL95) on the arithmetic mean concentration of each contaminant is compared directly to the corresponding BLT screening value. For certain releases with small areal distributions and low toxicity contaminants, it may be more advantageous and cost effective to collect a limited number of samples and compare the maximum contaminant concentration from the release area to the BLT screening values. When this approach is used, it is essential to ensure that the samples collected from the release area will reasonably contain the highest contaminant concentrations to conservatively characterize risk. A facility may opt to collect additional samples from the release area and calculate a UCL95 for comparison to the BLT screening values to more accurately characterize release concentrations. The EPA's *Supplemental Guidance to RAGS: Calculating the Concentration Term* (EPA 1992), provides additional guidance on statistical methods for accurately determining exposure point concentrations.

First for each release area, individual contaminant concentrations are compared to the high-priority BLT screening values. If a contaminant concentration exceeds the high-priority BLT screening value, the release area is a high-priority, "Address Now," site (i.e., exceeds $1x10^{-4}$ carcinogenic risk or a hazard quotient of 10). Next, the individual contaminant concentrations for release areas that did not exceed the high-priority BLT screening values are compared to the low-priority BLT screening values (i.e., 1×10^{-6} for carcinogens or exceed a hazard index of 1.0 for non-carcinogens). If an individual contaminant concentration for a release area does not exceed the low-priority BLT screening values, then the site is considered *de minimus* risk, and therefore, designated as no current Federal concern (NCFC). For releases that exceed the low-priority BLT for individual contaminants, but do not exceed the high-priority BLT screening values, these sites have risks or hazards within the National Oil and Hazardous Substances Contingency Plan risk range (i.e., 1×10^{-4} to 1×10^{-6} for carcinogens or exceed a hazard quotient of 1.0 for non-carcinogens) but may warrant further evaluation.

For those releases with multiple contaminants which exceed the low-priority BLT, but no individual contaminant exceeds a high-priority BLT screening value, it is known that site risk is above $1x10^{-6}$ for carcinogens and hazard quotient of 1, but it is not known if cumulative risk or hazards exceed $1x10^{-4}$ or a hazard index of 10, respectively. Therefore, these sites should be evaluated for their cumulative risk or hazards using the algorithm presented in the table below. Sites that exceed a $1x10^{-4}$ cumulative risk or hazard index of 10 should also be considered as high-priority or "Address Now" sites.

The following procedures should be used to estimate the cumulative risk for these releases:

Figure 4-2

Calculation of **cumulative carcinogenic risk** for releases with multiple contaminants that exceed the low-priority BLT.

Background on risk calculations:
For the purposes of this calculation Intake = Intake x Toxicity Criteria
Risk = Intake x Concentration
thus for the low-priority BLT: Concentration = Risk / Intake

Example calculation:
For the low-priority BLT, the contaminant specific screening values are based on a target risk of 1×10^{-6}. Lets assume that the low-priority BLT screening value for *Contaminant Z* is 50 mg/kg. Solving for Intake:

Intake = Risk / Concentration
Intake = $1 \times 10^{-6} / 50$
Intake = 2×10^{-8}

Let's say the concentration of *Contaminant Z* in soil at Site A is 89 mg/kg. To determine the risk associated with the concentration detected in soil, substitute the 89 mg/kg for the BLT value of 50 mg/kg and solve for the (target) risk.

Risk = Intake x Concentration
Risk = $2 \times 10^{-8} \times 89$
Risk = 1.78×10^{-6}

Do this for each of the contaminants which exceed the low-priority BLT screening value, sum the risks and you have total cumulative carcinogenic risk for a particular release area.

Calculation of **non-cancer risk (Hazard Index)** for releases with multiple contaminants that exceed the low-priority BLT.

For the purposes of release prioritization under the CAS, the non-cancer hazards associated with multiple chemicals will be conservatively evaluated by summing the hazard quotient for all chemicals of concern, regardless of target organ or response, to obtain the hazard index. If the hazard index for the release area exceeds 10, the release is categorized as a high priority site.

Step 7. Identify release areas as:

1. *HIGH PRIORITY*
2. *RELEASE THAT MAY WARRANT FURTHER EVALUATION*
3. *NO CURRENT FEDERAL CONCERN (NCFC)*

EPA Region 6 suggests that all facilities initially use the Screen to evaluate their releases as this is the most expeditious and cost-effective way to evaluate site risk thus categorizing releases as high priority, releases that may warrant further evaluation, or NCFC for human health (ecological risks must be evaluated before making a final determination). This prioritization will help identify for the administrative authority and facility work load and resource requirements for near and longer term responses.

5.0 SITE-SPECIFIC RISK ASSESSMENT - HUMAN HEALTH

This chapter describes . . .

Purpose of a site-specific risk assessment
The risk assessment process
- Data collection and evaluation
- Toxicity assessment
- Exposure assessment
- Risk characterization

5.1 BACKGROUND AND PURPOSE

The purpose of a site-specific risk assessment is to evaluate whether chemical releases pose unacceptable risks to current or future receptors and whether they warrant corrective action. Site-specific risk assessments allow for a more detailed evaluation of the potential risks posed by releases through the incorporation of actual site parameters and conditions, rather than relying on generic default (and usually conservative) assumptions.

As part of the CAS, site-specific risk assessments will usually be conducted after completion of the Screen using the BLTs described in Chapter 4. The Screen is a fast and a cost-effective tool used to evaluate all or most of the releases at a facility, but can also help determine which sites may benefit from additional site-specific risk evaluation. It may be apparent early on that some sites will need a site-specific risk assessment and therefore, may not need to go through the Screen. Gathering additional site-specific information and data may be costly and time consuming but may be necessary to evaluate risk in a site-specific risk assessment. Conversely, it may be apparent early on that a site-specific risk assessment is unnecessary if contaminant release concentrations significantly exceed the high-priority BLT risk-based screening values. In this case, it may be more cost effective to initiate remediation or other risk mitigation activities directly after conducting the Screen.

The CAS does not present the site-specific risk assessment process in detail. Numerous EPA risk assessment guidance documents on conducting site-specific risk assessments are available. The following

sections briefly describe the steps involved and highlight aspects of the risk assessment process where site-specific information may need to be collected to estimate risks more accurately.

The primary references and sources of information for conducting site-specific risk assessments include:

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation manual (Part A); EPA/540/1-89/002

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation manual (Part B - Development of Risk Based Preliminary Remediation Goals); EPA/540/R-92/003

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation manual (Part C - Risk Evaluation of Remedial Alternatives); EPA/540/R-92/004

Risk Assessment Guidance for Superfund: Volume I - Human Health Evaluation manual (Part D - Standardized Planning, Reporting, and Review of Superfund Risk Assessments); OSWER 9285.7 - 01D -1

Dermal Exposure Assessment: Principles and Application; EPA/600/8-91/011B

Guidance for Data Usability in Risk Assessment (Part A); PB92-963356

Exposure Factors Handbook: EPA/600/8-89/043

Integrated Risk Information System (IRIS) (EPA 2000)

Guidance for Risk Characterization (EPA 1995)

5.2 OVERVIEW OF THE HUMAN HEALTH SITE-SPECIFIC RISK ASSESSMENT PROCESS

A site-specific risk assessment is an evaluation of the potential for current or future adverse health effects resulting from direct or indirect contact with contaminant releases. The evaluation is conducted under the assumption that no controls or actions designed to mitigate exposures are in place or will be imposed in the future. Under this assumption, a no adverse health effects conclusion may be used to support a determination of unrestricted land use.

A risk assessment provides information to:

determine whether a remedial response is necessary to protect current or future receptors

define or modify remediation goals

support a determination of NCFC

guide remedial selection and/or evaluate the appropriateness of institutional controls to mitigate risk

Site-specific risk assessments will vary in complexity depending on site conditions and the type of chemical releases. Determining the level of effort and detail required will depend on current and future land use, number of detected contaminants, availability of toxicity information, number of applicable exposure pathways, and fate and transport mechanisms.

Regardless of the complexity of the site, the risk assessment process consists of four steps (Figure 5-1).

5.3 DATA COLLECTION AND EVALUATION

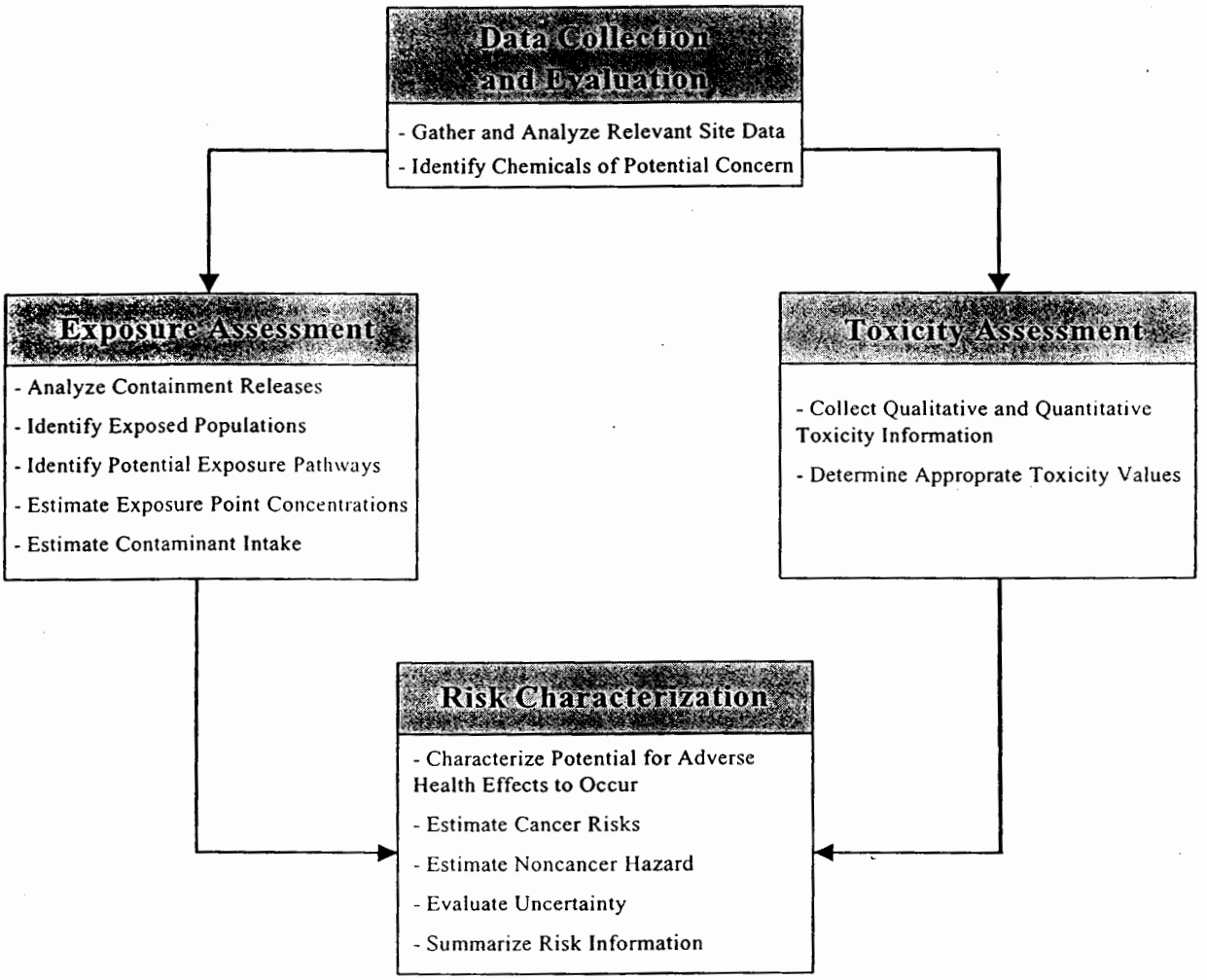
This step involves sampling and analysis of all potentially contaminated media. The primary objectives of this step are to develop a data set with sufficient sample quality and quantity to identify COCs and, ultimately, to estimate the exposure point concentration used to calculate a chemical intake.

The data collection process involves gathering and evaluating existing data sets, identifying data gaps, identifying modeling parameter requirements, collecting background data, and ensuring that data sets can be used to represent reasonable exposure conditions.

Figure 5 - 1

Site-Specific Risk Assessment Process

Risk Assessment Guidance for Superfund: Volume I (Part A); EPA/540/1-89/002



Data analysis involves evaluating analytical methods, detection limits, qualified and coded data, blanks, and tentatively identified compounds. Results from the data analysis and evaluation process are used to identify COCs. For some sites, the list of contaminants detected in the release area may be extensive. Carrying a large number of chemicals through the risk assessment can be complex, and may require an unnecessary amount of time and effort. It is important to focus the risk assessment only on contaminants that pose significant risks. Figure 5-2 presents a stepwise procedure for identifying a subset of detected chemicals that should be considered COCs.

As part of the process to identify COCs outlined in Figure 5-2, detected contaminants may be excluded from further consideration if it is determined that concentrations are less than background levels and below health-based levels. In some cases, however, background concentrations may present a significant risk, and while cleanups may or may not eliminate this risk, the background risk may be an important site characteristic to those exposed. The administrative authority will always have the option of considering the risk posed by naturally occurring background constituents separately. Often, however, the comparison of a site with background is unnecessary because of the low risk usually posed by the background constituents compared to site-related contaminants. In general, comparison with naturally occurring background levels is applicable only to inorganic constituents, because the majority of organic chemicals found at sites are not naturally occurring even though they may be ubiquitous.

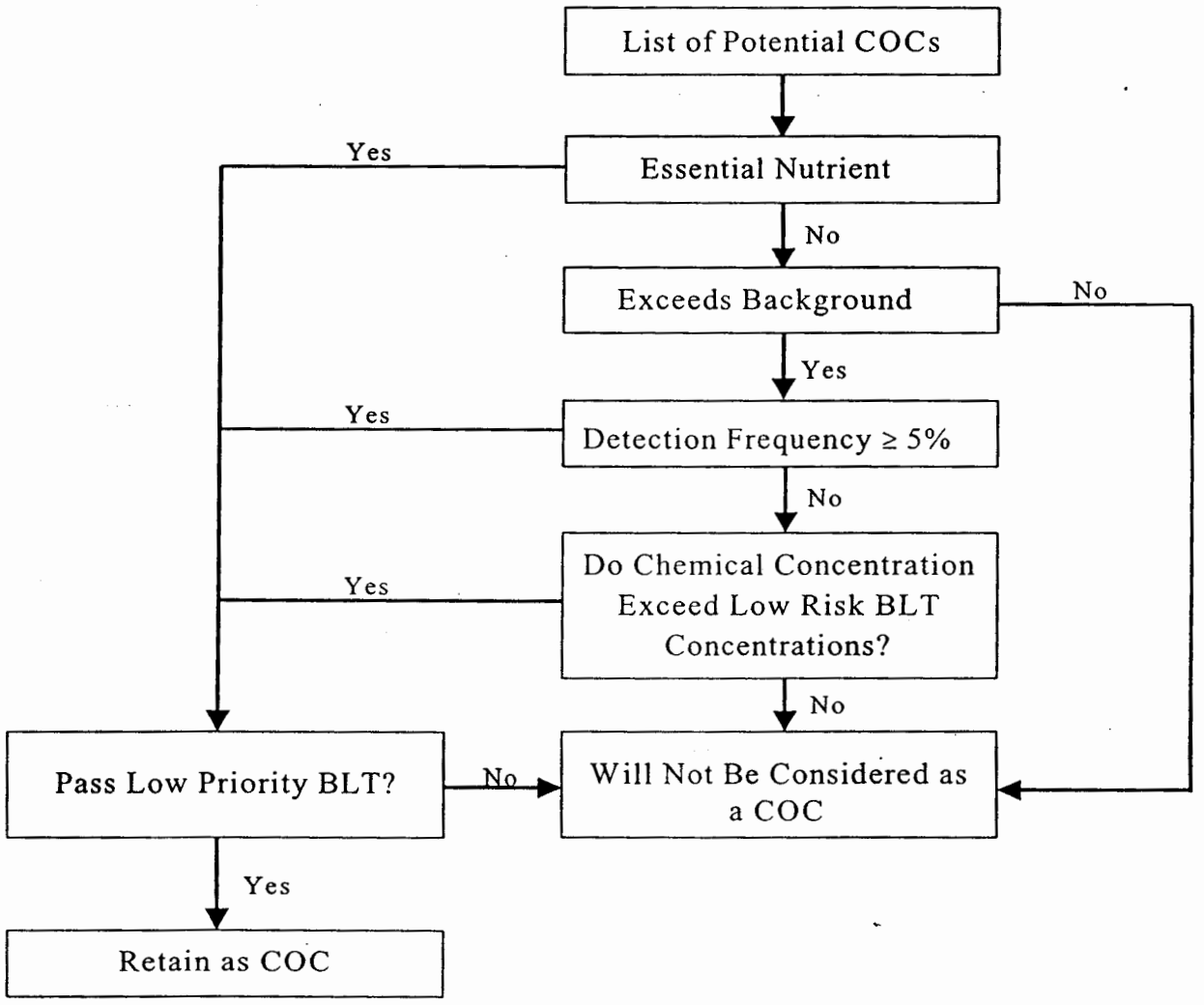
It should be noted that prior to exclusion of any contaminants, background concentrations must have been determined based on adequate sampling. *Risk Assessment Guidance for Superfund: Volume I (Part A); EPA/540/1-89/002* (RAGS) (EPA 1989) provides additional guidance for determining background concentrations and excluding potential COCs. Contaminants that cannot be eliminated after applying these criteria should be considered site-specific COCs and should be evaluated in the site-specific risk assessment.

5.4 EXPOSURE ASSESSMENT

An exposure assessment is conducted to estimate a chemical intake for each COC. A chemical intake is dependent on the magnitude, frequency, and duration of exposure. Several steps are involved in an exposure assessment including characterization of the physical setting of the chemical release area:

Figure 5 - 2

Selection Process for COCs



characterization of current and future land use and exposed populations; identification of complete exposure pathways, including the points of exposure and exposure routes; and estimation of chemical intake.

Estimating a chemical intake (which is used to directly calculate risk) is a two-step process. First, the exposure point concentration is calculated for each COC in each contaminated environmental media. Chemical intakes are then quantified for each exposure pathway.

Because of the uncertainty associated with estimating the true average concentration of a contaminant at a site, the UCL95 of the arithmetic mean should be used to estimate the exposure point concentration, (EPA's *Supplemental Guidance to RAGS: Calculating the Concentrations Term*, EPA 1992). However, for exposure areas with limited amounts of data or extreme variability in contaminant concentrations, the UCL95 may be greater than the highest measured or modeled concentration. In these cases, if additional data cannot be practically obtained (e.g., may not be warranted based on a small release area) the highest measured or modeled value could be used as the concentration term (if there is reasonable certainty that the data collected represents the highest concentration of contaminants), and approved by the administrative authority.

A fundamental assumption in the exposure assessment is that a receptor will contact randomly all areas, both contaminated and uncontaminated, within the area of exposure (e.g., residential lot, industrial operation area, etc.). Data from random sampling programs can be considered representative of random exposure. However, biased sampling programs that are designed to identify hot spots can overestimate risk, if it is assumed that the receptor is exposed continuously to the hot spot for the entire duration of exposure (25 to 30 years). Biased sampling data sets should be adjusted to take into account the fraction of time spent in the contaminated area assuming that adequate sample data is available for the exposure area not represented by the hot spot. Supporting information used to adjust data sets to reflect reasonable exposures should be fully documented.

At some sites, such as where previous interim measures have been conducted or monitored natural attenuation has been documented, it may be appropriate to collect data and incorporate natural attenuation information into the site-specific risk assessment to determine the need for further remedial action. Natural attenuation can occur through dilution, evaporation, and biodegradation of a contaminant to a less toxic

form. For example, some chemicals may degrade rapidly in soils or ground water. In these cases where conditions no longer represent a baseline condition, risks should be based on current site conditions and how the interim actions are likely to affect potential future exposures. If the site-specific risk evaluation involves a modification of the bioavailability or bioabsorption factor of a chemical (especially when a site-specific study is required), then documentation of this modification should be provided to the administrative authority for review and approval, prior to proceeding. EPA's *Use of Monitored Natural Attenuation at Superfund, RCRA Corrective Action, and Underground Storage Tank Sites* (EPA 1999) provides additional guidance on determining if natural attenuation is appropriate.

The final step of the exposure assessment is estimation of a chemical intake for all pertinent routes of exposure. A chemical intake is generally defined as the amount of chemical at the exchange boundary (e.g., skin, lungs, gut) and available for absorption. Intake, therefore, is not equivalent to an absorbed dose, which is the amount of chemical absorbed into the blood stream. Based on this definition, there may be some situations where it will be beneficial to determine the bioavailability or bioabsorption chemicals in a site-specific risk assessment. Assuming that all contacted chemicals enter the body may result in overestimating risk.

5.5 TOXICITY ASSESSMENT

The toxicity assessment step in a site-specific risk assessment evaluates the types of adverse health effects associated with chemical exposures, the relationship between the magnitude of exposure and adverse effects, and the uncertainty in toxicological or epidemiological studies. Generally, the toxicity assessment is composed of two components: hazard identification (type of toxic effect) and dose-response assessment (how much is necessary to produce the toxic effect).

Components of toxicity assessment are outlined below:

qualitative and quantitative toxicity information is obtained for constituents being evaluated

exposure periods for which toxicity values are necessary are identified

toxicity values for noncarcinogenic effects are determined

toxicity values for carcinogenic effects are determined

Toxicity information needed to conduct the site-specific risk assessment is presented in EPA's Integrated Risk Information System (IRIS) database.

It is important to verify that the molecular form (for organic chemicals) and chemical valency (for inorganic chemicals) detected at the site are the same as those presented in IRIS.

5.6 RISK CHARACTERIZATION

The risk characterization summarizes and combines the results from the exposure and toxicity assessments. Site risks are characterized after reviewing output from the toxicity and exposure assessments, by quantifying risks from individual chemicals, quantifying risks from multiple chemicals, combining risks across exposure pathways, and evaluating the uncertainty associated with the risk estimate. Risk characterization also includes an assessment of risks stemming from uncertainties associated with the site-specific risk assessment process. EPA's *Risk Assessment Guidance For Superfund Volume 1: Human Health Evaluation Manual, Part A* (EPA 1989) provides additional guidance on the assessment of uncertainty.

In the final step, the site-specific risk estimate is compared to the acceptable risk for the site.

6.0 RISK MANAGEMENT ACTIVITIES REMEDY EVALUATION AND SELECTION

This chapter describes . . .

The process for evaluating and selecting a remedy
"Tools" for developing a final remedy
- Remediation
- Engineered controls
- Institutional controls

6.1 THE PROCESS FOR EVALUATING AND SELECTING A REMEDY

This chapter describes the process of evaluating and selecting a risk management activity(ies) that will reduce risk to human health and the environment by addressing releases that do not meet the performance standards (i.e., source control, statutory/regulatory requirements, and final risk goal) as established by the administrative authority.

The range of potential risk management options evaluated will depend on the results of the risk-based priority screen (Screen), any site-specific risk assessments conducted, and ecological risk assessment (if necessary). Generally, the facility will evaluate and choose a risk management activity or combination of activities from three possible types of actions: remediation, engineered controls, and institutional controls. The administrative authority should provide assistance to the facility in identifying available risk management activities specific to the site, and by supplying information about the applicability of innovative or emerging technologies. The facility should consider many factors, including cost, in evaluating potential risk management activities; however, the primary criterion in selecting a risk management activity is the demonstration that the activity will achieve and maintain the performance standards.

When the facility has developed a course of action, a Risk Management Plan will be prepared to justify the facility's intended actions to ensure protection of human health and the environment. Because the

administrative authority is responsible for ensuring that the actions undertaken by the facility are protective of human health and the environment, as established by performance standards, the administrative authority should review and approve the Risk Management Plan. Figure 6-1 illustrates the remedy evaluation and selection process.

The approval process for the Risk Management Plan likely will be similar to that used currently for approving corrective action reports. The plan should be developed in accordance with all current and applicable laws and regulations, including public participation. Upon approval of the Risk Management Plan, the facility can begin its implementation.

6.2 REMEDIATION

Remediation is the process of removing or reducing the concentrations of COCs, as determined from the Screen or site-specific risk assessment, to lessen or eliminate impacts at locations where unacceptable exposure exists (i.e., risk reduction). Remediation may be performed by excavation and removal of COCs, in-situ treatment of COCs, or ex-situ treatment of COCs. The facility will identify concentrations of COCs in media that can be reduced to meet the performance standards, as established by the administrative authority. The use of a remedial alternative to meet a performance standard should include a mechanism to ensure that the remedy is protective over time. This can be accomplished by adequate design of operation, maintenance, and monitoring specifications.

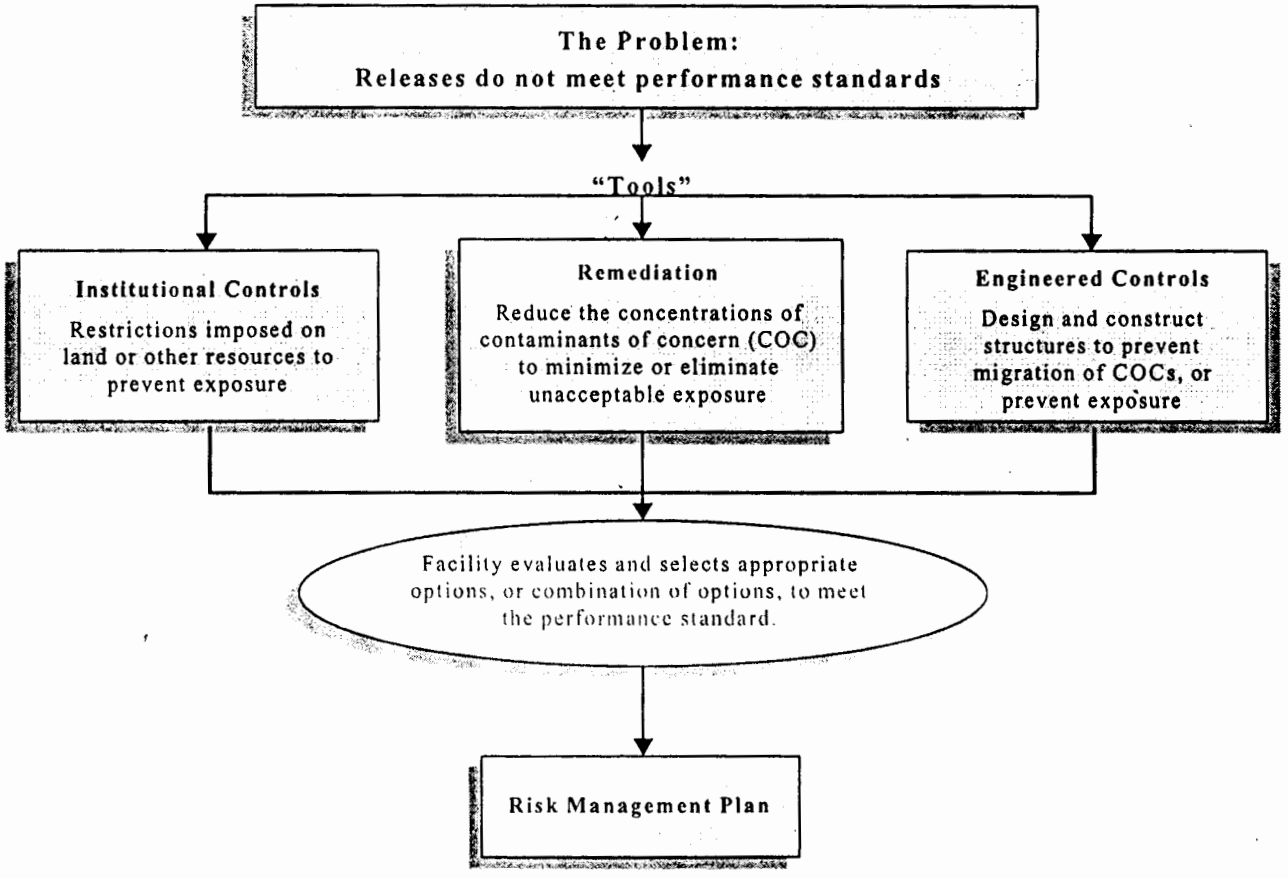
Risk Management Activities

RCRA regulations provide great latitude to facility owners on how to meet the corrective action objective of protecting human health and the environment.

EPA has found through Superfund and other programs, that treatment, while initially expensive, is often best to permanently and dramatically reduce environmental liability. Engineering controls, may initially cost less, but also carry with them ongoing operations and maintenance costs and continuing liability. Institutional controls are often initially the lowest cost risk management activity, but the effectiveness is much less certain over the long term, and does not reduce environmental liability as effectively.

Figure 6-1

Risk Management Activity Evaluation and Selection



In the NCP, nine criteria are discussed for evaluating remedial alternatives to ensure that all important considerations are factored into remedy selection. EPA also has issued numerous guidance documents that address the remedy selection framework presented in the NCP. *Rules of Thumb for Superfund Remedy Selection* (EPA 1997) provides a concise summary of the remedy selection expectations. The process of selecting remedial options for facilities under the RCRA statute should consider the remedy evaluation process outlined above.

Additional site characterization information also may be necessary for the facility to adequately evaluate and implement remedial alternatives. During release characterization, the focus of investigative activities (i.e., DQOs) is to evaluate the release in various media. For remedial planning, however, the DQOs may be considerably different and generally include characterization of the physical and chemical properties of the release to identify applicable and optimal remedial technologies. Remedial planning also may require other activities such as field investigations to characterize hydrogeologic conditions and monitor meteorological conditions. Some remedial alternatives may need to be evaluated through bench-scale or pilot testing. Appendix C contains references and web page links to current, emerging, and innovative remediation technologies that may be useful for evaluating and selecting cost-effective remedial alternatives.

6.2.1 Use of Presumptive Remedies

Use of presumptive remedies are a way to streamline investigations and speedup selection of a remedy. Based on information gathered throughout the history of site remediation, particular types of sites have similar characteristics, such as types of contaminants, disposal practices, and impacted media. During development of the CSM, a facility may identify a release that could be addressed through a streamlined approach using presumptive remedies. The use of presumptive remedies for RCRA corrective action sites should be similar to those used for CERCLA sites, as noted in the ANPR. There are several EPA guidance documents outlining the use of presumptive remedies at Superfund Sites for specific contaminants in soils and sediments, and presumptive response strategies for the restoration of ground water. While their use in not required for RCRA, they may be useful in remedy selection. EPA's presumptive remedies can be found at the following web site: http://www.epa.gov/superfund/resources/presump/index.htm

6.2.2 Use of Phased Remedies

Most permitted RCRA facilities are managed properties controlled by owners or operators who typically restrict access to their property. Exposure at such facilities is expected to be significantly less than exposure at sites where access is unrestricted. As first proposed in the 1990 Subpart S, a phased remedy would allow, at the administrative authority's discretion, an owner/operator to phase in a remedy over time, as long as certain conditions are met. These conditions for using a phased remedy would have to include, but not be limited to: provide financial assurance, achieve performance standards for releases that have migrated beyond the facility boundary, implement source control measures, and control further migration of on-site contamination impacting beneficial resources. The use of phased remedies would allow existing contamination to remain within the facility boundary, as established on a site-specific basis, for as long as the permit remains in effect. The administrative authority would set specific criteria for compliance with the phased remedy. The administrative authority should consider non-compliance with any of the specified criteria as a reason to terminate the phased remedy and request the implementation of a final remedy.

Timing of Corrective Action for Phased Remedies

Site remediation in a timely manner should be the ultimate objective for risk management activities. However, it is often necessary and appropriate, particularly for complex sites, to divide the facility for effective management and early action.

High priority releases should be addressed as early as possible since there is a high potential risk to human health or the environment. While actions are being undertaken at the high priority release areas, the facility may consider concurrently evaluating the lower risk releases in order to more efficiently use resources. Areas which were initially prioritized as lower risk releases may require more investigation or may be included in a site-specific risk assessment to determine the need for corrective action. If the investigation or site-specific risk assessment indicates that the area needs immediate attention due to unacceptable risk, the facility should be prepared to act as quickly as practical to implement the necessary corrective action. Conversely, some sites may not require further corrective action at that point. Facilities that fail to assess and address risks in a timely manner may continue to accrue liability from EPA, the state, adjacent land owners or natural resource trustees.

6.3 ENGINEERED CONTROLS

Engineered controls can be used to prevent or minimize impacts at points of exposure. Engineered controls are risk management tools that are physical structures designed and constructed to prevent

migration of COCs to locations where unacceptable exposure may occur, or prevent exposure to a COC. Typically, engineered controls do not directly reduce the COC concentrations, although concentrations may be reduced over time through natural attenuation.

The use of an engineered control to meet a performance standard should include a mechanism to ensure that it will be maintained or operated to protect over time. This is accomplished through adequate design, maintenance, and monitoring specifications, and by placing an institutional control on the property that will require current and future owners to maintain the protectiveness of the engineered control. In cases in which the engineered control is used in conjunction with a monitored natural attenuation remedy for ground water contamination, it should remain in place and operable until COC concentrations have attenuated to levels where unacceptable impacts at points of exposure no longer exist.

6.3.1 Types of Engineered Controls

Three categories of engineered controls are commonly used as risk management options: caps, cutoff walls, and hydraulic containment barriers.

Caps are protective covers that can be designed to prevent the infiltration of precipitation and surface water into a waste or contaminated media. The prevention of surface water infiltration can reduce leachate generation, the potential migration of contaminants in the subsurface soil and ground water, 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.

Cutoff walls are containment structures designed to prevent the migration of ground water from, or into, a source area. By preventing the migration of ground water, cutoff walls may minimize or prevent impacts from COCs in ground water. Common types of cutoff walls include slurry trenches, sheet piling barriers, and grouted barriers.

Hydraulic containment barriers usually consist of trenches, sumps, drains, and wells designed to reverse localized ground water flow gradients in such a manner as to reduce or prevent the migration of contaminated ground water. By preventing ground water migration, hydraulic containment barriers may

minimize or prevent impacts from COCs in ground water.

6.4 INSTITUTIONAL CONTROLS

Controls which restrict the use of land and other resources are often a key element of environmental cleanups. Institutional control refers to non-engineering measures. Institutional controls are usually legal controls intended to influence human activities in such a way as to prevent or reduce exposure to hazardous wastes or hazardous constituents.

The role that institutional controls play in the risk management approach for a facility is based on site-specific conditions and should be considered during the remedy selection process. Like any other remedial alternative, institutional controls should be rigorously evaluated to determine their appropriateness, feasibility, and long-term effectiveness in protecting human health and the environment.

Institutional controls often are used in conjunction with, or as a supplement to, other measures such as treatment or containment to prevent or reduce exposure. An institutional control or a group of institutional controls, under appropriate circumstances, though rare, may serve as the sole remedy at a facility. Institutional controls, however, are not intended to be used as secured abandonment (i.e., physically securing a site and preventing exposure while making little or no effort to ensure that COCs do not migrate to and beyond the property boundary). Institutional controls may not be appropriate as the sole remedy for off-site releases. EPA's expectation is for sites to be remediated to allow for reasonable beneficial reuse.

EPA has developed guidance on the use of institutional controls at Superfund and RCRA corrective action sites, and the guidance should be consulted for additional information concerning their applicability and use.

> *Institutional Controls: A Site Managers Guide to Identifying, Evaluating, and Selecting Institutional Controls at Superfund and RCRA Corrective Action Cleanups. EPA/540/F-00-005.* September 2000

Situations in which institutional controls may be an appropriate component of a remedy or are necessary to ensure that a remedy is protective include the following:

where cleanup is protective for industrial but not residential exposures

where ground water will remain contaminated for a period of time such that well drilling should be prevented

where surface water will remain contaminated such that fishing advisories or restrictions should be imposed

where soils are remediated at the surface but contamination at higher concentrations remains in the subsurface

where contaminant concentrations in soils are reduced to a level appropriate for residential use but a specific activity, such as gardening, might result in an unacceptable exposure

where contamination is capped to prevent exposure and/or reduce leaching to ground water, and activities that may degrade the cap must be prohibited

The use of an institutional control to meet a performance standard should include a mechanism to ensure the maintenance of the institutional control. Only certain types of institutional controls have such mechanisms (e.g., easements, zoning, and use restrictions). For institutional controls that do not have such mechanisms, an alternative mechanism for maintaining protectiveness should be put into place. Although the CAS does not advocate any particular mechanism for maintaining an institutional control, maintenance is critical until exposure to hazardous constituents would no longer result in unacceptable impacts.

6.4.1 Types of Institutional Controls

The CAS does not prescribe the use of any one particular institutional control over another, or preclude the use of multiple institutional controls when necessary. The following information is provided to help identify the various types of institutional controls that may be available and the tools that may be available to create them. The administrative authority should be consulted and provide assistance to the facility in identifying the institutional controls available for use.

Generally, there are four ways to control land and resource use: proprietary controls, which rely on property law; governmental controls, which rely on regulatory authorities (usually state or local government); enforcement tools; and non-enforceable information devices.

Proprietary controls: Private property law provides a variety of mechanisms that can restrict or affect the use of property. Common examples include covenants and easements that limit future land use or prohibit activities that may compromise specific engineering remedies. For example, an easement can be used to prevent an owner from developing a land parcel for residential use. Proprietary controls are based on generally applicable property law. As a result, they can be implemented without the intervention of any Federal, state or local regulatory authority. By their nature, the development, implementation, and enforceability of proprietary institutional controls are almost always a function of state law.

Governmental controls: Governmental controls rely on local and state governments to impose restrictions on the citizens and resources in their jurisdictions. Because they are implemented by third parties (state or local government), monitoring, maintenance, and enforcement are the most important considerations. Their effectiveness is predicated on the ability and desire of the governing authority to undertake such efforts. Examples of the mechanisms available to governmental authorities are zoning restrictions; restrictions on ground water use; building permits; issuance of advisories warning of potential risk; and creation of registries of hazardous waste sites.

Enforcement controls: A RCRA operating or closure permit may be used to require settling parties to put some other form of control in place, such as a proprietary control. For example, the permit could require the conveyance of an easement to the government or another third party. Typically enforcement tools are only binding on the party named in the agreement.

Non-enforceable information devices: Information devices such as deed notices are mechanisms for ensuring that parties to a real estate transaction (purchasers, tenants, and lenders) have an opportunity to become aware of the environmental status of the property prior to finalizing a transaction. For example, a deed notice can disclose the specific location of hazardous chemical residues at a site and list any restrictions on site use, access, and development. Because they do not convey any real property interests, information devices have no effect on the property owner's legal rights regarding the use of the property, and are not legally enforceable. Nonetheless, a properly drafted and filed deed notice can be effective by ensuring that future land owners and users are aware of all relevant environmental conditions at the site.

6.4.2 Other Considerations for Use of Institutional Controls

The evaluation and selection of appropriate risk management activities may be complicated by contamination that has migrated beyond the facility boundary or by contamination that poses an unacceptable risk to adjacent properties. EPA acknowledges that institutional controls are being used to restrict the use of land and other resources on onsite as well as offsite properties that have been impacted by the migration of contamination. As with the evaluation of institutional controls for an onsite remedy, the

evaluation of institutional controls for offsite property should include a determination of the appropriateness, feasibility, and long-term effectiveness in protecting human health and the environment afforded by the institutional control. An institutional control cannot be placed on neighboring property without first negotiating and receiving consent of the property owner. Although the administrative authority bears no responsibility in these negotiations, they need to ensure that the resulting agreement or settlements are protective of human health and the environment.

If the administrative authority considers the impacted offsite property a beneficial resource or objects to the use of institutional controls for impacted offsite property, the facility would need to achieve the performance standard(s) at the facility boundary.

7.0 PERFORMANCE MONITORING

This chapter describes . . .

A program for monitoring the performance of the risk management activity
Performance monitoring objectives
Performance monitoring parameters
- Land use changes
- Fate and transport verification
- Risk management activities

Periodic review and evaluation

7.1 A PROGRAM FOR PERFORMANCE MONITORING FOR A RISK MANAGEMENT ACTIVITY

When the facility has developed a course of action to achieve and maintain the performance standards, a Risk Management Plan, that justifies the facility's intended actions to ensure protection of human health and the environment, should be prepared (Section 2.4.4.1). The focus of this chapter is the demonstration of protectiveness over time through monitoring of the risk management activity, details of which are included in the Risk Management Plan. This chapter states the objectives of performance monitoring of the risk management activity undertaken by a facility, and provides guidelines for establishing both specific monitoring parameters and periodic performance reviews and evaluations.

The performance monitoring guidelines described in the following subsections are specific to the CAS, and are intended to complement, but not replace, monitoring requirements specified by statute, regulation, or other program components (e.g., permits required for the discharge of treated wastewater or air emissions). The administrative authority is responsible for reviewing and approving the Risk Management Plan, and ensuring that the actions undertaken by the facility are protective of human health and the environment.

7.2 PERFORMANCE MONITORING OBJECTIVES

The facility should develop a program for monitoring the performance of the risk management activity which includes specific criteria demonstrating that the activity implemented will remain protective.

The performance criteria should be specific to concentrations and distributions of COCs, and identify points of exposure (POE) and other physical parameters directly relevant to monitoring and measuring the protectiveness of the selected risk management activity. All performance parameters should focus on demonstrating that the performance standard is maintained once achieved; be based on site-specific conditions and implemented risk management activities; and establish specific monitoring parameters that, if exceeded, would trigger additional action to ensure protectiveness.

7.3 PERFORMANCE MONITORING PARAMETERS

The ultimate performance of a remedy is defined as achieving and maintaining the performance standard of an implemented risk management activity, and is dependent upon the long-term reliability of established exposure scenarios and land use assumptions, the validity of fate and transport parameters used in modeling, and the physical performance of the remedy or engineered control. This section provides guidelines for establishing the performance parameters described above.

7.3.1 Land Use Changes

Changes in the land use after a risk management activity has been implemented can influence both the types of receptors affected and the location of their exposure, thus, the exposure scenario evaluated under the previous land use may not adequately characterize the site risks. A mechanism, therefore, should be in place to ensure that the land use at the time of the remedy selection remains unchanged over time, or that actual changes in land use can be identified and the impacts re-evaluated.

Only certain types of institutional controls have mechanisms for limiting land use changes (i.e., easements, zoning, use restrictions). Institutional controls lacking such mechanisms should have alternative mechanisms for monitoring and maintaining land use put into place. Although the CAS does not recommend specific mechanisms for maintaining and monitoring land use changes, land use monitoring is critical and should be maintained until a potential change in land use would no longer result in unacceptable risk at the POE.

7.3.2 Fate and Transport Model Verification

The fate and transport of COCs in ground water, surface water, and air should be monitored to demonstrate the validity and representativeness of the ground water model if conducted as part of a site-specific risk assessment. This is particularly critical in demonstrating the protectiveness of the selected risk management activity if it includes monitored natural attenuation for ground water contamination, or if the POE is at the facility boundary (i.e., where the ground water under a facility is determined not to be a beneficial resource).

Monitoring should be conducted at locations that will validate the performance of the predictive model, and the values of key fate and transport parameters. The verification monitoring location should be along the route that a COC would most likely follow when being transported between the source area and the POE based on the site-specific risk evaluation. Consideration also should be given to the vertical pathways of likely migration. For example, a monitoring well intended to validate the predicted migration of ground water contamination should be screened in the zone where preferential migration would occur based on the physical and chemical properties of the COCs.

Analytical parameters selected for monitoring should be based on the compounds that are predicted to most significantly impact the POE of the media being monitored. While it may be convenient to monitor for all COCs, indicator compounds can be identified to provide a cost-effective validation of the model. At a minimum, the parameters to be monitored should include:

Use of Plume Management Zones

Regardless of ground water designation, EPA believes that site managers will seek to minimize the spread of ground water contamination.

Cost of treatment, recovery, and containment may increase exponentially with plume expansion, resulting in an increase in environmental liability at a site. On the other hand, site managers must contend with ground water contamination that has developed over years or decades of facility operations. Therefore, the CAS recognizes the use of plume management zones where ground water has been designated as a non-beneficial resource, and the following criteria have been evaluated:

- source control
- the potential for volatilization of ground water to indoor air,
- the potential for ground water to migrate to surface water or to an underlying beneficial use aquifer.

As with monitored natural attenuation (MNA), it is important to address the source of contamination to mitigate the further spread of contamination. With the evaluation of the above criteria, risk-based decisions can then be made by the administrative authority based on the presence or absence of significant risk at the point of exposure.

COCs that are expected to travel the fastest

COCs that are expected to travel the longest distance, including degradation and transformation products

COCs that have the greatest impact (risk) at the POE being evaluated (including cases where contaminants may migrate from one media to another, e.g., the POE is determined from a ground water to surface water pathway)

DQOs for the sample analysis should be established to ensure that adequate quantification is achieved so that potential and actual impacts can be determined with respect to the performance standard.

The monitoring frequency should allow adequate time for making adjustments to the risk management activity implemented. If fate and transport parameters must be revised based on the monitoring results, it may be necessary to re-evaluate the risk at the POE and to develop, design, and implement changes to the risk management activity to maintain protection of human health and the environment.

The duration of verification monitoring for fate and transport of selected COCs should be based on establishing a high degree of confidence that the modeled performance has been validated by field conditions (i.e., the COC concentrations predicted by the model are representative of what is actually happening at the site).

7.3.3 Risk Management Activity Performance

The performance of a risk management activity should be monitored to demonstrate that it is protective at the exposure locations. Performance monitoring may include measuring COC concentrations in various media or measuring physical parameters such as aquifer gradients.

The rationale for selecting where and how the performance monitoring should be conducted is based solely on demonstrating that the selected risk management activity (a remedy or an engineered control) meets the design criteria and objectives. Monitoring should adhere to the following:

performance should be monitored along the COC transport route from the source area to the POE

performance should be monitored at vertical locations within a media column where a

particular COC would most likely occur and at the POE

multiple monitoring points should be used as necessary

performance should be monitored at the areas where the remedy or engineered structure is subject to greatest stress after the perimeter of the area of action is verified

performance monitoring criteria should be based on appropriate COCs and other analytical and physical measurements specific to the system being monitored

monitoring frequency should allow adequate time for correcting potential problems and maintaining protectiveness at the POE

monitoring intervals should provide adequate time to identify, design, and implement an interim measure that would ensure protectiveness in the event that performance monitoring indicates a system failure

Performance monitoring for a risk management activity should continue until residual COCs no longer pose unacceptable risks at the points of exposure, and no potential exists for off-site migration of, or cross-media contamination from, residual COCs. These situations should be verified by field studies and actual measurements, rather than predictive modeling. Certain regulatory programs or situations may require specific monitoring periods.

7.4 PERIODIC PERFORMANCE REVIEW AND EVALUATION

Even when risk management activities have been implemented and it can be demonstrated that the performance standards have been achieved and are being maintained, it may be appropriate to review the overall performance of the remedy implemented at a facility. In its simplest form, a periodic review can consist of monitoring data summaries, accompanied by graphical and statistical analyses, if necessary, to demonstrate whether the implemented activities are consistently achieving and maintaining desired results. For more complicated remedial and engineering projects, a more thorough evaluation of overall performance may be warranted. The facility should consider putting in place long-term milestones, such as when and how periodic performance reviews should be conducted.

Monitoring data should be reviewed minimally on an annual basis. For long-term remedial projects, data review should be conducted every three to five years. The objective of periodic reviews is to

demonstrate continued progress toward meeting the final risk goal, based on the anticipated performance criteria of the specific actions implemented at a facility.

The periodic performance review procedures should include a mechanism to re-evaluate risk management activities in the event the implemented action does not maintain the established performance standard. The facility has the ongoing responsibility for maintaining protectiveness (in case of remedy failure) and should be prepared to take interim measures to maintain protectiveness if necessary.

GLOSSARY

Administrative Authority
The approved state program or EPA.

Beneficial Resource
Beneficial resources describes natural resources that are useful to human and ecological receptors. Individual states may establish statutes or regulations that identify certain environmental components, such as specific ground water or surface water sources, as a "Special Beneficial Resource, or a "Designated Beneficial Resource". The beneficial resources then may be entitled to greater protection from contamination.

Cancer Risk
EPA expresses cancer risk in terms of the likelihood that a person might develop cancer from exposure to contaminants from a facility. For example, a risk assessment might say that a receptor has an upper bound cancer risk of $1x10^{-4}$. The numerical estimate means that if 10,000 people received this level of exposure averaged over a 70-year lifetime, no more than one would have a probability of developing cancer.

Chemical of Concern (COC)
After the application of the risk-based priority screen (Screen), the COPCs that pose a significant risk are then labeled as chemicals of concern (COCs). Some COPCs may drop out from further evaluation. The remaining list of COPCs is called COCs.

Chemicals of Potential Concern (COPC)
Chemicals from hazardous waste and hazardous constituents that are potentially site related and have data of sufficient quality for use in the Screen (Chapter 4) or a site-specific risk assessment (Chapter 5). The facility should compile a list of COPCs for each release site based on existing sampling data, waste analysis reports, etc.

Conceptual Site Model (CSM)
The CSM is part of the Data Quality Objective (DQO) process that presents a three-dimensional picture of site conditions at a discrete point in time that conveys what is known about the facility, releases, release mechanisms, contaminant fate and transport, exposure pathways, potential receptors, and risks. The information for the CSM is documented into six profiles (Chapter 3 and Appendix B). The CSM evolves as data gaps in the profiles become more complete, and will be refined based upon results of site characterization data. The final CSM is documented in the Risk Management Plan (RMP).

Corrective Action
Corrective action is the process of identifying, evaluating, and if necessary remediation releases of hazardous constituents from waste management units and areas of concern to ensure protection of human health and the environment. Corrective action requirements apply to all solid waste management units (simus) at a facility needing a permit under RCRA.

Cross-Media Transfer
The movement of chemicals from one environmental medium to another (e.g., the movement of a chemical from soil to ground water).

Data Quality Objectives (DQO)
Data Quality Objectives are qualitative and quantitative statements derived from the output of each step of the DQO process. DQO's are used in the CAS to help clarify performance standards. The facility will use the DQO process as a guide to ensure quality data and defensible risk decisions.

Data Quality Objective (DQO) Process
A series of planning steps based on the Scientific Method that are designed to ensure that the type, quantity, and quality of environmental data used in decision making is appropriate for the intended application. Within the CAS, the DQO process involves evaluation of available data, developing the CSM, identifying problems to be solved, identifying data quantity and quality needs, and evaluating the data collection approach.

Data Reporting Limits
The minimum detection or quantitation limits for the laboratory or field analyses for the environmental data set collected. The data reporting limits must: be based on the intended use of the data, as determined during the development of the DQOs for the sample or data collected; establish prior to the collection of samples and confirmation that the chosen analytical method can achieve the limits; and achieve the most stringent (precision, accuracy, etc.) need of the data.

Ecological Exclusion Criteria Worksheet and Ecological Assessment Checklist (ECO Screen)
The ECO screen is a tool to help facilities and the administrative authority determine if an ecological risk assessment is necessary for a site or a portion of a site where corrective action is pursued. The exclusion criteria refer to those conditions at an affected property which preclude the need for a formal ecological risk assessment (ERA) because there are incomplete or insignificant ecological exposure pathways due to the nature of the affected property setting and/or the condition of the affected property media.

Engineering Controls
Physical barriers or other types of physical controls that are structures or natural or man-made systems that prevent exposure and/or the migration of chemicals of concern to the points of exposure. Examples are caps, slurry walls, permeable reactive barriers, sheet piling, hydraulic containment wells, and interceptor trenches.

Environmental Medium
All materials such as surface and subsurface soil, sediment, ground water, surface water, and air.

Exposure Pathway
The course a chemical or physical agent takes from a source to an exposed receptor. A unique mechanism by which an individual or population is exposed to chemicals or physical agents at, or originating from, a site. Each exposure pathway (e.g., ground water, soil vapor) includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure

medium (e.g., air) or other media also are included.

Exposure Route
The way a chemical or physical agent comes in contact with a receptor (i.e., by ingestion, inhalation, or dermal contact.)

Exposure Scenario
The setting of potential exposure, as described by exposure pathways and routes that affect a particular receptor.

Fate and Transport Modeling
The use of scientific models derived from mathematical formulas that simulate the movement and distribution of contaminants in environmental medium over a given period of time.

Facility
For purposes of defining the unit requiring a permit, the definition of facility includes all contiguous land, and structures, other appurtenances, and improvements on the land, used for treating, storing, or disposing of hazardous waste. A facility may consist of several treatment, storage, or disposal operational units (e.g., one or more landfills, surface impoundments, or combinations of them). For the purpose of implementing corrective action under 264.101, it includes all contiguous property under the control of the owner or operator seeking a permit under subtitle C of RCRA. This definition also applies to facilities implementing corrective action under RCRA Section 3008(h).

Final Risk Goal
A risk-based performance standard. The Final Risk Goal is based on site specific factors such as land use, presence of special subpopulations, contaminant concentrations based on acceptable risk, location at which the levels are to measured and achieved, and the remediation time frame. This performance standard can be proposed by the facility, but is established by the administrative authority following the scoping meeting. Once the final risk goal has been evaluated and assessed, it becomes the level of protectiveness to be achieved and maintained by the facility.

Hazard Index (HI)
Assesses potential for toxicity following exposure to multiple contaminants. It is equal to the sum of the hazard quotients. However, where information is available to identify the critical toxic effect for non-carcinogens, only hazard quotients with associated similar critical effects (target organs) are combined.

Hazard Quotient (HQ)
EPA expresses non-cancer health risk as a ratio, known as the Hazard Quotient (HQ), which is defined as the calculated exposure from a single contaminant in a single medium divided by a reference dose. The reference dose is the level of exposure that EPA believes will be without adverse effect in human populations, including sensitive individuals. Note that some chemicals may be associated with both carcinongenic and non-carcinogenic effects (such as kidney or liver disease).

Institutional Control

A non-engineering measure, intended to influence human activities in such a way as to prevent or reduce exposure to hazardous constituents. Institutional controls should be rigorously evaluated to determine their appropriateness, feasibility, and long-term effectiveness in protecting human health and the environment. Mechanisms to ensure the maintenance of the institutional control should be in place to ensure protectiveness, such as the layering of controls (more than one control used simultaneously). Some examples of institutional controls are deed notices, restrictive easements and covenants, and zoning laws.

Interim Measures
Actions undertaken by a facility or administrative authority to prevent or mitigate exposure, or in some instances, the migration of contamination from a release. Generally, interim measures can be stabilization measures implemented before formal evaluation is complete and after sufficient information is available to indicate that unacceptable risks and hazards are present.

Performance Standard
Performance standards describe EPA's expectations for the outcome of corrective action at a facility that will achieve and maintain protection of human health and the environment. The three performance standards in the CAS (source control, statutory/regulatory requirements and final risk goal) combine existing policy and regulatory requirements with a risk-based goal for protectiveness. Under the CAS, the performance standards applicable to releases at a facility are established early in the corrective action process. EPA believes that by establishing performance standards early in the process investigations will be better focused toward specific endpoints, and facilities will be able to more efficiently allocate resources to those activities that EPA deems most protective.

Plume Management Zone
The zone delineated for allowable plume growth within ground water that is not utilized for a drinking water supply or other beneficial uses as determined by the State regulatory authority.

Point of Exposure (POE)
The location within an environmental medium where a receptor is assumed to have a reasonable potential to come into contact with the chemicals of concern (COCs).

Profile
A particular aspect, or view, of the conceptual site model that facilitates understanding of site conditions. The guide describes potential profiles, including the facility profile, land use and exposure profile, ecological profile, physical profile, release profile, and risk management profile.

Release and Release Area
EPA has interpreted the term *release* to mean, "any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping or disposing into the environment." (50 FR 2873, July 15, 1985). This definition also includes abandoned or discarded barrels, containers, and other closed receptacles containing hazardous wastes or constituents. In the CAS, the term *release area* refers to areas of concern, SWMUs, or groups of SWMUs at a facility where there has been a release or there is a potential for a release of hazardous waste constituents to the environment.

Release Characterization
The collection of current information and possible additional sampling data to identify COPC's, and evaluate potential adverse effects. Sampling and analytical techniques should be selected based on the ability to obtain the necessary data to meet DQO's for each release.

Risk Management Plan
The report a facility uses to document the work performed and remedies to be implemented.

Risk-Based Priority Screen
A risk management tool that allows facilities to prioritize the areas that have potential or confirmed releases of contaminants to the environment. It consists of two bright line tables, with the objective of ranking release areas at the facility into two primary groups. The first group includes sites that pose high-risk or high threats to human health and the environment which need to be addressed first. The second group includes the lower-risk, low-level threat sites. The high-risk screen is used to help identify release areas that have the highest risk and could pose an immediate threat, and are the areas where facilities and the administrative authority should concentrate their resources (time and money) in the near term with the goal of achieving the maximum risk reduction for the facility in the shortest period of time. This is consistent, with and should accomplish the goal of, achieving EPA's environmental indicators for the protection of human health and the environment and control of ground water (EPA RCRIS database CA725/CA750 codes).

Site-Specific Risk Assessment
The Site-Specific Risk Assessment is a risk management tool that allows facilities to take a closer look at release areas that pose a significant risk after the application of the risk screen. Facilities are allowed to input site-specific data into fate and transport models to more accurately predict the concentration of contaminants at points of exposure to evaluate risk.

Solid Waste Management Unit
Any discernible unit at which solid wastes have been placed at any time, irrespective of whether the unit was intended for the management of solid or hazardous waste. Such units include any area at a facility at which solid wastes have been routinely and systematically released.

Source Materials
Source materials are defined as those which include or contain hazardous wastes or hazardous constituents that act as a reservoir for migration of contamination to soil, to ground water, to surface water, to air, or acts as a source for direct exposure. Sources are not always stationary, but can migrate from a location, such as a landfill or surface impoundment, where contamination originally was released. Contaminated ground water plumes are generally not considered to be a source material, although nonaqueous phase liquids (NAPL) in the ground water generally would be viewed as such (Rules of Thumb for Superfund Remedy Selection, 1997).

ACRONYMS

ACL	Alternate Concentration Limit
ANPR	Advanced Notice for Proposed Rulemaking
BLT	Bright-Line Table
CAP	RCRA Corrective Action Plan
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CMI	Corrective Measures Implementation
CMS	Corrective Measures Study
COC	Contaminants of Concern
COPC	Contaminants of Potential Concern
CSGWPP	Comprehensive State Ground Water Protection Program
CSM	Conceptual Site Model
DQO	Data Quality Objective
DNAPL	Dense Non-aqueous Phase Liquids
EI	Environmental Indicator
EPA	U.S. Environmental Protection Agency
ERA	Ecological Risk Assessment
GAO	Government Accounting Office
GPRA	Government Performance and Results Act
HI	Hazard Index
HQ	Hazard Quotient
LNAPL	Light Non-Aqueous Phase Liquids
MCL	Maximum Contaminant Levels
MCLGs	Maximum Contaminant Level Goals
MSSL	Media-Specific Screening Levels
NAPL	Non-Aqueous Phase Liquids
NCFC	No Current Federal Concern
NCP	National Oil and Hazardous Substances Contingency Plan
NFA	No Further Action
PAHs	Polycyclic Aromatic Hydrocarbons
PCBs	Poly Chlorinated Biphenols
POC	Point of Compliance
POE	Point of Exposure
QA	Quality Assurance
QAPP	Quality Assurance Project Plan
QC	Quality Control
RAGS	Risk Assessment Guidance for Superfund
RCRA	Resource Conservation and Recovery Act
RCRIS	RCRA Information System database
RFA	RCRA Facility Assessment
RFI	RCRA Facility Investigation
RMP	Risk Management Plan

Los Alamos National Laboratory
Material Disposal Area High Performing Team Meeting
November 20-21, 2000
Cities of Gold Casino

PARTICIPANTS

MDA High Performing Team	Participants	Facilitators
Woody Woodworth, DOE Eliza Frank, NMED Neelam Dhawan, NMED John Hopkins, LANL Diana Hollis, LANL	Phebe Davol, TechLaw Tara Athan, LANL Gian Bacigalupa, LANL Paul Schuman, LANL Paula Bertino, LANL Alice Barr, LANL	Kevin Kytola, PPC Jeff Smyth, PPC

MEETING SUMMARY

The Material Disposal Area High Performing Team (MDA-HPT) met November 20-21, 2000. Specific objectives of the meeting for the MDA-HPT were:

1. Define objectives, role and responsibility for the MDA-HPT

2. Begin development of the MDA strategy

Specific MDA-HPT agreements are summarized in Table 1.

Some outstanding issues for the MDA-HPT to consider:

1. Specific definition of how and why MDA-HPT members are added. Given the identified role as decision-makers for their respective organizations, MDA-HPT members are limited to State, DOE and LANL employees with this designated authority. However, it is not clear who decides the specific members of the MDA-HPT that represent their respective organization.

2. The MDA-HPT generally defined their role to be "visionary" as opposed to "review and approve". This role needs to be continually reinforced. One means of doing this is making sure that the MDA-HPT directs activities (e.g., defines expectations) prior to the development of reports, analysis, etc.