Risk-Based Decision Making

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Strategies for Today's Environmental Partnership

American Petroleum Institute

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- To commit to reduce overall emissions and waste generation.
- To work with others to resolve problems created by handling and disposal of hazardous substances from our operations.
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- To promote these principles and practices by sharing experiences and offering assistance to others who produce, handle, use, transport or dispose of similar raw materials, petroleum products and wastes.

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Manufacturing, Distribution and Marketing Department

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SECTION 1—INTRODUCTION

A risk-based decision making approach can be utilized both to focus remedial measures and funds on petroleum hydrocarbon release sites while being protective of human health and the environment and to facilitate timely closure of hydrocarbon-impacted sites. The approach combines the petroleum information gathered during a site investigation with data on the health effects of the site-related petroleum hydrocarbon compounds to evaluate whether a particular site requires remedial action. A risk assessment demonstrating protection of human health and the environment can be helpful in determining if active remediation is warranted at a site and to what degree, and if active remediation may be discontinued prior to removing all petroleum hydrocarbon compounds from a medium at a site. Therefore, considerable monetary savings can be realized while protecting human health and the environment.

A risk-based decision making approach is increasingly becoming an integral component in most regulatory programs under supervision by both federal and state agency personnel. A three-tiered risk-based decision making approach to be used for petroleum releases was developed by the American Society for Testing and Materials (ASTM) in the *Standard Guide for Risk-Based Corrective Action Applied at Petroleum Release Sites* (ASTM 1995). The process integrates components of the site assessment, risk assessment, risk management, and remediation into a holistic site-specific approach that is consistent and technically defensible while still being practical and cost effective. This Publication addresses the application of a tiered or phased risk-based decision making approach to hydrocarbon-impacted sites.

The U.S. Environmental Protection Agency (USEPA) has stated that six components represent the bulk of the risk assessment process regardless of the intended goal or the point in the project when a risk assessment is performed. These components include:

a. Site characterization.
b. Data evaluation or chemical(s) of concern characterization.
c. Exposure assessment.
d. Toxicity assessment or hazard characterization.
e. Risk characterization or development of remediation goals.
f. Uncertainties.

Each of these components (and the information each is comprised of) will be discussed later in greater detail.

Utilizing a risk-based decision making approach to identify the project termination point involves at a minimum, conducting an exposure assessment to identify complete exposure pathways by which receptors (people and/or the environment) could potentially be exposed to site-related chemical(s) of concern. Prior to utilizing a risk-based decision making approach, an organization should evaluate the regulatory climate and discuss the process with the lead regulatory agency to determine whether adopting this approach to corrective action or remediation will be acceptable. If the regulatory climate is favorable, there are certain data requirements beyond those typically collected in a site assessment that should be met to facilitate use of a risk-based decision making approach to remediation (API 1993; ASTM 1996).

SECTION 2—USES OF RISK-BASED DECISION MAKING

2.1 Overview

Risk-based decision making is useful in identifying and managing potential health risks associated with release sites. Risk-based decision making can provide a framework for decision-making at sites and assist in streamlining the corrective action process. Specific objectives necessary to realize this goal include the following: (a) an analysis of baseline risks (potential adverse health risks that could result in the absence of any remediation activities at a site) to determine the necessity for remedial action, (b) concentrations of chemical(s) of concern that can remain in place and not threaten human health and the environment, (c) a basis for comparing health impacts potentially associated with various remedial alternatives, and (d) a consistent and logical process for evaluating potential threats to human health and the environment at release sites (USEPA 1989a).

Risk-based decision making is a process that quantifies (a) the potential risks to identified receptors associated with exposure to site-related chemicals of concern or (b) site-specific remediation target levels for impacted media that will protect human health if exposure to the identified receptors occurs. Generally, a baseline risk assessment is used to predict the potential adverse risks to human health and the environment associated with chemical(s) of concern at a site in the absence of remediation or institutional controls to control/prevent exposure to the chemical(s) of concern. However, exposure/risk assessments also are conducted at

impacted sites before corrective action is undertaken to identify remedial target levels that, when reached, represent the project termination point at which human health and the environment are protected. The latter approach is used in the Risk-Based Corrective Action (RBCA) process (ASTM 1995). Risk assessments may be used after active remediation is complete to predict the risks associated with residual concentrations of chemical(s) of concern left in-place.

2.2 Risk-Based Corrective Action

Risk-Based Corrective Action (RBCA) is an approach that incorporates risk and exposure assessment practices with the traditional components of corrective action, i.e., emergency response, initial abatement, site assessment, and remedial action to focus remedial measures and resources consistent with the level of risk posed by a site to human health and the environment, and to facilitate timely closure of hydrocarbon release sites. The RBCA approach combines the information gathered during a site assessment with data on the health effects of the chemicals identified on site to evaluate a particular site for remedial actions. Chemical(s) and pathways of concern are identified, and site-specific target levels are determined. By definition, risk is dependent on both exposure and toxicity; without an exposure, there is no risk. By applying the risk assessment principles, the likelihood that adverse health or environmental effects will occur as a result of exposure to chemical(s) of concern can be determined.

The ASTM RBCA standard provides a framework to make decisions related to the urgency of response, site-specific target levels, and remedial measures based on protection of human health and the environment. Use of the RBCA process yields a technically defensible, protective, and cost-effective approach to address petroleum release sites.

A risk-based approach considering protection of human health and the environment should be used for all sites. Considerable resource/cost savings may be realized utilizing this approach while still protecting human health and the environment. Regulators in many states and the USEPA now accept risk-based options. Before using a risk-based approach, the regulatory climate should be assessed and the process discussed with the lead regulatory agency to establish applicability and goals for a risk-based approach to corrective action.

2.2.1 INITIAL SITE ASSESSMENT AND SITE CLASSIFICATION

The RBCA process begins with an initial site assessment and site classification. Initial data requirements should be focused from a risk perspective to characterize the land use (for example residential, commercial, or industrial) and resource use (for example ground water used as a drinking water supply) of the site and adjacent properties; identify chemical(s) of concern, source areas, potential exposure pathways, and receptors; and identify concentrations of chemical(s) of concern at the source area and point(s) of exposure. This information can be collected from historical records, site inspection, and limited site assessment activities.

Using the initial data collection, the site can be classified based on level of potential threats to human health and the environment; initial response actions can be taken as appropriate. Site classification is designed to focus resources on those sites posing the greatest threat to human health and the environment. Responses may range from emergency response and initial abatement actions for those sites posing an immediate threat, to monitoring programs sites having little potential for current or future impacts. Each classification defines responses that are appropriate for that classification.

2.2.2 TIERED EVALUATION

The RBCA tiered evaluation process begins with the first tier and moves to higher tiers as warranted. Moving through the tiers requires more focused site assessment activities and the development of more site-specific data. The three-tiered risk-based decision-making process reduces the data collection and evaluation burden at many sites. Sites with minor releases may be addressed through a health-protective screening approach in Tier 1. The majority of petroleum hydrocarbon sites can probably be addressed through a quantitative approach involving the assumption of realistic current and future site use, and health-protective and ecological-protective site-specific exposure parameters as described by a Tier 2 evaluation. For those sites where multiple human or ecological exposure pathways exist, a more detailed and comprehensive evaluation may be warranted; these sites would fall into Tier 3. Because site assessment and risk assessment processes increase in complexity with each tier level, the required costs, data needs, and level of sophistication also increase.

2.2.2.1 Tier 1 Evaluation

Tier 1 involves the comparison of site-specific concentrations of chemical(s) of concern with a Tier 1 look-up table. The Tier 1 look-up table contains conservative, non-site-specific risk-based screening level (RBSL) concentrations for chemical(s) of concern for a variety of potential exposure scenarios (for example residential or industrial) and exposure pathways (for example groundwater ingestion or dermal contact) to environmental media such as ground water, soil, and vapors. Typically, these values are derived based on protection of human health and the environment. They may also consider aesthetic criteria and will be applied consistently to all sites. These values are compared to site-

specific concentrations of chemical(s) of concern for the site. If the concentrations of chemical(s) of concern are below the screening level concentrations, then no further action is appropriate. If the concentrations are above the screening level concentrations, further tier evaluation to develop site-specific target levels may be appropriate. Remedial action using Tier 1 screening levels as target levels may also be considered.

2.2.2.2 Further Tiered Evaluation

If further tiered evaluation is appropriate, provisions are available under Tiers 2 and 3 to develop site-specific target levels (SSTLs). An important factor in any RBCA analysis is the protection of human health and the environment. In each case, the site-specific target levels will be health protective to the same overall level [for example, a target risk of 1 in 100,000 (10^{-5})]. The difference in higher tiers will be the use of site-specific data and chemical fate and transport analysis to replace the conservative assumptions and analysis. The decision to move to a higher tier is based on the following:

a. Is the approach or are the assumptions used to derive the current tier's site-specific target levels appropriate for conditions at this site?
b. Will the site-specific target levels developed under the next higher tier be significantly different from current tier?
c. Will site-specific target levels developed under the next tier significantly modify the remedial action activities?
d. Will the cost of remedial action to current tier target levels likely be greater than further tier evaluation and subsequent remedial action?

2.2.2.3 Tier 2 Evaluation

Tier 2 uses more site-specific data than Tier 1. This level of effort will apply to the majority of UST sites. This is a more site-specific assessment and typically involves "reasonable use" exposure assumptions as well as consideration of actual beneficial uses of resources. Tier 2 provides a tool for determining point(s) of compliance. Additional site assessment data may be needed as part of this evaluation. Site-specific target levels can be developed under a Tier 2 evaluation using any one or combination of the following:

a. Use the methods and equations for development of the Tier 1 screening levels but replacing the default assumptions with site-specific parameters.
b. Apply the Tier 1 screening levels at point(s) of exposure, then back-calculate acceptable concentrations at the source area(s) based on estimated (for example, predictive models), measured, or monitored attenuation.
c. Develop statistical representation of the source area(s) concentrations of chemical(s) of concern and compare the representative concentrations to the screening levels or site-specific target levels.

2.2.2.4 Tier 3 Evaluation

Tier 3 involves the highest level of effort and may include the use of site-specific numerical models, probabilistic analyses (such as those involving Monte Carlo), or sophisticated analytical tools. Tier 3 may also utilize tools such as API's Decision Support System for Exposure and Risk Assessment (API 1993) that provide analyses to support site-specific decisions. This tier may be best suited for sites where multiple pathway analysis (for example, exposure of receptors could occur during work activities, recreational activities, and trespassing or a detailed analysis of ecological exposures) is required. Tier 3 will typically require significant additional site-specific data for the use of complex numerical models and probabilistic analyses.

2.2.3 REMEDIAL ACTION AND MONITORING

In the RBCA process, remedial action is determined to be appropriate based on the comparison of representative concentrations to the target levels determined under the tier evaluation. Remedial actions may include a combination of aggressive and passive measures (including natural attenuation, source removal, engineering controls and institutional controls) designed to reduce concentrations of chemical(s) of concern target levels. In each case, the type of remedial action is selected to meet the target levels developed using a risk-based approach. This allows the project to focus only on those areas or media posing a potential threat to human health or the environment. Monitoring should be conducted following or during a remedial action to demonstrate that target levels are met and continue to be met, and to verify the assumptions and predictions used in Tier 2 and Tier 3.

SECTION 3—COMPONENTS OF A RISK ASSESSMENT

3.1 Overview

This section discusses risk assessment principles used to implement a risk-based approach for evaluating potential threats to human health and the environment from the release of petroleum products. These principles are the basis for the RBCA process discussed in Section 2.

Risk assessments are useful in identifying and managing potential human health risks or risks to ecological receptors associated with impacted sites. Risk assessment is a pro-

cess that quantifies (a) the potential risks to identified receptors associated with exposure to site-related chemicals, or (b) the site-specific remediation target levels for impacted media that will protect human health and ecological receptors if exposure to the identified receptors occurs. Generally, a risk assessment is used to predict the potential adverse risks to human health and the environment associated with exposure to chemical(s) of concern at a site. Risk assessment methodology can serve as a cost effective tool to determine if residual concentrations of chemicals of concern threaten human health and the environment using a tiered approach. This process is outlined in the Section 2.

3.2 Risk Assessment

The goal of a risk assessment is to evaluate the magnitude and probability of actual or potential harm by the threatened or actual release. The components that are required to achieve this goal are:

a. Analyze all relevant environmental media (air, soil, water).
b. Evaluate relevant environmental fate and transport mechanisms.
c. Evaluate potential exposure pathways and extent of expected exposure.
d. Identify human and ecological populations at risk.
e. Identify the intrinsic toxicological properties of the released materials or components of the released materials at or near the site.
f. Evaluate the extent of expected harm and the likelihood of such harm occurring (that is, characterize the risk).

The risk assessment process can be reduced to three areas of investigation, which are described below:

a. Exposure Assessment.
b. Toxicity Assessment.
c. Risk Characterization.

3.2.1 SITE CHARACTERIZATION

Prior to conducting a risk assessment and during the site assessment, data are collected on the site and surrounding area. Typically, the nature and extent of chemical(s) of concern are delineated. Additional information on land use surrounding the site should be collected to help identify potential receptors in the next step of the risk assessment, which is exposure characterization.

A second step within the site characterization is identification of the chemical(s) of concern. The chemical(s) of concern encountered in hydrocarbon releases typically include benzene, toluene, xylenes, and lead (for example, for a leaded gasoline release). Benzene and toluene are mobile chemicals that readily partition into vapor- and dissolved-phase hydrocarbons. Lead occurs in free liquid and residual hydrocarbons sorbed to soil particles, and leaches into ground water with the dissolved-phase hydrocarbons. Caution should be exercised in using lead as a chemical of concern, as it occurs naturally in soil material. The use of lead as a chemical of concern has decreased since the phase out of leaded gasoline production.

3.2.2 EXPOSURE ASSESSMENT

An exposure assessment is conducted to predict possible migration routes and to identify areas where a hydrocarbon release may have an impact on human health or the environment. In an exposure assessment, all available information must be integrated to determine the movement of all hydrocarbon phases toward potential receptors. A complete exposure pathway consists of a source, a transport mechanism, a point of exposure, and an exposure route. The pathways for liquid- and vapor-phase hydrocarbons in the subsurface environment are dictated by natural soil conditions and geologic barriers and conduits, as well as by man-made structures.

Whether emanating from petroleum hydrocarbon trapped in soil or floating on or dissolved in the water table, hydrocarbon vapors tend to migrate along the paths of least resistance and toward areas of lower pressure. Although vapor migration can be halted by buried structures, vapors will readily follow other more convenient pathways through backfill materials surrounding structures such as water, sewer, and utility lines. Vapors can enter structures through drains or cracks in foundations and accumulate in basements.

If a facility is located over or near public water supplies or private wells, the possibility that any amount of released hydrocarbons could affect water quality is likely to be a concern. Nevertheless, attention to sites in industrialized areas or in areas that rely on remote water supplies should not be minimized.

Present and future potential exposure pathways and receptors should be identified, and their impacts on site use should be evaluated. The evaluation of exposure pathways and receptors may include constructing a map of the distribution of hydrocarbon phases and all potential pathways; developing a conceptual understanding of the migration of liquid-, vapor-, and dissolved-phase hydrocarbons beneath and near the release site; and evaluating the migration rates and concentrations of mobile hydrocarbon phases reaching potential receptors.

Data collected in the site assessment are used to develop a conceptual understanding of how the various hydrocarbon phases are migrating from the source area. The factors that should be considered include the following:

a. Volume released.
b. Adsorptive capacity of the soil.
c. Presence of perched groundwater and primary and sec-

ondary porosities in the earth materials.
d. Relative permeability of the soil to dissolved- and vapor-phase hydrocarbons and LNAPL.
e. Rates and directions of groundwater movement.
f. Processes such as dispersion, advection, and degradation that reduce concentrations and limit the area of the hydrocarbon-impacted zones.

The potential for soils containing residual LNAPL to act as a long-term source of hydrocarbons in ground water should be considered. Computer models (both analytical and numerical with varying levels of complexity and data requirements) are available to predict the impact of residual hydrocarbons in soil on groundwater concentrations. These models can be used with information collected during the site assessment to estimate the approximate concentration of hydrocarbons in groundwater at a given time and location. A monitoring well network capable of delineating the hydrocarbon plume can be established to verify the model being used. The model then can be refined based on the monitoring data. These models can be very useful in (a) determining the need for corrective action, (b) establishing target levels and time frames, and (c) selecting and designing appropriate remedial actions based on the target levels.

3.2.3 TOXICITY ASSESSMENT

This section summarizes the methodology to be used in evaluating risk from exposure to the chemical(s) of concern. The general methodology for the classification of health effects and the development of health effects criteria is described in more detail in the "Technical Bulletin on Risk-Based Corrective Action."

For risk assessment purposes, USEPA guidance recommends that chemicals be separated into two categories of toxicity depending on whether they exhibit non-carcinogenic or carcinogenic effects (USEPA 1989). This distinction relates to the currently-held scientific opinion that the mechanisms of action for these categories differ. For carcinogens, any exposure is assumed to have a finite possibility of causing cancer (that is, no threshold). Non-carcinogenic effects are assumed to occur if exposures are above a minimum dose, termed a *threshold*.

3.2.3.1 Health Effects Criteria for Potential Non-Carcinogens

Reference doses (RfDs) and reference concentrations (RfCs) are generally used as health criteria for chemicals exhibiting non-carcinogenic effects. The RfD and RfC, expressed in units of mg/kg/day and mg/day, respectively, are estimates of the maximum human daily exposure level likely to be without an appreciable risk of deleterious effects during a lifetime. RfDs and RfCs are usually derived either from human studies involving workplace exposures or from animal studies and are adjusted using uncertainty factors (Barnes et al. 1987). An attempt is made to consider sensitive subpopulations in deriving the RfD and RfC. The RfD and RfC provide a benchmark against which human intakes of chemicals estimated from exposures to contaminated environmental media may be compared.

3.2.3.2 Health Effects Criteria for Potential Carcinogens

Cancer slope factors are generally used as health criteria for potentially carcinogenic chemicals. They are derived from the results of chronic animal bioassays or human epidemological studies, and are expressed in units of $(mg/kg/day)^{-1}$. Animal bioassays are usually conducted at dose levels that are much higher than those resulting from human exposure to environmental media. This procedure is followed to permit detection of possible adverse effects in the small test populations used in these studies. Since humans are generally exposed at lower doses, the animal data are adjusted using mathematical models. A linearized multistage model is typically fitted to data from animal studies to obtain a dose-response curve. The 95th percent upper confidence limit (UCL) on the slope of the dose-response curve is subjected to various adjustments, and an interspecies scaling factor is usually applied to derive a cancer slope factor for humans. Dose-response data derived from human epidemiological studies are fitted to dose-time-response curves on an a situational basis. In both types of analysis, health-conservative assumptions are applied. Then, the actual risks associated with exposure to potential carcinogens are not likely to exceed the risks estimated, but may be much lower.

3.2.3.3 Health Effects Criteria for Exposure to Lead

The USEPA has not established oral inhalation RfDs for lead (Intergrated Risk Information System 1995), because measurement of blood lead provides a more accurate indication of potential health effects. A correlation can be made between exposure to lead and increases in blood lead levels, and the health effects associated with these levels. Additionally, the available dose-response data and results of animal studies do not adequately characterize the toxicity of lead (ATSDR 1990).

Blood lead levels have been accepted as the best measure of the external dose of lead. Sensitive populations include preschool-age children, fetuses, and white males between 40 and 59 years of age. In both adults and children, a blood lead level of 10 micrograms per deciliter (µg/dL) has been associated with a level at which no adverse effects would be expected to occur.

Children have been considered to be the most sensitive receptors for lead exposure. The USEPA has developed a biokinetic/uptake model to calculate the blood lead level

resulting from exposure to lead at a site and in background exposures such as air or drinking water. USEPA has developed a computer program of the biokinetic model called LEAD99. LEAD99 can be used to calculate a soil concentration that will not cause blood lead levels in children to exceed 10 mg/dL. A similar method can be used to evaluate exposure of adults to lead (Sager and Jones 1991).

3.2.4 RISK CHARACTERIZATION

This section summarizes the tools used to quantitatively evaluate risk. To quantitatively assess the potential risks to human health associated with the current and future use exposure scenarios considered in an assessment, the concentrations of chemicals in relevant environmental media (that is, exposure point concentrations) are used to calculate chronic daily intakes (CDIs) or doses. CDIs are the amount of a substance taken into the body per unit body weight per unit time, expressed in units of mg/kg/day. A CDI is averaged over a lifetime for carcinogens (USEPA 1986; 1989) and over the exposure period for non-carcinogens (USEPA 1986; 1989).

For recognized and/or potential carcinogens, excess lifetime cancer risks are obtained by multiplying the CDI of the constituent under consideration by its cancer slope factor. A risk level of 10^{-6}, representing the probability of one excess cancer case per one million exposed individuals, has been used by USEPA as a point of departure. USEPA (1990) considers potential excess lifetime cancer risks within the range of 10^{-4} to 10^{-6} to be acceptable and has recently stated that: "Where the cumulative carcinogenic site risk to an individual based on reasonable maximum exposure for both current and future land use is less than 10^{-4}, and the non-carcinogenic hazard quotient is less than 1, action generally is not warranted unless there are adverse environmental impacts" (USEPA 1991).

The likelihood of manifesting non-carcinogenic effects is not expressed as a probability as is the likelihood for carcinogenic risk. USEPA (1989) recommends evaluation of non-carcinogenic potential using a calculation of hazard quotients (HQs) and hazard indices (HIs). The HQ is a pathway-specific (for example, ingestion or inhalation) ratio of the calculated CDI for each constituent compared to the constituent-specific RfD. The HI is the sum of all the HQs for an individual pathway and from all pathways of exposure. If either the HI or HQ exceeds a value of one, there "may be a concern for potential non-carcinogenic effects" (USEPA 1989). An HQ or HI less than one indicates a low potential of adverse health effects occurring for the evaluated exposure scenarios.

3.3 Development of Target Levels

Target levels are typically calculated to derive concentrations of chemical(s) of concern that are protective of potential human health exposures at release sites. Target levels are medium-specific (for example, soil) and chemical-specific (for example, lead) values calculated using assumptions based on potential current and/or future exposures. The assumptions developed in the exposure assessment are used to develop target levels. Target levels are basically a "back" calculation of a concentration (for example, soil) to which an individual could be exposed and no adverse health effects would occur.

Currently, there are no federal standards for acceptable levels of lead in soil. Typically, critical toxicity values established by USEPA (for example, cancer slope factors, RfDs) are used to calculate soil target levels. The blood lead approach described above would be used to calculate soil target levels for lead.

Regulatory agencies such as the USEPA typically require that a baseline risk assessment (an evaluation of current conditions) be performed prior to development of target levels. If this was the case, target levels need to be calculated only for those pathways that present a potential risk to human health. More recently, target levels have been derived early in the site investigation process to help focus the remedial investigation or to provide a basis for determining whether or not remedial action is required at a site (see Section 2).

3.4 Risk Management

Risk characterization serves as the bridge between risk assessment and risk management, thus playing an important role in the ultimate decision-making process at a site. *Risk assessment* means applying focused scientific methodology in an effort to predict the potential for risks to health in a certain set of circumstances (ACS 1989). *Risk management* means determining the level of acceptable risk for a certain situation and selecting a combination of treatment technologies and institutional controls to manage the associated risks. Potential concerns may never be eliminated entirely at a site, but they can be minimized, controlled, and managed through eliminating complete exposure pathways or using a combination of treatment and control methods. In many cases, it may be more effective to manage the potential risks associated with site-related chemical(s) of concern than to eliminate the risks through the utilization of active remedial strategies. Examples of risk management techniques include a deed restriction disallowing the use of groundwater at a site, or employing physical barriers to prevent exposure to affected soil. Minimizing the possibility of unnecessary risks, making responsible decisions, and adopting cost-effective remedial action when necessary to protect human health and the environment are the ultimate goals of the risk assessment and risk management process.

3.5 Uncertainties

The final component of any risk assessment is the uncertainty analysis. Uncertainty is inherent in the risk assess-

ment process with each of the three basic building blocks (monitoring data, exposure scenarios, and toxicity values) contributing to the cumulative uncertainty. Exposure doses may be calculated assuming that current concentrations of chemical(s) of concern will remain stable over the exposure period (up to 30 years for residents living in one home), although the use of decay constants in identifying source concentrations and exposure point concentrations is becoming more prevalent. Disregarding the effects of degradation and assuming that exposure to a stable concentration of chemical(s) of concern occurs over time oversimplifies reality because the effects of natural attenuation, especially important with hydrocarbon compounds, are disregarded.

Most regulatory guidelines for risk assessment mandate that potential risks at a site must not exceed a designated acceptable level of risk for more than 5 to 10 percent of the population that may be exposed to impacted media. This should include abnormal exposures (for example, a child known to eat abnormally large amounts of soil) and the reasonable maximum exposure (RME) (Burmaster and Harris 1993). However, the use of health-protective exposure assumptions, as mandated in guidance, often results in exposure and potential risk estimates that far exceed the 99th percentile. This leads to remedial decisions that are based on protection against health risks that are highly improbable (Burmaster and Harris, 1993). The use of health-protective default assumptions compounds the conservatism and affects the accuracy of the predicted risks, thus contributing significant uncertainty.

The toxicity values used are associated with significant uncertainty because they are generally developed using results of studies in which laboratory animals are exposed to high chemical doses, instead of the low doses typically encountered by humans. Laboratory animals may also exhibit different responses than humans. Additionally, data are often insufficient to compensate for differences in chemical absorption, distribution, metabolism, excretion, and target organ sensitivity among species. The conservative method used in the derivation of the cancer slope factor (CSF) has long created controversy in the scientific community (Burmaster and Harris, 1993). The conservatism built into the CSFs and RfDs used to either quantify potential risks or develop target levels is believed to result in either an overestimation of human health risk or an underestimation of acceptable concentrations that can remain in-place.

The inherent uncertainty in the risk assessment can be quantified through use of statistical techniques such as, Monte Carlo simulation sensitivity analysis. Because an increased level of sophistication, effort, and data collection is required to utilize such techniques, this approach may not be applicable to all release sites.

SECTION 4—DETERMINATION OF TERMINATION POINT

4.1 Overview

Site remediation involves the development and implementation of containment or clean-up strategies. Containment strategies are intended to prevent further migration of mobile hydrocarbon phases by controlling hydrocarbon plume movement over a defined period within a specific area until concentrations are reduced to an acceptable level. The primary benefit of a containment strategy is that further migration is forestalled. Once the LNAPL is recovered, the need for additional clean-up measures should be assessed, as residual hydrocarbons that come in contact with groundwater may act as a continuing source of dissolved hydrocarbons.

Site assessments, site characterization, exposure assessment, regulatory review, and development of clean-up objectives may be made in accordance with ASTM's RBCA standard or other risk-based decision-making procedures acceptable to the applicable state and federal regulatory agencies. The choice of remedial strategy and the scope are governed by site conditions, possible methods of source control, the results of the exposure assessment, economic considerations, and the potential impact on the affected areas as determined during the tiered assessment.

There are many proven remedial technologies, and no single approach can universally be applied with equal success at all sites. Two or more technologies are often required at a site, and may be applied sequentially or in tandem. Available remedial technologies and the capabilities and limitations of each are discussed in this section.

The following four steps are typically followed in developing a remedial solution:

a. Establish target levels. As discussed in Section 2, this involves identifying the areal extent and depths of hydrocarbon phases to be remediated, and establishing the concentrations to which the phases will be reduced at key locations. The RBCA tiered process demonstrating protection of human health and the environment can be used to determine if active remediation is unwarranted at a site; if remediation is warranted, the process provides a method by which the degree of remediation is established.

b. Evaluate remedial alternatives and select the site-specific recovery system. Remedial alternatives are identified based on knowledge of the site hydrogeology, the target levels, and the exposure assessment. The best alternative is selected on the basis of achieving required level of risk reduction considering technical feasibility, target levels, and

costs. The remedial design should recognize that as the remediation project progresses (time), the rate of removal (concentration) decreases. Therefore, the remedial action plan should be prepared to efficiently address these changing concentrations over the "life-cycle" of the remediation project.

c. Prepare final designs and construct the remedial system.
d. Monitor and maintain the system, and make adjustments as remediation proceeds.

4.2 Target Levels

In general, the removal of various hydrocarbon phases from earth materials and groundwater continues until concentrations decline to levels acceptable for the protection of health and the environment. The selection, design, and operation of a remedial system depends on the target levels determined. Target levels may be applied to in-situ remediation situations; water, air, or soil being discharged or disposed off-site; or expected future uses of the site. These levels may be obtained from a RBCA Tier 1 look-up table or developed using site-specific data in Tier 2 or 3.

Site-specific factors affecting selection of target levels include the following:

a. Hydrogeologic conditions that affect the mobility of hydrocarbon phases.
b. The presence of receptors and potential threat to human health and the environment.
c. Potential for fire or explosive conditions.

The requirements for disposal or discharge of materials from the site may be based on the following considerations:

a. State regulations for waste disposal/treatment.
b. Permits and control for wastewater discharges.
c. Permits and control for air emissions.

The objectives governing the continued operation of an existing remediation system are typically determined based on one or more of the following conditions:

a. Potential for exposure as determined from the migration potential of the chemical(s) of concern and the exposure assessment.
b. Background levels of off-site or naturally occurring chemicals.
c. Concentrations of chemical(s) of concern approach an asymptotic level (that is, continued remediation results in negligible concentration declines).
d. Potential for natural attenuation through the processes of biodegradation, volatilization, adsorption, and dispersion.
e. Resource management considerations such as the classification of the groundwater or aquifer based on local use and economics.
f. Statutory requirements.
g. Levels that constitute a nuisance (offensive odors).
h. Leaching potential of chemical(s) of concern from soil to groundwater.

4.3 Closure

The target levels established for the site determine when the remedial program can be terminated. Compliance monitoring and reporting are necessary to demonstrate that progress is being made, that modeling predictions and assumptions about the site are correct, and when target levels have been reached. Often, remediation may be halted when one or more of the following conditions are fulfilled:

a. Concentrations reach the target levels.
b. Concentrations approach an asymptotic level, and existing concentrations of chemical(s) of concern no longer pose a long-term threat to human health and the environment.
c. Regulatory agency approval is granted.

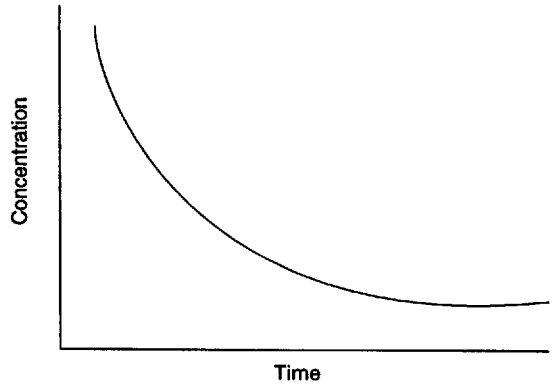
The remedial action plan depends on site-specific conditions and usually requires approval from the pertinent regulatory agency before implementation. A remedial action plan should consider the concepts of risk-based corrective action and life-cycle design.

4.3.1 LIFE-CYCLE OF A REMEDIATION PROJECT

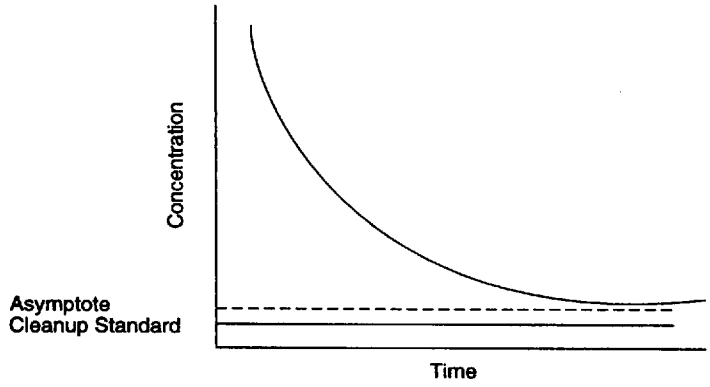
Figure 1a shows the normal life-cycle concentration of a remediation project. Often, a remedial design is based only on concentrations found during the site assessment (the early portion of life-cycle curve). However, the concentration changes over the life of the project and any design must address all of the concentrations encountered during the entire project.

Figure 1a is a conceptual plot of concentration versus time. The plot shows that, as time increases, the concentrations decrease in a nonlinear relationship. As the project progresses over time, the rate of hydrocarbon removal decreases. Figure 1a shows the curve becoming almost parallel (asymptotic) to the horizontal axis over a period of time. There are several processes that may contribute to the flattening of this curve. These processes include physical processes (dilution, dispersion, filtration, and gas bubbles), chemical processes (complexation, acid-base reactions, redox reactions, precipitation-dissolution, and sorption-desorption), and chemical reactions (decay, respiration, degradation, and co-metabolism).

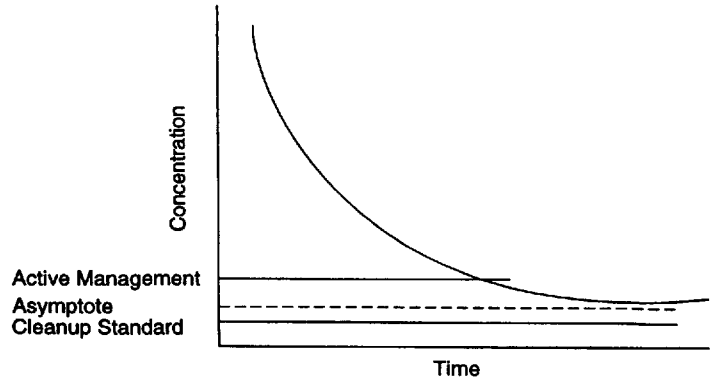
In the past, the methods used to determine what is "clean" and when a remediation project could be terminated have been based on federal drinking-water standards, analytical detection limits, background concentrations, or some other regulatory or statutory requirement. The difficulty with this definition of "clean" is shown in Figure 1b. As the site gets closer to "clean," the hydrocarbon concentration approaches an asymptote. While Figure 1b represents a worst-case sce-



a. Life Cycle Concentration During a Remediation Project



b. Achieving "Clean" During a Remediation Project



c. Active Management vs. What is Clean During a Remediation Project

Figure 1—Life Cycle of a Remediation Project

nario in that the site never achieves the "clean-up" concentration, even in those cases where the site does reach "clean," the process can take many years.

During the last years of the project, a remediation system is subject to diminishing returns. The remediation system continues to operate, but the reduction in concentration is significantly reduced.

Another level of the project life-cycle concept can be defined as *active management*, which is defined as that period of time during the project when active remediation occurs. Figure 1c shows the life-cycle curve with the "clean" line and an active management line. The active management line represents the stage in the life-cycle where active remediation (for example, pumping, venting, or sparging) will no longer facilitate the clean-up of the site. Active remediation could cease at this time. The period of time after active management ceases, but before cleanup objectives are achieved, is a period of passive management where natural processes continue remediation. Monitoring would be the key project activity during this period.

4.3.2 EVALUATION OF NATURAL ATTENUATION IN THE CLOSURE DETERMINATION

Data collected from numerous hydrocarbon remediations have shown both responsible parties and regulatory agencies that there are alternative methods to determining the end of remediation rather than remediating until achieving background levels or state-specific generic action levels. A risk-based decision making approach can be used to determine: (a) what level of corrective action is necessary at a site to protect human health and the environment, (b) site-specific remediation goals, (c) residual concentrations that can be left in-place and which will not impact human health and the environment (the termination point of the project), and (d) immediacy of response (that is, the time frame in which corrective action must be completed). This is the cornerstone of the ASTM RBCA process.

When conducting exposure assessments as a part of the risk assessment process, it is important to evaluate the natural attenuation of hydrocarbons. Where applicable, natural degradation has the potential to contain the migration of hydrocarbons and effectively reduce hydrocarbon concentrations in soil and groundwater by converting them to carbon dioxide and water. This process acts to stabilize soluble plumes and naturally clean up the site over time. Such information can support a proposal for no further action at sites 1) where active remediation has already been undertaken and data show that it is no longer cost effective to continue (after active management), and 2) sites where active remediation is not required to protect human health and the environment.

The natural degradation process can be quantified through an appropriate site investigation process. One effective method to incorporate hydrocarbon compound attenuation factors is to conduct a simple model based on site soil and groundwater conditions determined during the site assessment to predict the movement and degradation of the site-related compounds over time. The concentration decay curve (the rate of compound-specific degradation divided by the time) can then be correlated to existing site concentrations by adjusting the attenuation rate. These methods include decay rates determined by temporal (time) and spatial analysis. No matter what type of model is utilized, it is important to always match the model output (what is predicted to remain in place at a specific time assuming degradation has occurred since the release) to existing site concentrations.

The risk assessment may include an evaluation of the mitigating effects of intrinsic or natural biodegradation and the potential for reaching acceptable target levels, or further decreasing concentrations without undertaking active measures. Documentating the presence of all factors required for biodegradation to occur at a particular site will further support agency acceptance of a site closure.

SECTION 5—OTHER CONSIDERATIONS

Using risk-based decision making to establish health-protective remedial measures and controls at a site is innovative in comparison to the traditional "clean to generic standards" approach. The misapplication/misuse/abuse of the approach could cause a regulatory agency to be reluctant to accept the results of the exposure/risk assessment process. Providing an easily read document with all necessary information and complete references facilitates agency review. It also decreases the probability that a careful review of the risk assessment will be postponed.

Full delineation of concentrations in soil and groundwater is not always necessary when developing target levels because the goals are often intended to guide the remedial efforts to be undertaken. However, if the extent of groundwater concentrations within the plume are not fully delineated, the credibility of the report is weakened. In these cases, additional data will be needed.

Because TPH analyses results represent a mixture of hydrocarbons, no toxicity values specific to TPH are available. Therefore, TPH should generally be qualitatively evaluated in a risk assessment and not identified as a chemical of concern because of the lack of appropriate toxicity values with which to quantify potential risks or develop target levels. Also, the analytical data reported for TPH are often

flawed and inaccurate due to the weaknesses in the analytical methods used. The results and conclusions of the risk assessment are only as good as the quality of data on which the assessment is based. Using faulty data seriously undermines the resulting conclusions of the risk assessment. Recently, a coalition of interested parties formed the "TPH Criteria Working Group," and is evaluating alternative approaches for considering TPH from a RBCA perspective.

When conducting ecological risk assessments, it is important to remember that ecosystems can be extremely complex and that our understanding of them is limited. An ecological risk assessment looks at some portions or aspects of an ecosystem and attempts to make a judgment on the potential for negative impacts based on this partial information. A qualitative ecological impact evaluation or assessment may eliminate ecological risks as being a significant concern. Ecological risks are likely to be important near estuaries, wetlands, and sensitive ecological habitats. Difficulties encountered in preparing ecological risk assessments are largely a function of gauging the appropriate level of effort required for each site. Rigorous sampling and studying of each site to determine the ecological impacts is not always possible due to resource constraints, nor is it necessary because remedial activities at the site may be driven by the human health risks posed by the site.

Because each state requires a unique level of effort for the preparation of an exposure/risk assessment an organization should determine the requirements before conducting a risk assessment. Many state agencies recognize the use of a risk-based decision making approach as a viable tool for determining the level of remedial action required for a site, and documents such as this publication are useful in enhancing the understanding and application of exposure/risk assessments. A number of state guidance documents include risk assessment as an option for determining remedial action; some states have, or are developing, specific detailed guidance for the preparation and documentation of the analysis. Broaching the idea of utilizing a risk assessment to make site-specific remedial decisions with the regulatory agency early in the process, allowing them to participate in the project scope definition, and educating the regulatory agency staff with good science and practical applications, should facilitate acceptance of the risk-based decision making approach.

APPENDIX A—BIBLIOGRAPHY

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