Overview Document

Use of Risk Assessment in Management of Contaminated Sites

August 2008

Prepared by
The Interstate Technology & Regulatory Council
Risk Assessment Resources Team

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Risk Assessment Resources Team

50 F Street NW, Suite 350, Washington, DC 20001

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Members of the Risk Assessment Resources Team (listed in Appendix D) participated in the writing and reviewing of the document. We also wish to thank the organizations that made the expertise of these individuals available to the ITRC. Primary authors of the document include the following individuals:

- Stephen DiZio, California Environmental Protection Agency, Department of Toxic Substances Control, Team Co-Lead
- Brian Espy, Alabama Department Environmental Management, Team Co-Lead
- Smita Siddhanti, Program Advisor, EnDyna, Inc.
- David Bell, Air Force Institute for Operational Health
- Marlena Brewer, Alaska Department of Environmental Conservation
- Jim Brown, Georgia Environmental Protection Division
- Anna H. Butler, U.S. Army Corps of Engineers
- Frank Camera, New Jersey Department of Environmental Protection
- Fran Collier, California Environmental Protection Agency, Department of Toxic Substances Control
- Jennifer Corack, Navy and Marine Corps Public Health Center
- Kurt Frantzen, Kleinfelder
- Dibakar (Dib) Goswami, Washington State Department of Ecology
- Paul Hadley, California Environmental Protection Agency, Department of Toxic Substances Control
- Jeanene Hanley, Arizona Department of Environmental Quality
- Scott Hill, U.S. Army Environmental Center
- Keith Hoddinott, U.S. Army Center for Health Promotion and Preventative Medicine
- Bennett D. Kottler, Nevada Division of Environmental Protection
- Irwin Lourie, Pennsylvania Department of Environmental Protection
- Anita Meyer, U.S. Army Corps of Engineers
- Ligia Mora-Applegate, Florida Department of Environmental Protection
- Stephen D. Mueller, Wisconsin Department of Commerce

- Katherine Owens, Paragon Professional Associates
- Ashley Whitlow, Arkansas Department of Health

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EXECUTIVE SUMMARY

The Interstate Technology & Regulatory Council's (ITRC) Risk Assessment Resources Team examined the use of risk assessment and risk-related practices in the management of contaminated sites through a series of case studies. The influence of risk-based practices and risk assessment approaches employed by state regulatory agencies on risk management outcomes was our primary interest.

Debate and controversy invariably surround the development of a risk-based numerical criterion for a chemical. The team's previous report on risk-based soil screening values determined that, for the most part, states follow a similar process and only minimal variation results in risk-based numerical criteria. In the development of this overview document, the team determined that the implementation of risk-based numerical criteria—the way in which the criteria are used in the field and in the management of contaminated sites via risk assessment—introduces orders of magnitude of variation in decision outcomes. Thus, while it is generally no surprise to risk assessors, risk managers are advised that field implementation of risk-based numerical criteria deserves far more attention than that subject has historically been given.

The approach of the Risk Assessment Resources Team in producing this overview document is to reflect the outcome of some of the more common practices and approaches employed in site cleanup back to ITRC's members. To this extent the team believes it is shining a light on a significant matter not addressed elsewhere.

Traditional case studies were conducted on five sites where risk assessment or risk-based principles and practices were used. The team observed that while many traditional stumbling blocks to site cleanup were apparent, several innovations and unique approaches—field screening methods, composite sampling, and probabilistic risk assessment—enhanced both the assessment and management of risk at several sites.

The team then developed an approach that came to be known as the "comparative case study." State and federal representatives were provided the same data sets and asked to address key issues in the risk assessment and risk management process. The results were then as directly comparable as possible.

The comparative case studies presented herein enabled the Risk Assessment Resources Team to pinpoint steps in the risk assessment process where variations can lead to differences in risk management outcomes. As a result, recommendations were team-developed guidance to not only identify the likely sources of variation in risk assessment but also identify the resulting variation in risk management. In addition, the team recommends not only that the site assessment/ remediation process focus the appropriate resources to ensure a high level of transparency and predictability, but also that systematic project planning principles with robust and continually evolving conceptual site models be incorporated throughout the assessment/remediation process.

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USE OF RISK ASSESSMENT IN MANAGEMENT OF CONTAMINATED SITES

1. INTRODUCTION

The Interstate Technology & Regulatory Council (ITRC) is a state-led coalition that develops reports and trainings and conducts other activities on environmental technologies and related topics. At ITRC's 2001 annual meeting, the development and use of risk-based criteria, including elements of the risk assessment process, were identified as topics of high interest to a broad range of ITRC's membership. In response to this interest, ITRC launched a technical team known as the Risk Assessment Resources Team in 2003. The team's first effort resulted in the *Examination of Risk-Based Screening Values and Approaches of Selected States* (RISK-1, ITRC 2005), a compilation of factors used by states to develop numerical criteria for soil. The team then developed this overview to identify how different organizations use the process of risk assessment (from sampling to risk characterization) in managing risks at contaminated sites.

Specifically, the current document identifies how various numerical risk-based approaches or criteria are applied throughout the processes of screening, characterization, and remediation of contaminated sites. It considers the real-world implementation of risk assessment and how the various assumptions and calculations described in RISK-1 manifest at actual contaminated sites. For the purpose of this report, a "contaminated site" is an area or property with soil constituents at levels that exceed the particular state's screening criteria and may require a risk assessment.

While a number of reports, papers, and publications present the numerical criteria/approaches used by various regulatory agencies overseeing cleanups, these papers do not provide the details of how such criteria/approaches are used in actual practice. This report provides some answers to the question, "How is risk assessment used in management of contaminated sites?"—an issue that the team has not seen extensively examined in other publications or conferences on risk assessment at contaminated sites. Finally, this document provides a framework suggesting how to improve the use of the risk assessment process and should lead to improved site characterization and better-informed risk management decisions.

1.1 Purpose

Increasingly, environmental decisions are being described as "risk based," especially in site cleanup and corrective actions, where risk-based decisions are thought of as more appropriate and cost-effective than decisions based either on "background" or "nondetectable" levels of chemicals or on numerical criteria developed without recognition of risk assessment principles.

The Risk Assessment Resources Team, ITRC membership, and the general risk analysis community are interested in exactly how risk assessment is considered during the different stages of the site cleanup process in various states and what similarities and differences exist among the state programs throughout various stages of cleanup. To illustrate these differences, this report focuses on the simplest exposure pathway, that is, the ingestion of contaminated soil. Other pathways involving migration or uptake into the food chain could be the subject of future work.

This document builds on the team's previous work identifying variation in the development of numerical criteria used in risk assessment. A key objective is to identify and explain the variation in the use of risk assessment and risk management. However, the overall purpose of this document is not only to shed light on variation of application and use of risk assessment in managing sites but also to provide guidance to improve the use of risk assessment in making better risk management decisions. For resources and relevant documents related to risk assessment and risk management, please refer to the "Electronic Risk Resource Sheet" (www.itrcweb.org/Documents/Risk_Resource_8_20_08.pdf), developed by the Risk Assessment Resources Team and available on the team's "Risk Resources & Links" Web page at www.itrcweb.org/Team/Resources?teamID=13.

1.2 Background on the Use of Risk Assessment at Contaminated Sites

The Risk Assessment Resources Team spent its first two years surveying and researching the technical bases for various numerical criteria for soil that have been developed and implemented by state agencies involved in site cleanup. The team catalogued the factors used by states in developing numerical soil screening criteria for the soil ingestion pathway for five chemicals: arsenic, lead, trichloroethene, benzo(a)pyrene, and polychlorinated biphenyls (PCBs). This effort resulted in the document entitled *Examination of Risk-Based Screening Values and Approaches of Selected States* (ITRC 2005).

The 2005 report identified similarities and differences in the various factors used to develop soil screening criteria and evaluated differences among those various criteria. Despite exhaustive efforts at refining—and debating at the national level—the factors used in the calculations, the risk-based numerical screening criteria are very similar. The main conclusions of the report were as follows:

- A lack of transparency exists in the derivation of published screening levels, and the assumptions used to derive them need to be published with the values.
- It is often unclear how states intend for their screening levels to be used on sites. The next step in such a process is often the decision to take some form of "action," which can range from further sampling and analysis to remediation.
- There should be a clear understanding of the expectations of all parties when numerical criteria are used in the development of performance standards for cleanup technologies.

Sections 1.2.1–4 discuss the role risk assessment plays in site characterization and site cleanup and the associated issues and challenges.

1.2.1 Role of Site Characterization in Risk Assessment and the Relationship to Risk Management

Site characterization is the method used by cleanup programs to establish the nature and extent of contamination and subsequently any risks potentially posed by contamination at sites. During site characterization, sampling and analysis plans are implemented, and field data are collected and analyzed to determine the nature and extent of threats to human health and the environment.

Risk assessment activities are ideally intertwined with site characterization activities, with an eye on informing the risk management decisions that need to be made. Therefore, site characterization activities are ideally designed to support risk assessments, which in turn support risk management decision making.

While a textbook version of how risk should be integrated into the cleanup process can be developed with relative ease, implementation of such an approach faces a multitude of trade-offs that must be accepted. Many of the most difficult technical challenges come when trying to sample a site. The simple question, "What chemical should we analyze the samples for?" can provide a range of possible answers, usually constrained by the eventual cost. The questions of, "Where should we sample?" and, "How many samples should be taken?" produce similar ranges of answers. Real-world considerations like budgetary constraints influence the development of a sampling plan that often settles on the pragmatic standard of "the best that can be done" to investigate the complex and controversial conditions that consistently surround environmental contamination at sites. Such issues are ideally addressed by considering the trade-offs of cost and uncertainty.

These considerations emphasize the need for an approach where a conceptual site model (CSM) is developed early and is iteratively refined through the project life cycle. Each piece of data that is collected should serve to refine the model. Risk assessment uses site characterization information to provide a means to inform management of risks at a site. Exploring and clarifying the connections between sampling, risk assessment, and risk management are therefore desired outcomes of this current effort and related activities of the Risk Assessment Resources Team.

1.2.2 The Uncertainty in Risk Characterization—Protection versus Prediction

In its simplest form, risk assessment comes down to a comparison of the actual or projected level of exposure, based on predictive equations and models, with a reference level of acceptable risk or hazard. Much research, analysis, discussion, and even formidable debate at the national level can take place as the regulatory world establishes which level of exposure or dose delineates "significant" from "insignificant."

While predictive tools, including standardized exposure scenarios and the analyses and assumptions embodied therein, are integral to many risk assessments, an overarching theme of being conservative or protective guides the effort. Scientific progress in toxicology, sampling, and modeling will continue to be brought to the forefront, and confidence in risk assessments will no doubt be enhanced. However, the purpose of using risk assessment at a contaminated site is to provide confidence in the protectiveness of the remedy. In this light, well-established traditions of conservativeness in related fields such as industrial hygiene and health physics are followed in the assessment of contaminated sites.

The team's goal in this effort is to identify and objectively portray the important sources of variation in risk assessment. As the team is composed largely of persons active in the practice of risk assessment at contaminated sites, its members are keenly aware of the controversy that can develop around the topic of how conservative or protective a risk assessment should be. To the extent possible, the team has sought to avoid judgments concerning, "How protective is protective enough?"; nevertheless, the team has clearly accepted the challenge of identifying—in a quantitative sense—the variation among regulatory programs in how they estimate levels of exposure and risk from contaminated sites and how they apply risk-based screening levels and remediation goals to sites.

1.2.3 The Role of Risk Assessment in the Cleanup Process

Most state and federal agencies have a general mandate in their regulatory programs to protect human health and the environment from current and potential threats posed by uncontrolled or permitted hazardous substance releases. To help meet this mandate, the agencies have established programs that incorporate risk-based criteria or risk assessments into cleanups. Risk assessments are typically used to determine baseline risk (i.e., risk that exists in the absence of remediation at contaminated sites). Alternatively, equations for risk estimation are back-calculated to develop risk-based criteria: default screening values, target cleanup levels, and even site-specific target levels.

Risk assessment has been used at many sites to pinpoint the problems of significance, typically identified as contamination that could give rise to significant risk, and then identify cost-effective solutions for mitigating or remediating those risks. This approach is in contrast to that of a mandated maximum level that might motivate cleanup in the absence of an actual risk. The environmental community saw a large rise in the development and publication of risk-based standards and criteria after publication of the American Society for Testing and Materials (ASTM) *Standard Guide for Risk-Based Corrective Action at Petroleum Sites* in 1995 and *Provisional Standard Guide for Risk-Based Corrective Actions* in 1998.

One of the team’s interests lies in considering how site-specific uses of risk assessment and risk-based criteria have progressed after years of application and as part of the cleanup process, that is, under real-world constraints and considerations, such as technical and financial limitations, time pressures, perceptions and preferences held by agency management, community stakeholders, potentially impacted parties such as future property owners, and the entities paying for the cleanup.

1.2.4 Risk Assessment and Cleanup Program Challenges

Risk assessment has been described as a tool for evaluation of contaminated sites that has the potential of focusing the investigation, characterization, and eventual remediation of contamination. The risk assessment conducted for a site, however, may often be the source of greater uncertainty and misunderstanding than virtually any other phase of the cleanup process. Some of this controversy may be attributed to lack of resources to completely characterize all of the unknowns at a site. Many times literature values or models must be used in lieu of actual site information. Additionally, to ensure protectiveness, regulatory agencies require use of “95% upper confidence limits [UCLs] of the mean contaminant concentration,” “reasonable maximum exposure,” and toxicity values that have several uncertainty factors applied to them. Much of this controversy can also be attributed to the lack of consensus regarding certain factors used in the process, agreeing upon what constitutes a significant risk, and especially defining, “How clean is clean?” during the remedial design/remedial action phase. This problem occurs not only among regulatory agency staff, but also within the larger community of risk assessors.

Like other problems associated with contaminated sites, risks are characterized with data. These data are typically chemical analyses of air, water, soil, or biota. Which samples are collected for laboratory analysis and how the results of those analyses are interpreted determine how significant risks associated with a contaminated site are identified. However, it is not uncommon for the risk assessor to be disconnected or isolated from the planning and implementation of data collection. Understanding and awareness of what data are needed for risk assessment, how data are used, and how all the information will be used to make site decisions can improve the development of effective sampling plans, as well as improve the overall execution a project from site discovery to site closeout. Such understanding is common to projects that are systematically planned (see *Technical and Regulatory Guidance for the Triad Approach: A New Paradigm for Environmental Project Management*, ITRC 2003b).

Table 1-1 presents examples of common challenges for state agencies implementing cleanup programs and many of the practices adopted to deal with those challenges. These include challenges of variation in site size and soils, sampling methods, emerging chemicals, exposure estimation for variety of populations, and estimating uncertainty. The reader should note that some challenges do not have common or even effective solutions. These practices and preferences are, in part, responsible for the variation in the risk assessment process that results when applied to real-world sites.

Table 1-1. Examples of common challenges/common practices in implementing risk assessments

Challenge	Example approaches
Range of complexities and sizes of sites	Use of tiered approach to tackle site risk; default values for risk assessment
Emerging chemicals	Hierarchy of sources of toxicology data
Soil variation	Use systematic planning to evaluate cost-effective methods to meet data quality objectives (DQOs) and manage uncertainty; excavate hot spots; compositing often discouraged
Reconciling data generated by multiple analytical methods	Consult with project chemist; ensure that DQOs to meet risk assessment data needs are adhered to
Reconciling duplicates/splits	Select higher concentration; calculate the mean concentration
Sampling the deeper subsurface for volatile organic compounds (VOCs)	Soil gas sampling
Reconciling modeling output with real site conditions	If the model cannot be verified for site conditions, run another model to see ranges of output; conduct verification sampling
Estimating time patterns of exposure	Assume constant rate/level of exposure; may lead to orders of magnitude more conservative (exaggerated) estimate of risk
Multiple possible populations exposed	Default to most conservative (e.g., single-family well vs. municipal supply well)
Statistical determination for exposure point concentration (nondetects)	Mean; 95% UCL; quantiles; Monte Carlo analysis
Estimating/managing uncertainty	Use probabilistic risk assessment (PRA) techniques to quantify uncertainty and variation
Possible synergism/additivity of effects	Linearly additive (carcinogens)
Acute subchronic exposure duration	Developed in Florida for eight contaminants
Advances in risk assessment	Promote use of new methods when they may decrease project uncertainty

These and new challenges will continue to present themselves. To resolve such challenges, resource expenditures may be significant. Consequently, consensus should be sought among all affected and interested parties early in the design and implementation phases of site investigation.

1.3 Technical Approach and Analysis

The goal of this document is to illustrate the connection between data collection, risk assessment, and risk management at waste sites. The document demonstrates variation that exists in risk assessment processes and shows how such variation may impact risk management decisions made by a state agency for a waste site. The document accomplishes this goal through the use of actual site case studies, participation by states in comparative case studies, participation in a survey relative to background, and a presentation of information gathered relative to state approaches to hot spots. To examine the use of risk assessment and in risk management, members of the Risk Assessment Resources Team conducted the following three approaches:

- Risk Assessment Concepts. The team researched selected concepts in risk assessment to identify federal and state-level requirements or guidance on risk assessment for cleanup. The goal was to document the variation in the ways each participating state deals with concepts and approaches to risk assessment that could influence the management of risk at sites. These were examined by conducting state surveys with questionnaires about specific topics, such as background concentrations and hot spots, and their use in risk assessment.

- Case Studies. The application of the participating states' regulatory guidance was examined in actual case studies. The team analyzed five case studies to examine the use of risk assessment in the risk management of real cleanup sites.

- Comparative Case Studies. The team also developed two comparative case studies designed to capture judgments and decisions made regarding assessment and cleanup of sites by state regulators. Variation was easier to capture when all participants were working from the same set of data and circumstances in a comparative site. Each of these methods for collecting information is described in more detail in Sections 1.3.2 and 1.3.3.

1.3.1 Review of Specific State Program Approaches to Determine Variability in Risk Assessment that Influences Risk Management

State regulatory programs at times differ in both development and application of various factors used in risk assessments. The variation in development of soil screening levels was shown in the team's first report (ITRC 2005). In this current effort, several common sources of variation in the risk assessment process are identified, including approaches to soil sampling, identification of hot spots, determination of background, and tiered approaches to site assessment and the characterization of risk. These topics can be pertinent at virtually any site and are commonly dealt with by risk assessors—both government and private sector—working on sites. These topics are illustrative and are not necessarily comprehensive of all sources of variation encountered.

One topic the team considered important to risk assessments was the determination of background levels of natural or anthropogenic constituents. Therefore, state representatives participating on the team and others were surveyed regarding conventions concerning background. The question, "What is background?" can raise technical complications as to how to discriminate between compounds released at a site and those same compounds that would be present from natural or anthropogenic sources. Beyond the technical challenge, an immediate risk management challenge can arise, since ambient levels of some compounds can be above the health-based levels generated by environmental regulatory agencies. Many of these challenges shape the scope and nature of a site investigation, can play heavily into the risk assessment, and might influence or even dictate the risk management options available or practical for implementation.

All states surveyed allow consideration of background as a higher threshold for establishing a cleanup criterion. However, as with the development of numerical screening values, states differ in their approaches to establishing background values, including the sampling strategies deployed and the statistical treatment of the results from those samples. States can differ from federal guidance on whether all risks, including background risks, should be aggregated or be determined as an increment due to a contaminated site. This report explores the use of background values as one of the elements where risk assessment may contribute to or influence risk management decisions regarding remediation.

The survey results are summarized and discussed in Section 3.3. In addition, the reader should consider the second comparative case study, where the chemicals of concern (COCs) were also present in "background" conditions. The state representatives completing the second comparative case study were asked to process and incorporate into the risk assessment the background levels apparent for this site according to the guidance and practices of their respective states. Similar state surveys were conducted for definition of hot spots in various states and tiered approaches to risk management. The analysis also deals with issues of sampling for site characterization and how it is related (or not related) to risk assessment.

1.3.2 Case Study Analysis

The team chose to examine how risk assessment is used during a project's life cycle by examining how a contaminated site is managed, how it is sampled, and whether the data warrant that remediation is necessary. The team compiled case studies of the use of risk assessment at contaminated sites as a way of examining real-world use of risk assessment in risk management and site cleanup. The first set of case studies presents actual data that demonstrate how various states deal with the contaminated sites under various scenarios (i.e., residential use, commercial use, etc.).

Case study sites were solicited from the ITRC's network of team leaders and state points of contact, and Risk Assessment Resources Team members were invited to submit candidate sites. In consultation with persons familiar with the project or site, typically a case or project manager completed a questionnaire. After review and refinement, the case study was considered complete, and the write-up was shared with the broader team for review and analysis. The site case studies are described and discussed in Chapter 4.

Midway through the case studies effort, members of the team recommended that the case studies of actual site cleanup projects be augmented. While there was much to learn from the actual cleanups captured by the case studies, the limited number that could be accomplished allowed for only a handful of state programs to be represented. In addition, the case studies for actual cleanups were generally for large areas or sites and had been completed several years prior to the formation of the team. The analysis of those case studies was “descriptive”; two “comparative” site case studies were incorporated into the team’s activities to illustrate similarities and differences in approaches and their rationale among state representatives.

1.3.3 Comparative Case Studies

To discern similarities and differences among states, the case studies of actual projects were augmented with two comparative case studies using hypothetical sites, and participants demonstrated how they would approach these sites. These case studies were termed “comparative” because they were used to compare state approaches. For these, site history, maps, sampling points, and contaminant concentrations were provided to participants. The participants answered questions relative to how risk-based criteria would be applied or how a risk assessment would be performed. Examined elements included area of contamination averaging, averaging over the vertical soil column, background determination, and specific areas that would require risk management.

The comparative case studies developed for this report and detailed herein are a first-of-their-kind outcome of the team’s collaborative efforts. Other individuals and organizations interested in risk assessment and risk management—particularly state regulatory agencies—are encouraged to conduct these same comparative case studies on their own due to their instructive power.

The first comparative site was designed to be a former skeet range with lead contamination that was proposed for residential development. The second comparative case study was for a series of properties—residential, commercial, recreational, and a school setting—where multiple contaminants were present. Results compiled in a series of tables highlighting the similarities and differences among responses are presented in Chapter 5.

Taken together, the “real” case studies and the two comparative case studies provided a useful data set for accomplishing one of the overall objectives of the team: to evaluate how risk is integrated into site cleanups.

1.4 Organization of this Document

This document is organized into seven chapters (Figure 1-1) and a series of appendices. Chapter 1 defines the purpose and background of use of risk assessment in managing risk at sites and the team’s technical approach used to develop this guidance. Chapter 2 includes information on federal and state regulatory requirements for the use of risk assessment in cleanup. Chapter 3 provides an overview of the application of risk assessment in the cleanup process. It outlines specific steps in the risk assessment process, with focus on issues that can lead to variation among states as to how risk assessments are conducted, which directly influences management of site risk. Chapter 4 provides five case studies, from different states and with various cleanup challenges, in which risk assessment was used. Chapter 5 provides state regulators’ responses to the hypothetical sites for comparative case studies that the team developed. Chapter 6 provides perspectives of stakeholders, end users, and regulators. Chapter 7 concludes with lessons learned from case studies and provides guidance for an improved process of risk management at contaminated sites. Three appendices providing supplemental information are on the CD-ROM that accompanies this document (see inside back cover).

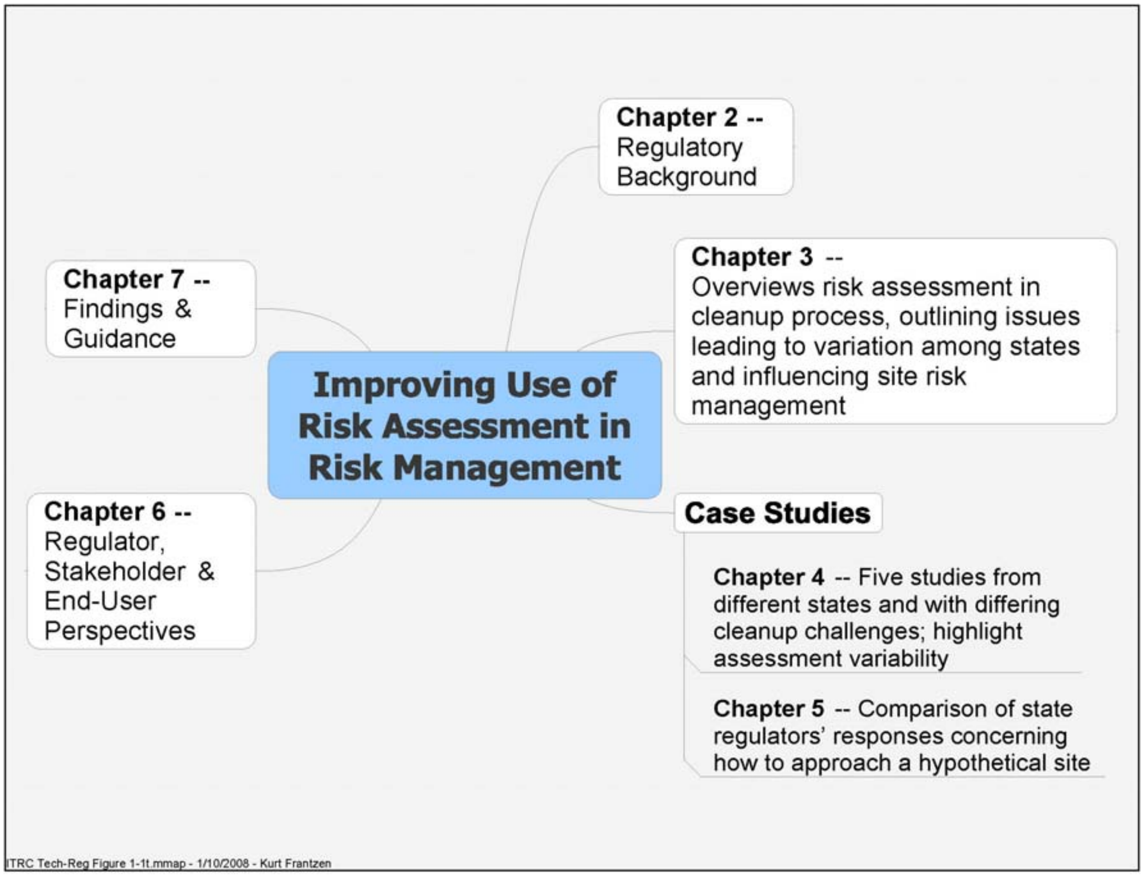

Figure 1-1. Schematic illustrating the relationship of the chapters of this report.

2. USE OF RISK ASSESSMENT IN MANAGING CONTAMINATED SITES: REGULATORY BACKGROUND

2.1 Introduction

This chapter provides a general overview of the protocol of risk assessment and discusses its application in the site cleanup process at both the federal and state levels. Through this review certain common challenges become apparent and serve as a starting point for the detailed discussion of how these challenges have and are being met to achieve evidence-based, rational risk management decisions.

The use of risk assessment in decision making is not unique to hazardous waste sites. The federal government has several programs based on statutes that require the use of risk assessment (in various formats) to control many risks, including exposure to toxic chemicals. Examples include U.S. Food and Drug Administration programs for licensing drugs and food additives; U.S. Occupational Safety and Health Administration regulations for protecting worker safety; and U.S. Environmental Protection Agency (EPA) programs for registering pesticides, controlling hazards of chemicals in commercial production, establishing national air emission standards, and establishing maximum contaminant levels for drinking water. Unlike these broader programs, the use of risk assessment in regulation of cleanup of hazardous waste sites is applied on a site-specific basis to meet protectiveness requirements.

Section 2.2 outlines the major laws and regulations that dictate site cleanup and risk assessment. Section 2.3 outlines the assessment protocol and its application to site cleanup. The discussion proceeds in Section 2.4 to consider federal regulatory requirements and highlight the guidance available for the use of risk assessment. Next, Section 2.5 points out requirements for risk assessment and some of the guidance of certain states and outlines variation across these states. Section 2.6 concludes the chapter by highlighting common problems facing risk assessors and users of risk assessment.

2.2 Major Environmental Laws Dictating Site Cleanup and Risk Assessment

Major environmental laws enacted in the United States are based on the premise of protecting human health and the environment from emissions, discharges, or releases of pollutants. These laws or statutes direct EPA to carry out their mandates. In the area of environmental cleanup of hazardous wastes and hazardous substances released or spilled from past activities, two major statutes are applicable: the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA, 1980), as amended by the Superfund Amendments and Reauthorization Act (1986), commonly called Superfund, and the Resource Conservation and Recovery Act (RCRA, 1976), as amended by the Hazardous and Solid Waste Amendments (1984).

Since environmental cleanup under CERCLA and RCRA is driven by determination of unacceptable risk to human health and the environment, risk assessment is used throughout these regulatory programs to help formulate management (regulatory) decisions about whether remedial actions or corrective measures are warranted. Development of the regulatory requirements and guidance involving the risk assessment concepts of environmental exposure, dose, and risk were greatly influenced by the 1983 study by a committee of the National Research Council (NRC), an entity of the National Academy of Sciences (NAS), titled *Risk Assessment in the Federal Government: Managing the Process* (commonly referred to as "the Red Book"). This publication provided organizing principles for presenting risk information, applying risk reduction measures, and allowing public policy to be developed based on risk.

According to the NAS/NRC Red Book, risk assessment results in a characterization of potentially adverse human health or environmental (ecological) impacts resulting from exposure to hazardous waste, hazardous substances, or other stressors (chemical, biological, physical, etc.). This process contrasts with risk management, the process of interpreting the available data and information and weighing alternatives to select an appropriate action based on the integration of risk assessment findings; engineering studies; and legal, social, economic, and political concerns. The most notable contribution of the Red Book is the succinct description of the four steps of risk assessment:

1. *Hazard identification* is a process of determining whether a hazard exists (where "hazard" is defined as the likelihood that an injury might occur in a given situation or setting). In particular, it focuses on whether a potential for exposure exists between a person or

environmental resource and a hazardous stressor (such as a hazardous substance or hazardous waste).

2. *Exposure assessment* is the process of estimating the magnitude, frequency, duration, and route of exposure (that is, contact, inhalation, or ingestion of a chemical, for example). The estimate may be qualitative or quantitative. Exposure is estimated in terms of the amount of the stressor or agent available at the exchange boundary (lung, skin, or gut) and available for absorption.
3. *Toxicity assessment* results in the characterization of a chemical's toxicity, including establishing the relationship between the dose a person might receive and the occurrence of adverse health effects in the exposed population.
4. *Risk characterization* combines the exposure and toxicity assessments into a quantitative expression of risk. Exposure estimates combined with chemical-specific toxicity helps to determine the likelihood of adverse health effects in the potentially exposed populations.

2.3 Overview of the Application of Risk Assessment in the Site Cleanup Process

Risk assessment is applied in various components or phases of federal or state Superfund programs for contaminated sites, as well as in RCRA processes, to assist in facility investigation and cleanup. From site identification to site closeout, risk assessment helps form management decisions made at each stage of a site's life cycle. The goal of the human health and environmental evaluation process is the development of risk information to determine whether a removal action and/or remedial action is necessary, or conversely, whether the site may be closed out with no further action (NFA). The discussion below consolidates the common elements of risk assessment applied to sites and facilities using as a template the EPA model in *Risk Assessment Guidance for Superfund, Vol. I, Human Health Evaluation Manual, Part A* (EPA 1989b).

2.3.1 Data Collection and Evaluation

Risk assessment depends on environmental data, the assessment process, and the assumptions that are used. The collected data identify whether a release has occurred and provide the detail for understanding the potential sources of contamination and the fate and transport of those contaminants in the environment. Several factors impact data collection, such as the potential receptors that may be exposed at the site as well as the pathways or routes of exposure present. Thus, in defining the nature and extent of contamination, a sufficient data set is required to delineate the fate and transport of contaminants and the type and nature of contaminant exposure.

2.3.2 Exposure Assessment

Exposure assessment is the process of estimating the type and magnitude of exposure to contaminants at the site for the different receptors identified there. The data set from the sampling and analysis described above is combined with information (land use, demographics, and real estate status and trends) regarding who may be exposed to the contamination, how those individuals may be exposed, and for how long they may be exposed. The data collected at the site must be sufficient to establish an exposure concentration for the different contaminants at the site for all impacted media and current and potential receptors.

2.3.3 Toxicity Assessment

Calculation of risk-based screening values or cleanup target levels requires chemical-specific toxicity values, either reference doses (RfDs) for systemic (noncancer vs. cancer effects) toxicants or cancer slope factors (CSFs). When available, these toxicity values are taken from various EPA sources. In December 2003, EPA's Office of Superfund Remediation and Technology Innovation issued a directive that provided the hierarchy for selecting human health toxicity values based on the quality of the underlying toxicity database and the extent of peer review. While many states follow this hierarchy (listed below), some have issued their own tier-based values, as discussed in more detail in Chapter 3:

- *Tier 1*—EPA's Integrated Risk Information System (IRIS) values. The chemicals listed in IRIS have undergone peer review and are continuously rereviewed.

- *Tier 2*—EPA's Provisional Peer-Reviewed Toxicity Values (PPRTVs). The Office of Research and Development/National Center for Environmental Assessment/Superfund Health Risk Technical Support Center develops PPRTVs on a chemical-specific basis when requested by EPA's Superfund program for use in site-specific risk assessments. PPRTVs are developed in a shorter period of time, and although these assessments undergo external peer review, their development does not include a multiprogram consensus review as is done with the IRIS assessments.

- *Tier 3*—Other Toxicity Values. This tier includes additional EPA/non-EPA sources of toxicity information. Priority should be given to sources of information that are most current, peer-reviewed, transparent, and publicly available. Example sources include the California Environmental Protection Agency (CalEPA) toxicity values, the Agency for Toxic Substances and Disease Registry (ATSDR) minimal risk levels, and Health Effects Assessment Summary Tables (HEAST) values.

When toxicity values for a given chemical are not available from any of the primary sources discussed above, there are alternative approaches. In a few instances, some toxicity values need to be extrapolated using one of several approaches, including route-to-route extrapolation, surrogate values, the toxicity equivalence factor approach, and/or extrapolation from occupational exposure limits.

2.3.4 Risk Characterization and Remedy Selection

Risk characterization is the final step of the process. It characterizes potential risk through the combination of exposure assessment results with appropriate toxicity values to yield quantitative estimates. Along with the numerical estimates of potential health risks and hazards, a narrative is produced describing the primary contributors to health and/or environmental risks and hazards and factors qualifying those results, such as an uncertainty analysis.

For noncarcinogens, an exposure dose or—in the case of inhalation, an exposure concentration—is compared to the chemical's RfD (or reference concentration in the case of inhalation), where the RfD is the level of intake that is recognized as unlikely to result in adverse noncarcinogenic health effects. A hazard index (HI) of unity (or 1.0), for example, indicates that the chemical intake estimated in the exposure assessment is equal to the RfD.

For screening purposes, the default assumption is that chemical effects are additive. Exceptions occur, for example when effects on the lung by the inhalation pathway cannot be reproduced by dosing by the oral route. Where the default HI is above 1.0, the individual effects need to be examined and analyzed on a chemical- and organ-specific basis to better inform risk management decisions.

Risk from carcinogens is expressed as an incremental probability of an individual's developing cancer over a lifetime due to exposure to site carcinogens. The estimate is incremental because it does not consider any other factors or exposures than those assessed in the risk assessment (such as smoking or genetic predispositions). Cancer risk is expressed as a probability; for example, 1 person in 100,000 exposed to contaminants at the site has the chance of contracting cancer as a result of a lifetime of exposure—also written as 1×10^{-5}, or simply 10^{-5}.

Under the CERCLA statute and in EPA's Superfund program, remedial actions are generally not considered when hazards are acceptable (that is, an HI less than 1.0) and cancer risks are within the 10^{-4} to 10^{-6} risk range. Some states have their own acceptable risk definitions in their regulations. When risks are deemed unacceptable, remedial actions are considered to remove contaminants or otherwise prevent exposure to contaminated media. However, most EPA policies include other background exposures as part of the risk assessment, a practice not embraced by all authorities or practitioners.

2.4 Use of Risk Assessment in Risk Management

The original interpretation of the Red Book was that risk assessment and risk management were distinct, highly separated activities, based on the reasonable expectation that the *measurement* of risk should have a distance or separation from the actual problem-solving aspect of risk management. Experience has shown the need for an appropriate level of interaction between risk assessors and others involved in risk management. The Red Book identified the limitations of strictly separating risk assessment and management and recommended a process of iteration:

> Separation of the risk assessment function from an agency's regulatory activities is likely to inhibit the interaction between assessors and regulators that is necessary for the proper interpretation of risk estimates and the evaluation of risk management options. Separation can lead to disjunction between assessment and regulatory agendas and cause delays in regulatory proceedings.

Risk assessment and risk management must interact. These two activities have a critically shared communication requirement: risk communication. Risk communication is an ongoing exchange of information about health and environmental risks among risk assessors and managers, interested parties, stakeholders, the public, the media, and others. Over time, greater efficacy in communication, transparency in process, and appreciation of differing perspectives have improved the process.

The implementation of risk assessment by regulatory agencies has been difficult. In some organizations risk assessment was brought forward after programs were already in place. In some circumstances there are other priorities—not the least of which have been mandates and directives provided to the agencies by higher authorities—that have been difficult to reconcile with the outcomes of a risk assessment. Nonetheless, risk assessment continues to be relied upon more broadly in most jurisdictions.

Risk assessment is recognized as an essential tool by policy makers, but it is not the solution for all of the problems in policy making. For example, it is the responsibility of the risk manager to establish a decision-making process that engenders public trust and credibility. The value of sound risk assessments can be rendered useless by poorly trained or motivated risk managers or risk communicators. At the same time, better risk assessment practices can ultimately help risk mangers and communicators do a better job.

Table 2-1 compares and contrasts risk assessment and risk management in key policy documents.

Table 2-1. Comparison of risk assessment and risk management definitions in key policy documents (adopted from the Department of Energy's working draft on risk-based end state effort)

Reference	Risk assessment	Risk management
Risk Assessment in the Federal Government: Managing the Process (NRC 1983)	Risk assessment is the use of the factual basis to define the health effects of exposure of individuals or populations to hazardous materials and situations.	Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action and integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision.
Guidance on Risk Characterization for Risk Managers and Risk Assessors (EPA 1992b)	Risk assessment is a technical analysis of scientific information on existing and projected risks to human health and the environment. As practiced at EPA, the risk assessment process depends on many different kinds of scientific data (e.g., exposure, toxicity, and epidemiology), all of which are used to "characterize" the expected risk to human health or the environment. Informed use of reliable scientific data from many different sources is a central feature of the risk assessment process.	Regarding the interface between risk assessment and risk management, risk assessment information must be clearly presented, separate from any nonscientific risk management considerations. Discussion of risk management options should follow, based on consideration of all relevant factors, scientific and nonscientific. Note: The guidance also stresses the need to clearly articulate assumptions, strengths, limitations, and uncertainties of the assessment.
Improving Risk Communication (NRC 1989)	Risk assessment is the characterization of potential adverse effects of exposures to hazards. It includes estimates of risk and of uncertainties in measurements, analytical techniques, and interpretive models. Quantitative risk assessment characterizes risk in numerical representations.	Risk management is the evaluation of alternative risk control actions (including doing nothing), selecting among them, and implementing them. The responsible individual or office (risk manager) sometimes oversees preparation of risk assessments, risk control assessments, and risk messages (risk communication). Risk management may or may not be open to outside individuals or organizations.

Reference	Risk assessment	Risk management
Risk Assessment Guidance for Superfund, Vol. I: Human Health Manual, Part A (EPA 1989b)	The risk assessor is the individual or team that actually organizes and analyzes site data, develops exposure and risk calculation, and prepares human health evaluation (i.e., risk assessment) report.	The risk manager is the individual or group of individuals who serves as the primary decision maker for a site.
Risk Assessment Guidance for Superfund, Vol. I: Human Health Manual, Part B (EPA 1991a)	For *generators* of the assessment, distinguishing between risk assessment and risk management means that scientific information is selected, evaluated, and presented without considering nonscientific factors, including how the scientific analysis might influence the regulatory decision. Assessors are charged with (1) generating a credible, objective, realistic, and balanced analysis; (2) presenting information on hazard, dose-response, exposure, and risk; and (3) explaining confidence in each assessment by clearly delineating uncertainties and assumptions along with the impacts of these factors (e.g., confidence limits, use of conservative/nonconservative assumptions) on the overall assessment. They do not make decision on the acceptability of any risk level for protecting public health or selecting procedure for reducing risk. The term "risk assessment" often has a narrower and broader meaning than we have adapted here. For some observers, the term is synonymous with "quantitative risk assessment" and emphasizes reliance on numerical results. Our broader definition includes quantification but also includes qualitative expressions or risk.	For *users* of the assessment and for decision makers who integrate these assessment into regulatory decisions, the distinction between risk assessment and risk management means refraining from influencing the risk description through consideration of nonscientific factors—e.g., the regulatory outcome—and from attempting to shape the risk assessment to avoid statutory constraints, meet regulatory objectives, or sever political purposes. Such management considerations are often legitimate consideration for the overall regulatory decision (see next principle below), but they have no role in estimating or describing risk. Risk characterization, the last step in risk assessment, is the starting point for risk management consideration and foundation for regulatory decision making, but it is only one of several important components in such decision. Each of the environmental laws administered by EPA calls for consideration of nonscientific facts at various stages in the regulatory process. As authorized by the different statues, decision makers evaluate technical feasibility (e.g., treatability, detection limits) economic, social, political, and legal factors as part of the analysis of whether or not regulate and, if so, to what extent. Thus, regulatory decisions are usually based on a combination of technical analysis used to develop the risk assessment and information from other fields. …Risk management decisions involve numerous assumption and uncertainties regarding technology, economics, and social factors, which need to be explicitly identified for the decision makers and the public.

Reference	Risk assessment	Risk management
Framework for Environmental Health Risk Management (Presidential/ Congressional Commission on Risk Assessment and Risk Management 1997)	(Vol. II) Risk assessment is an organized process used to describe and estimate the likelihood of adverse health outcomes from environmental exposures from chemicals. The four steps are hazard identification, dose response assessment, exposure assessment, and risk characterizations.	(Vol. I) Risk management is the process of analyzing, selecting, implementing, and evaluating actions to reduce risk to human health and to ecosystems. The goal of risk management is scientifically sound, cost-effective, integrated actions that reduce or prevent risks while taking into account social, cultural, ethical, political, and legal considerations. (Vol. II) The process of analyzing, selecting, implementing, and evaluating actions to reduce risk.
Region 6 Corrective Action Strategy for Pilot Projects (EPA 2000b)	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. Body of Region 6 Report 5.2: 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 contamination releases. The evaluation is conducted under the assumption that no controls or actions designed to mitigate exposure are in place or will be imposed in the future.	The report a facility uses to document work performed and remedies to be implemented.
Risk Assessment Guidance for Superfund, Vol. I: Human Health Evaluation Manual, Part D (EPA 1998)	The five-risk assessment activities: • Data collection • Data evaluation • Exposure assessment • Toxicity assessment • Risk characterization	
Risk Assessment Guidance, Vol. III, Part A: Process for Conducting Probabilistic Risk Assessment (EPA 2001b)	References the NRC and Presidential Commission on Risk Assessment and Risk Management reports.	References the NRC and Presidential Commission on Risk Assessment and Risk Management reports.

Reference	Risk assessment	Risk management
Draft Final Guidelines for Carcinogen Risk Assessments (EPA 2003)	Risk assessment uses available scientific information about chemicals and contaminants on the properties of an agent and its effects in biological systems to provide an evaluation of the potential for harm as a consequence of environmental exposure.	Risk management applies directives in statutes, which may require consideration of potential risk or solely hazard or exposure potential, along with social, economic, technical and other factors in decision making. Risk assessments may be used to support decisions, but in order to maintain their integrity as decision-making tools, they are not influenced by consideration of the social or economic consequence of regulatory action.

2.5 Federal Regulatory Requirements and Guidance

To effectively implement the requirements of the above statutes, EPA promulgated or proposed rules and regulations, which also explained the intent of the Congress and the President in the preambles to the regulations. The regulations provided standards or requirements for relevant provisions in the statutes. The implementing regulation for CERLCA is the National Oil and Hazardous Substances Pollution Contingency Plan published at Title 40 Code of Federal Regulations (CFR) Section 300.

The RCRA corrective action process is not similarly set forth in the CFR and contains only the broad requirement for a corrective action program at permitted facilities (40 CFR 264.100 and 101). Regulations EPA proposed for RCRA corrective action were withdrawn later; the rationale for the withdrawal is described in "Corrective Action for Solid Waste Management Units at Hazardous Waste Management Facilities" (EPA 1999). Section 2.5.1 details CERCLA's risk assessment requirements; Section 2.5.2 details similar requirements under RCRA.

2.5.1 Risk Assessment under CERCLA (1980)

Risk assessment is used in the process of addressing contaminated sites under the National Contingency Plan (NCP) for the following purposes:

- Identify sites that pose no threat to public health and the environment and require no further study.
- Determine whether a removal action is appropriate to address immediate threats.
- Assess risks to human health and the environment in the remedial investigation to determine whether remedial action is necessary.
- Establish remedial action objectives and alternatives when remedial action is warranted.
- Establish acceptable exposure levels and remediation goals that are protective of human health and the environment.

EPA has developed several guidance documents for risk assessment for use in the Superfund program. Primary of these documents is the *Risk Assessment Guidance for Superfund, Vol. I*, Parts A through E:

- *Risk Assessment Guidance for Superfund (RAGS), Vol. I: Human Health Evaluation Manual, Part A,* Interim Final (EPA 1989b). This document provides a detailed discussion on how a baseline risk assessment (BRA) should be conducted. The document presents key components of a risk assessment: site description, data evaluation, selection of chemicals of potential concern (COPCs), exposure assessment, toxicity assessment, risk characterization, and uncertainty analyses.

- *Risk Assessment Guidance for Superfund (RAGS), Vol. I: Human Health Evaluation Manual, Part B (Development of Preliminary Remediation Goals)*, Interim Final (EPA 1991a). This document presents the methodologies and algorithms used to calculate risk-based preliminary remediation goals (PRGs) for individual chemicals in the soil, groundwater, and air media. The document stresses that risk-based PRGs are part of the applicable or relevant and appropriate requirements (ARARs) to be considered, along with remedial technologies and analytical detection limits, in the risk management and remedy selection processes.

- *Risk Assessment Guidance for Superfund (RAGS), Vol. I: Human Health Evaluation Manual, Part C (Risk Evaluation of Remedial Alternatives)*, Interim Final (EPA 1991b). This document presents the approach and risk information used to evaluate remedial alternatives during the feasibility study. The evaluation (either qualitative or quantitative) compares risk-based benefits of alternatives, investigates potential risks to the nearby communities (short-term and long-term/residual) and remediation workers (short-term), determines the need for engineering controls to mitigate potential risks, and assesses the need for a five-year review where required in the NCP. The guidance describes selected remedial technologies and provides references for quantifying the potential releases from conducting such remedial activities.

- *Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual, Part D (Standardized Planning, Reporting, and Review of Superfund Risk Assessments)*, Interim (EPA 1998). This document includes three basic elements: (1) use of the standard tools, (2) continuous involvement of the EPA risk assessor, and (3) electronic data transfer to the National Superfund Database.

- *Risk Assessment Guidance for Superfund (RAGS), Vol. I: Human Health Evaluation Manual, Part E (Supplemental Guidance for Dermal Risk Assessment)*, Interim (EPA 2002b). This guidance is intended to assist risk assessors and others in addressing concerns resulting from the evaluation of dermal exposure risk assessment pathways. It proposes a consistent methodology for assessing the exposures from the dermal pathway for Superfund human health risk assessments. It incorporates and updates principles of the 1992 EPA interim report *Dermal Exposure Assessment: Principles and Applications*.

These and other Superfund guidance documents may be found at www.epa.gov/oswer/riskassessment/risk_superfund.htm.

Other federal agencies such as the Department of Defense and its components have issued supplementary guidance for risk assessments performed in their programs. Examples include the U.S. Navy's *Human Health Risk Assessment Guidance* (U.S. Navy 2001, available at www-nehc.med.navy.mil/hhra/process/index.htm) and the U.S. Army Corps of Engineers' *Risk*

Assessment Handbook, Vol. I: Human Health Evaluation (USACE 1999) and *Vol. II: Environmental Evaluation* (USACE 1996).

2.5.2 Risk Assessment under RCRA

Within RCRA, risk assessment is used in a variety of ways. Risk information is one factor used by EPA to determine whether industrial wastes should be deemed hazardous and require management under the RCRA hazardous waste system. Risk assessment also is used in targeting waste minimization efforts and in issuing operating permits.

EPA has issued specific guidance for risk assessment used in the permitting process at combustion facilities entitled *Human Health Risk Assessment Protocol (HHRAP) for Hazardous Waste Combustion Facilities—Final* (EPA 2005). Risk assessment is used in the RCRA corrective action program to determine the need for cleanup actions at permitted facilities and in setting cleanup goals. At the federal level there is very little guidance specific to risk assessment in the corrective action program, which primarily uses CERCLA risk assessment guidance. Overall program guidance for the RCRA may be found at www.epa.gov/rcraonline/. The RCRA combustion risk assessment guidance may be found at www.epa.gov/epaoswer/hazwaste/hazcmbst.htm#riskassess.

2.6 State Requirements and Guidance

The number of sites potentially managed by states dwarfs the number under either CERCLA or RCRA, and in most cases the responsible parties are not obligated by the states to follow the ARAR process. Nevertheless, most states use some form of risk assessment to establish the significance of the threat to human health and the environment, as well as to establish the level of cleanup required. States generally seek to permanently control or remove source(s) (both primary and secondary source types) and control or eliminate currently critical exposures and risks, and most states allow the projected (future) land use to inform the risk assessment process and decision making about the requisite level of cleanup.[1]

A number of states have their own guidance, such as New Jersey, California, Florida (Florida Department of Environmental Protection 2005), Massachusetts, and Alaska; other states use the federal guidance, such as Idaho and Wisconsin, or other state guidance. There is a wide variety of approaches to the process of risk assessment under states' laws, statues, regulations, and guidance. Some examples follow:

- Hawaii follows EPA's CERCLA risk assessment guidance.

- New Jersey has more than 40,000 known or suspected contaminated sites currently regulated by federal and state remediation programs. Prior to "Technical Requirements for Site Remediation" (N.J.A.C. 2003), the New Jersey Department of Environmental Protection (NJDEP) closely followed EPA's Superfund process and based the need for remediation at a site on the results of a BRA for human health. While EPA's risk assessment process is appropriate to characterize risk and develop remediation levels for a small number of

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[1] This approach is embraced by not only states but by EPA as well (see EPA 1995, 2001a).

Superfund sites, it has not been an efficient, cost-effective method to handle the thousands of sites throughout the state of New Jersey.

To standardize and streamline the evaluation and remediation of contaminated sites, NJDEP reevaluated the remediation process and established minimum technical requirements. In 1993, NJDEP proposed and adopted "Technical Requirements for Site Remediation," setting rules on remediation of contaminated sites throughout the state. The use of BRA was replaced with an established procedure to meet soil cleanup criteria and other NJDEP-established media standards.

Currently, interim soil cleanup criteria are used for case-by-case remediation decisions until final standards are promulgated. The criteria have been updated since the 1992 rule proposal and can be found on NJDEP's Web site. They are derived using accepted risk assessment methodology developed by EPA to be protective of human health. The models and assumptions employed are rooted in current EPA policy, guidance, and regulations. In accordance with public policy to ensure negligible health risks or adverse effects, the cleanup criteria are based on a 10^{-6} risk level (1-in-1,000,000 additional lifetime cancer risk) for carcinogens and an HI of 1 for noncarcinogenic effects. Practical considerations, including analytical limitations and natural background, are also taken into consideration.

While the goal of the "Technical Requirements" and cleanup criteria/standards is consistent treatment of sites across programs, NJDEP recognizes that considerations unique to particular contaminants and sites may require modifications of the approaches and assumptions used in the development of criteria on a chemical-specific basis. NJDEP has retained the flexibility to modify assumptions, models, or exposure pathways, if warranted, to ensure adequate protection of human health on a case-by-case basis.

With the adoption of the "Technical Requirements," NJDEP has abandoned the use of EPA's BRA and the acceptable risk range concept. EPA uses a BRA as a decision-making tool which provides risk managers with an understanding of actual and potential risk posed by the site and conveys any associated uncertainties. Where cumulative carcinogenic site risk based on reasonable maximum exposure for both current and future land use is less than 10^{-4} or the noncarcinogenic HI is less than 1.0, action is generally not warranted.

By law, NJDEP does not allow for the use of a BRA or accept EPA's risk range to determine the need for remedial actions. If the area of concern is out of compliance as defined by the "Technical Requirements," it must meet the soil cleanup criteria and other media standards through remediation and/or institutional and engineering controls.

- Washington uses predetermined risk-based soil criteria for common hazardous substances based on health protective assumptions that vary on the basis of land use (and, therefore, exposure assumptions). These exposures (for soil) are direct contact, leaching (to groundwater), vapor intrusion, and environmental protection. Washington uses a three-tiered approach and relies on the definition of a point of compliance, a point at a site where cleanup level compliance may be effectively measured.

- Less complex and typically three-tiered risk assessment systems are used in Alabama, Indiana, Florida, and Massachusetts, among others. The tiers are typically as follows:
    - a simple set of risk-based cleanup criteria established by the state
    - a well-defined risk assessment approach that allows variation of the aforementioned set of cleanup criteria based upon a stringent set of site-specific exposure parameters
    - a complete detailed risk assessment approach that may follow EPA guidelines or a complete and detailed set of guidelines issued by the state

3. SELECTED TECHNICAL AND REGULATORY FACTORS INFLUENCING VARIATIONS IN RISK ASSESSMENT

3.1 Introduction

Each risk assessment that was conducted under various state agencies and evaluated in this document contains part or all of the many elements and processes described in Chapter 2. However, there may be differences in how some of the individual components within each risk assessment process were handled. The area that contained the greatest source of these differences among states was the many components involved with data collection and evaluation. Because these differences occur in the initial stages of the risk assessment, variation in process at this stage can lead to a significant impact on the results of the risk assessment. In contrast, there is much less variation between and states in the toxicity assessment component of the risk assessment process, with all agencies almost uniformly following the toxicity hierarchy described in Section 2.3.3.

A goal of this document is to illustrate not only that several sources of variation exist in the risk assessment processes, but also how the variability may impact the risk management decisions made by a state agency for a waste site. The case studies examined were confined only to soil as an exposure medium to simplify the discussions and illustrate the types of variation that exist from state to state. This chapter highlights some of these topics examining the variations and their impacts.

Chapter 3 Highlights

- Site characterization and its interface with risk assessment are major challenges and the source of variation in risk management outcomes. It is not unexpected that variation would exist in site characterization, but optimally these differences would exist on a site-specific basis to serve different project and data quality objectives. It is common though for those in the risk assessment community to find that data collection was planned without consideration to risk assessment data needs and without involvement in project planning.
- Fundamental challenges associated with site characterization are compounded by differences in approach to interpreting the data—leading to variation in risk assessment findings and risk management outcomes—differences that are apparent in questions such as, “Is the highest value representative of the level of exposure or is it an average?” and, “How is soil variation dealt with, if at all?”
- Efforts to simplify risk assessment process, such as “default values,” tiers, and even the provision of regulatory flexibility, do not necessarily always lead to the level of simplification hoped for.
- The range in risk assessment practices indicates that there can be improvement in the collection of data, the interpretation of data, and the use of risk assessment principles as a unifying forum for improving both data collection and interpretation.

Several common sources of variation in the risk assessment process are discussed in this chapter: approaches to soil sampling (Section 3.2), identification of hot spots (Section 3.2.1), determination of background (Section 3.3), and tiered approaches to site assessment and the characterization of risk (Section 3.4). These topics can be pertinent at virtually any site and are commonly dealt with by risk assessors—both government and private sector—working on sites. These topics are illustrative and are not necessarily comprehensive of all sources of variation encountered.

3.2 Soil Sampling to Support Risk Assessment

Typically, soil samples are taken at contaminated sites with the primary objective of determining the extent of contamination—that is, identifying and delineating areas that are contaminated and the concentrations present. Most samples are taken in areas where the possibility of contamination is highest, as determined by site history, available site assessment data, and the physical features of the site. This approach makes sense for identifying source areas in early project phases but may not make sense for determining average concentrations over an exposure area.

During the initial phase of site assessment, human activities at the site are considered, but predominantly in the context of activities that might have led to the introduction or spread of contamination. Based on initial results, additional sampling often occurs to further identify the location(s) of the highest contamination and the margins of the contaminated area. What usually results is a site that is intensely sampled in some areas, with little or no sampling in areas presumed to be clean. For the purpose of contamination assessment, this approach may be satisfactory. For the purposes of risk assessment, however, it may lead to estimates of exposure that are biased high.

When evaluating risks from contact with contaminants at a site, human activity patterns become very important. Where, how often, and to what extent individuals come in contact with contaminated media are key determinants of risk. The concentration of contaminant(s) an individual would be exposed to would be the true average of the exposure unit (EU). Determining the true average concentration would require measuring every point in the EU. Most agencies accept the use a 95% UCL estimate of the average. Ideally, samples would be taken randomly over the area to have the best chance of capturing the true mean concentration.

Unfortunately, as discussed above, the data set available was not developed for the purpose of conducting a risk assessment but for other purposes linked to identifying contamination for that purpose alone. As a result, the data points are not randomly distributed, may not be amenable to a statistical analysis if that is a desired characteristic of the data set, and usually were not collected with an objective of determining an average concentration over an EU. Because the areas with the greatest contamination usually have the greatest sampling density, they are often overrepresented in the averaging process. That is, a greater number of samples are taken per unit area, and these areas consequently have a greater influence than they should in estimating the mean concentration.

As a practical matter, this approach can result in an overestimation of the mean concentration, which is conservative. Because it is conservative, it is acceptable to regulatory agencies, but not ideal or beneficial to the site owner, operator, or responsible party. There are several types of sampling design options that may be considered in project planning to better estimate the average concentration and thus provide a more accurate calculation of risk. Trade-offs associated with various data collection schemes should be considered to meet project objectives and various data uses. Examples of various schemes include the following:

- Random sampling can satisfy statistical requirements to generate an unbiased estimate of mean contaminant concentrations but frequently requires a large number of samples that may be cost-prohibitive. In many cases it may be optimal to consider a stratified random sampling scheme to more effectively use project resources.

- Purposeful sampling, discussed earlier in this section, places samples in areas suspected of highest contamination with subsequent sampling to delineate boundaries of contamination. Areas of contamination may be defined, but the associated trade-off is that mean concentrations over the area of exposure will likely be biased high.

- Geostatistical sampling could allow use of existing data, avoiding the extra cost of a resampling effort. Geostatistical approaches may consider the variable distribution of contaminants in soil. However, geostatistical techniques for analyzing data are complex and difficult to understand and evaluate on a technical level without special expertise. Further, to be done well, they require a relatively extensive data set that may not be available.

More information relative to systematic planning and sampling design can be found through EPA's Quality System Web site and a tool located at www.epa.gov/QUALITY/qksampl.html.

Regardless of the sampling option selected, one underlying objective of both site assessment and risk assessment is to minimize the uncertainty associated with the site. One approach that can facilitate this shared goal of identifying and minimizing uncertainty is Triad. Triad recognizes that the heterogeneous nature of environmental media can affect sampling and/or remedy design, data collection methods and analytical performance, spatial interpretation of data, toxicity, and risk assessment. Triad focuses on the greatest source of data uncertainty, which is data variation caused by the heterogeneity of the contaminants and the impacted environmental media. Table 3-1 illustrates the major components of the Triad approach and the questions answered by each component.

The illustration provided in Table 3-1 should be considered an open-ended process that begins at the top with systematic planning and continues to decision making, reiterating several times until complete. For more information on the Triad approach, see *Technical and Regulatory Guidance for the Triad Approach: A New Paradigm for Environmental Project Management* (ITRC 2003b).

Table 3-1. Triad process overview

Systematic project planning	***Project initiation*** Assemble project team Define project objectives Identify key decision makers Define decisions to be made Develop initial CSM	***Answers:*** Who? What? Why?
Dynamic work strategy	***Project start-up*** Ongoing revision of CSM Draft adaptive work plan and sampling strategy/decision logic Develop detailed analytical strategy: field-based or fixed lab Develop data management plan Develop quality assurance plan Develop health and safety plan	***Answers:*** What? Why? How? When? Where? Who?
Adaptive work plan implementation	***Plan approval*** Client/regulator/stakeholder review/approval Refine project decision logic and finalize plans	***Answers:*** Who? What? Why? How?
Real-time measurement technologies	***Field program*** Sampling and analysis to fill data gaps Data validation, verification, and assessment	***Answers:*** When? Where? Who? What? How?
Decision making	***Are project objectives met?*** Evolve/refine CSM Modify adaptive work plan Client/regulatory/stakeholder review/approval	***Answers:*** Why? What? How? Who?

According to the Triad approach, the CSM is an especially useful tool to address heterogeneity with respect to risk assessment. The CSM is the primary tool used to

- describe contaminant heterogeneity, the nature of spatial patterning, and migration pathways
- assess whether heterogeneity impacts the performance of statistical sampling plans
- understand "data representativeness"
- integrate knowledge of heterogeneity and spatial pattering into decisions about exposure pathways

While many of these Triad principles and practices are finding acceptance for site characterization activities, the integration of data needs for risk assessment has not routinely been accomplished. Thus, an opportunity exists at many sites to include the risk assessor in the systematic project planning team. The inclusion of a risk assessor on the systematic project planning team would undoubtedly be the best way of closing many of the gaps between data collection and risk assessment identified previously in this section.

3.2.1 Hot Spots: Definitions and Implications

The distribution of contaminants in soil is typically highly variable. From location to location—even a few inches apart—samples can yield remarkably different results. Even within the few grams of soil actually used for chemical analysis in the laboratory one would expect to find regions of more contamination and regions of far less contamination. This situation can be readily apparent when a small amount of soil is "split" and analyzed identically, only to yield quite different results.

Various programs have identified some of these conditions as "hot spots" of soil contamination. It is not uncommon for persons developing sampling plans to be instructed to "look for hot spots" as well as investigate source areas. In addition, upon review of sampling results, a hot spot is often identified when making relative comparisons in concentrations of the site. Concentrations identified as a hot spot at one site may not be a cause for concern at another more highly contaminated area.

Several programs have developed characteristics and even definitions of hot spots. This section considers some of the various characteristics and written definitions. Additionally, some theoretical and practical considerations are presented and discussed briefly.

Table 3-2 presents some written definitions and characteristics for hot spots of soil contamination. As can be seen in the table, the characteristics and written definitions of hot spots fall by and large into two categories: those with nonquantified attributes and those that are numerical. An example of a nonquantifed definition would be one where a hot spot is identified as "an area of elevated contamination." However, since neither "area" nor ”elevated" are specified, the definition would not lead to the same answer to the question, "Is there a hot spot here?" if several different people were viewing the same data set.

The identification of a hot spot of soil contamination is often related to or derived from a soil screening value for the contaminant of interest. Soil screening values are typically developed for evaluating exposure pathways of contaminants in shallow soil in an exposure scenario. For instance, guidance on evaluating exposure to contaminants in shallow soil in a residential setting requires comparing the average level of contaminants throughout an EU to the numerical soil screening value—typically the dimension of the residential lot, but other dimensions are possible. Once again the question, "Should a person evaluate an average value or the highest value from an individual sample?" emerges; if the answer is, "Average," then, "Average of what?" is the next question.

The pursuit of hot spots in sampling can complicate the data collection activity, the analysis of results for risk assessment purposes, and the eventual remediation and/or risk management. The range of characteristics identified for hot spots suggests that a range of sampling objectives and approaches, sampling frequency, data interpretations and analyses, and risk assessment outcomes would result. A single sample result in the field of many other sampling results can delay—even change considerably—a site cleanup. This type of impact on risk management is consistent with the experience of the Risk Assessment Resources Team and also consistent with the observations made later in this report through case studies.

Table 3-2. Hot spot table

State	EPA region	Formal definition[a]	Definition (formal or informal)	Numerical criteria	Area/volume represented	How do you sample for it?
AK	10	No	No definition in regulations.	Generally greater than applicable cleanup level.	Area defined by sampling results exceeding regulatory cleanup level.	Field screening initially to be confirmed by fixed analytical laboratory sample analysis.
AL	4	No	There is no official definition. The term is usually in reference to a localized area or areas with concentrations substantially higher than the rest of the exposure domain.	During the screening process, the maximum concentration within the exposure domain should not be exceeded. If the screening value is exceeded, then a 95% UCL or a maximum concentration may be used to compare to a site-specific risk-based target level. During this phase, the cumulative risk determines whether additional remediation is needed.	A hot spot is not used to determine size of area represented by a single sample. Areas represented are based on activity differences throughout a site as they relate to changes in exposure.	Not specified, but method for establishing sampling plan is found in state guidance documents; see the Alabama Environmental Investigation and Remediation Guidance and Alabama Risk-Based Corrective Action located at www.adem.state.al.us/LandDivision/Guidance/guidance.htm.
AR	6	No	Not in online searchable document and databases.	Not specified.	Not specified.	Not specified.
AZ	9	No	The phrase is used without any quantitative or qualitative definition.	Not specified.	Not specified.	Not specified.
CA	9	No	Definition(s) is site specific and changes through the life cycle of the project.	Not specified.	A sample result showing elevated concentrations without nearby sampling results may be called a hot spot, meaning that more sampling is required to determine the volume of contaminated material.	Not specified.

State	EPA region	Formal definition[a]	Definition (formal or informal)	Numerical criteria	Area/volume represented	How do you sample for it?
FL	4	No	The term is usually in reference to a localized area or areas with concentrations substantially higher than the rest of the site.	If the 95% approach is used, the maximum concentration should not exceed any cleanup target level based on acute toxicity and shall not exceed three times the applicable direct exposure soil cleanup target level based on chronic toxicity unless a site-specific risk assessment justifies something higher.	Not specified.	Sampling location and density are determined based on best professional judgment on a site-specific basis. 62-780.680 Florida Administrative Code.
GA	4	No	Not defined in rules or act.	NA	NA	NA
IN	5	No	Closest equivalent would be "source area," which is the horizontal and vertical geographical area where COC concentrations exceed residential default closure levels.	Default residential closure levels (10^{-5} for carcinogens, 1.0 for noncarcinogens).	Not specified.	Random, directed, or judgmental sampling.
MA	1	Yes	A discrete area where the concentrations of hazardous material are substantially higher than those present in the surrounding area.	Average concentration > 100× immediately surrounding average concentration; 10× < average concentration < 100× immediately surrounding average concentration, unless no greater exposure potential.	Not specified.	Systematic or random sampling (guidance is presented for calculating an area-weighted average when biased sampling is conducted).

State	EPA region	Formal definition[a]	Definition (formal or informal)	Numerical criteria	Area/volume represented	How do you sample for it?
MI	5	No—informal definition in training material (*Sampling Strategies and Statistics Training Materials for Part 201 Cleanup Criteria* [S^{3}TM]).	The definition of a hot spot is based on spatial correlation of elevation concentrations. The definition provided in the S^{3}TM guidance manual is: "Two or more adjacent sample locations in reasonably close proximity at which concentrations are sufficiently above criteria and surrounding location (i.e., spatially correlated concentrations sufficiently above criteria) to indicate that they represent a different statistical population and pose a potential risk that should not be masked by a statistical analysis." Additionally, even a single sample location with indications that it represents a different statistical population may represent a hot spot.	Land-use, risk-based, cleanup criteria (Part 201 of Act 451).	Dependent on the sampling locations/grid established for the unit being evaluated.	Systematic random (statistical/grid) sampling for medium (1/4–3 acre) and large (>3 acre) sites. Biased (judgmental) sampling for small sites (<1/4 acre).
NE	7	No	No definition. Term used anecdotally and casually in a case-specific context.	None.	Case specific.	Consistent with the facility investigation plan. Open to proposed methodologies.
NH	1	No	In Field Sampling Procedures Guidance Manual: "…any region that exceeds some threshold concentration" [see Numerical Criteria] "…occurs in randomly distributed lenses" "assumed circular in the horizontal plane and elliptical in the vertical plane" "size is the dimension of the long axis."	The threshold levels of contamination are the concentrations listed in the NH Department of Environmental Services Risk Characterization and Management Policy.	Methods and equations for calculating mass are presented in the guidance.	Initially conduct biased sampling to locate release area(s). Then "establish a nine-point grid with modal spacing of 20 feet centered over principal release. If contamination is encountered in one of the perimeter soil borings, establish an additional four-point grid with 20-foot spacing to include the perimeter boring with contamination."
NJ	2	No	Not specified.	Not specified.	Not specified.	Not specified.

State	EPA region	Formal definition[a]	Definition (formal or informal)	Numerical criteria	Area/volume represented	How do you sample for it?
NY	2	No	Functionally equivalent term is "source area" or "source"—"a portion of a site...where the investigation has identified a discrete area of soil...containing contaminants in sufficient concentrations to migrate in that medium, or to release significant levels of contaminants to another environmental medium, which could result in a threat to public health or the environment."	Tabulated "soil cleanup objectives" for residential, restricted-residential, commercial, and industrial sites (Part 375-6.8).	Defined on a site-specific basis.	Simple random and systematic random sampling.
OH	5	No	"[A]reas of high contaminant concentrations relative to other areas of the unit" "an area of contamination, with constituents of concern attributable to the closing [RCRA] unit, which requires remediation, or a risk evaluation."	Not specified.	Not specified.	Detailed methodology in sampling guidance manual that uses Gilbert (1987) grid-spacing methods and EPA (1984) Simple Exceedance Rule Method.
OR	10	Yes	"[T]he extent to which the hazardous substances…are present in concentrations exceeding risk-based concentrations corresponding to [see Numerical Criteria]" and will migrate or cannot be contained.	100× acceptable human risk from individual carcinogens; 10× acceptable human risk from individual noncarcinogens; 10× acceptable risk to individual or populations of ecological receptors to individual hazardous substances.	Not specified.	Refer to EPA 1989b, 1992c.
TN	4	No	Not defined in rules or searchable online documents.	Not specified.	Not specified.	Not specified.

State	EPA region	Formal definition[a]	Definition (formal or informal)	Numerical criteria	Area/volume represented	How do you sample for it?
TX	6	Yes, protective concentration level (PCL) exceedance zone	"[A] distinctly apparent area of elevated contaminant concentrations that are associated with risks or hazards for individual contaminants which significantly exceed the acceptable regulatory thresholds of [see Numerical Criteria]."	Specified in PCL tables found at www.tceq.state.tx.us/remediation/trrp/guidance.html.	0.5-acre source area.	Specified in www.tceq.state.tx.us/remediation/trrp/guidance.html.
WA	10	No	"[S]mall patches of higher-level contamination."	Not specified.	Not specified.	Refer to Gilbert (1987).
WI	5	No	"[E]levated concentrations."	Not specified.	Not specified.	Refer to Gilbert (1987) and EPA 1991a, 1992b.
WY	8	No	General informal definition: "Based on land use and exposure area. Area or zone of contamination that poses an unacceptable risk (>10^{-6}) or that drives an unacceptable risk within an exposure area. Voluntary Remediation Program (VRP) Fact Sheet #21, Remedy Selection, uses the term 'hot spot' as synonymous with source areas of contamination."	Unrestricted use: cleanup values in VRP Fact Sheet (10^{-6}). Restricted use: site-specific, risk-based levels. (Target risk level of 10^{-6}. Risk range of 10^{-4} to 10^{-6} if target risk level cannot be achieved.)	Unrestricted use: 1/5 acre; Restricted use: site specific. (Depends on land use, exposure area size, DQOs, etc. Based on sampling and data variation, calculate probability of missing a hot spot of a specific size/volume).	Unrestricted use: specified—1/5 acre sampling required. Restricted use: not specified—site-specific sampling plan and DQOs. (Depends on land use, exposure area size, DQOs, probability of missing a hot spot of a specific size based on type of sampling and data variation, etc.)
ASTM			"[A] localized area of soil...contamination."	"[A] discrete volume of buried waste or contaminated soil where the concentration of a contaminant of interest exceeds some prespecified threshold value."	Not specified.	Systematic grid sampling (resolution based on project budget).

State	EPA region	Formal definition[a]	Definition (formal or informal)	Numerical criteria	Area/volume represented	How do you sample for it?
EPA		No	"[A] small portion of the EA [exposure area] has very high levels."	Not specified.	Not specified.	Systematic grid sampling with a random starting point is preferred; systematic random sampling is recommended for irregular EAs and systematic contaminant trends across EAs.

[a] In law, statute, rule, act, code, etc.

References: EPA 1984, 1989a, 1989b, 1992c; Gilbert 1987. Chapter 62-780 Florida Administrative Code specifies that if a 95% UCL is used to determine no further action, the maximum concentration should not exceed 3× the soil cleanup target level unless a site-specific risk assessment justifies something higher.

3.3 Background Concentrations of Chemicals of Potential Concern

An evaluation of local background concentrations may be appropriate at a cleanup site whenever it is suspected that certain contaminants detected above applicable screening or cleanup criteria may be equal to, or less than, ambient natural or anthropogenic (where accepted) background concentrations. A properly established background concentration can be designated as the alternative screening or cleanup level for some constituents.

At least two states (New Jersey and Massachusetts) have recognized that large portions of urban areas have been subjected to prolonged industrial use (Brownfield and Site Remediation Act, 1998), and background levels of many compounds are likely to be reflective of anthropogenic activities as much or more than natural processes. While these two states have identified large areas within which "natural background" may be obscured by man's activities, virtually all states face similar complications at some time or another. Lead (Pb), polynuclear aromatic hydrocarbons (PAHs), and arsenic are examples of compounds found both naturally and also as a result of human activities. Widespread use of a variety of agricultural chemicals has made it a common situation that pesticide residues and other chemicals are present in acreage being considered for residential development. At least one relatively new COC (perchlorate) is present naturally in the environment but is also introduced quite widely through a variety of uses (such as fireworks or flares), some of which are common in a residential setting.

For more than 25 years, the topic of background has been widely discussed. Although sampling approaches and their statistical underpinnings have been available for decades, the issue persists as one that in many instances is not easily dealt with. The widespread occurrence of chemicals—those that may also occur naturally as well as those strictly of anthropogenic origin—raises some difficult questions for the risk assessment and risk management processes. These difficulties have lead to variations among states in just how "background" is incorporated into the risk assessment process, some of which are addressed below. Section 3.3.1 discusses anthropogenic and natural background; Section 3.3.2 details various states' sampling processes for determining background concentrations, including sampling locations, number of samples, sample collection methods, and statistical methods for data analysis.

3.3.1 Anthropogenic and Natural Background

According to EPA, background chemicals fall into the following two categories:

- *Naturally occurring chemicals* are present as a result of geochemical processes that have not been influenced by human activity. Naturally occurring organic and inorganic background chemicals in soil and in groundwater are attributable to the natural geological, hydrogeological, ecological, and biochemical characteristics of the area.

- *Anthropogenic chemicals* are synthetic constituents or natural substances that have been released to the environment as a result of human activities that are not related to specific activities conducted at the site. EPA (1991a) considers the following to be sources of anthropogenic background chemicals: agricultural runoff, septic systems, irrigation (agricultural and residential application of pesticides), air pollution, industrial discharges, landfills, and urban pollution (lead and PAHs from automobiles and combustion process). States also have definitions of anthropogenic background that may be different.

Anthropogenic background chemicals typically are widely distributed in the environment due to human activities and are either not related to site sources or releases or are attributable to past and present legal applications or sources. In some cases it is not possible to determine whether a constituent is naturally occurring or anthropogenic in origin; thus, these background data are difficult to use to establish site-specific alternate cleanup levels. Depending on the various state statutes, one can be directed to conduct "natural" or "anthropogenic" background studies.

3.3.2 State-Specific Guidance on Background Levels

Table 3-3 summarizes the approaches used by states for the use and treatment of background samples in risk assessment and a discussion follows. More detailed descriptions of several states' approaches are provided in Appendix A (on the accompanying CD-ROM).

Table 3-3. State responses to questions about use of background in risk assessment

CONSIDERATION OF BACKGROUND	
1. Does your state have formal guidance on the use of background in risk assessments?	
Alabama	Yes. *Alabama Environmental Investigation and Remediation Guidance* (September 2005)
Arkansas	Yes. EPA Region 6 Human Health Medium-Specific Screening Levels (HHMSSL) (November 2005) www.epa.gov/earth1r6/6pd/rcra_c/pd-n/r6screenbackground.pdf
California	Yes. *Selecting Inorganic Constituents as Chemicals of Potential Concern at Risk Assessments at Hazardous Waste Sites and Permitted Facilities* (February 1997) www.dtsc.ca.gov/AssessingRisk/upload/Backgrnd.pdf
Florida	Yes. If the potential contaminant is below natural background concentrations, the contaminant is not considered in the risk assessment. *Guidance for Comparing Background and Site Chemical Concentrations in Soil* (March 2008) www.dep.state.fl.us/waste/quick_topics/publications/wc/BackgroundSoilGuidance-03-08.pdf
Georgia	No, but screening site contaminants versus background concentrations is discussed in *Georgia Environmental Protection Division Guidance for Selecting Media Remediation Levels at RCRA Solid Waste Management Units* (1996). www.gaepd.org/Files_PDF/techguide/hwb/swmurisk.pdf
Massachusetts	Yes. "Guidance for Disposal Site Risk Characterization in Support of the Massachusetts Contingency Plan" (1995), BWSC/ORS Policy 95-141, Section 2.3
New Jersey	Yes, however, New Jersey does not do risk assessment (baseline). Background is considered in establishment of cleanup criteria/remediation. N.J.A.C. 7:26E, "Technical Regulations for Site Remediation"
Wisconsin	Yes. *Guidance for Determining Soil Contaminant Background Levels at Remediation Sites* (December 2005)
2. Does your state consider background in soil risk assessments?	
Alabama	Yes.
Arkansas	Yes.
California	Yes.
Florida	Yes, to eliminate a chemical as being a COC if natural background levels are higher than a risk-based criterion.
Georgia	Yes.
Massachusetts	Yes.
New Jersey	Yes. Again, New Jersey does not do risk assessment (baseline). Background is considered in establishment of cleanup criteria/remediation.
Wisconsin	Yes.

CONSIDERATION OF BACKGROUND	
2a. If yes, under what circumstances?	
Alabama	Under all circumstances where a background concentration level may be reasonably and accurately determined.
Arkansas	During a baseline risk assessment, if initial COCs do not pass screening levels from the Region 6 HHMSSLs, a site has the option of providing calculated site-specific remediation goals, including site-specific background values for soil remediation consideration.
California	Indirectly. If a potential contaminant is below background concentrations, the contaminant is not considered in risk assessments.
Florida	In delineating contamination attributable to a site and whenever risk-based cleanup targets might be less than site-specific natural background levels.
Georgia	Per Georgia Environmental Protection Division (GAEPD) guidance, which incorporates EPA Region 4 guidance, for naturally occurring inorganics and radionuclides, the maximum detected concentration is compared to two times the average site-specific background level as part of the screening process. Although EPA Region 4 and GAEPD guidance allows the use of statistics in background data evaluation, the use of statistics may not be sufficiently conservative at the screening stage of the risk assessment. In most cases, a sufficient number of samples will not be available for conducting a statistical analysis with appropriate power. Therefore, the use of the twice background criterion is recommended. GAEPD should be consulted before using any type of statistical approach.
Massachusetts	Background should be considered in all risk assessments. Anthropogenic background is referred to as “local conditions.”
New Jersey	For elevated level of naturally occurring elements.
Wisconsin	Generally, only naturally occurring metals, lead, and some ubiquitous organics, such as PAHs and PCBs from widespread atmospheric deposition (i.e., widespread deposition of contaminants from the air that cannot be traced to a specific source) are candidates for background soil determinations. Other contaminants found at a discharge site, such as VOCs, are generally not candidates for such determinations. Contaminants that should not be considered background include those from surface runoff from specific sources, such as parking lots and storage facilities where spills have occurred; railroad tie–related contaminants, such as creosote (PAHs, benzene, toluene, and ethylene can be present in creosote); contaminants from spills at railroad facilities and in railroad rights-of-way; surface contamination adjacent to roads caused by vehicle emissions; and air emissions–related contamination from specific sources.
2b. If yes, which type of background—natural or anthropogenic—is acceptable?	
Alabama	Both.
Arkansas	Both.
California	Both.
Florida	Anthropogenic—Yes, but only for delineation of contamination attributable to a site. Natural—Yes, mandated by Florida statutes.
Georgia	Natural.
Massachusetts	Both are considered.
New Jersey	Natural.
Wisconsin	Both.

ANTHROPOGENIC VS. NATURAL BACKGROUND	
3. Should anthropogenic levels be considered similarly or differently from natural background?	
Alabama	Similarly.
Arkansas	Differently.
California	Similarly.
Florida	Differently.
Georgia	Differently.
Massachusetts	Differently.
New Jersey	Differently.
Wisconsin	Similarly.

ANTHROPOGENIC VS. NATURAL BACKGROUND	
3a. If differently, please describe the difference.	
Alabama	N/A
Arkansas	Natural background can use the Region 6 HHMSSL recommended ranges, while anthropogenic levels must be calculated using site-specific conditions. In some site-specific cases, a less formal approach is taken by taking a minimum of four background samples (away from the contaminated site but representative of the overall characteristics of the area) and derive a value based on the mean ±2 standard deviations.
California	N/A
Florida	Anthropogenic background is an issue in determining the boundaries at which contamination can be attributable to a site, i.e., where contamination from the site ends and contamination from other sources begins. Natural background is a lower limit for cleanup targets; that is, sites are not cleaned up to concentrations below natural background.
Georgia	Only naturally occurring inorganics and radionuclides are compared to their background concentrations.
Massachusetts	Definition of background makes clear that the term is not limited to “pristine” conditions and that the department recognizes that historic human activities have resulted in the presence of some chemicals in the environment. Such nonpristine conditions must meet the conditions described in both of the clauses of the definition, however. It is important to note that, under this definition, oil or hazardous material from one release cannot be considered background for another release. Anthropogenic backgrounds, known as “local conditions,” are then treated similarly as natural background levels are in comparisons with exposure point concentrations.
New Jersey	Anthropogenic compounds such as PAHs are treated in a fashion similar to historic fill in New Jersey; that is, delineation and institutional controls with possibly engineering controls would be required.
Wisconsin	N/A
4. Is background determined using site-specific soil samples, literature references, or either one?	
Alabama	Site-specific soil samples.
Arkansas	Either is acceptable; it depends on the overall site conditions and circumstances.
California	Site-specific soil samples.
Florida	Site-specific soil samples.
Georgia	Site-specific soil samples.
Massachusetts	Site-specific soil samples are recommended/preferred, but in certain circumstances, accepted literature values (specifically those published by the Massachusetts Department of Environmental Protection [MADEP]) can be accepted. Site-specific background determinations are necessary for chemicals not included in the list(s) of generic MADEP background concentrations. Site-specific background determinations may also be made where it is believed that site-specific background may, in fact, be higher or lower than the published Massachusetts values.
New Jersey	Site-specific soil samples are the minimum requirement. Literature references can be cited in addition to the above sampling. It should be noted that literature references are specific to New Jersey (regional and county).
Wisconsin	Either is acceptable.
4a. If literature references are used, please provide citation(s).	
Alabama	N/A
Arkansas	EPA Region 6 HHMSSLs (November 2005) www.epa.gov/earth1r6/6pd/rcra_c/pd-n/r6screenbackground.pdf
California	N/A
Florida	N/A
Georgia	N/A
Massachusetts	*Background Levels of Polycyclic Aromatic Hydrocarbons and Metals in Soil*, MADEP (2002)
New Jersey	*Summary of Selected Soil Constituents and Contaminants at Background Locations in New Jersey*, Fields et al. (September 1993); *Ambient Levels of Metals in New Jersey Soils*, Sanders (May 2003)
Wisconsin	Generally, published background levels do not exist for most areas in Wisconsin. If published levels are found, they may be considered, but the locations of the samples and soil types should be sufficiently similar to the discharge site to be used.

ANTHROPOGENIC VS. NATURAL BACKGROUND	
5. Are background concentrations outside the ranges reported in literature references for background levels considered?	
Alabama	Yes, all decisions are made on site-specific data.
Arkansas	No.
California	Yes.
Florida	Yes, although with some skepticism.
Georgia	Yes.
Massachusetts	Yes, with site-specific data.
New Jersey	Yes, see [answer to] 4 above.
Wisconsin	Yes.
6. Is background from another area/region acceptable in place of site-specific data?	
Alabama	No.
Arkansas	No.
California	Yes, if located nearby and soil is from same parent material.
Florida	No.
Georgia	No.
Massachusetts	No.
New Jersey	Yes, just off site usually.
Wisconsin	No.
7. Is background determined from a heavily industrialized urban area valid for a light industrial suburban area?	
Alabama	No.
Arkansas	No.
California	No.
Florida	No.
Georgia	No.
Massachusetts	No.
New Jersey	No.
Wisconsin	No.
8. Can background samples be compared to site samples from different depth intervals?	
Alabama	Yes and no. It depends on the magnitude of difference between background depth interval and the contaminated soil sample depth.
Arkansas	Yes.
California	Yes, if parent material is similar.
Florida	No.
Georgia	No.
Massachusetts	Yes.
New Jersey	Yes, since in New Jersey we require both surface and subsurface background samples.
Wisconsin	No.
9. How far apart should samples be spaced?	
Alabama	Site-specific decision.
Arkansas	No specific guidance stipulated for spacing requirements. Most default requirements found in EPA soil screening guidance (1996, 2002c).
California	Depends on the site and surrounding area. Typically, off-site background samples come from public parks or sites with approved background sample data set. These can be spaced quite widely.
Florida	Site-specific determination.
Georgia	Site-specific decision.
Massachusetts	Site-specific decision.
New Jersey	Not specified in New Jersey Technical Regulations, 7:26E-3.10(a). A site-specific determination.
Wisconsin	Not specified in state codes or guidance, but sampling plan should be submitted for review and approval.

NUMBER OF SAMPLES	
10. How is the number of background samples required determined?	
Alabama	Site-specific decision made.
Arkansas	EPA soil screening guidance (1996, 2002c). In some site-specific cases, a less formal approach is taken by taking a minimum of four background samples (away from the contaminated site but representative of the overall characteristics of the area) and derive a value based on the mean ±2 standard deviations.
California	Site-specific, for screening purposes; minimum number is specified in our *Preliminary Endangerment Assessment Guidance*.
Florida	Seven samples for nonstatistical tests. For statistical tests, the required number of background samples is site specific.
Georgia	Site-specific decision made.
Massachusetts	The specific number of samples needed depends in part on the method used to compare the results. A number of documents have been prepared by EPA which describe approaches to determining what is an adequate number of samples. A particularly useful publication is *Guidance for Data Usability in Risk Assessment* (1992), which contains equations that can be used to calculate the minimum number of samples required to achieve specific statistical goals, such as levels of power, confidence, and minimum detectable relative difference. It is clear from discussions in environmental statistics texts that the range of chemical concentrations reported is as important as the magnitude of the concentrations when making background-to-site comparisons.
New Jersey	10, which is based on policy and pursuant to 7:26E-3.10(a)
Wisconsin	Based on the number of soil types/horizons of direct-contact concern.
11. What is the minimum number of background samples acceptable?	
Alabama	4.
Arkansas	4.
California	Preferably at least 10, but will accept a minimum of 4 for screening purposes.
Florida	7 samples for nonstatistical tests. For statistical tests, the required number of background samples is site specific.
Georgia	1.
Massachusetts	The number of samples that is sufficient depends on a variety of factors. It is not possible to specify the optimal sample size a priori. However, these “rules of thumb” are offered to provide rough indication of what MADEP is likely to consider adequate.
New Jersey	10.
Wisconsin	At least 4 samples for each soil type/horizon of direct contact concern.

SAMPLE COLLECTION	
12. Are discrete samples required?	
Alabama	Yes.
Arkansas	No.
California	Yes.
Florida	Yes.
Georgia	No.
Massachusetts	Yes.
New Jersey	Yes.
Wisconsin	Yes (during site investigation/characterization).
13. Is compositing allowed?	
Alabama	Yes, in some cases, based on the COCs and background conditions.
Arkansas	Yes.
California	No.
Florida	No.
Georgia	Site-specific determination.
Massachusetts	No.
New Jersey	No.
Wisconsin	Yes—nonvolatile contaminants like PAHs, metals; no—semivolatile and volatile contaminants.

ANALYSIS	
14. Does your state analyze only for constituents of concern, or do you analyze others?	
Alabama	Typically, just COCs, but in some cases other chemicals may be analyzed for.
Arkansas	For an initial baseline risk assessment, all constituents that may reasonably exist at a site due to the nature of past or present activity need to be screened using the Region 6 HHMSSL values (i.e., all VOCs, semivolatile organic compounds, metals). If a constituent does not pass screening using a site-specific background value, only recognized COCs need to be analyzed.
California	Typically 17 common metals and trace elements are evaluated to compare site data to background data to determine COPCs.
Florida	Required only for COCs.
Georgia	Site-specific determination.
Massachusetts	It is up to the Licensed Site Professional to determine for which chemicals to test. At a minimum, COCs should be measured.
New Jersey	Normally, COCs only.
Wisconsin	For background determination purposes, only nonvolatile COCs are analyzed.
15. Can the methods used to analyze background and site samples for the same constituents of concern differ?	
Alabama	No.
Arkansas	No.
California	No.
Florida	No. Analytical methods should be the same.
Georgia	No.
Massachusetts	Background sample collection and sample analysis methods should be consistent with those for other site-related samples and should be collected concurrently whenever possible, to ensure that the analytical results are comparable.
New Jersey	No, analytical methods should be the same.
Wisconsin	No, except method detection limits may vary between contaminated samples (elevated limits) and background samples (lower limits).
15a. If yes, what are the differences in analytical methods?	
Alabama	N/A
Arkansas	N/A
California	N/A
Florida	N/A
Georgia	N/A
Massachusetts	N/A
New Jersey	N/A
Wisconsin	N/A

ALTERNATIVE CLEANUP TARGET LEVELS BASED ON BACKGROUND	
16. Are statistical tests or nonstatistical tests used?	
Alabama	Statistical.
Arkansas	Statistical.
California	California uses a tiered approach. First tier is nonstatistical; the others are statistical.
Florida	Both.
Georgia	Both.

ALTERNATIVE CLEANUP TARGET LEVELS BASED ON BACKGROUND	
16. Are statistical tests or nonstatistical tests used?	
Massachusetts	MADEP considers site conditions consistent with background if • Both the median and maximum values for the site samples are less than or equal to the corresponding background values, or • The median value for the site samples is less than or equal to the background samples medium, and the maximum site sample is less than 50% greater than the maximum background concentration, or • The maximum value for the site samples is less than or equal to the background sample maximum, and the median site sample is less than 50% greater than the background medium. However, the "gold standard" for comparisons of site and background data is the use of a statistical test. Statistical tests using a sample size large enough to provide appropriate power, confidence, and minimal detectable relative difference provide conclusive determinations about the relationship between site concentrations and background levels. A statistical test of the hypothesis that the contaminant levels at the site do not significantly differ from the background levels, if done properly, is the most conclusive evidence of that chemical concentrations at the site are consistent with background levels.
New Jersey	Nonstatistical.
Wisconsin	Statistical—Upper 95% confidence limit on the arithmetic mean is the suggested method. Nonstatistical—The mean level of the concentrations of the samples for each soil type/horizon may be used, provided that the levels from each sample are sufficiently similar to average together.
16a. Does the state have a preference, or is either acceptable for determining difference a between site and background?	
Alabama	Statistical preference.
Arkansas	No preference.
California	Tiered approach.
Florida	Both are acceptable depending upon the number of site and background samples available.
Georgia	Georgia allows the use of statistical methods for the calculation of background concentrations as long as the data set supports the statistical method being used. This is a site-specific determination.
Massachusetts	N/A
New Jersey	Nonstatistical preference.
Wisconsin	No preference.

As is evident in Table 3-3, not all states have specific guidance on background; some defer to regional EPA guidance, though none cite EPA headquarters guidance or policy. Sampling quantity requirements differ across the states and may or not be mandated by statute or regulation. For example, one state allows a single sample, while others mandate a minimum of four. Some states allow composite sampling, while others accept only discrete sample results. Unless specific requirements are spelled out for numbers of samples, sampling methods, and types of analyses, "best professional judgment" is allowed.

In cases in which risk-based screening values are lower than background, the burden of proof to establish the background level is typically placed on the responsible party. Constituents whose background levels exceed risk-based screening concentrations can be excluded as a COC from a risk assessment; however, some states may request that it be considered to characterize total site risk.

The EPA Region 4 states (Alabama, Florida, Georgia) allow similar approaches to soil background: the nonstatistical method that uses the comparison of twice the mean to the maximum soil concentration at a site, as cited in multiple EPA documents[2] and statistical approaches like those described in *Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites* (EPA 2002a).

Whether to include chemicals at background concentrations as COPCs in risk assessments, what to include in "background," how to sample to determine background, and how to conduct the evaluation can vary. Variation is most apparent in "yes" versus "no" answers to the same question and also in answers conveyed with discussion. These are among the examples of the complications and variations that "background" can introduce into site characterization, risk assessment and eventually risk management.

3.4 Tiered Approaches in Risk-Based Investigation and Remediation

Risk assessments have traditionally been conducted as a tool for decision making regarding which chemicals have to be "cleaned up" and what concentrations constitute the "clean enough" level. For large sites or sites with numerous contaminants, this process can be very time- and resource-intensive. To make risk assessments more focused, a tiered approach using various risk assessment tools has been adopted or used by numerous state and federal agencies. The reason for using tiers is to appropriately allocate the amount of effort spent on investigation based on the apparent significance of the level contamination. Thus, far more resources can be assigned to a complicated and significant situation than to one considered routine and relatively minor.

States apply different versions of a tiered approach (either explicitly or implicitly); however, many share some common elements. First, most tiered approaches use three tiers, or "options." The first tier is usually a table of "look-up" or "not to exceed" numerical criteria and is prominently used in screening sites or in small-scale remediation. The second tier involves some calculations, but default vales for environmental parameters are made available to simplify and therefore expedite the analysis. The third tier is essentially a formal risk assessment and is most common for large or complicated sites. Risk management is used to determine whether to proceed to another tier for further study or to use a lower tier with more conservative values as cleanup goals.

Although the Tier 1 level is widely viewed as the simplest and suitable for the smallest contamination conditions, it should be apparent that complexities and complications abound. There can be more than one Tier 1 look-up number for a single chemical in a single media, especially when comparing various states and state programs. It is common to find that, while a common Tier 1 look-up number exists for residential uses, this might not be the case for other land use scenarios, such as industrial and recreational. While Tier 1 screening values may be developed for a perceived limited range of conditions and applications, it is now less common but not unheard of that they become the default "cleanup" values, short-circuiting or even making irrelevant the effort put into a risk assessment.

Though much diversity that may occur within the Tier 1 arena itself, usually it is the Tier 1 stage of evaluation that is most prescriptive and well defined. Beyond the Tier 1 stage, very few agencies or programs have defined the tangible boundaries and constraints that should be

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[2] EPA 1989b, 1989c, 1991a, 1991b, and *Memo and Policy Statement: Role of Background in the CERCLA Cleanup Program*, April 26, 2002, OSWER 9285.6-07P.

afforded to the Tier 2 or Tier 3 stages. Not only are the aspects of variation discussed above for Tier 1 also potentially found in the higher tiers, but add to that the following issues:

- Which fate and transport modeling will be accepted or used?
- What point or what area must comply with the calculated Tier 2 or Tier 3 standard?
- If different from the representative site concentration, how is the exposure point concentration (EPC) determined?
- How much and what types of data collection are required to support each determination of Tier 2 or 3 standard?
- Will PRA be allowed, and at what tier?
- At what point, if at all, are the cost of data collection in support of and the cost to conduct the Tier 2 or 3 evaluation considered?
- Can Tier 1 cleanup numbers be mixed or matched with Tiers 2 or 3 in conducting corrective actions?

Guides have been published that describe the general business of and the tools for a risk-based tiered approach to addressing contamination at sites. In addition to state-specific guidelines (Michigan, Oklahoma, New Mexico, Arkansas, Oregon, Ohio, Illinois, Texas, Florida, etc.), ASTM has prepared two standards documents: *Standard Guide for Risk-Based Corrective Actions at Petroleum Release Sites* (1995) and *Provisional Standard Guide for Risk-Based Corrective Action* (1998). EPA has also issued two guidance documents: *Soil Screening Guidance* (1996) and *Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites* (2002c). The EPA documents provide generic soil screening levels (i.e., Tier 1 look-up values), as well as a tiered framework for developing risk-based, site-specific soil cleanup levels. However, it is up to each agency and program to determine how to work within these provided frameworks.

Practical application of a tiered risk-based approach has frequently shown that time, money, and/or resources are not saved unless the start and stop points for the various tiers are clearly defined and measurable. Setting measurable and predictable upper and lower boundaries for each tier has proven to be a challenge, and thus variation can be observed in the implementation of tiered approaches as well as in the risk management outcomes.

4. CASE STUDIES: USE OF RISK ASSESSMENT IN RISK MANAGEMENT OF CONTAMINATED SITES

The purpose of this chapter is to examine the use of risk assessment in actual cleanup decisions at various sites. Section 4.1 details the information collected for each case study. Section 4.2 provides summaries of the cases examined.

4.1 Information Collected for Each Case Study

Relevant information was collected for each case study. The team developed a data collection form to ensure that a consistent framework was used for the case studies. The questions addressed by the case studies can be found with the full case study reports in Appendix B (on the accompanying CD-ROM).

The information collected dealt with background information, sampling strategies employed, and pertinent risk questions. Basic background data included standard information (e.g., the name and location of the site; the regulating authorities; and a brief history of the site, such as source(s) and duration of contamination). Additional background questions included whether the site was considered a single operable unit, the size of the site and operable units, and the status of the site.

Questions about the sampling strategy covered which sampling methodology was used, which sample values (averages, maxima, UCLs) were used in the risk assessment, which values compared to numerical criteria, how sampling densities were derived, and which soils were considered "available" for exposure.

Risk questions dealt with risk-based criteria (when they were applied, how or from where they were derived, what the numerical values were, and what risk level they represent, etc.), availability of guidance, use of background concentration data, risk management strategies employed, and how confirmation sample concentrations were compared to remedial criteria (what area, and/or how may sampling points were used).

Chapter 4 Highlights

- Four of the five case studies were large-scale and highly resourced projects.
- At large-scale projects, extra resources spent on complex, site-specific risk assessments may help decrease uncertainty and overall project costs due to avoidance of remediation and/or reduction in the number of contaminants that require remediation.
- Classical use of risk assessment with other factors in risk management is demonstrated by the case studies.
  - Further study to decrease site uncertainty can decrease project costs through avoidance of remediation and/or reduction of the number of contaminants that require management.
  - Probabilistic risk assessment may provide more representative ranges of risk associated with actual site conditions.
- Community/stakeholder involvement is important in remedial decisions that affect their properties and community. Stakeholder support can facilitate decisions and their implementation.
- Volumes of contaminated media that require treatment or disposal may be reduced if risk-based remediation goals using statistical approaches, rather than "bright lines" or not-to-exceed criteria, are applied.
- Basing site decisions on single discrete samples is likely to be overly restrictive.
- Use of data collection methods not commonly used to support risk assessment may be facilitated through careful DQO development during project planning.
  - Composite sampling strategies may be valid for informing decisions of whether further study is required and may be appropriate for risk assessment if uncertainties are appropriately addressed in the risk assessment.
  - Use of field analytical methods to collect data for use in risk assessment may be appropriate if the method is corroborated with fixed laboratory analysis.

4.2 Summaries of Cases Examined

4.2.1 Spring Valley, Washington, DC

The Spring Valley site is a 668-acre formerly used defense site located on what is presently known as American University and some adjoining properties surrounding the university. During World War I (WWI), the site was used to conduct research, development, testing, and evaluation of chemical warfare materiel. After WWI, the temporary facilities were dismantled and excess materials disposed of. Over time, the area surrounding the university was developed into a residential community called Spring Valley, which currently consists of private residences, foreign embassies, educational institutions, and many commercial properties. Two typical properties, each roughly ½ acre in area and only a small fraction of the Spring Valley site, were chosen for study by the ITRC Risk Assessment Resources Team. Arsenic was identified as the primary COC, and surficial soil was identified as the primary medium of concern at the two properties.

- Formerly used defense site for conducting chemical warfare tests.
- Arsenic is the primary COC; direct contact to surface soil is the primary risk pathway.
- Cleanup goals, calculated after initial study of properties and applied to subsequent residences, were based on residential child cancer risk and background considerations.
- Cleanup goals of 43 mg/kg for inaccessible soils, 20 mg/kg for accessible soils.
- Composite and discrete samples were both used to make decisions for the site.

The Spring Valley case study focused on the sampling activities (both representative site samples and background samples) and the risk assessment activities and methodologies used at the site. Following risk assessment activities, a consensus was reached among the Spring Valley Partners that an appropriate arsenic cleanup level of 43 mg/kg would be used for inaccessible soils under hardscapes (e.g., driveways, patios, etc.) and a cleanup level of 20 mg/kg (maximum discrete sample concentration within the grid) would be used for all accessible soils. The objective behind the development of the cleanup levels was to reduce the risk of arsenic exposure to human health and the environment. Cleanup levels developed were considerably influenced by the background of arsenic and results of the risk assessment.

Once the cleanup values were determined, the remaining properties of concern (with the exception of the large properties) were sampled using an EU of approximately ½-acre lots. EPA soil screening guidance was used to inform the development of the sampling scheme used to determine whether lots required further study for remediation. Lots in areas suspected to contain contamination were divided into quadrants, and six samples were taken as a composite in each quadrant for a total of four samples analyzed/lot. Lots in areas with lesser probability for contamination were divided into two halves with eight subsamples taken per half and composited. If any of the composite samples exceeded an action level of 12.6 mg/kg arsenic, the lot was then surveyed to establish 20 × 20 foot grids. Sampling and remedial activities were then conducted using the grid layout to determine when remediation was complete or warranted within certain areas of the EU. Each grid cell was represented by a single discrete sample. Grid cells containing arsenic above the 20 mg/kg cleanup goal for arsenic were removed and disposed of off site. Deviations from the aforementioned sampling/remediation scheme were made on a case-by-case basis typically due to either a larger property, previous investigative activities within the property boundary, or location of the property being outside the central testing area.

Lessons Learned

The case study demonstrates an approach where criteria derived using risk-based factors were systematically used to influence risk management decisions. Criteria and sampling strategies varied through different phases of the study. The Spring Valley case study demonstrates that composite soil samples may be used for making risk-based decisions. This type of sampling strategy was used during in the initial stages of site sampling to determine whether chemicals were present at concentrations of concern that may have warranted further delineation. If a lot exceeded the initial screening criteria, the lot was gridded, and discrete samples were collected from each grid. Soils were removed from grids where concentrations exceeded the risk-based cleanup levels (RBCLs). Composite sampling can be a cost-effective strategy for site characterization due to the reduced number of samples sent for laboratory analysis.

Because the land had been redeveloped into individual lots, the property owners had significant voice in establishing cleanup goals for the project. Most of the community supported the cleanup process since the property owners had input in setting the cleanup goals and the remediation strategy. This case illustrates the importance of community participation during the investigation and remediation.

The 20 mg/kg arsenic cleanup goal was applied as a not-to-exceed concentration, and soils with arsenic levels above 20 mg/kg were removed and replaced with clean fill. Such a removal strategy would, in most cases, result in a post-removal EPC that is lower than the remediation goal. In other words, more contaminated soil than necessary was removed and disposed of off site. However, in terms of implementation, impacts to the project from any overexcavation were insignificant due to low off-site disposal costs. Impacts to property owners from any overexcavation were also low due to their involvement in selecting less stringent cleanup goals to save desired landscape features where necessary. Managing the risk at the site was integrated with property owners' needs by involving them in decisions such as using a higher remediation goal to preserve landscape features.

4.2.2 Evergreen, Washington

- U.S. Army former firing range and training facility.
- Triad approach used to develop sampling plan that included field characterization methods, with focus on collecting sufficient data for potential future actions.
- Lead, antimony, and copper were COCs; lead was the risk driver.
- IEUBK with safety factor used to calculate cleanup goal.
- Soils excavated, treated on site, and used to construct a new berm.

The Evergreen Site is a 4-acre former firing range/ training facility that was removed from service in 1965. The property was slated for construction of barracks in the near future and therefore required immediate evaluation. The Triad approach with field characterization methods was used to determine the metals concentrations in surface soils. In the state of Washington the upper 15 feet is considered to be available for direct contact exposure. Lead was determined to be the COC, with a maximum detected concentration level of 62,500 mg/kg. The initial collection of samples also demonstrated that the contamination was limited to the impact berm and the area located immediately behind the berm. The total depth of contamination was determined to be 9 feet below ground surface (bgs); therefore, the entire site was considered to be the EU.

Following the initial characterization and the determination that cleanup activities needed to be expedited due to the construction schedule, a cleanup criterion of 250 mg/kg for lead was determined using the Washington State Department of Ecology Model Toxics Control Act *Guidance on Sampling and Data Analysis* (1995). The 250 mg/kg value was calculated using an unrestricted land use scenario; therefore, the guidance recommended the use of the integrated exposure uptake biokinetic (IEUBK) model for lead in children to be used along with a safety factor. The goal behind the use of the IEUBK model was to prevent unacceptable blood lead levels in children who might come in contact with the contaminated soils. Impacted soils ranging

0–7 feet bgs were excavated, treated on site, and then moved to an active firing range and used to construct additional berms. The land at the Evergreen Site was available in time for the barracks construction to begin on schedule. These activities were completed using ITRC's guidance document *Characterization and Remediation of Soils at Closed Small Arms Firing Ranges* (ITRC 2003a).

Lessons Learned

This case study demonstrates that field analytic methods, such as X-ray fluorescence (XRF), a field analytical method employed to characterize lead at the Evergreen Site, can play a role in risk-based decisions. Many believe that real-time data should not be used in risk assessment. However, this project included a demonstration of the field method's applicability and the field method's ability to appropriately match off-site laboratory results and also meet desired detection limits prior to implementing the method site-wide. With appropriate quality assurance/quality control (QA/QC), data collected in the field can be a reliable source suitable for risk assessment. Effective use of field instrumentation not only allowed the project to be completed in a shorter time frame than is usual but also allowed for more data points to be collected within the project's budget. The collection of more data points reduced the uncertainty related to the heterogeneity of contamination.

The project used risk management to select cleanup goals and selected a cleanup goal that is more conservative than is usually implemented on lead sites to move the site into remediation quickly. In selecting the cleanup goal, the costs of managing excess lead-impacted soils and additional study to support a higher cleanup goal were balanced with the land manager's desire to quickly reuse the property for a construction project. The amount of soils that required handling may have been reduced if a statistical approach had been used to establish a site-specific cleanup goal, as opposed to a more stringent ("brightline") goal. Instead, it was decided that 10% of samples could not exceed the 250 mg/kg criteria, and the 95% upper confidence of the mean concentration of post-excavation soils could not exceed 250 mg/kg. Two times the remediation goal was applied as a not-to-exceed criteria and appeared be to an arbitrary, rather than statistical, determination.

4.2.3 Whitebridge, California

- Former commercial orchard proposed for residential redevelopment.
- Lead, arsenic, dieldrin, DDT, DDE, endosulfan, sulfate, and endrin aldehyde all determined to be COPCs.
- Preliminary risk assessment and subsequent site-specific risk assessment both showed potential for risk.
- Probabilistic modeling ruled out risk at part of site and reduced number of COCs. Arsenic was risk driver.
- RBCL for arsenic was the 95th percentile probabilistically derived value of 36 mg/kg.

The Whitebridge, California site was proposed for residential development after commercial orchard operations at the site ceased in the late 1980s. The site consisted of a 184-acre parcel of land containing 93 acres used in the past as an orchard. The remaining acreage was undeveloped native forest and brush land. The past land use resulted in concern about potential residual pesticides that could impact future residents. The property was proposed for division into parcels with an average size of five acres and using individual septic systems. The developer wanted to retain as much native soil as possible to meet the requirements for septic systems and, thus, wanted to minimize soil removal.

Initial investigations conducted 1998–2001 confirmed that pesticides had been used on the property. Arsenic, lead, and organochlorine-based compounds, including DDT, were all detected in the surficial soils (defined here as 0–12 inches bgs) in the orchard area of the site. During initial investigations, it was discovered that the former chemical-mixing area (a.k.a. the remote fill area) was also contaminated. Eight COPCs were determined in this area: lead, arsenic, dieldrin, DDT, DDE, endosulfan, sulfate, and endrin aldehyde.

Following the initial investigation, a screening level risk assessment was conducted. The risk assessment was based on EPA's RAGS and used the maximum concentrations as the EPC. The cumulative risk goals to receive an NFA determination were set at 1×10^{-6} for the individual excess lifetime cancer risk level (IELCR) and at 1.0 for the HI level. The lead risk evaluation, however, was different. The LeadSpread model (California Department of Toxic Substances Control [DTSC]/Office of Environmental and Human Health Assessment [OEHHA]) was used to estimate blood lead levels and compare them to a screening level of 10 µg/dL of lead in blood. The initial risk assessment indicated that COPCs may pose a risk to human health.

A more site-specific approach to the risk assessment was then employed. Using RAGS, CalEPA toxicity criteria, and the CalEPA LeadSpread model, a deterministic risk assessment was conducted, using more site-specific exposure values as well as the 95th UCL of the mean (instead of the maximum detected concentration) to determine the EPC. Results from the deterministic risk assessment indicated that the orchard area and the remote fill area contained levels of COPCs that may pose unacceptable risks to human health. The site-specific assessment demonstrated the potential for an unacceptable risk to the child and adult receptors in both areas and the construction worker receptor in the remote fill area. Background concentration of arsenic was identified as 27 mg/kg based on sample results from undisturbed soils in the area. To remove soils containing arsenic above background would have made several of the lots potentially unusable for septic systems.

To further evaluate the range of potential risk, a PRA was completed in accordance with EPA guidance. While deterministic risk evaluation uses one value as "representative" of the entire receptor population, the PRA "samples" from the distribution of values for selected parameters (e.g., body weight, inhalation rate, etc.). Multiple iterations of risk calculations are performed, resulting in a distribution of calculations for risk and hazard. Risk managers then select the remedial goal from this distribution. The 95th percentile was selected, and the RBCL was calculated at 36 mg/kg arsenic. The PRA indicated that COPC levels within the orchard area did not pose risk above the risk management goal and, therefore, no remedial action was necessary. Arsenic concentrations ranged from less than 1.0 mg/kg to 124 mg/kg.

The results of the PRA in the remote fill area, however, indicated that potential exposures could lead to noncarcinogenic health risks for both the adult and child receptors. Furthermore, it was determined that arsenic contributed to more than 98% of the risks present in the remote fill area. Therefore, it was determined that it was necessary to develop an RBCL only for arsenic in the remote fill area. The RBCL for arsenic was the 95th percentile probabilistically derived value of

36 mg/kg. To verify that the 36 mg/kg was health-protective, a deterministic risk assessment was completed that demonstrated that the cumulative risk for the remote fill area would yield an HI of 1.0 and an IELCR of 2×10^{-5}, which are within the acceptable risk management range.

Although 1×10^{-6} was used as the point of departure for deterministic risk assessment, which uses conservative values for all parameters, the probabilistic evaluation uses the entire the distribution of possible values and can be more representative of actual expected outcomes. As such, the Tier 3 risk assessment verified that the RBCL of 36 mg/kg was within the acceptable risk management range. This case study shows how risk assessment and risk management can be intertwined in the site cleanup process. In addition, to minimize cost, the contaminated soils were placed under roads and in an on-site containment cell, which were both deed restricted.

Lessons Learned

This case study illustrates an iterative approach to risk assessment and risk management. Several decision points were reached in this case study. During the investigation and remediation activities the following choices had to be made:

- whether to use the risk assessment conclusion and the uncertainty associated with assessment as the basis for selecting remedial alternatives
- whether to decrease the uncertainty of the risk assessment by investing in further study

Investing in further study (i.e., the PRA) likely led to overall project cost savings, as it resulted in a finding of acceptable risk, avoidance of site remediation for some portions of the property, and a reduction of COCs for other portions of the property. This case study also showed an innovative use of contaminated material by allowing it to be placed as fill under roadways and in an on-site containment cell that were deed restricted so that contamination would not be accessible for direct contact by residents. PRA may be more representative of the ranges of actual conditions that could occur at a site than the more conservative deterministic assessment. PRA results can be useful in showing risk managers the range of potential risk estimates using site-specific values for the various evaluation parameters.

4.2.4 Grand Street, New Jersey

Two buildings and an asphalt-covered parking area in Hoboken, New Jersey constitute the Grand Street Mercury Site (GSMS). One of the buildings, a five-story former industrial building, was converted into 16 residential/studio spaces between 1993 and 1995. All but one of the conversions were completed prior to identification of site-wide mercury contamination.

The site was contaminated as a result of more than 50 years of production of mercury vapor lamps and mercury connector switches. Free-flowing liquid (elemental) mercury was observed between flooring layers throughout the former industrial building. Mercury vapors were detected above health-based concentrations throughout both buildings. Mercury was also observed to have adsorbed to porous wood, brick, and tar surfaces throughout the former industrial building.

- Former mercury gas lamp and mercury switch manufacturer.
- Contamination discovered upon completion of conversion to residential units.
- Residents relocated upon discovery of high levels of contamination.
- Cleanup goals (23 mg/kg mercury in soil) based on residential risk from soil ingestion, as well as protective of inhalation. Higher goal developed for subsurface soils protective of utility workers.
- Composite and discrete samples were both used to make risk-based decisions for the site.
- Remediation consisted of demolition followed by excavation and off-site disposal of contaminated soil and building debris.
- This case study highlights not only how risk assessment is managed in New Jersey but also how risk assessment is managed at a Superfund site located in the state.

Investigations indicated that inhalation of or direct contact with mercury at the site posed a threat to human health. In addition, soils were contaminated with mercury above residential health-based levels. Sampling results determined that 20 residents, including five children, possessed levels of mercury in their urine that might cause subtle neurological changes and renal tubule (kidney) effects. Mercury was widespread, and the building could not be remediated for residential purposes.

In April 1997, EPA conducted a Baseline Human Health Risk Assessment (BHHRA) that identified significant risk to both children and adults residing at the site, as well as to potential future workers, due to inhalation of mercury vapors. The BHHRA also identified potential unacceptable risk to children exposed to contaminated soil. In September 1997, EPA issued a record of decision (ROD) for the site that included permanent relocation of residents from the site; demolition of the two contaminated buildings; sampling, excavation, and off-site disposal of contaminated soil at EPA-approved facilities; and groundwater and off-site soil monitoring.

EPA provided relocation (temporary then permanent) to all affected residents by January 1996. Twenty-four-hour security was provided, the buildings were maintained to prevent exposure to the elements, and further off-site migration of mercury was prevented.

The site-specific preliminary cleanup goal of 23 mg/kg, based on an HI of 1, was determined using the results of the BHHRA to be protective of the inhalation and ingestion pathways (the Draft Final BHHRA as prepared by Weston for EPA Region 2, April 1997). At the time of this site decision, the New Jersey residential criterion of 14 mg/kg was under revision and subsequently determined to be 23 mg/kg. The ROD was modified in April 2003 through an explanation of significant differences (ESD) explaining that the soil remedy had been changed to include removal and off-site disposal of all soils on the adjacent properties found to contain mercury at levels greater than 23 mg/kg and restoration of the adjacent properties to their preconstruction conditions. The soil remedy was modified again in July 2004 through another ESD to provide for additional soil excavation and off-site disposal. Specifically, site subsurface soils located below the water table and having an average mercury concentration of 520 mg/kg would be excavated (based on potential risk to an on-site utility worker) and disposed of off site.

A third ESD was issued in September 2005, indicating no action for the underlying groundwater would be needed since it was found to pose no risk to human health or the environment. The third ESD completed all planned remedial actions for the site. Since the issuance of the ROD in 1997, the residents of the former industrial buildings at the site have been permanently relocated, the former industrial buildings have been demolished, contaminated soils have been excavated, the excavations have been backfilled with clean soil, and the debris has been disposed of at EPA-approved facilities. The site owner plans to build condominiums on the property in the future.

Lessons Learned

This case study used different kinds of sampling schemes to inform risk-based decisions. Both discrete sampling and core composite samples were used to characterize the site and in the risk assessment. The uncertainty of using such a sampling strategy was addressed in the risk assessment's uncertainty analysis as potentially underestimating risk. This case study shows that creation of different cleanup goals for surface soils and subsurface soils may be appropriate and provide for protection of different populations that may encounter soils at the site in the future. In this case 23 mg/kg mercury in surface soils is based on ingestion and protective of inhalation by future residents, but a value more than 20 times higher (520 mg/kg mercury) was protective for soils below the water table where contact (by utility workers) would be much less frequent.

Although GSMS was an EPA National Priorities List (NPL) lead site, NJDEP worked closely with EPA Region 2 to ensure compliance with New Jersey Administrative Code 7:26E Technical Requirements for Site Remediation (TRSR). This case study compares and contrasts not only New Jersey's and EPA Region 2's approach to risk assessment but, just as importantly, the manner in which the risk-based cleanup number(s) were used throughout all investigative as well as remedial phases of the case. Below is a general comparison table of risk assessment and its use by New Jersey and EPA Region 2. More comparisons and contrasts, especially in regard to how the risk assessment generated number(s) were used, are presented in Appendix B (on the accompanying CD-ROM).

Table 4-1. EPA Region 2 vs. NJDEP comparison table

	EPA Region 2	**NJDEP Site Remediation Program***
BHHRA required?	Yes	No
Risk range—carcinogenic	1×10^{-4} to 1×10^{-6}	1×10^{-6}
Hazard index—noncarcinogens	1	1
Surface vs. subsurface distinction	Yes	No
Required depth of delineation	Typically 0–2 feet	To a "clean zone"—regardless of depth
Discrete or composite sampling (surficial)	Both	Discrete only
Grid or biased sampling	Grid or combination	Biased only

In regard to reconciling differences, EPA Region 2 agreed to collect discrete post-excavation samples at the request of NJDEP. In addition, delineation was accomplished to the most stringent criterion (23 ppm).

The GSMS case study shows that, although this NPL site was addressed through federal and potentially responsible party actions, NJDEP worked closely with EPA Region 2 to ensure compliance with the New Jersey requirement of TRSR.

4.2.5 Wisconsin LUST Site

The Wisconsin leaking underground storage tank (LUST) site is an operating gasoline station in Milwaukee. The site is located in a high-traffic commercial and light industrial area and is approximately 0.7 acre (31,000 ft^2) in size. During installation of a new petroleum underground

- Operating gasoline station with release from tank system being replaced.
- Benzene is the primary COC with concentrations up to 13 mg/kg.
- Benzene concentrations exceeded Wisconsin's direct-contact concentrations and inhalation and ingestion concentrations using EPA's soil screening guidance calculator.
- Based on the discovery of a hot spot, a barrier cover maintained per institutional control to prevent direct-contact human exposure was required.
- Change in law requires "detailed closure letter" in lieu of deed restriction.

storage tank (UST) system in 1994, soil samples were collected from the tank basin walls and at dispenser piping trench locations to assess the site for previously released petroleum. The trench samples were collected at an approximate depth of 3 feet bgs; the basin samples were collected 6–7 feet bgs, the depth of the petroleum contamination "smear zone" across the groundwater table.

Benzene, the primary COC, was detected at 13 mg/kg in one of the piping trench samples—a roughly 20 g "discrete" soil sample collected beneath a former fueling dispenser. The benzene concentration exceeded Wisconsin's direct-contact soil screening level of 1.10 mg/kg. In Wisconsin, the direct-contact zone is the 0–4-foot depth interval at a site; therefore, the benzene concentration in the piping trench sample constituted a potential direct-contact risk.

In addition to exceeding Wisconsin's direct-contact screening level, the benzene concentration exceeded the "inhalation of volatiles" (infinite mass) and "age-adjusted ingestion" soil screening levels (1.6 mg/kg and 11.6 mg/kg) calculated using EPA's soil screening guidance calculator.

Based on historical soil boring data and the results of three direct-push borings installed near the hot spot sample location, the benzene hot spot was estimated to possibly cover 0.05 acre, or 6.3% of the station property. Because the site is an operating filling station no longer owned and operated by the responsible party (RP) and the hot spot is located beneath the existing dispenser island pad, excavation of the area was not an option the current owner was willing to consider. In addition, it was not a cost-effective option that the state would have reimbursed.

Consequently, the selected approach to case closure was a requirement that the current and future site owner must maintain a "barrier cover" of at least 2 feet of "clean" soil (or soil and pavement) over the hot spot area, per state guidance. Initially, the requirement, including a barrier cover maintenance plan, was to be recorded on the site's property deed as a deed restriction; however, with a subsequent change in state law, the site was closed with a "detailed" closure letter that included the land-use limitation (i.e., barrier cover and maintenance plan). The site was placed on the state's geographic information system Registry of Closed Remediation Sites to notify the public.

This was the most cost-effective and least disruptive approach for closing the site, and, with the change in state law, was less onerous and stigmatizing than placing a restriction (essentially a permanent record) on the property deed. Furthermore, because the residual hot spot contamination was more than 2 feet below the site pavement, the RP (in this case, the former site owner) was clear of future liability for maintaining the pavement.

In summary, the site was closed with a "barrier cover" requirement to prevent possible human direct-contact exposure to benzene detected above the risk-screening level.

Lessons Learned

This case study illustrates limitations commonly encountered when developing remediation and/or closure plans based on limited soil data collected during investigations at small petroleum storage tank sites (e.g., corner gasoline stations). Typically, soil sampling is focused on determining the extent and magnitude of contamination associated with releases at known or suspected source locations. Sampling is generally not conducted in a systematic way to support risk assessment of LUST sites.

If a site is an operating facility, such as the Wisconsin LUST site, sampling may not be possible where the actual or potential risk from shallow contamination is greatest (e.g., under fuel dispensers and piping runs, near tanks). Potential risk is often detected incidentally, such as when a shallow soil sample from a given soil boring is selected for laboratory analysis because it appears to exhibit the highest contamination level in the boring or, as exemplified by the Wisconsin LUST site, soil samples are collected at prescribed locations under a tank system during a tank system site assessment. Usually, more highly contaminated soil samples from the water table "smear" zone are submitted for analysis, while shallower contaminant levels are inferred from field (e.g., photoionization detector) measurements of soil vapor levels.

All too commonly, potential risk is identified and addressed at the time a state regulator reviews a request from the RP for site closure. At this point, it is often left to the regulator to establish the final requirements for site closure. In states such as Wisconsin, where petroleum tank site investigation and remediation costs are heavily reimbursed by the state, addressing risk at the time of closure becomes an exercise in generic risk management. In other words, protective decisions are made based on possible risk (i.e., a soil sample or two exceeding a risk-based soil screening level), not actual (validated) risk. This approach often leads to overly restrictive site closures and, on occasion, excessive remediation efforts (e.g., placement of a "barrier cover" over a possible direct-contact risk location).

The outcome for the Wisconsin LUST site was based on a single soil sample hot spot and illustrates the need for further development of practical risk management/decision-making processes, at least relative to petroleum contamination.

5. STATE REGULATORS' PERSPECTIVES: COMPARATIVE CASE STUDIES

After completing the review and evaluation of five case studies (Spring Valley, Evergreen, New Jersey Mercury Site, Whitebridge, and a petroleum site in Wisconsin), Risk Assessment Resources Team members embarked on creating and evaluating hypothetical sites. The objective of this undertaking was to present state regulators with the same data set and background information to evaluate how approaches, numerical criteria, analyses, and determinations would compare among responders. The undertaking complemented the effort made in evaluating case studies of actual sites and projects by limiting the many variables apparent when evaluating multiple sites and allowing a more objective comparison between various state approaches. The evaluation of hypothetical sites became known as "comparative case studies."

Chapter 5 Highlights

- Variation in risk assessment practices can be based in programmatic preferences or in technical differences of opinion.
- Variations in risk assessment practices can have significant impacts on risk assessment outcomes and subsequent risk management decisions.
- The major source of variation discerned in the comparative case studies is that the linkage between how one establishes (defines) an EU, samples that EU, and evaluates (analyzes) the results leads to major differences in risk management outcomes.
- The variation observed in the comparative case studies is over application of fundamental risk assessment principles applied to relatively simple conditions. This finding has implications (would be applicable, perhaps extrapolatable?) for more complicated conditions.
- The comparative case studies proved to be an invaluable tool for understanding approaches and differences in risk assessment. The team encourages risk assessment professionals not only to undertake for their own understanding the comparative case studies developed for this report, but to expand the concept to more complicated site conditions and settings.

The team conducted two comparative case studies. The first began with creation of a hypothetical site, including background information and soil analyses. Then state regulator team members were asked to complete a modified version of the data collection sheet used for the five case studies discussed in Chapter 4. It soon became apparent that the most efficient approach was to collect state representatives' responses to pertinent questions directly into tables. This became the format for conducting both the first and second comparative case studies.

Both the first and second comparative case studies focused on "simple" risk assessment scenarios. The sites were constructed to have soil contamination and CSMs that would have only a completed soil ingestion pathway—other pathways were not significant—to enable the most direct comparison of approaches and in the hope that risk assessment principles and practices associated with the use of soil exposure criteria would be most readily apparent.

The first hypothetical site includes one compound (lead) and one potential exposure scenario (future residential land use). The questions of interest focused on how soil contamination data would be used to evaluate the site, what remediation goals might be developed, and how they would be implemented. The second hypothetical site was created to have multiple contaminants with current residential land use. In the second hypothetical site, several variables, including the definition of "shallow soil" and the numerical criteria used to evaluate the contaminants, were fixed and not allowed to vary among responders. This approach was taken to enable a clearer examination of any variations in how numerical criteria are used by the respondents.

The results of both the first and second comparative case studies are summarized here in Chapter 5. The responses to all questions for both the first and second comparative case studies are available in Appendix C (on the accompanying CD-ROM).

5.1 The First Comparative Case Study

The hypothetical site constructed for the first comparative case study is a former skeet range that is proposed to be developed into a six-lot residential neighborhood. The former skeet range was sampled at 77 locations for lead. Soil samples were taken from 0–6 and 6–12 inches at each sampling location, and occasionally a third sample was taken 2 feet bgs. Some duplicate samples were included in the data set. EPA Method 6010/6020 was considered to be the method used to analyze samples, and analytical results were provided. A plan view of the proposed development—including the sampling locations—is provided in Appendix C. The data set associated with the comparative case study is also provided in Appendix C.

Participants were initially asked to complete case study data collection sheets, which had been modified from the previous case study exercise to be more reflective of the comparative case study. The participants in the comparative case study were asked to complete the case study data collection sheets in the prospective mode—describing what options might be acceptable and what the preferences and requirements (sampling, removal, etc.) might be for those options. This approach evolved into collecting state representatives' answers directly into tables and providing opportunity for clarification and explanation in the text.

5.1.1 Information Collected from Each State Representative

A major objective in undertaking the first comparative case study was to capture similarities and differences among participants concerning several key interests of the team. Some of those interests were probed through questions such as these:

- What value is measured/calculated at the site, the highest value or an average, and over what area/volume do you average?
- How is the average developed (simple average, UCL, etc.)?
- What value is measured/calculated to compare against the various risk-based criteria? Does that vary throughout the site cleanup process?
- How are risk-based criteria used throughout the sampling and cleanup process of a project?
- How would you handle the relatively "high" measurements that are commonly reported, especially those "high" measurements that might be surrounded by less remarkable levels of lead?
- Would the "high" measurements be averaged with adjacent samples to provide an estimate of the average level throughout an exposure area (volume), and what would that area (volume) be? Or, would hot spot removal be required regardless of surrounding measurements? What is the basis and available guidance?

The results of this comparative case study are presented in a series of summary tables in Appendix C. Answers to selected questions are discussed here in this chapter.

5.1.2 What Values for Lead Are Used Throughout the Remediation Process?

When contamination is encountered in soil, invariably the first question asked is, "What is the number for that chemical?" That "number" may come from any one of several resources, and, as seen in the five case studies of actual projects described in Chapter 4, may vary with stage of the remediation process or other considerations associated with the project.

State representatives were asked to provide the "number" or "numbers" for lead in soil that would be appropriate throughout the various stages of remediation of the comparative case study. The objective was to determine similarities, sources for the various "numbers," and when a specific value might change throughout the remediation process. Table 5-1 presents the responses.

Table 5-1. Values for lead (mg/kg) throughout the course of the remedial process

State	Early	Remedial investigation	Risk	Feas-ibility study	Remedy moni-toring	Confirm-ation of remedy
Alabama	400	After initial assessment, site-specific input is used and use of the IEUBK Model or the Adult Lead Model is required for those calculations.				
Arkansas	400 or 800 (heavy industrial)	After initial assessment value, site-specific input is used.				
California	150 (value of 150 LeadSpread model is basis)	150	150. Might change as a result of risk assessment and/or risk management.	150	150	150
Florida	400	400 mg/kg throughout, based on the IEUBK model, but from here on the IEUBK model could be run with site-specific inputs.				
Georgia—RCRA	400	Based on risk assessment and use of IEUBK and/or Georgia Adult Lead Model.				
Georgia—HSRP	75	After initial assessment, default values of 75 residential/400 nonresidential can be used or site-specific based on IEUBK or Georgia Adult Lead Model. 75 is default regulatory value for state program.				
Massachusetts	300	Under different situations, default values of 100, 300, or 600 mg/kg can be used, or a site-specific risk-based value may be calculated.				
New Jersey	400	400 mg/kg throughout, based on the IEUBK model, but from here on the IEUBK model could be run with site-specific inputs when appropriate.				
Tennessee	400	400	400	400	400	400

The hypothetical site for the first comparative case study was constructed to have varying levels of lead in soil across the six residential lots. The case study respondents were asked to identify the numerical criterion (or criteria) that would be used to evaluate the contamination, given that a residential development would be a future residential exposure scenario.

Values of numerical criteria to evaluate soil contamination with lead ranged from 75 mg/kg up to 400 mg/kg, with most state respondents including the value of 400 mg/kg that comes from the IUEBK model and is the residential soil screening value used by EPA Regions 4, 9, and 3. However, other sources and variations to the IUEBK model were identified by some responders.

Several states indicated that the value identified as most appropriate for the initial stages of the investigation would change based on site-specific information and site-specific risk assessments.

5.1.3 Are Lots Evaluated Individually or All Together as One Unit?

The first comparative case study presented 170 measurements of lead in soil from 77 sampling locations distributed across approximately 1.2 acres, along with a plan for development that would eventually provide six residential lots. The values one would calculate as averages would be different depending on whether one considers the six proposed residential lots together or separately. In large measure this question was asked to surface differences in how the data would be processed: Would all 170 data points be linked together, or would the data points on each proposed lot be linked together?

Several state respondents indicated that the proposed lots would be evaluated individually (Table 5-2). This approach would give rise to data "sets" for each lot (with 6–23 sampling locations, with samples at two and sometimes three depths for each location) that would be evaluated for each proposed lot. Other states indicated that all six proposed lots would be evaluated together—creating only one data set.

Table 5-2. How are data evaluated—by lot or all together?

State	Individual lots	All 6 lots together	Notes
Alabama	X		Under a "current conditions" scenario where the exposure scenarios are the same and the property is owned by one person, that entire area would be considered one exposure area. However, in this case, it has been defined that the area will be owned in the future by separate entities. This causes the risk to be evaluated based on a "future use" scenario. Each lot will be treated as a separate exposure area (or "exposure domain" as Alabama refers to it).
Arkansas		X	Note: All six together would be typical, but individually might be accepted in Brownfield Program.
California	X		Individually, since lots are legally described.
Florida	X		
Georgia—RCRA		X	Properties would be considered one solid waste management unit.
Georgia—HSRP		X	The properties would be considered one site since there is one source of a release.
Massachusetts	X		Every data point is evaluated in hot spot evaluation.
New Jersey	X		
Tennessee	X		Each lot would be considered an exposure area.

Arkansas indicated that the question of how to evaluate the data might be treated differently in different programs. Georgia was clear that the data would be treated differently among different programs: under the Hazardous Site Response Program (HSRP), every data point would be considered individually against the program-specific number for lead; under the RCRA program, all data would be considered together.

While all states have a mechanism for evaluating data points in sets, all states consider each data point at some point in the process. In the context of a risk assessment, this dichotomy—allowing groupings of data but still evaluating individual data points—would not allow a single answer to the question, "What value should be measured at the site to be compared against the numerical criterion?"

This situation may underscore a fundamental distrust of statistics (i.e., averaging), concern that the exposure will indeed be random, or concern of the uncertainties associated with site characterization. The evaluation of hot spots—elevated singular measurements—was suggested to be based upon the premise that future land use is uncertain. However, in the current case residential land use was specified.

5.1.4 How Is the EU Determined?

Risk assessment focuses on identifying the time-variable (prolonged) level of exposure that—if sufficient—would cause an adverse response. Central to this approach is the development of an exposure scenario that would create any exposure in the first place. In the first comparative case study, a (proposed) residential setting was selected, and exposure to shallow soil was the focus as a way of simplifying the analysis and allowing a more direct comparison of responses.

In risk assessment terminology, exposures to shallow soil are evaluated throughout an area, typically called the EU. Table 5-3 shows the responses to the question, "How is the EU determined?"

Table 5-3. How is the EU determined?

State	Notes
Alabama	Site specific
Arkansas	Site specific
California	Site specific
Florida	¼ acre = default lot size
Georgia—RCRA	Site specific
Georgia—HSRP	Averages not allowed
Massachusetts	Lot size
New Jersey	Lot size
Tennessee	Site specific

In approaches to risk assessment, the concept of an EU defines the area throughout which extended exposure is assumed to occur. The concentration used when quantifying the risk to a receptor across an EU is an estimate of the true average concentration for a chemical within that EU. This concentration is referred to as the EPC. It was assumed that the answer to, "How is the EU determined?" should be equivalent to the answer to the question, "How would you evaluate the project—by individual lot or all lots together?"; however, this was not the case.

One state (Florida) has clearly defined by regulation a default value for the area of an EU, which corresponds to a typical residential lot. Other states would set the dimensions of an EU based on the size of a residential lot. One state that relies on risk assessment variously throughout the remediation process (New Jersey) would still define an EU, even though that EU would not be relevant when every sample is required to comply with the soil criterion during remediation and confirmation.

5.1.5 Is Horizontal Averaging Allowed?

As a follow-up to the question about EU, it was of interest to evaluate how horizontal averaging (which for purposes of risk assessment should be used to establish an EPC for a given EU) was practiced. Table 5-4 presents responses to the question, "Is horizontal averaging allowed?"

Table 5-4. Is horizontal averaging allowed?

State	Yes	No	Method
Alabama	X		95% UCL about the mean measured over the site-specific EU.
Arkansas	X		
California	X		Lots evaluated individually. Excavation proceeds until 95% UCL of the mean concentration for each lot is less than the remedial goal.
Florida	X		95% UCL averaged over ¼ acre for a default residential lot.
Georgia—RCRA	X		Averaged over solid waste management unit.
Georgia—HSRP		X	
Massachusetts	X		Median or 95% UCL (provided there are enough data points).
New Jersey	X		During the remedial investigation phase (only) pursuant to 7:26E-4.8(c) 3i.
Tennessee	X		Over "contamination"—not a set area/dimension.

As expected, most states responding with relative certainty to the question concerning establishing an EU also allowed horizontal averaging. The one exception noted above is the Georgia HSRP, which requires that all sample points must comply with the cleanup criteria. One state (Florida) reiterated default averaging area—that of the typical residential lot (¼ acre). Four states volunteered that the average needed to be the 95% UCL.

Interestingly, New Jersey allows averaging but did not specify the area. Georgia's RCRA Program and Tennessee's respondent suggested that averaging could be over the area of contamination (over the area of a solid waste management unit in Georgia), which could be significantly different—larger or smaller—than the default size of a residential EU.

5.1.6 How Are Shallow and Deep Soil Defined?

In the context of exposure to contaminated soil, there is some interval near the surface where one should sample to evaluate whether the level of exposure exceeds a direct exposure criterion. At the same time, there is some depth beyond which soil is unlikely to be brought to the surface and available for direct contact exposure. These depths depend on human behavior and construction activities that would bring deep soil to the surface and redistribute it there and are not related to any level of contamination. This was discussed briefly in Chapter 3 as a source of difference between sampling for risk assessment and for identification of contamination. State representatives were asked how—if at all—"shallow" and "deep" soil were differentiated. Table 5-5 shows the answers to this question.

Most state responders provided a quantitative difference between "shallow" and "deep" soil. In at least one case (Massachusetts) three zones were identified, based on construction practices. Only two states set a "limit" on what constitutes deep soil; Massachusetts, down to 15 feet, and California, more than 10 feet. Other states do not address this limit, have no limit, or consider all soil to the water table available for redistribution to the surface.

Table 5-5. Definitions of shallow and deep soil

State	Shallow	Deep
Alabama	0–12 inches	12 inches to water table
Arkansas	0–12 inches	12 inches to water table
California	10 feet available (defined by concentration)	Below 10 feet
Florida	0–6 inches	24 inches to water table
Georgia—RCRA	0–12 inches	12 inches to water table
Georgia—HSRP	0–24 inches	24 inches to water table
Massachusetts	0–1 foot (imminent hazard [[IH]) 0–3 feet (residential) 0–15 feet (construction)	36–180 inches
New Jersey	0–6 inches initial characterization soil samples (except VOCs) pursuant to 7:26E-3.6(a)3.	No limit
Tennessee	0–2 inches (surficial) 0–24 inches (possible contact hazard)	Not defined

There is a general similarity in that "shallow" soil is often considered to be the top 6–12 inches. However, the depth at which soil is considered to be "deep" and less available for direct contact varies for California, which does not identify a unique horizon as "shallow"—that depth is 10 feet. However, the respondent for California indicated that the actual depth considered would be limited to the depth of contamination if less than 10 feet. This approach contrasts the aforementioned concept that the activities that might redistribute contaminated soil to the surface are independent of the occurrence of contamination and are related to construction and excavation activities typical of a residential setting.

In contrast, the respondent from Massachusetts indicated that averaging over the top 3 feet would be appropriate. As will be seen later (Sections 5.1.11 and 5.1.12), the Massachusetts respondent averaged over the top 3 feet even though conditions were essentially at "background" below 2 feet. At the same time, the California respondent averaged over increments of 6 inches within the top 1 foot.

Several states have a defined shallow soil limit, below which is a defined deep soil limit. However, New Jersey sets no limit at which soil would be considered deep enough to not be excavated and redistributed to the surface.

5.1.7 Is Vertical Averaging Allowed?

Most state respondents recognized a difference between shallow and deep soil as far as the conditions that would produce an unwarranted level of exposure. That recognition is manifested in some programs by identifying discrete depth zones within which an "average" value is appropriate and by identifying zones across which it is not suitable to calculate an "average" value for purposes of site or risk assessment. Table 5-6 provides responses to the question, "Is vertical averaging allowed?"

Responders from states with a practice of identifying discreet zones with depth generally allow averaging of results throughout that interval (horizontally) but not across depth intervals. Massachusetts and Florida appear to be the most definitive as to what can be averaged, allowing samples throughout zones from 6 inches thick to up to 15 feet thick in some instances.

Table 5-6. Is vertical averaging allowed?

State	Yes	No	Comments
Alabama	X		0–12 inches OK
Arkansas	X		Discrete zones
California	X		Site specific
Florida	X		0–6 inches 6 inches–2 feet 2–4 feet and every 2 feet thereafter
Georgia—RCRA	X		In most cases, data are separated into surface and subsurface soil
Georgia—HSRP		X	
Massachusetts	X		0–1 feet IH
	X		0–3 feet for residential (non-IH)
	X		0–15 feet for construction
New Jersey		X	
Tennessee		X	

Responders from states with a practice of identifying discreet zones with depth generally allow averaging of results throughout that interval (horizontally) but not across depth intervals. Massachusetts and Florida appear to be the most definitive as to what can be averaged, allowing samples throughout zones from 6 inches thick to up to 15 feet thick in some instances.

5.1.8 Are Composites Allowed?

Composite sampling provides a physical approach to determining an average value throughout an area or volume. While compositing has the disadvantage of not allowing a statistical determination of variance and hot spots, it has utility if the primary goal is determining the mean. In many circumstances, compositing is discouraged and perhaps not allowed because it might "miss" something. However, in some other circumstances compositing is allowed and even facilitated, as evidenced by guidance on the subject available from Alabama.

State participants were asked about compositing samples, and their responses are provided in Table 5-7.

Table 5-7. Are composites allowed?

State	Yes/No	Comment
Alabama	Yes	A minimum of five multiincrement samples each composed of a minimum of 30 increments may be used. This procedure enables the central limit theorem to be invoked, which then makes it appropriate to calculate a 95% UCL about the true mean. See Appendix A of the Alabama Risk-Based Corrective Action Guidance Manual (www.adem.state.al.us/).
Arkansas	Yes	Site-specific determination.
California	Maybe	Not for risk or confirmation.
Florida	No	Vertical composites are allowed within specified intervals: 0–6 inches, 6 inches–2 feet, 2–4 feet, and every 2 feet thereafter.
Georgia—RCRA	Maybe	Site by site determination.
Georgia—HSRP	No	
Massachusetts	Yes	Although allowed, not preferred.
New Jersey	No	
Tennessee	Yes	

5.1.9 Handling of Duplicate Samples

Soil contamination is spatially variable. If the small amount of soil actually used for chemical analysis were examined closely—as under a high-power microscope—one might discern pockets of soil with relative abundances of chemicals and pockets with relative absences of chemicals. A "sample" of each pocket would give a dramatically different result. Samples collected from next to one another would yield different analytical results.

Within the data set for the first comparative case study there were several duplicate samples. These duplicates gave rise to different results. How the state responders would address and use these different results was the objective of a question, the responses to which are provided in Table 5-8.

Table 5-8. Handling of duplicate samples

State	Comment
Alabama	Duplicates were averaged.
Arkansas	Not averaged.
California	Hot spots discussed. Duplicates not used other than for QA/QC.
Florida	Duplicates were averaged.
Georgia—RCRA	Duplicates were averaged.
Georgia—HSRP	Not relevant—all samples considered individually.
Massachusetts	Hot spots discussed. Use average of all detected concentrations (exclude nondetects unless all are nondetects).
New Jersey	Not averaged; highest of split.
Tennessee	Averaged.

State responders in some instances allowed duplicate samples to be averaged. In some cases the highest measurement was the one evaluated. This was true of New Jersey and under the Georgia HSRP, where the highest value would be the one compared with the numerical criterion. One state responder (California) suggested the duplicates would be used for QA/QC purposes and also discussed hot spots.

5.1.10 Can a Sample Be Considered a Site?

This question was asked to probe the various approaches to soil variability and also to test the confidence in both site assessment and risk assessment. In most cases, determining an EPC for shallow soil contamination in a proposed residential setting would require a number of measurements to be averaged—theoretically all measurements throughout the identified EU. However, soil contamination can be highly variable. This variability can test the confidence of anyone who would want to average values across an area—whether across an EU or some other dimension. Often there can be a concern stated that "something might have been missed."

The question, "Can a sample be considered a site?" is something of a surrogate question for probing approaches to addressing variability of soil contamination and also for probing the common practice of identifying hot spots. Two things seem expected from risk assessment on this subject. First, that early on in the investigation a single measurement—especially if it is one of only a handful of measurements—would be sufficient to consider a sample a "site"—or at least a condition meriting more investigation of the site. Second, as more measurements are made, it would seem that some logical groupings of data—as across an EU—could be used to represent the EPC.

Table 5-9 provides responses to the question, "Can a sample be considered a site?"—which asked for answers at various stages of the site cleanup process.

Table 5-9. Can a sample be considered a site?

State	Early	Remedial investigation	Risk	Feasibility study	Remedy monitoring	Confirmation of remedy
Alabama	Yes	No	No	No	No	No
Arkansas	Yes	No	No	No	No	No
California	Yes	No	No	No	No	No
Florida	Yes	No—needs delineation	No	No	No	No
Georgia—RCRA	Yes	Probably not	Probably not	Probably not	Probably not	Probably not
Georgia—HSRP	Yes—program standards are enforced as a brightline	Yes	Yes	Yes	Yes	Yes
Massachusetts	Yes—when a hot spot is considered to constitute a site	Yes	Yes	Yes	Yes	Yes
New Jersey	Yes	No	No	No	Yes	Yes
Tennessee	Yes	No	No	No	Yes	Yes

As expected, most states indicated that early on in the investigative phase of a site, a single sample could be sufficient for at least further sampling if not some identification of the property as an actual "site." One state (Massachusetts) would be categorized as considering "a sample as a site" throughout the various phases if a hot spot were reported.

Interestingly, respondents from two states with relatively different answers for other questions (New Jersey and Tennessee) would consider "a sample as a site" both at the start and during the end phases of a project. In New Jersey's response this would be attributable to the practice of comparing every sample to a numerical criterion at critical phases of the project (entry and exit) but allowing risk assessment in the intervening steps. In Tennessee's response this was attributable to following a similar practice at more critical phases of the remediation process where essentially "go/no go" decisions are required.

5.1.11 Supplemental Question #1—What Is (Are) the EPC(s) for the Comparative Site Case Study?

The responders were asked to process the data provided by estimating the EPC (or concentrations) for the data set provided. Table 5-10 provides their answers.

Table 5-10. Exposure point concentration(s) (mg/kg) for first comparative case study

State	**Lot A**			**Lot B**			**Lot C**			**Lot D**			**Lot E**			**Lot F**			**Across all lots**		
	0–6"	**6–12"**	**12–24"**	**0–6"**	**6–12"**	**12–24"**	**0–6"**	**6–12"**	**12–24"**	**95 0–6"**	**6–12"**	**12–24"**	**0–6"**	**6–12"**	**12–24"**	**0–6"**	**6–12"**	**12–24"**	**0–6"**	**6–12"**	**12–24"**
AL	412			480			350			493			134			132					
	95% Chebyshev, as recommended by ProUCL			95% Chebyshev, as recommended by ProUCL			95% Chebyshev, as recommended by ProUCL			95% Chebyshev, as recommended by ProUCL			95% Chebyshev, as recommended by ProUCL			95% Chebyshev, as recommended by ProUCL					
AR	Did not calculate an EPC. Used all data points above 400 mg/kg in 0–6 inch horizon.																				
CA	760	182		773	129		638	258		857	221	127	181	67	86	179	68	68			
	95% UCL using FL UCL (www.dep.state.fl.us/waste/categories/wc/pages/ProgramTechnicalSupport.htm) except for Lot F; with fewer than 10 samples, the highest value was used.																				
FL	760	182		773	129		638	258		857	221	127	181	67	86	179	68	68			
	95% UCL using FL UCL (www.dep.state.fl.us/waste/categories/wc/pages/ProgramTechnicalSupport.htm) except for Lot F; with fewer than 10 samples, the highest value was used.																				
GA-RCRA	281			281			281			281			281			281					
	Pro UCL			Pro UCL			Pro UCL			Pro UCL			Pro UCL			Pro UCL					
	Since the entire firing range is considered one solid waste management unit and therefore one exposure area, the EPC is the 95% UCL of all sample results for the entire site separated into surface soil and subsurface soil.																				
GA-HSRP	An exposure point concentration is not derived, and all sample results are individually compared to the cleanup concentration.																				
MA	193.4			284.4			185.5			200			78.8			70.3					
	Averages over the top 3 feet of the soil.																				
NJ	NJ does not use baseline risk assessment; all points above 400 mg/kg would require delineation and remediation (eliminate exposure) pursuant to 7:26E (Technical Requirements For Site Remediation N.J.A.C. 7:26E).																				
TN	289	98	NA	465	104	NA	250	120	NA	289	116	127	110	50	NA	98	43	NA	289	93	NA
	Simple average.																				

The state representatives responding to these questions provided a range of answers based on various approaches. Some states (Arkansas and New Jersey) did not provide a calculated EPC but rather identified sampling locations where a measurement of lead was reported to be higher than the numerical criterion. Two state responders (Massachusetts and Tennessee) provided a simple average. For Tennessee, reliance on the simple average is a practice limited to lead, and a statistical estimate would be undertaken for other compounds. In Massachusetts the reliance on the simple average appears to be the common practice.

Two states (Florida and California) provided lot-by-lot and depth-discrete estimates of EPCs.

5.1.12 Supplemental Question #2—What Soils Would Merit Risk Management?

State participants were asked to identify which areas of the hypothetical site would merit risk management. Approaches to this answer varied. One state (Florida) used the Florida UCL Calculator computer software to calculate 95% UCLs and to identify areas that—following a "virtual remediation"—would reduce the 95% UCL to below the numerical criterion. Most state responders identified areas bearing risk management based on hand-drawn contours and circles.

The range of answers to this question was quite large. The responder from Massachusetts indicated no risk management would be necessary. Massachusetts' approach was to develop a simple average over the entire area to a depth of 3 feet. In Georgia, the RCRA program—which averages the surface soil over the entire area—would require no risk management because the average concentration was below the remedial level, but another program would require risk management on a point-by-point basis. In Georgia under the HSRP, a leaching analysis would also be required to develop a site-specific cleanup level, so the actual risk management required might differ from that based on strictly direct contact exposures considered in this comparative case study.

In contrast to responses where no risk management would be required, New Jersey indicated that further delineation—or removal to a condition of no samples remaining above the numerical criterion—would be required.

As expected, the largest area identified meriting risk management was for California, where the numerical criterion for lead was identified as 150 mg/kg, less than half the value for other states.

Illustrations submitted to answer this question are provided in alphabetical order below. Where a state did not submit an illustration, the text describing the approach is provided.

Alabama

The state of Alabama cannot provide an illustration due to the nature of how the Alabama Department of Environmental Management handles risk management at sites. The areas of risk management within the EU are left up to the site to determine. The criterion that must be met following risk management is an appropriate number of confirmatory samples indicating that the 95% UCL is below the risk management value of 400 mg/kg for lead.

Arkansas

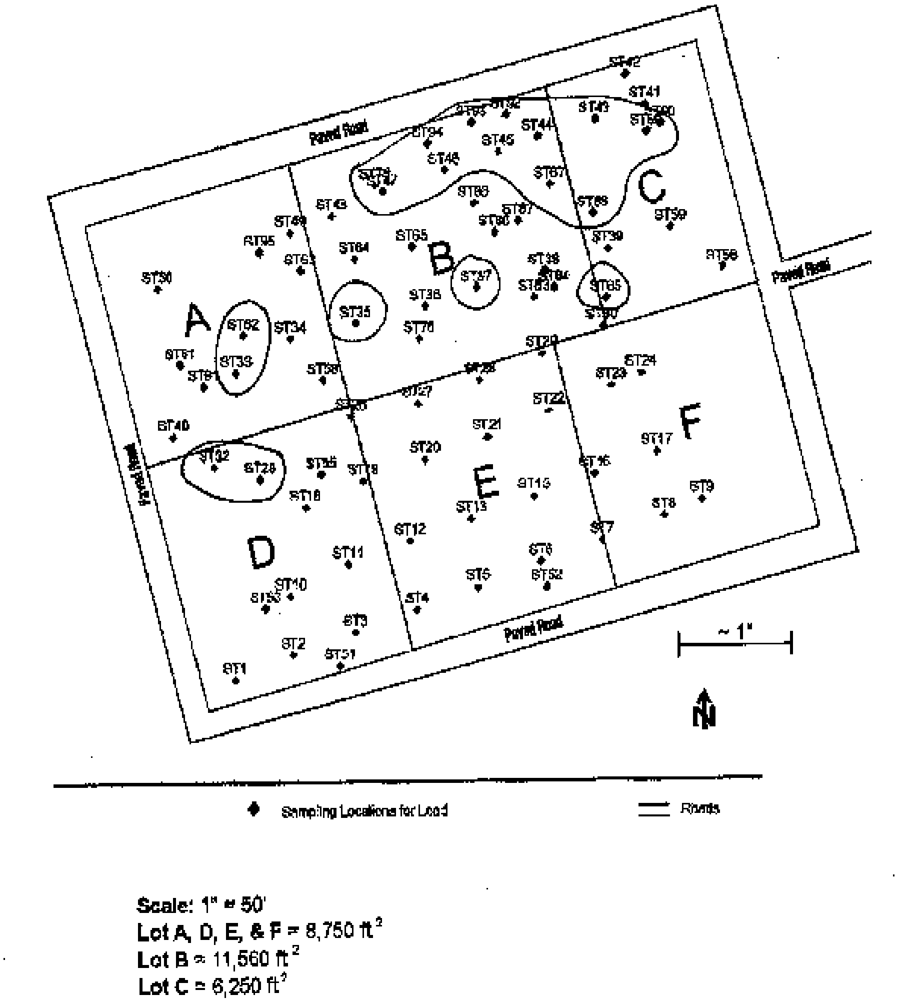


Figure 5-1. What soils would merit risk management for Arkansas?

California

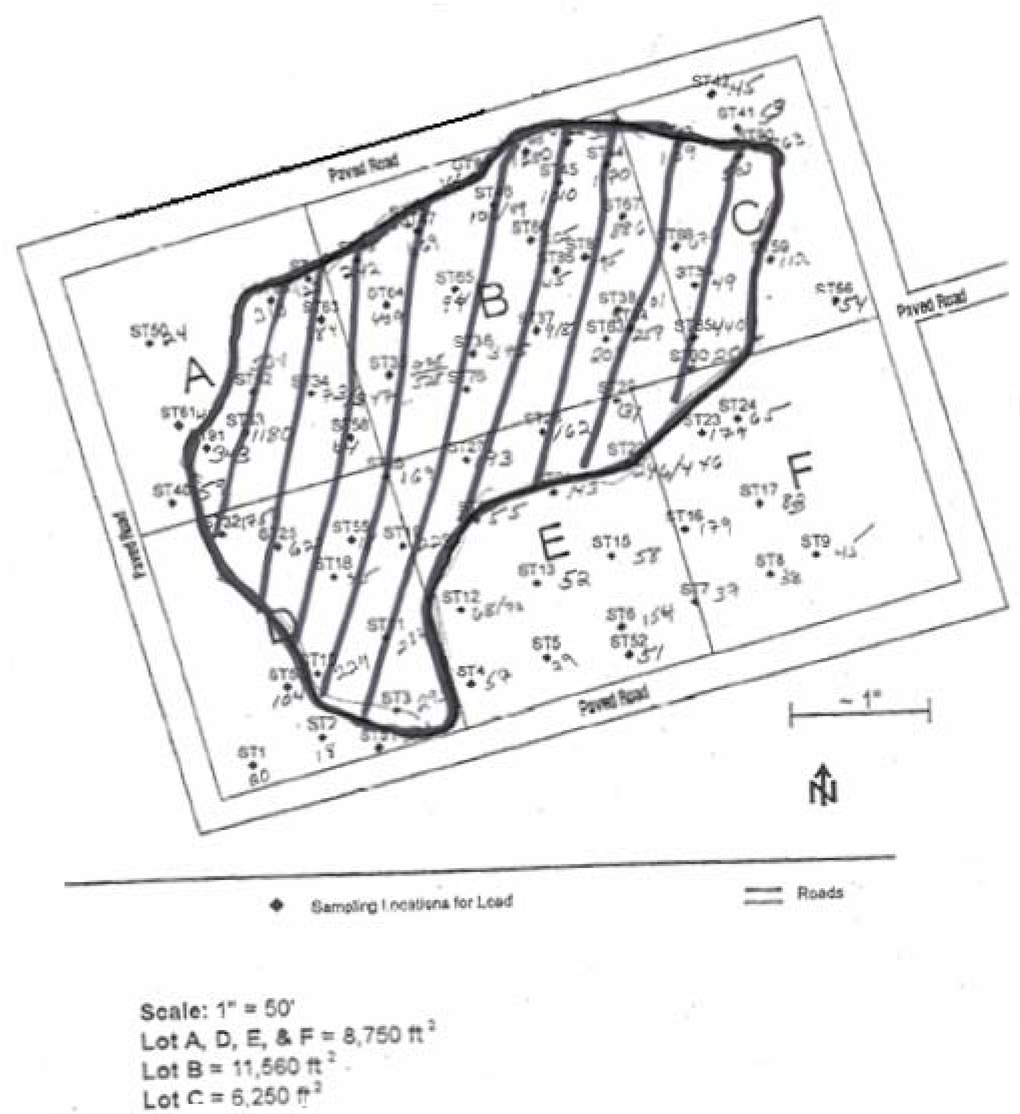


Figure 5-2. What soils would merit risk management for California (0–6 inches)?

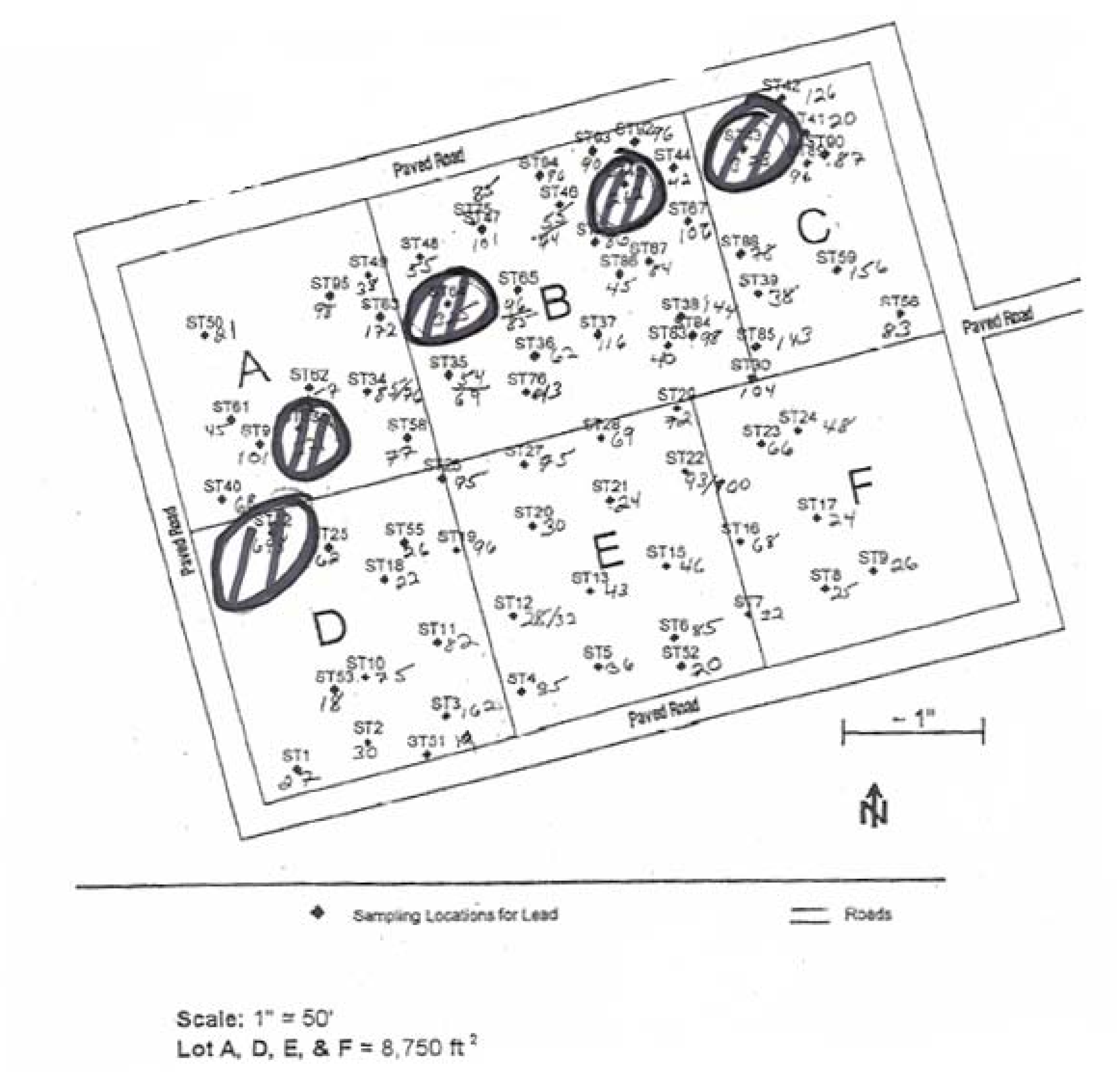


Figure 5-3. What soils would merit risk management for California (6–12 inches)?

Following excavation of both strata volumes, confirmation samples would be collected from the floor and sidewalls. California would look at the 95% UCL of the mean to compare to the action level, which in this case is about 150 mg/kg based on LeadSpread 7.

Florida

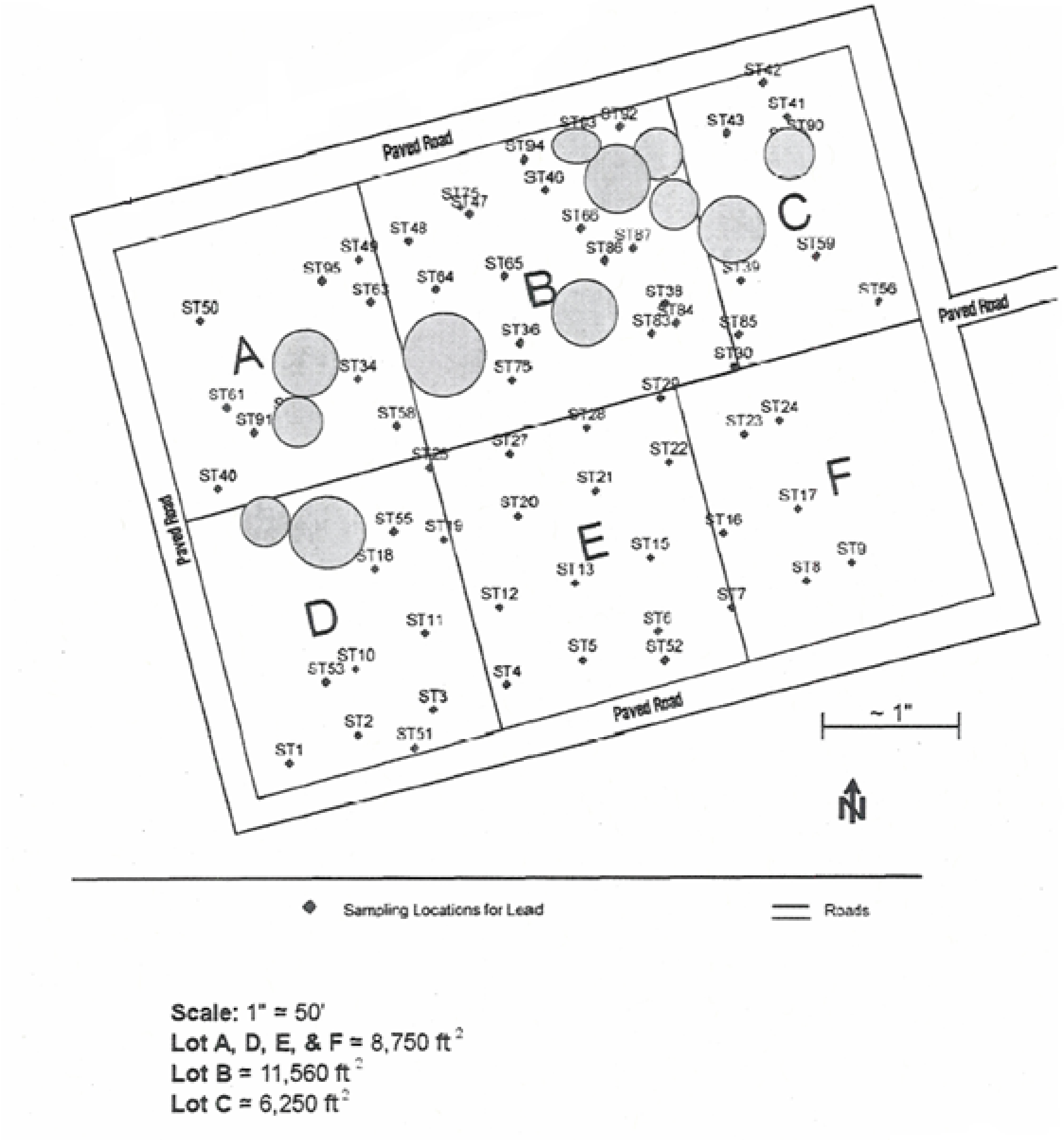


Figure 5-4. What soils would merit risk management for Florida (0–6 inches)?

Capping would also be allowed in Florida to manage risks; with any engineering control an institutional control would be required.

Georgia

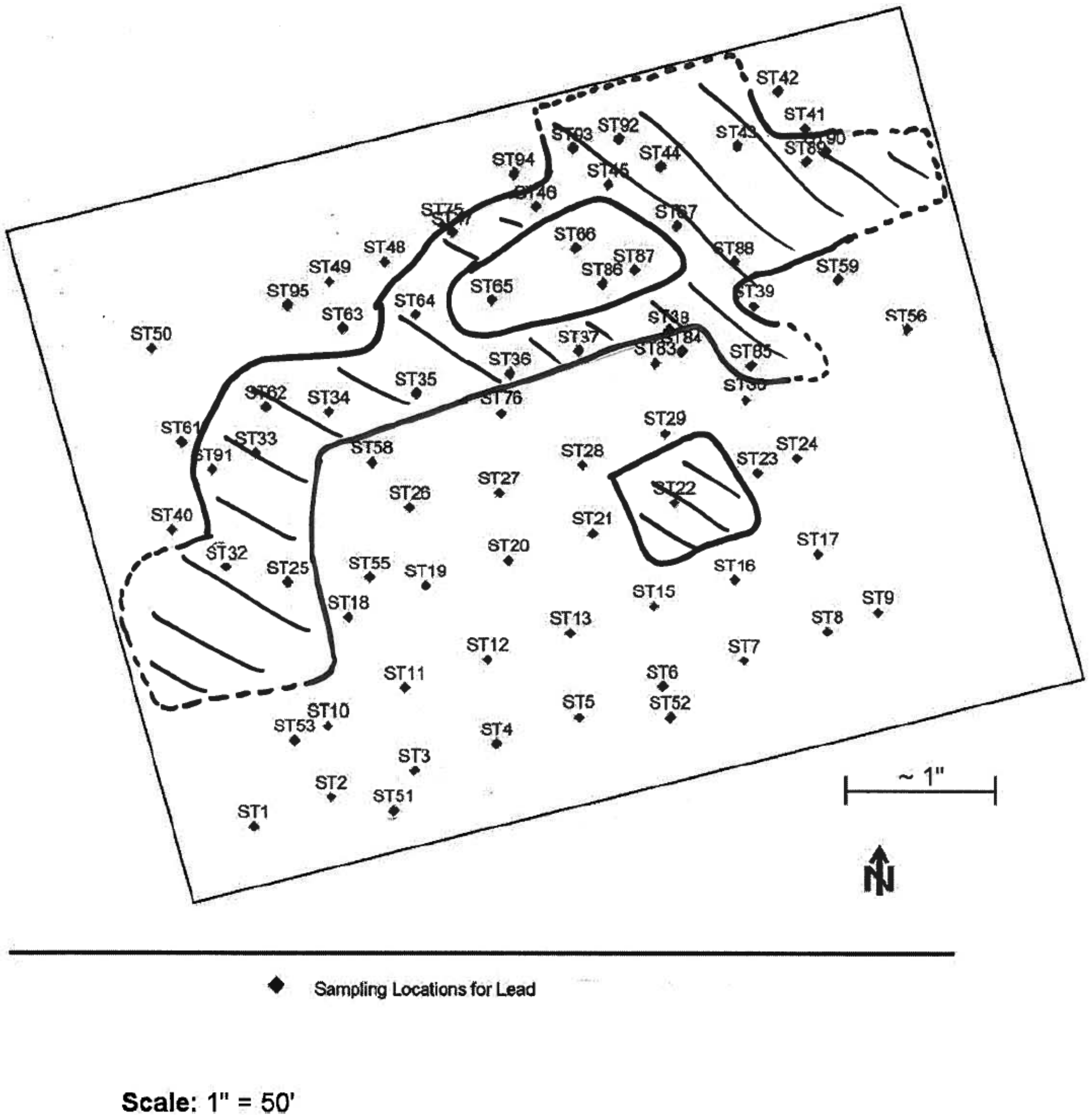


Figure 5-5. What soils would merit risk management for Georgia?

In Georgia, under the RCRA Program, the lots would be considered one regulated unit, and a 95% UCL could be used as an EPC. Based on the data set, all of the sample results from 0–12 inches would be used to develop the EPC for surface soil. Since the maximum concentration in subsurface soil (the 12–24 inch samples) is below the screening value of 400 mg/kg, then that media would drop out of the risk assessment, and no risk management action would be required for subsurface soil. The surface soil EPC would then be compared to the risk management level developed using the IEUBK model based on a future residential child receptor. Assuming no lead in groundwater with a detection limit of 5 µg/L, risk management would be 332 mg/kg lead. Using the 95% UCL of the surface soil samples, the EPC is 281.6 mg/kg, which is less than the risk management level of 332 mg/kg. Consequently, the site would not require any corrective action for surface soil.

Under the HSRP all points where the concentration exceeds the risk management level would need to be either removed or decontaminated. The default residential risk management level in the program is 75 mg/kg for lead. A site-specific risk management level consisting of the lower of the IEUBK model results and a concentration protective of groundwater could be developed. Using the same assumptions listed above, the site-specific risk management level would be 322 mg/kg as long as a leachability analysis showed that soil at this concentration would not cause an unacceptable groundwater concentration. If this was the case, then all soil associated with sample results above 322 mg/kg would need to be either removed or decontaminated.

Massachusetts

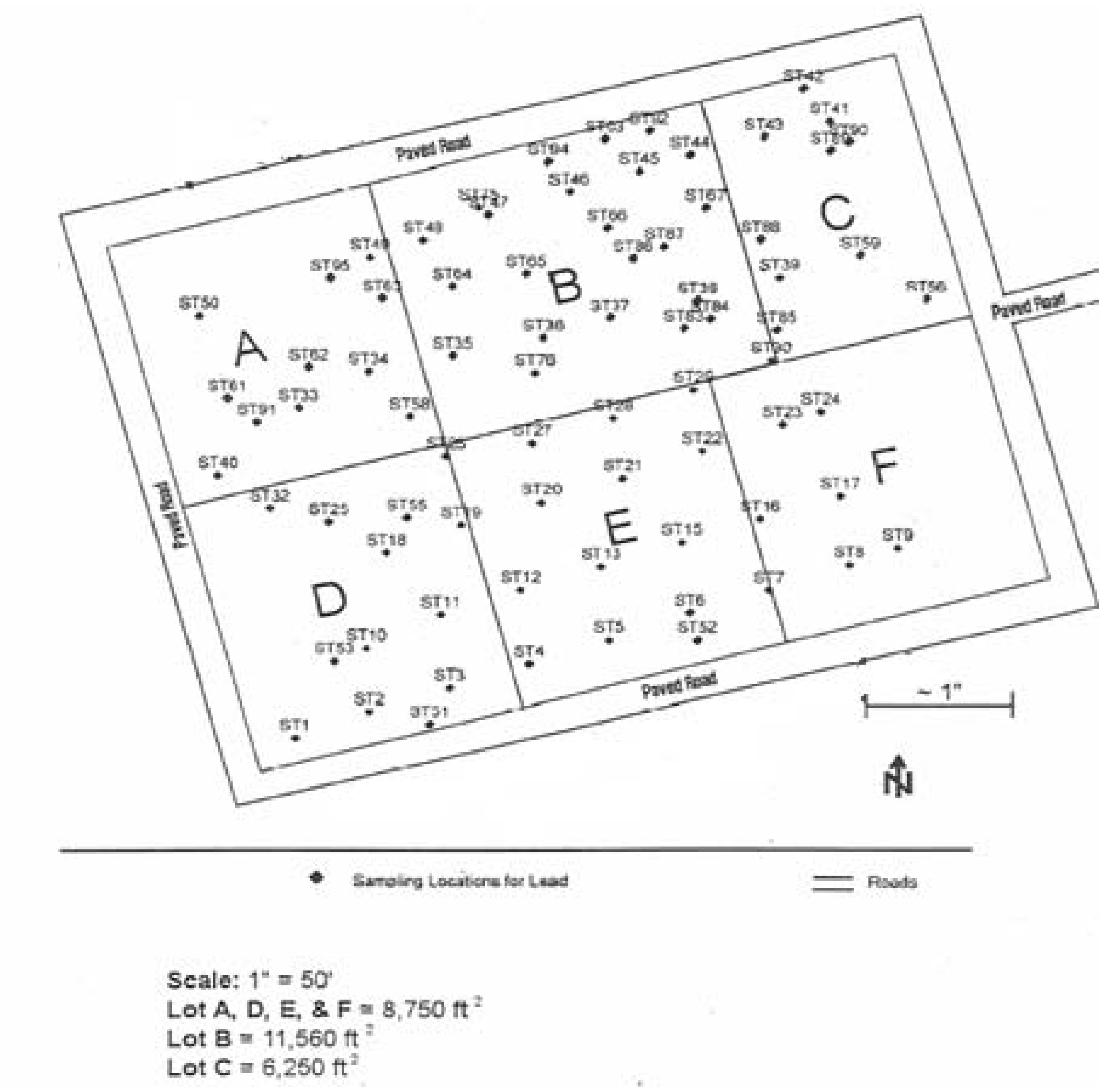


Figure 5-6. What soils would merit risk management for Massachusetts?

Since all EPCs were below the Method 1 standards, no risk management would be required due to a Method 1 Risk Assessment.

New Jersey

Slight/marginal exceedances—namely the 401 (ST38S1) and 409 (ST64S1) mg/kg results—would probably not require further evaluation, risk management, etc. Again, with a residential reuse, the 400 mg/kg number is applied throughout the soil column, initially for delineation and then for risk management. If not all contamination is managed, then an engineering control (cap) with deed notice would be required.

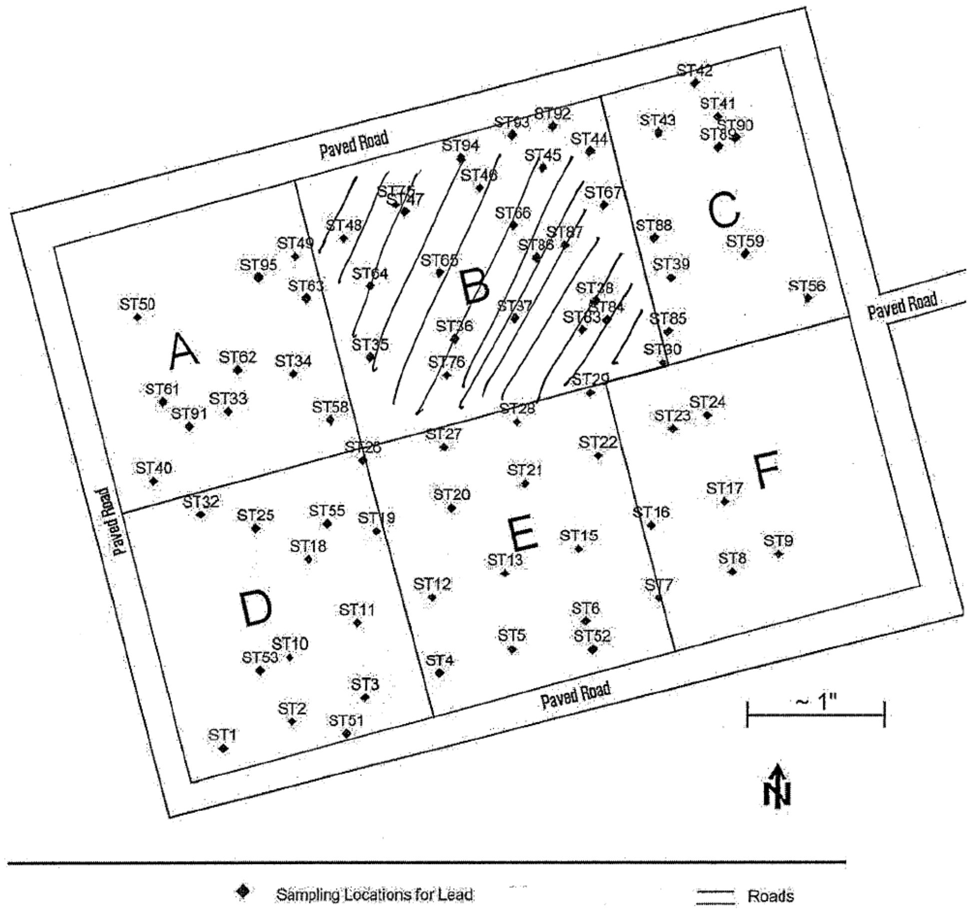
Unless risk management were to take place to the present "clean zones," horizontal delineation (see below) would be necessary to limit (hopefully) the area to be managed/excavated.

- Lot A—Vertical delineation complete. Horizontal delineation necessary at ST62 (534) and ST33 (1,180).
- Lot B—Vertical delineation complete. Horizontal delineation necessary at ST93 (1,280), ST47 (669), ST46 (1,010), ST45 (1,010), ST44 (1,170), ST35 (978), ST37 (918), and ST67 (886).
- Lot C—Vertical delineation complete. Horizontal delineation necessary at ST85 (440), ST89 (503), and ST88 (676).
- Lot D—Vertical delineation necessary at ST32 (1,750/698). Horizontal delineation necessary at ST25 (623).
- Lot E—Vertical delineation complete. Horizontal delineation necessary at ST22 (446).
- Lot F—Vertical delineation and horizontal delineation complete. Although one may question why the lack of samples in the eastern portion of this lot, NFA appears to be appropriate.

After delineation (mentioned above) takes place and the extent of impacted soil is better known, then decisions can be made in regard to risk management (excavation with post-excavation sampling or alternatively to a "clean zone").

Therefore, the short answer is that for each lot every data point is considered separately.

Tennessee



Scale: 1" = 50'
Lot A, D, E, & F = 8,750 ft^2
Lot B = 11,560 ft^2
Lot C = 6,250 ft^2

Figure 5-7. What soils would merit risk management for Tennessee?

For the purposes of this survey, the Tennessee Department of Environment and Conservation (TDEC) assumes that the pellets are no longer leaching significant lead and that the large areas in lots A, D, and F are not sampled because field determinations have adequately shown them as clean (e.g., previous removals or lack of lead pellets).

The cleanup goal and the screening level for this site would both be 400 mg/kg in soil. The 400 mg/kg cleanup goal is the result of IEUBK methodology from EPA. This model with its corresponding guidance recommends a mathematical average of lead concentrations to calculate the EPC. If the site contaminant were virtually any other constituent, the EPC would be a 95% UCL of the mean calculated in a manner consistent with the distribution of the sampling results.

TDEC would require the risk management of Lot B, the only lot that exceeds the 400 mg/kg threshold. Risk management could include removals, placement under buildings or any technically and economically feasible remedial action. However, on residential properties TDEC would likely urge the removal of contaminated materials because deed notices and other controls are not as effective on residential property and are much harder to monitor and enforce (EPA 2007).

5.1.13 Summary Discussion of First Comparative Site Case Study

The effort of undertaking the first comparative case study was in many ways an experiment. While many other entities have listed compilations of soil screening values or presented risk assessments, none have provided the comparison of practices and preferences of state organizations involved in evaluating risk at waste sites. The nature of the inquiry made here should be sharply contrasted with other surveys where a table of numbers is provided—numbers for which there is no meaning or guidance as to how they should be used.

Variation is seen in the EPC evaluated from a specific data set by respondents. Variation is also seen in the estimate of the amount of soil posing an unacceptable risk, which is a quantitative reflection of the risk management outcome. State respondents indicated that everything from "no remediation" to remediation of almost the entire hypothetical six-lot residential development would be the outcome. This range illustrates how the inputs and assumptions to risk assessment have a significant effect on the output of the risk assessment, leading to a wide range of risk management actions.

While the values of the soil exposure criteria for lead used in the first comparative case study ranged 150–400 ppm, as shown in Table 5-10, the amount of area requiring management varied from zero to around 70% of surface soils being managed. This range is due in large part to the approaches and assumptions associated with evaluating the soil analytical results, primarily based on the area defined as an EU.

5.2 The Second Comparative Case Study

After completion of the first comparative case study, it became apparent that many of the issues of interest to the Risk Assessment Resources Team could not be addressed through only one comparative case study. To examine additional team interests, a second hypothetical site was created and used to conduct another comparative case study.

Many of the parameters allowed to vary in the first comparative case study were fixed in the second comparative case study. Specifically, the second comparative case study provided a developed area having fixed lot sizes and boundaries, fixed locations of surface structures, fixed land use, fixed screening values, fixed background levels, and a fixed restriction of contamination to surficial soils. Therefore, the goal of the second comparative case study was to examine differences in the approach to the risk assessment process and identify additional issues and drivers in the practice of risk assessment.

It should be noted that the participants were asked to evaluate this case study based on the information and constraints provided to them. Because this case study is limited in its scope, it cannot encompass the breadth of each agency's guidance and policies. Data presented by this case study do not reflect any state or federal official policy, regulatory standards, background concentrations, screening levels, or acceptable risk outcomes. Representatives from the states of California, Florida, Alaska, Alabama, and Arizona participated. In addition, representatives from the departments of Army, Navy, and Air Force collaborated to demonstrate how an "end user," (a.k.a. the "regulated community") would evaluate the site in the absence of any specific state regulations.

Table 5-11 compares the key variables considered in creating both the first and second comparative case studies. The team endeavored to clearly probe the practices of state and federal risk assessors and risk managers by controlling some of the key variables typically present in risk assessment so that the two comparative case studies would be complementary in design.

Table 5-11. Comparison of variables in both comparative case studies

Variable	First comparative case study	Second comparative case study
Numerical criterion	Varied	Fixed by design[a]
Land use	Residential	Residential, commercial, elementary school
Compounds	Single compound	Multiple (three) compounds, two of which are potentially similar in effect
Vertical averaging	Allowed to vary	Fixed by design

[a] The values for numerical criteria that would actually be implemented in various states are different from those that were assigned for the comparative case study.

Section 5.2.1 provides the case study information for the second comparative case study. Sections 5.2.2–5.2.5 discuss the topics for sets of questions provided to the participants. The responses provided to the questions are shown in Table 5-13 as an abbreviated summary. Sections 5.2.6–5.2.10 provide observations on the responses provided under each topic of interest. Appendix C provides the complete survey, including plot plans of the lots considered in this comparative case study and an expanded set of answers.

5.2.1 Background on Second Comparative Case Study

State representatives and a group of end users were asked to complete an evaluation of a hypothetical consisting of a description of the study area, the COPCs, maps of lots with sampling locations, and respective analytical data for each location. Also provided were statistical analyses of the data collected for each individual lot of the site. Appendix C provides the data package, including an illustration of the lots constructed for this hypothetical site and the sampling locations.

The hypothetical site consists of nine lots that have land uses as either residential, commercial, or an elementary school. The chemicals released were arsenic, copper, and lead, distributed throughout this area of an existing community. Contaminant migration occurred via rainfall-entrapped deposition of suspended particulates, surface water runoff, airborne particulate settling, and human traffic in and among the affected areas. All direct-contact routes of exposure are complete. The leaching to groundwater pathway has been eliminated. No surface water bodies are present. No edible crops are cultivated on these or adjacent properties. All properties were affected over the same release period. Sampling has been conducted at accessible locations where a surface structure did not impede sample acquisition. All contamination is limited to surficial soil. For this second comparative case study, surficial soil is defined as that depth which meets current state requirements. Concentrations shown are for surficial soil at that location. Lots are all approximately ½ acre except Lot 7, which is ¾ acre.

To limit the variation that might be attributable to different values for screening values, the applicable screening levels were provided as shown in Table 5-12. For purposes of this exercise, these values were considered generically applicable to all sites by use of conservative default factors in standardized reverse risk assessment methodology for each of the categories of land use; i.e., the screening levels were not determined using a site-specific risk assessment). The background shown is naturally occurring.

Table 5-12. Predetermined screening levels[a]

Chemical	Residential	Commercial	Background
Arsenic	1.0	2.0	10
Copper	1,150	3,000	100
Lead	200	800	18

[a]These values were established and fixed for purposes of the comparative case study, and actual values used by responders may be different.

Specific questions are presented later in Table 5-13; the general areas of inquiry included approaches to data use, data needs, risk assessment, and risk management.

5.2.2 Inquires about Approaches to Data Use

The intent of this set of questions was to determine—given defined land use categories, a fixed set of samples per lot, fixed locations of samples collected, the analytical data, and a fixed set of initial screening values—how participants define an EU, how they define the EPC, and how they screen chemicals from further consideration. Specifically, does the number of lots to be sampled, the type of land use category, or the stage of site evaluation have any bearing on whether certain lots could be combined to define an EU? Also, does the concentration used for comparison against the initial screening level differ from the EPC? Can the EPC be affected by using a lot-wide composite?

5.2.3 Inquiries about Data Needs

The goal of this group of questions was to examine whether there were additional data requirements to support the risk assessment process, other than those defined by the study. Specifically, what criteria are used to determine adequacy or deficiency in sampling? Each lot in the hypothetical site is approximate ½ acre, except the school site at Lot 7 which is ¾ acre. The sample numbers were shown in summary statistics for each lot. The number of samples ranged from 14 to 34 per lot and more, affected by the area extent of surface structures present. The lot with the school had the most samples at 52.

5.2.4 Inquiries about Risk Assessment

The goal of this question set was to use the risk assessment process in the reverse calculation mode to define "site-specific" risk-based chemical concentrations, rather than the generically derived initial screening values, based on measurable properties that the site and lots had in common. Based on these site-specific risk-based concentrations, would a secondary screening be conducted, and would any chemicals be eliminated from further evaluation in risk characterization? What factors would lead to a chemical's being included for determination of cumulative health effects?

5.2.5 Inquiries about Risk Management Decisions

The goal of this set of questions was to examine the relationship between the risk assessment results and the risk management decisions. Often this step in the process is a gray area. Given the same set of risk characterization results, would different risk management options be selected, and what is the process for choosing the most suitable option? Specifically, what risk assessment results drive the decision to remediate; i.e., is it the "reverse" calculated risk-based target levels for each chemical, or is it the cumulative risk/hazard? Even if the EPC is less than the risk-based target level, do "spot" exceedances of this level still trigger remediation? What role does uncertainty have in the decision, and do schools present a unique level of decision making?

5.2.6 Second Comparative Case Study—Observations

As shown in Table 5-13, some participants do have similar methodologies, practices, or approaches. However, it is quite apparent that there are distinct differences. Some of these variations account for little impact on the final outcome of the risk assessment conclusions, while others are significant.

5.2.6.1 Observations on Approaches to Data Use

The responders consistently determined the EU to be an individual lot. The basis for this practice is commonly based on ownership, lot size, or future use, while the stage of the investigation and the number of lots to be evaluated had no impact. Alabama provides for EUs to be redefined if, at the time of investigation, it is known that properties will be subdivided or combined. Only the Tri-Services (regulated community) and Arizona consider aggregation of certain lots for defining the EPC to decrease potential cost impacts and resource limitations posed by the evaluation of a large number of lots.

All but two responders would evaluate exposure over the area of a lot; Florida would allow consideration of more than one EU within a given property. The response from the Tri-Services would allow more than one EU per lot, based on the CSM developed for the project. However, further details are not provided on how an EU would be established at a size smaller than a residential lot.

Nearly everyone uses the maximum site concentration for comparison to the initial screening level. Only Florida allows the use of the average concentration for Pb. For any chemical Florida places an additional requirement that, if the 95% UCL is used, 10 samples are needed and no concentration may be present in excess of three times the screening level. Otherwise, nearly everyone uses the 95% UCL as the EPC, which is the site concentration used after the initial screening, with Alaska specifying that the maximum concentration be used in the event that the 95% UCL exceeds the maximum concentration (this is common practice for every state).

Table 5-13. Second comparative case study participant responses

	Alaska	**Alabama**	**Arizona**	**California**	**Florida**	**Regulated community example: Armed Services**
Approaches to data use						
Can lots having similar land use, e.g., residential, be treated aggregately or must they be evaluated separately?	Separately	Separately if owned by different entities; combined if adjacent lots are owned by the same entity unless the future use is going to be separate lots owned by different entities.[1]	Separately	Separately	Separately	Separately[2]
If contaminant release/deposition/migration had instead occurred over 50 lots instead of nine, would you treat lots aggregately or individually? Why?	Individually	The number of lots is not the driver. Aggregately vs. individually is based on ownership and/or future use.	Some lots would have been aggregated.[3]	Individually. The exposure area (i.e., the lot) becomes the driver.	Individually, as, each lot is a separate exposure unit.	The number of lots is not the driver.
Does grouping or segregation of the nine lots depend on the stage of evaluation? Initial screening: Yes/No	No	No	No	No	No	No
Calculating EPC: Yes/No	No	No	No	No	No	No
Conducting risk assessment: Yes/No	No	No	No	No	No	No
State whether the value used for the initial screening of chemicals is the maximum concentration, the arithmetic average, or the 95% UCL.	Maximum	Maximum	Maximum	Maximum	All three can be used.[4]	Maximum
On the attached data sheets, circle the lot numbers for those lots which failed initial screening and the chemical name(s) which failed.	As, Cu, Pb: Lots 1–9	As, Cu, Pb: Lots 1, 3–8; As, Cu: Lot 2; As: Lot 9	As, Cu, Pb: Lots 1–9[5]	As, Cu, Pb: Lots 1, 2, 4–8; As, Cu: Lot 3; As: Lot 9	As, Cu, Pb: Lots 3–5, 8; As, Cu: Lots 6, 7; As: Lots 1, 2, 9	Lots 1–9 if screened against residential; Lots 1, 2, 9 when screened against commercial[6]

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[1] The goal is to make the EU match the area which an individual has the greatest duration and frequency of exposure.

[2] However, it depends on the needs of the customer, potentially exposed individuals, regulators, and similarities of the exposure parameters for residential lots and those for commercial lots.

[3] Because sampling at this density over 50 lots is cost-prohibitive, attempts to define contaminant distribution patters are acceptable but would require extensive statistical and spatial analysis to establish a single EPC for multiple lots. Remediation and risk management decisions would be based on individual lot EUs.

[4] The maximum concentration must be used for copper under all conditions where a child is present because the target level is based on acute toxicity. Lead may use the maximum, average, or the 95% UCL. Arsenic may use the maximum or the 95% UCL. However, arsenic or lead must use the maximum concentration if it exceeds three times the screening level.

	Alaska	**Alabama**	**Arizona**	**California**	**Florida**	**Regulated community example: Armed Services**
If lots are evaluated individually, indicate the method used to determine the EPC.	95% UCL	95% UCL	95% UCL	95% UCL	As 95% UCL: Lots 1–9; Cu 95% UCL: Lots 1, 2, 9; Cu max.: Lots 3–8; Pb average: Lots 1–9	95% UCL
Can more than one EU be determined within any of these nine lots?	No	No	No	No	Yes	No[7]
Had all the samples within a lot been composited in equal volume aliquots, would you use the average concentration shown for the EPC?	No, composites not allowed.	No	No[8]	No	No, composites not allowed.	Answers vary among services.[9]
Data needs						
Indicate on the lot maps which lots have an inadequate sampling density to meet the data quality requirements for a risk assessment.	Depends on the statistical validity of the 95% UCLs.	None, assuming random sampling.	None	None	Lots 4, 6, 8, 9 due to As. Lot 4 due to Cu.	None
State the density or frequency of sampling required, and mark the area on the map needing further sampling as "S."	None marked on maps.[10]	Sampling shown is adequate for ½-acre lot EUs.	None required.	A minimum of 10 samples is preferred; no sampling for screening or risk assessment.	At property boundaries, lots must meet the criteria for the adjacent land use, i.e., Lots 4, 6, 8, 9.	None required.
Indicate on the lot map whether additional sampling depends on the concentration of an adjacent sample, land use, or other.	None marked on maps.[11]	Not applicable; no further sampling required.	Not applicable; no further sampling required.	None required.	Based on sample concentration exceeding the criteria for the neighboring lot land use.	Additional sampling not needed, but if desired, needs scientific basis to justify.

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[5] Screening against commercial levels is allowed only if an institutional control is placed on the property.

[6] There is no determination whether commercial lots must be screened against residential levels or can elect to be screened against commercial levels. The residential only screening did not specify which chemicals failed. Commercial lots 1, 2, and 9 failed for arsenic, with copper and lead varying between services.

[7] More than one EU within a lot is possible only if the site-specific CSM supports it.

[8] Based on the maximum concentration > $1/n^{th}$ screening concentration, where n = number of samples taken on a lot.

[9] Discrete sampling was determined by only one; another provided discretion of the project manager(s) to determine between compositing vs. discrete sampling. If compositing had been allowed, the mean would be applied due to lack of options.

[10] Any location which exceeds background or screening levels requires step-out sampling.

[11] Sampling should identify the source and extent of contamination exceeding residential screening levels.

<table>
<tr><th></th><th>Alaska</th><th>Alabama</th><th>Arizona</th><th>California</th><th>Florida</th><th>Regulated community example: Armed Services</th></tr>
<tr><td><i>Risk assessment</i></td><td></td><td></td><td></td><td></td><td></td><td></td></tr>
<tr><td>Please write “RA” under each lot number on the data sheets for those lots eligible to conduct a site-specific risk assessment.</td><td>All lots.</td><td>All lots.</td><td>All lots.</td><td>All lots.</td><td>All lots.</td><td>Secondary screening against the site-specific risk concentrations shown in the table is recommended prior to conducting the baseline risk assessment.</td></tr>
<tr><td>A reverse risk assessment has been conducted which shows the following site-specific concentrations at the indicated excess lifetime cancer risk or HI. Does any chemical on any lot now become eliminated from any further consideration? Please state which lots, based on which chemical.
<table>
<tr><th></th><th colspan="2">Residential</th><th colspan="2">Commercial</th></tr>
<tr><td>Chemical</td><td>10^{-6}</td><td>HI = 1</td><td>10^{-6}</td><td>HI = 1</td></tr>
<tr><td>Arsenic</td><td>12</td><td>33</td><td>48</td><td>390</td></tr>
<tr><td>Copper</td><td>▨</td><td>3,100</td><td>▨</td><td>5,800</td></tr>
<tr><td>Lead*</td><td colspan="2">400</td><td colspan="2">1,000</td></tr>
</table>
*Based on achieving target blood lead level by pharmacokinetic modeling.</td><td>None eliminated, though Lots 4, 6, 9 pass for Cu. Cu is retained for cumulative considerations.</td><td>Pb: Lots 1, 4, 6, 7. Pb is considered separately from cumulative health risk and hazard. As/Cu cannot be eliminated by screening against a site-specific target level.</td><td>Cu, Pb: Lots 1, 2, 4, 6–9; Cu only: Lots 3, 5.</td><td>No. Chemicals cannot be eliminated by comparison to a site-specific risk-based level as a secondary screening. Also, As/Cu/Pb cannot be screened out as all three exceed background levels.</td><td>Lots 4 and 5: Cu and Pb. Lots 7 and 8: Pb only.</td><td>Results of secondary screening were not provided, but would be used to screen out additional chemicals or sites. One service uses reverse risk-based levels only after the cumulative forward risk assessment to establish cleanup goals.</td></tr>
</table>

	Alaska	**Alabama**	**Arizona**	**California**	**Florida**	**Regulated community example: Armed Services**
Using the table above, please calculate the cumulative health risk and hazard for those lots which exceeded the applicable cleanup levels.	Lot 1: 1e^{-5}, HI = 1; Lot 2: 1e^{-5}, HI = 1; Lot 3: 7e^{-5}, HI = 3; Lot 4: 5e^{-5}, HI = 2; Lot 5: 7e^{-5}, HI = 3; Lot 6: 7e^{-5}, HI = 3; Lot 7: 7e^{-5}, HI = 3; Lot 8: 1e^{-4}, HI = 4; Lot 9: 1e^{-5}, HI = 1	Lot 1: <1e^{-5}, HI < 1; Lot 2: <1e^{-5}, HI < 1; Lot 3: <1e^{-5}, HI = 3.22; Lot 4: <1e^{-5}, HI = 1.96; Lot 5: <1e^{-5}, HI = 2.73; Lot 6: <1e^{-5}, HI = 3.04; Lot 7: <1e^{-5}, HI = 2.84; Lot 8: <1e^{-5}, HI = 3.96; Lot 9: <1e^{-5}, HI < 1	Lot 1: 5.6e^{-6}, HI = 2.0; Lot 2: 5.7e^{-6}, HI = 2.1; Lot 3: 7.3e^{-6}, HI = 2.6; Lot 4: 4.5e^{-6}, HI = 1.6; Lot 5: 6.5e^{-6}, HI = 2.4; Lot 6: 7.0e^{-6}, HI = 2.5; Lot 7: 6.5e^{-6}, HI = 2.4; Lot 8: 1.0e^{-5}, HI = 3.5; Lot 9: 5.1e^{-6}, HI = 1.8. Pb: exceeded for Lots 3, 5	Lot 1: 1.4e^{-6}, HI = 0.59; Lot 2: 1.4e^{-6}, HI = 0.47; Lot 3: 7.3e^{-6}, HI = 3.23; Lot 4: 4.5e^{-6}, HI = 1.96; Lot 5: 6.5e^{-6}, HI = 2.72; Lot 6: 5.3e^{-6}, HI = 2.43; Lot 7: 6.5e^{-6}, HI = 2.83; Lot 8: 9.5e^{-6}, HI = 3.98; Lot 9: 1.2e^{-6}, HI = 0.22	Lot 1: 1.4e10^{-6}; Lot 2: 1.4e10^{-6}; Lot 3: 7.3e10^{-6}, HI = 1.8; Lot 4: 4.5e10^{-6}; Lot 5: 6.5e10^{-6}; Lot 6: 7.0e10^{-6}, HI = 1.2; Lot 7[12]; Lot 8: 9.5e10^{-6}, HI = 1.5; Lot 9: 1.3e10^{-6}	No. If eliminated, it was not included.
Were all chemicals included, even if eliminated in the initial screening or screening against the EPC?	Yes, none were eliminated.	No, not if screened out at initial screening.	No; if eliminated, it was not included.	Yes	No, because these chemicals did not have the same target organ or effect.	Yes
Was the noncarcinogenic arsenic contribution to the HI included?	Yes	Yes	Yes	Yes	No	Separately
Was lead considered separately or combined by some method for contribution to the overall health hazard?	Separately	Separately	Separately	Separately	Separately	N/A
Federal guidance suggests that arsenic and lead have greater than additive effects on neurological toxicity. How would you account for this: (i) quantitatively in the risk characterization calculation?	No	No	No	No	No	N/A
(ii) qualitatively in the uncertainty section?	Yes	Yes	Yes	Yes	No	N/A

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[12] The cumulative health risk and hazard for the school (Lot 7) should be done on a case-by-case site-specific forward risk assessment.

	Alaska	**Alabama**	**Arizona**	**California**	**Florida**	**Regulated community example: Armed Services**
(iii) use this information in setting risk management decision and final cleanup goals?	Yes	Yes	Yes	No	No	Unlikely to be accounted for due to lack of specific EPA guidance or method for quantifying.
(iv) other?	No	No	No	No	Yes, noncarcinogenic effects are dropped for carcinogens.	Yes[13]
Do you account for the contribution of background levels in the risk characterization? Indicate if the level of risk due to background is: (i) quantified and combined with the risk estimate due to the contaminant release	No	No	Yes, only for Pb.	No	No	No
(ii) quantified and not included with the overall risk estimate but used in risk management decision making	Yes	Yes	Yes for As, carcinogen and noncarcinogen contribution.	No	Yes	N/A
(iii) discussed qualitatively in the uncertainty section only	No	No	No	No	No	No
(iv) other	No	No	Background copper too low to be relevant.	No adjustments made.	No	Carcinogenic risk exceeded $1e^{-6}$ but was less than $1e^{-4}$. Specific lots having these values were not identified. Non-carcinogenic hazard > 1 was exceeded for Lots 3–8, due mainly to arsenic.[14]

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[13] Background is used to screen out chemicals when site concentrations are less. Background is not subtracted from the overall risk/hazard estimate.

[14] Actual risk values varied slightly between services due to differences in inclusion or elimination of certain chemicals.

	Alaska	Alabama	Arizona	California	Florida	Regulated community example: Armed Services
Risk management decisions						
For those lots having the EPC in excess of the site-specific cleanup level, do you remediate the whole lot for that chemical or just portions? If portions, circle the areas on lot maps as "R."	Either	Either. It depends on the desires of the remediating party.	Portions, as determined by hot spot excavation and resampling results to calculate an EPC until less than cleanup level.	Portions of the commercial lots which exceed. Since arsenic uniformly exceeds at residential/ school lots, the entire lot is remediated.	Portions. The highest concentrations are remediated/ managed until the resulting EPC meets the cleanup level.[15]	Portions, relative to exposure area and EPC, such that not all areas require remediation below the cleanup goal.
Is the remediation different had the site-specific risk assessment not been conducted?	Possibly[16]	Yes	Yes	Yes[17]	Yes	Yes[18]
What elements of this site would you require to be discussed in the uncertainty section of the risk assessment, and would any elements result in a determination of a more stringent cleanup level for one or more chemicals?	Sampling rationale; lead risks; per lot, discuss single chemical and combined chemical risk contribution, especially for collocated Pb/As; background; future contaminant relocation by trafficking and fugitive dusts; future edible plant uptake.	Separate evaluation of Pb from the cumulative risk and health hazard; As/Pb greater than additive effects on neurotoxicity; a process for selection of a more stringent cleanup level is not well defined and subject to consideration of additional factors.	Bioavailability; sensitive receptors due to health conditions or coexposures to chemicals impacting same target organs/ tissue/mode of action; combined exposures to children residing on a residential lot and going to this school; synergistic Pb/As; these may impact the elected/ negotiated cleanup levels.	As bioavailability in soil; low-dose extrapolation for carcinogenicity; safety factors for reference doses; variability for each exposure parameter; unknown contaminant concentration beneath surface structures erected post-release.	Any elements in which uncertainty is associated. None would result in more stringent cleanup levels.	All elements of the risk assessment should be addressed.

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[15] An institutional control must be applied when contamination is managed rather than remediated OR a lot exceeds ¼ acre and the 95% UCL was used as the EPC.

[16] The area or extent of remediation is not linked to exceedances of the initial screening level vs. the site-specific risk-based level. Remediation is linked to hot spot excavation down to either cleanup level with subsequent confirmation sampling OR selected portions of the lot remediated and follow-up sample results used to calculate a new 95% UCL which meets cleanup standards.

[17] Lots 1, 2, and 9 pass the site-specific assessment and would have required remediation based on failure of the initial screening. Also, residential lots may have no or limited remediation based on risk manager considerations of low risk/hazard ($<5e^{-6}$ and <2, respectively).

[18] The decision to conduct the site-specific risk assessment is at the discretion of the project manager(s).

	Alaska	Alabama	Arizona	California	Florida	Regulated community example: Armed Services
How was the school lot treated differently in this scenario?	Use of the Child Lead Model and childhood exposure factors.	It was treated the same as residential.	The remedial target level would have been set at $1e^{-6}$, and teacher, landscaper, maintenance worker receptor groups would also have been evaluated.	It was treated as unrestricted use, which is equivalent to residential use and other sensitive uses. Teacher exposures typically drive the cleanup goals.	A site-specific risk assessment would be conducted using site-specific values for the age group(s) present and conditions at the school, i.e., average body weight, average surface area, exposure duration. The lower of the site-specific levels protective of school children or teachers would be used.	Could either be treated as residential or school-specific, depending on the discretion of project manager(s).

All the state representatives responding to a question about the use of composites indicated that composite sampling would not be acceptable. However the response from the Tri-Services indicated that answers from states can vary and that the use of composites would be determined by states and/or project offices. The use of composites is an important topic since analytical costs are a significant portion of the many project budgets.

Similarly, the variability of soil contamination is a critical feature of site investigations and analyses. Soil contamination is typically highly spatially variable on waste sites. Dealing with that phenomenon is a huge challenge to sampling efforts. Compositing is one approach suggested for overcoming this complication but still producing an estimate of the mean. It appears that compositing, in this case, is generally not acceptable to the broad range of regulatory agencies.

5.2.6.2 Observations on Data Needs

Building on the first topic (approaches to data uses), the second area considers the adequacy of the sampling. All lots had at least 14 sampling locations, with more than 50 sampling locations in one lot. By most estimates, this would be considered a very large number of samples for a project. Still, the Alaska response suggests that step-out sampling would be required for locations exceeding background. The California responder suggested that a minimum of 10 samples is wanted for a residential lot when 95% UCL are used but did not give a reference or citation. The Florida Administrative Code specifies in 62-780 that when 95% UCL is used, a minimum of 10 samples is needed. The response from Florida indicated that additional sampling around property lines would also be necessary to address “next door” considerations and concerns.

In the first comparative case study, the answers provided to the lines of inquiry about soil sampling indicated that a broad range of approaches exists about what area (volume) one can average the data from soil sampling. Typically, a risk assessment involves determining the level of exposure by estimating the mean level over what is known as an “EU,” which typically corresponds in size to a residential lot. While some responders in the first comparative case study suggested that averaging of soil sampling results could occur over a vast volume of soil (essentially averaging all data points in the hypothetical site presented), other responders would have required every sample to be evaluated. A range of answers also emerges from this second comparative case study. While averaging over an EU appears to be acceptable, a sample-by-sample analysis indicated by references to hot spots is sometimes employed to determine the adequacy of sampling efforts.

Taken together with the answers about approaches to data uses, many responders allow averaging over the area of an EU, while at the same time they often require additional sampling or remediation responding to individual measurements. While one answer to this dichotomy is that soils are variable and an understandable measure of caution is exhibited in deciding that the sampling is adequate, no responder had an analytical (quantitative) answer addressing the inherent variability of soil contamination. Some states allow statistical averaging (i.e., calculation of a 95% UCL from discrete samples) but do not support sampling methodologies that are designed to determine an average concentration (i.e., compositing) because in their regulations there is an additional requirement that when a 95% UCL is used, the maximum cannot exceed a multiplier of the screening value.

5.2.6.3 Observations on Risk Assessment

This portion of the second comparative case study looks into the processing of soil sampling data that had already been analyzed statistically. To reduce the number of variables and to complement the questions asked in the first comparative case study, preestablished numerical criteria were used for the three compounds of concern (lead, copper, and arsenic). These criteria fixed the exposure level considered to represent an HI of 1 and/or a carcinogenic risk of 1×10^{-6} increased incidence of cancer. Pharmacokinetic information for lead was also presented. In addition, summary statistics were provided for the levels of these compounds. Lead and arsenic—suspected by some of having similar effects—were specifically included in the data set to consider how possible synergistic effects are addressed. In comparing the soil sampling results with the preestablished numerical criteria, responders varied in their estimates of HI and risk. However, all lots were identified as having some failure—either an HI greater than 1 or a risk greater than 1×10^{-6}.

Lead is a common compound in our environment. It was included in the second comparative case study for two major reasons: it is often evaluated on a pharmacokinetic basis and separate from other noncarcinogens and, along with arsenic, it can often pose a significant question about how to evaluate background versus site conditions.

Responders varied in how they evaluated risks from specific compounds. Most responders would drop contaminants from further consideration if they did not exceed a numerical screening criterion. Responders from Alaska and California indicated that they would retain all three compounds throughout the analysis. Most responders agreed that lead should be evaluated separately. Only one responder (Florida) would not consider the noncarcinogenic effects of arsenic since it already considered the carcinogenic effects for additivity.

On the specific topic of federal suggestions that arsenic and lead have greater than additive effects, no responder provided a quantitative approach to this possibility. In other responses to this topic, it appears that the possibility of more-than-additive effects for lead and arsenic might be considered qualitatively but not quantitatively. Similarly, responses were mixed about whether to use the possibility of more-than-additive effects for these two compounds at all in risk management.

Responders also varied in their approaches to evaluating background conditions. For one responder (Arizona), background lead conditions would be included in the risk characterization. For others, it would not. Similar differences are apparent in the answers to additional questions about how background would be included into the risk assessment process. The differences apparent in previous discussion provided in this report about determination of background are apparent in the second comparative case study.

5.2.6.4 Observations on Risk Management Decisions

The end use of a risk assessment is to inform risk management decisions. Only one respondent (Florida) provided a map of the areas meriting risk management. This response may be due in part to the complexity of the data set, with many sampling points provided. Consequently, it is not clear how multiple compounds with similar effects would be quantitatively evaluated.

Lastly, it was of interest to see how responders would address an exposure scenario involving a school. Several approaches were described, ranging from a school-specific model to the use of residential exposure scenarios. Interestingly, responders indicated that adults—construction workers, landscapers, and teachers—might end up being the more sensitive receptors than students.

A clear message in the responses under this section is that additional (more sophisticated) risk assessment analysis would afford different risk management decisions, including different remediation. This suggestion is consistent with most Risk Assessment Resources Team members' willingness to accept risk assessments where the input parameters are determined from site characterization results, including some PRAs done on the same basis.

5.3 Summary of the First and Second Comparative Case Studies

The team conducted two comparative case studies as a part of this report. State representatives and a group of end users were provided comprehensive data sets representing soil contamination on two hypothetical sites. The participants were asked to address a series of common but significant questions that come up when conducting risk assessments at contaminated sites. This approach allowed a quantitative comparison of approaches among responders.

The comparative case studies probed issues and complications faced quite frequently by state risk assessors, including how to evaluate the toxicity of various compounds, how to evaluate soil sampling results, and how to address the significant complications that can be associated with background levels of the same compounds occurring on site. The focus of the comparative case studies was to observe the interface and interaction between risk assessment and risk management through pointed questions asking risk assessors to identify areas meriting remediation.

Answers from responders for both comparative case studies show significant variation. This variation is exhibited in the range given for numerical soil criteria for lead (150–400 mg/kg). More significantly, how to use those same numerical criteria ranged even more. In the first comparative case study some responders applied their jurisdiction's risk-based numerical criteria to every sample, while others applied their numerical criteria to an average throughout as much as the entire volume of contamination. This second range—in how the numerical criteria are used—spans several orders of magnitude of volume of contaminated soil.

Throughout both comparative case studies, it was apparent from conversations among responders that most are open to receiving sophisticated risk assessments. For example, most participants in the case studies were interested in and receptive to the PRA for one of the case study projects described in Chapter 4. However, several of the basic steps associated with any risk assessment were not readily addressed by state responders. A seemingly fundamental question—"What do you measure at the site to compare against the criterion?"—receives a broad range of answers. "How do you handle background?" again produces a range of answers, as does the question, "How do you address potential synergistic (more-than-additive) effects?"

The variation in many of the answers to these and other questions seems to be rooted in program implementation and in a difference of opinion about appropriate technical solutions. For example, where an RP chooses to go forward with a cleanup to a conservative end point, state regulators are understandably reluctant to require an in-depth risk assessment. Where thousands of potential sites merit attention, exhaustive risk assessment and review by a limited number of state staff would create a bottleneck and delay that many states feel can be avoided by relying on conservative default risk assessment assumptions and approaches that facilitate prudent risk management decisions. Many state cleanup programs were organized well before risk assessment's widespread use, and so there are some instances where the most straightforward risk assessment approach is limited by regulatory requirements. This situation accounts for some of the variation in risk management approaches observed in the case studies.

Still, there appear to be several technical fundamentals that might link site assessment, risk assessment, and risk management but that are not widely practiced even though they are not prevented by regulations. The logical flow of a risk assessment for simple contamination cases such as were developed for the hypothetical case studies would include addressing the following questions: How should the EU be established, and what are the appropriate dimensions (breadth and depth)? How should it be sampled? How should the results be processed to determine the EPC, and does the EPC exceed the appropriate numerical criterion? These questions—asked in the comparative case studies—produced a range of responses.

Several points can be gleaned from the outcomes of the two comparative case studies. First, considering the wide range of responses on many topics, there are fundamental differences in using risk-based criteria at waste sites. The team's first effort (ITRC 2005) determined that the basic approach for establishing soil screening criteria is quite similar in various states. However, there is significant divergence as to what the appropriate risk-based criterion ought to be for lead, with values ranging 150–400 mg/kg.

Another area of difference is in how various programs identify an EU, either for a standard exposure scenario or for a specific site, and how that determination drives the sampling and interpretation of results. In the first comparative case study, several responders changed their initial answers for concerning how an EU is determined from initially evaluating all six lots together to eventually evaluating the lots individually. Some states (Arkansas and Georgia) would have different approaches depending on which program is overseeing the project. The dimensions for establishing an EU—both depth and breadth—ranged from responder to responder, and this range accounted for significant differences in the EPC determined and eventually in the amounts of soil identified as meriting remediation. Much of the variation in this area of risk assessment could be attributed to individual program differences, and this alone can account for the significant variation in risk management outcomes observed in the comparative case studies. However, it also underscores a divergence of approach on fundamental steps that link site assessment to risk assessment and eventually to risk management decisions.

Based on the experiences of the members of the team in conducting two comparative case studies, several observations and recommendations can be offered. One is that at present some relatively sophisticated risk assessments are more acceptable at waste sites than the "one number" cleanups that typified remediation projects just several years ago. This observation suggests that risk assessment is gaining in application and acceptance. However, despite the increased acceptance of sophisticated analyses, several fundamental questions—How does one establish the dimensions of an EU? How is soil variability addressed? Can a (single) sample be considered a site? How are synergistic effects evaluated?—were handled differently by the responders in the comparative case studies. This finding suggests that despite the acceptance of risk assessment, some basic questions still do not have uniform answers. Further, the range of risk management outcomes based on those answers indicates the significance of several key, fundamental questions that still confront risk assessors.

Chapter 4 of this report considers several real-world, risk-based cleanups. Those projects include alternative sampling strategies (compositing), alternative analytical methods (such as XRF), and advanced analysis (PRA). To the extent those innovations can address the fundamental questions and complications associated with risk assessment at waste sites, most participants in the comparative case studies were willing to incorporate innovative data collection strategies to the extent practical. However, in some cases the sampling approach and the interpretation of the results has been prescribed in guidance, policy, practice, or even rule, albeit by consensus, which can have the unintended consequence of discouraging progress and innovation.

Every state cleanup program faces the same questions and problems. Regardless of approach, there are always questions of what to sample for, how to sample, how to process and interpret the results, and how to respond appropriately. The risk assessment–risk management paradigm has been offered as the appropriate path along which these question and problems can be tackled in a logical progression.

Through these case studies and comparative case studies, we can extrapolate how the risk assessment–risk management paradigm might play out in real-world settings. Many of the questions inherent in waste site cleanup draw a range of answers—some based in programmatic preferences, some in response to the inherent uncertainty associated with site cleanup, and some due to a lack of consensus about what constitutes the best answer. Consequently, the team considers the case studies conducted for this report as a springboard for addressing many of the fundamental questions for which risk assessment professionals cannot yet provide confident answers, and as a tool for increasing the communication among risk assessors, risk managers, and stakeholders in site cleanup projects.

6. REGULATOR, STAKEHOLDER, AND END-USER PERSPECTIVES ON USE OF RISK ASSESSMENT IN RISK MANAGEMENT

This chapter provides insiders' points of view on the use of risk assessment in management of waste sites. Risk Assessment Resources Team members who are regulators, stakeholders, and end users have contributed their suggestions for improving the use of risk assessment from their unique perspectives. The issues and perspectives discussed in Sections 6.1–6.3 were contributed by team members from each of the respective groups; however, many of the issues/perspectives are appropriate for all the groups.

6.1 Regulator Perspective

Both federal and state governments have programs that rely on guidelines for performing risk assessments to identify and control many risks, including exposure to regulated chemicals. In spite of available regulations, guidance, methods, and procedures, regulators often struggle to defend their decisions and answer related questions from the public and stakeholders. Often these issues are related to consistency, transparency, and uncertainty associated with a risk-based cleanup.

6.1.1 Consistency

In its first document (ITRC 2005), the team examined how state programs derive risk-based soil screening levels, finding that, contrary to popular opinion, state programs have a high level of similarity and consistency in the processes and approaches to deriving soil screening values. This document builds on that previous effort by examining how risk assessment, including those soil screening values, are applied.

While state programs are relatively similar in how they derive numerical soil screening criteria, they can differ in both development and application of the factors and assumptions used in risk assessment to evaluate exposure and fate and transport of contaminants at sites. State regulations and guidelines can also differ from federal guidance. For example, some states may not include background risks into the summation of risk from a particular site. With the opportunity for differences to come at many steps in the risk assessment process, some questions arise:

- How do we define consistency?
- How should it be achieved?
- How can consistency be maintained?
- What is the best way to successfully apply it in managing the various cleanup steps of screening, characterization, and remediation?

Some of these questions are asked of state risk assessors by stakeholders and end users. Some regulators are asked these questions by risk managers and program managers in their organizations. And risk assessors in regulatory agencies ask themselves these same questions.

Analyzing the case studies presented herein demonstrates that, although various states use different approaches to the same problem, they still share common elements. In some cases, states supplement the traditional risk assessment process steps, making the application more beneficial to use. For example, there are many different versions of a tiered approach. Even so, there are ways to improve (see Chapter 7).

The team recommends that their counterparts in other state organizations conduct comparative case studies on their own as a way to address consistency and related issues among their peers and perhaps among their various programs. Florida has used the approach of considering an example site in the public offering of its risk-based corrective action (RBCA) training with great success.

The comparative case studies presented in this report illustrate how both individual assessors and programs process the same risk assessment (site assessment) data differently, with different outcomes (decisions) being the net result. Some of the observed variation is clearly due to programmatic preferences. Given that the comparative case studies used herein are relatively simple, one might expect that more complex sites (with multiple chemicals and several potential pathways of exposure) would perhaps demonstrate even greater variation. One explanation for this variation is the lack of widespread agreement as to the "best" methodologies to process site characterization data for purposes of risk assessment. Discussion of how to best evaluate site characterization data is a complication not only for state risk assessors, but for virtually everyone involved in site assessment and remediation.

While some states (notably Florida) have developed guidance that tends to increase consistency, many states have not developed or adopted such guidance. Many states represented on the team, however, are receptive to relatively sophisticated methods of analysis (such as PRA) for dealing with complex situations. Such acceptance indicates that, if there were a demonstrably "best" methodology for characterizing and assessing sites, state regulatory agency staff would have accepted it long ago.

Clearly, there is an opportunity for work beyond the scope of this document to discuss in more detail the steps linking site assessment and risk assessment as well as risk assessment and risk management, both at a basic level and at more advanced levels, and how that effort can improve consistency. Members of the team explored many difficult topics, including consistency, through the comparative case studies performed in this report. Readers are strongly encouraged—even challenged—to show similar leadership by undertaking these same comparative case studies themselves and to offer the opportunity to complete the comparative case studies to others in their organizations (worksheets are available in Appendix C). A discussion and comparison of results has a high potential of being productive and enlightening. Matters of consistency are not limited to state regulators and their programs.

6.1.2 Transparency

Ideally, risk assessment activities are intertwined with site characterization activities, with an eye on informing the risk management decisions that need to be made. Thus, a site characterization should be designed to incorporate the needs of the risk assessment process, which in turn supports risk-management decision making. While a textbook version of how risk should be integrated in the management process can be developed with relative ease, this study demonstrates that implementation faces many challenges.

Often it is unclear (to those not directly involved) why a decision was made in the site characterization and/or risk assessment. Risk information must be presented clearly, separate from any nonscientific risk management considerations. Discussion of risk management options should be based on consideration of all relevant factors, scientific and nonscientific, articulating various assumptions, strengths, limitations, and uncertainties. Risk management discussions should outline the specific steps in the risk assessment process with focus on issues that can lead to variation as to how risk assessments are conducted that directly influence management of site risk.

6.1.3 Uncertainty and Conservatism in Risk Management

Simply speaking, risk assessment is a comparison of actual or projected levels of exposure (often based on predictive equations or models) with a reference level of exposure that has been predetermined as posing an insignificant hazard or risk. Much research, analysis, discussion, and even formidable debate at the national level occur when the regulatory world defines an exposure level or dose as being "significant."

An informative risk assessment must provide estimates of the risk consequences and uncertainties (including data accuracy and precision and how they affect the assessment's outcome) that are commensurate with available data, knowledge, and understanding. Providing meaningful analyses of uncertainty is a challenge to risk assessment. There are a number of sources of uncertainty—from the basic data for deriving a numerical criterion through the site assessment—that provide a challenge to quantifying uncertainty in a meaningful way.

A risk assessment that reports only a single value for the level of adverse health and environmental consequences may belie the inherent uncertainty in the process. In most cases, regulators and the state programs they work for have not adopted deterministic approaches in quantifying uncertainty and its significance. And while sophisticated approaches such as PRA are gaining acceptance, they can describe only sources of uncertainty. There will always be uncertainties in risk assessments; however, conservatism is built into the process of risk assessment and decision making to ensure the protection of human health and the environment.

The "posture of conservatism" is not immune from controversy. Toxicological estimates and epidemiological data used when quantifying the risk at a site often have protection factors included in their final values that can add orders of magnitude of conservativeness to risk calculations. Similarly, some exposure scenarios and assumptions associated with exposure assessments can incorporate orders of magnitude of conservativeness in the calculated risk or hazard. Bringing conservative factors together in a multiplicative manner and then comparing them to statutorily "safe" levels are often criticized. Thus, it is important to correctly identify and objectively portray these sources of conservatism to properly inform the risk management process. Not necessarily all the variables are conservative. Some of these variables are in the 95th percentile, and others are based on central tendency, such as body weight, skin surface area, dermal absorption, and inhalation (Florida Department of Environmental Protection 2005).

This conservative approach has roots in public health policy, but in the case of waste sites, there is also a very human element. When staring at a sampling result that is significantly larger than either a published screening level or surrounding measurements, who would not wonder if that "high" result represents a source of contamination or is just a result of heterogeneous contamination often typical of waste sites? In addition, incorporating such results into a risk assessment often poses a problem unless there is clear guidance on how to deal with this type of data. This predicament is likely the cause for the myriad of definitions of hot spots and not-to-exceed criteria that are common in state regulatory programs.

6.2 Stakeholder Perspective

In any risk assessment, it is critical at the outset to be prepared to integrate perspectives and anticipate issues. It is necessary for the risk assessor, regulator, and the RP to identify, understand, and integrate the needs and objectives of others within the regulatory, political, and socioeconomic aspects of the site. This is not to say that the assessment must be all things to all people, only that it must meet its objectives by clearly stating its purpose and approach and provide a means of effectively addressing the concerns of those who consider themselves "at risk" from the contamination or "at risk" by the overarching remedial/regulatory process itself.

Citizen stakeholders often see themselves as affected by "the site." They may have information, knowledge, resources, or positions that may be affected by or may influence the risk assessment and risk-management decision process. More importantly, they may control mechanisms instrumental for intervening. Therefore, identify stakeholders as early as possible and plan for their inclusion in the process. Moreover, consider how different stakeholders stand on the following:

- What is of importance to them in terms of risk?
- How do they define risk as harm for them?
- How are they likely to evaluate the significance of risk?
- What are their concerns about uncertainty?

By appreciating these concerns early on, it may be possible to better explain the risk assessment process and conduct the process itself in a more open, transparent, and understandable fashion that will meet stakeholders' expectations of fairness. They want to be engaged. They seek explanations that speak to their concerns about risk. Finally, they desire that the expectations associated with the process are clear from the start.

Early and effective communications with stakeholders addressing these concerns is a crucial component in the risk management and decision-making process. Citizen stakeholders, especially, need to understand how the technical aspects of risk assessment relate to them on a personal level in terms to which they can relate. The bottom line is that citizen stakeholders need to come away from any risk assessment discussion with the sense that they and their loved ones are safe and that no threat exists to their continued well-being. If an exposure has occurred or is going to occur, stakeholders need to know the associated mitigation plan to stop the exposure, to what extent they were or will be affected, and information on any related compensation.

The benefits derived from this document for the citizen stakeholder are that the various case studies illustrate risk assessments as site specific and that many different variables come into play toward reaching a final remediation value. Two different sites may be addressing the same kind of contamination problem, but the target cleanup values could be very different due to these site-specific variables such as naturally occurring background, hydrogeology, land use, receptors, etc. Although the final cleanup values may differ for those respective sites, the citizen stakeholders at those sites are protected under the applicable state and federal regulatory standards.

6.3 End User Perspective

Below are the issues represented by end users of risk assessment. For the purposes of this document, end users are defined as RP risk managers and the responsible party risk assessors working with them.

6.3.1 Impacts to Program and Project Management

Many risk assessment end users manage programs of a national scope, having sites in more than one state. The comparative case studies presented herein document what many have experienced and, at times, found frustrating. Risk assessment practices and application of their results in risk management vary between states and can even vary by program within states. A site requiring no further action in one state may require action in another. Efficiencies that could be gained through standardized practices for site characterization and assessment cannot be realized due to this variation, confounding resource planning.

6.3.2 Risk Assessment and Risk Management

The health risk assessment discipline uses toxicology data (from animal studies and human epidemiology) combined with information about the degree of exposure to predict quantitatively the likelihood of a particular adverse response in a human population. RP risk managers use this evaluation to make informed decisions about the need and extent of remediation.

On a site-specific basis, end users face the difficult challenge of balancing inherently conservative exposure and risk estimates with the expectation to achieve the unreasonable goal of negligible, if not "zero" risk. While there are prescribed methodologies and guides to develop risk assessments, few such guides are available to help the risk manager interpret the information in an assessment.

Risk managers should not be expected to be highly trained in the practice of risk assessment but should be expected to seek an understanding of what the results mean beyond just a single numerical output. At a minimum, the risk assessor should inform the risk manager of the major uncertainties and variation affecting an assessment's findings and conclusions. Sensitivity analysis can be a useful tool to demonstrate which parameters have the most influence on the risk estimate.

The lack of consistent guidelines for risk management, coupled with the inherent lack of understanding of the nuances of the risk assessment, sometimes means that the interpretation of the environmental risks will give more weight to the political or social pressures behind each of the agencies involved. It is not uncommon for risk managers to become frustrated with an assessment and its seemingly confusing results and then seek to clean up to a conservative criterion rather than "suffer" the risk assessment process because they feel that they would have ended up with a conservative cleanup regardless.

The assessment of risk in environmental remediation is intended to support risk-based remediation that ensures contaminated sites no longer pose unacceptable hazards, meaning that the RP has to remediate for the purpose of risk reduction, not the reduction of concentration or the removal of every toxic molecule. The result is that some of the chemical "contamination" may remain, while limited resources are focused to achieve the greatest benefit at an optimal cost. As the case studies show, there is variation in the ways risk assessment and risk-based criteria are used to develop remedial action goals and how they are applied in remedial design and action. Applying criteria as a "not-to-exceed" value for each scoopful of soil at one site may be practical, whereas at another it could lead to an expensive overexcavation of site soils.

Balancing of the science of risk assessment, effective engineering/construction solutions, and cost considerations is the art of effective risk management. Risk assessors translating what they used as an EU to a "decision unit" for risk management can lead to more effective application of risk-based criteria.

6.3.3 Toxicity Assessment

Development of toxicity values for use in risk assessment typically involves extrapolation from relatively high doses administered to experimental animals to low doses more likely to result from environmental exposure. Another source of data comes from exposures reported in occupational studies. The low-dose extrapolation is a significant source of uncertainty, especially for carcinogens. While there is recent movement towards techniques that will lead to less uncertainty in toxicity values, years or perhaps a decade will be required before EPA's IRIS database is sufficiently updated with values informed by more modern methods. Thus, given this uncertainty, communication between risk managers and toxicologists is essential to enhance everyone's understanding of chemical toxicity, which in turn will facilitate communication to the public regarding site risks.

6.3.4 Exposure Assessment

Exposure assessment uncertainties are unavoidable because assumptions are made relative to the exposed population (e.g., body weight, exposed skin surface area, etc.), the rate at which they contact environmental contaminants (e.g., inhalation rate, ingestion rate, etc.), and the amount of a contaminant to which they are exposed over time.

The primary routes of exposure to chemicals in the environment are inhalation of dusts and vapors; dermal contact with contaminated soils or dusts; and ingestion of contaminated foods, water, or soil. Experience has shown that, in attempts to be prudent (i.e., "protective") in decision making, there is a common overemphasis on the "reasonably maximum exposed" individual to the detriment of other exposure groups. Risk assessments should characterize the risks of exposure for those exposure scenarios that are currently, or likely, to occur at the site and not give undue weight to special groups that are not representative of site land use (e.g., subsistence fisherman or subsistence farmers) or are unlikely to occur in the foreseeable future. The use of conservative assumptions has to be reasonable and appropriate for protectiveness while not artificially inflating the calculated results in a risk assessment.

Risk managers and the public want to know the confidence in risk estimates as well as the critical factors that contribute to risk. Sensitivity analyses can yield important information about critical exposure variables; its use should be encouraged in the practice of risk assessment.

Heterogeneity of site contamination brings a great deal of uncertainty to the site characterization process as well as the exposure assessment. Resource constraints typically do not allow statistically derived random sampling schemes. The actual site case studies in Chapter 4 show that composite and Triad approaches are useful in managing site heterogeneity and achieving optimally characterized sites. Data collected using these methods should not be excluded from the risk assessment as long as the data are determined to be of appropriate quality and representative of site conditions.

Risk assessment needs to account for the environmental fate of chemicals. Many factors, such as degradation (by sunlight, soil and water microbes, and evaporation), bioavailability, and bioaccessibility, can dramatically influence the degree of exposure. Yet, many assessments have frequently assumed (falsely) that concentrations measured today will exist in perpetuity. Finally, the validity of human exposure models should be verified for use in risk assessment through the use of biological monitoring whenever plausible.

6.3.5 Risk Characterization

A first-rate risk characterization offers numerous opportunities to describe the "big picture." In the United States, it is generally accepted that theoretical increases in cancer risk of 10^{-6} or even 10^{-5} due to environmental exposures should not be depicted as a serious health risk. Risks predicted in most assessments are usually the upper, not the best, estimate of risk. It has been recommended that every assessment should state that risk estimates represent an upper bound of plausible risk (when appropriate) and are highly unlikely to underestimate risk.

6.4 Summary of the Various Perspectives

Notwithstanding the three main perspectives described above, a preferred risk management strategy should always use the best scientific, social, and economic information. The consideration of options necessarily involves value judgments that balance information from the human health and/or ecological risk assessment with an assessment of the relative costs, regulatory policy, and—most importantly—community acceptance of any solution (including the no-action alternative). The risk management process also includes undertaking any necessary monitoring and evaluation of the results and actions taken, as well as ongoing communication with stakeholders and the interested public. This chapter presented perspectives from regulators, stakeholders, and responsible party members of the Risk Assessment Resources Team. Below is a summary of the points made by each group.

Regulators

- State regulators face the same basic questions as other remediation professionals about the adequacy and accuracy of site characterization activities and how site characterization informs estimates of risk.
- State regulators would like to know the best methods to characterize sites and to have great confidence in the risk assessments done with those data. This report is a small step towards encouraging that end, and we hope that future work can focus on making more efficient the linkages between site assessment, risk assessment, and risk management.

Stakeholders

- Identify stakeholders early in the risk assessment process, communicate effectively with them, plan for their inclusion throughout the project life cycle, and actively include them.

Responsible Party End Users

- Inconsistent practices of risk assessment and risk management across states confound centralized resource planning and standard approaches to site characterization.
- Risk assessors should effectively translate the uncertainty and variation associated with the results of a risk assessment to those making decisions to facilitate fully informed risk management decisions.
- Decisions should be based on reasonably expected future land use.
- It is critical to include those that will be using site data in the project planning process. Inclusion of those using the data can ensure that their data requirements are met and can facilitate the use of innovative site characterization methods on sites.
- Protective and cost-effective remediation may be more effectively achieved when those implementing risk-based cleanups understand how the numbers derived for media should be applied in terms of averaging over areas or depths.

Figure 6-1 illustrates the road to improvement for the use of risk assessment in risk management.

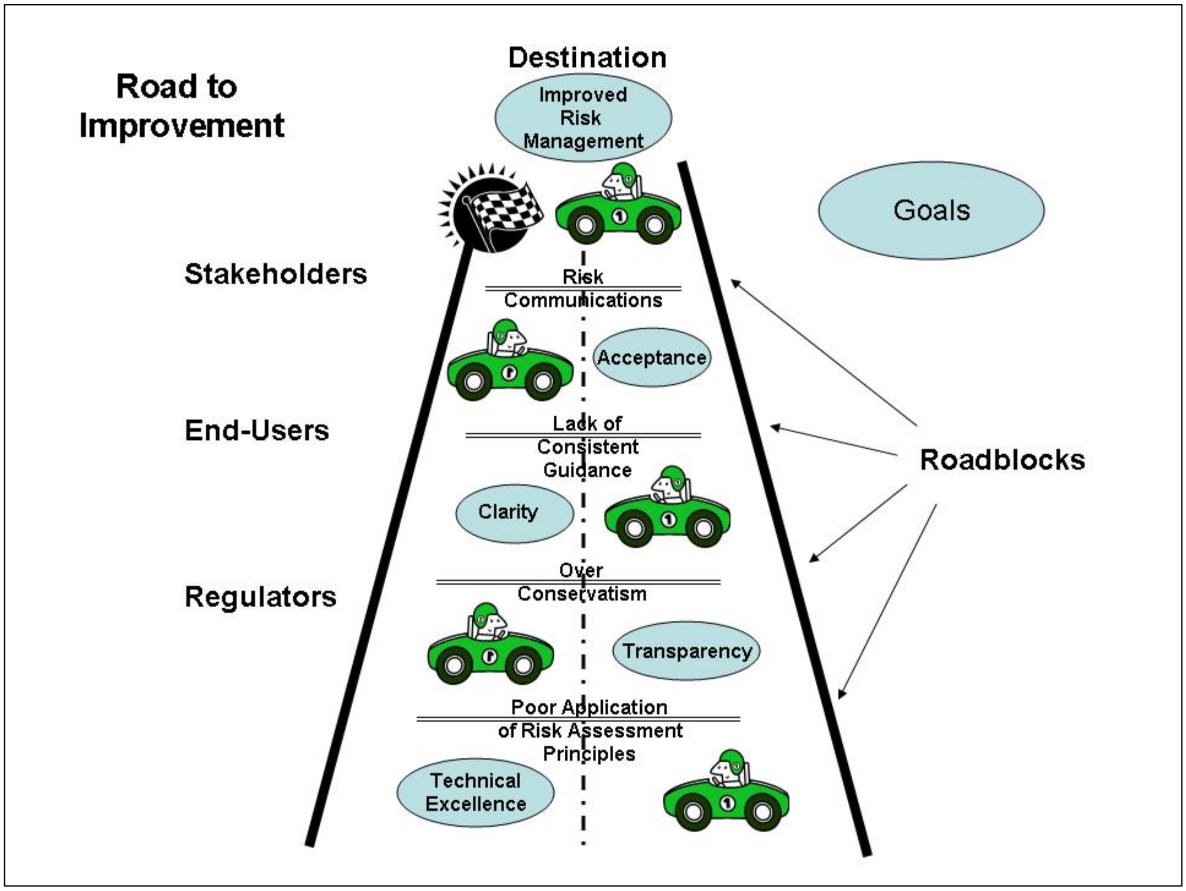

Figure 6-1. Risk assessment in risk management—road to improvement.

7. CONCLUSIONS

While the science of risk assessment is the same across states, the actual practice of risk assessment and the ensuing risk management decisions vary. This variation was a focus of the Risk Assessment Resources Team in its effort to improve the use of risk assessment in risk management. This current effort builds on previous work (ITRC 2005) in identifying variation in the development of numerical criteria used in risk assessment.

Exactly how risk assessment is considered during the different stages of the site cleanup process in various states and what similarities and differences exist among the state programs throughout various stages of cleanup are matters of interest to the team, ITRC, and the general risk assessment community. The team recognizes the importance of identifying variables that lead to differences program to program and state to state, such as the following:

- differences in legal basis and framework
- differences due to regulatory policy structure
- differences in technical approach
- differences in decision making
- differences due to political factors

The team could address only some of these variables, specifically, technical approach and decision making. The other sources of variation are difficult to address in this type of document and thus await discussion elsewhere.

This chapter summarizes the conclusions arising from the chapter identifying the many variables present within risk assessment (Chapter 2), findings of the team's survey of the use of risk assessment in risk management by eight states (Chapter 3), case study results (Chapter 4), comparative case study results (Chapter 5), and perspectives of regulators, nongovernmental stakeholders, and end users (Chapter 6). More critically, the team has developed an overarching framework of recommendations to help risk assessors and risk managers appreciate how variations arise and how to avoid potential decision-making pitfalls.

7.1 Key Findings

State regulatory programs can differ in both development and application of various factors that contribute to risk assessments (ITRC 2005). One topic considered of particular importance by the team was the difference among the states' determination of "background." Thus, states were surveyed concerning the use of background as a higher threshold for establishing a cleanup criterion. States seem to differ from federal guidance on whether all risks—including "background" risks—require aggregating together or whether risk should be determined as an increment due to a contaminated site. This report explores the use of background values as one of the elements where risk assessment may contribute to or influence risk management and decisions about risk management. The team's efforts also included a case study approach to highlight the use of risk assessment currently in the real-world application by risk management. The case studies present data to see how various states would deal with the contaminated sites under different scenarios (i.e., residential use, commercial use, etc.).

7.1.1 Selected Factors Influencing Variations in Risk Assessment

Chapter 3 provides an analysis and discussion of several issues/drivers that significantly influence the variation observed between states and programs:

- Sampling to support risk assessment, in particular
  - site characterization of hot spots
  - determination of EUs
  - use of collaborative data sets (i.e., field data in conjunction with fixed laboratory–validated data)
- Variations regarding the treatment of background concentration levels in soil.
- The application of tiered approaches to the risk management process across states.
- Site characterization and its interface with risk assessment is a major challenge and source of variation in risk management outcomes. It is not unexpected that variation would exist in site characterization, but optimally, these differences would exist on a site-specific basis to serve different project and DQOs. It is common though for those in the risk assessment community to find that data collection was planned without consideration to risk assessment data needs and without involvement in project planning.
- Fundamental challenges associated with site characterization are compounded by differences in approach to interpreting the data, leading to variation in risk assessment findings and risk management outcomes—differences that are apparent in questions such as, "Is the highest value representative of the level of exposure or is it an average?" and "How is soil variation dealt with, if at all?"
- Efforts to simplify risk assessment process, such as "default values," tiers, and even the provision of regulatory flexibility, do not necessarily always lead to the level of simplification hoped for.
- The range in risk assessment practices indicates that there can be improvement in the collection of data, the interpretation of data, and the use of risk assessment principles as a unifying forum for improving both data collection and interpretation.

7.1.2 Use of Risk Assessment in Risk Management of Contaminated Sites—Case Studies

Chapter 4 provides five case studies, from different states and with various cleanup challenges, in which risk assessment was used.

- Four of the five case studies were large-scale and highly resourced projects.
- Degree of risk assessment used is not proportional to its value added, which includes decreasing uncertainty and project cost (through avoidance of risk management and/or reduction of the number of contaminants that require management).
- Classical use of risk assessment with other factors in risk management is demonstrated by the case studies.
  - Further study to decrease site uncertainty can decrease project costs through avoidance of risk management and/or reduction of the number of contaminants that require management.
  - Probabilistic risk assessment may provide more representative ranges of risk associated with actual site conditions.

- Community/stakeholder involvement is important in remedial decisions that affect their properties and community. Stakeholder support can facilitate decisions and their implementation.
- Volumes of contaminated media that require treatment or disposal may be reduced if risk-based risk management goals using statistical approaches, rather than “bright lines” or not-to-exceed criteria, are applied.
- Basing site decisions on single, discrete samples is likely to be overly restrictive.
- Use of data collection methods uncommonly used to support risk assessment may be facilitated through careful DQO development during project planning.
    - Composite sampling strategies may be valid for informing decisions of whether further study is required and may be appropriate for risk assessment if uncertainties are appropriately addressed in the risk analysis.
    - Use of field analytical methods to collect data for use in risk assessment may be appropriate if the method is corroborated with fixed laboratory analysis.

7.1.3 State Regulators’ Perspectives: Comparative Case Studies

Chapter 5 provides state regulators’ responses to the hypothetical sites for comparative case studies that the team developed:

- Variations in risk assessment practices can be based in programmatic preferences or in technical differences of opinion.
- Variations in risk assessment practices can have significant impacts on risk assessment outcomes and subsequent risk management decisions.
- The major source of variation discerned in the comparative case studies is that the linkage between how one defines an EU, samples that EU, and evaluates the results leads to differences in risk management outcomes.
- The variation observed in the comparative case studies is over application of fundamental risk assessment principles applied to relatively simple conditions, which has implications for more complicated conditions.
- The comparative case studies proved to be an invaluable tool for understanding approaches and differences in risk assessment. The team encourages risk assessment professionals not only to undertake for their own understanding the comparative case studies developed for this report, but to expand the concept to more complicated site conditions and settings.

7.2 Recommendations

Risk assessment is a fact-driven exercise, contextualized by values ensconced in law and regulation. Risk assessors must recognize that we are involved in a fact-intense business; but stakeholders and end users are value driven, and their values can and should equally frame the effort. The best way to collapse the “fact-value gap” that exists between assessors, stakeholders, and end users is through the development of a CSM at the earliest point possible, designed in a fashion that anticipates the values at issue. Based on its studies and reflection on the lessons learned, the team concludes that it is possible to recommend an improved framework to help collapse the “fact-value gap” that often arises between the science (“facts”) used in risk assessment, and the “values” embraced by regulators making decisions and taking actions under a particular legal and regulatory framework (risk managers), end users (those affected by risk management decisions), and stakeholders (those often at risk).

Figure 7-1 provides an overview of this document's structure and the recommendations arising from the team's findings.

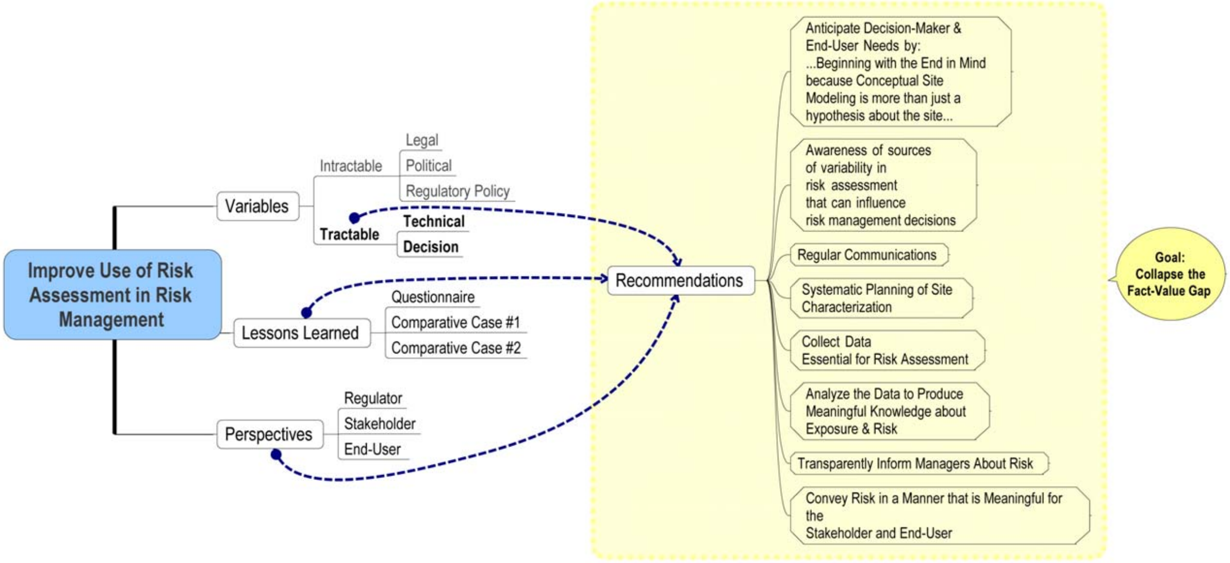

Figure 7-1. Recommendations arising from the lessons learned and perspectives.

The team took a focused and structured status quo query of how certain variables are handled in risk assessment, and the two comparative cases studies provide specific insights concerning how risk assessment is being used in risk management and capture current perspectives of regulators, stakeholders, and end users. The team used this information to formulate specific recommendations, in particular, to improve the use of risk assessment in risk management, anticipating decision-maker and end-user needs to inform systematic planning that results in an effective collection and analysis of meaningful data, which transparently informs managers about risk when they make decisions and must communicate results. These recommendations are discussed in detail below.

In previous chapters, particularly Chapter 2, the team outlined the classic risk assessment–risk management process that is typically applied by most states. The left side of Figure 7-2 presents this classic process. If one applies the recommendations discussed herein, the team believes that the process of using risk assessment in risk management of sites will improve, as shown on the right side of Figure 7-2. While some might interpret the improved process as idealized, it is firmly grounded in reality. The improved process reflects the reality that while involving stakeholders early in the process might not be required, it anticipates the eventual involvement of stakeholders. Without factoring stakeholder involvement into the process, the process could be viewed as flawed, which might affect the final decision, create decision delays, or increase costs. The improved process uses an approach that addresses the needs of stakeholders and the needs of end users with valid scientific research in a timely, cost-effective manner. The details of each step follow.

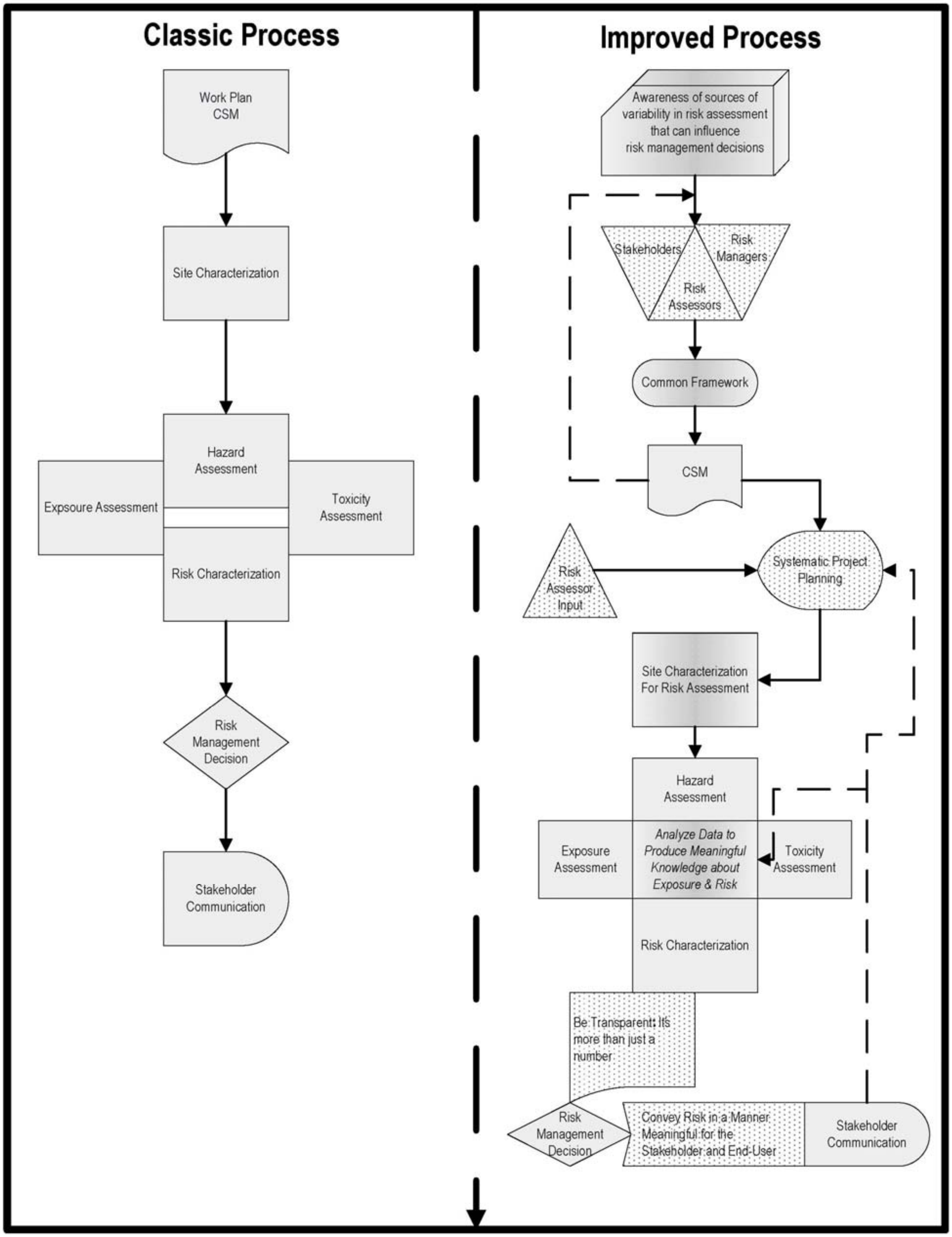

Figure 7-2. Applying this report's recommendations to the classic process to achieve an improved and more transparent risk assessment–risk management process.

7.2.1 Anticipate Decision Maker and End User Needs

It is critical to begin the remedial process and risk assessment with the end (of the process) in mind (Frantzen 2001) because the CSM is more than just a hypothesis about a contaminated site. The CSM establishes a common framework for understanding the site and its environs and how the contaminants may have been and continue to be transported in the environment. It also outlines how the risk assessment will work through the details to establish the potential for hazard and the risk for adverse effects.

Thus, the CSM articulates—in schematic, flow chart, or cartoon form—the general understanding the site, and it should reflect the values held as important by all involved. Thus, it is dynamic, requiring update as more information about the site becomes available. In this way, the CSM provides a concise and concrete depiction of the conditions being investigated due to their importance and the issues deemed critical for the risk assessment. Similarly, it allows those involved as well as potential skeptics to appreciate the data gaps that may exist due to a particular focus established early on in the process.

7.2.2 Be Aware of Sources of Variation in Risk Assessment

It is critical that all involved be aware of sources of variation in risk assessment and how such variation influences downstream risk management decisions. As a detailed reading of the comparative case studies will show, the participants in the case studies vary in their approaches and assumptions to some of the basic components of a risk assessment. For example, how the participants approached the EU and EPC appears to be a significant source of variation.

The first comparative case study showed a range in the dimensions of the EU, which resulted in a comparable range in risk management decisions. Variation also arose because some participants did not average the soil data, others did, and a third set applied a more robust statistical approach to averaging. The net variation is reflected in the illustrations in Chapter 5 identifying soil that would merit risk management.

In its simplest form, risk assessment relies on comparing the actual or projected exposure (either dose or environmental exposure concentration) with what has been determined to be the "allowable" exposure (dose or concentration). In applying risk assessment to contaminated properties or sites, three main elements are reconciled to establish the actual or project exposure:

- sampling
- the physical dimensions/characteristics of the site itself
- risk assessment principles

The outcome of this effort produces an estimate of risk or hazard that is used to inform risk management decisions.

Risk assessment and risk management for contaminated sites and properties takes place within a regulatory framework where various requirements, preferences, and practices can influence not only the risk assessment but also the risk management options. While addressing contaminated sites and properties can be a significant challenge, risk assessment principles provide a structure and process so that this goal can be accomplished better than without those principles. Still, each step in the risk assessment process can be subject to interpretation and variation.

In this report, some of those sources of variation have been examined with an interest in their influence on risk management outcomes. A major focus has been on examining the variation in how sampling results are used in conducting in risk assessments. The results of the team's examinations have lead to recommendations that the "classic" risk assessment process can be improved through an appreciation of how variation in risk assessment practices can lead to variation in risk assessment outcomes and eventually can influence risk management decisions.

7.2.3 Communicate Regularly

Risk communication is not just for the end of the process, but must be practiced throughout it. Whoever is leading the remedial process must begin early engagement with stakeholders, risk assessors, and risk managers to develop a common framework of perceiving the site to effectively build a meaningful CSM. Dialog is essential to appreciate the deeper sides of others' positions, resulting in the development of overlaps of understanding, achieving definitions with which all can agree, and clarifying issues of critical importance requiring data and the least amount of uncertainty (Fratzen 2001). The goal is the establishment of a fair process (Kim and Mauborgne 1997) of

- engagement (talk and reason together)
- explanation (in simple language explain what was done and why)
- expectation clarity (the rules must be understood by all involved)

7.2.4 Plan Systematically

From the proceeding discussion, it should be clear that it takes a team that effectively communicates and is committed to carefully weighing decisions in the light of the awareness described above to plan systematically (USACE 1998, EPA 2000a, ITRC 2003b).

- When developing the CSM and systematically planning the site characterization, involve risk assessors to ensure that all necessary data are collected.
- Define the EU[21] (in terms of area and depth).

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[21] Even EPA defines this term differently; consider these examples:

- "An exposure point (also called an exposure area or EU) is a location within which an exposed receptor may reasonably be assumed to move at random and where contact with an environmental medium (e.g., soil) is equally likely at all sublocations." (from the EPA Region 8 at www.epa.gov/region08/r8risk/hh_exposure.html)
- "The 'EU' concept should be considered in the development of the exposure assessment. An EU denotes an areal extent of a receptor's movements during a single day—analogous to the idea of a home range used in an ecological risk assessment. For example, a young child under the age of 6 will probably range over the area of a typical residential lot (less than a acre) where a maintenance worker at a large industrial facility may move about the entire facility. This concept is important in determining which samples should be included in the calculation of the EPC. The exposure assessment for a large site with one or more small areas of highly contaminated media should consider a hot-spot analysis. The hot-spot analysis involves the use of the Fraction Ingested (FI) Term applied to the appropriate EU." (from EPA Region 4 at www.epa.gov/region4/waste/ots/healtbul.htm)

- How will EPCs be determined and how do they relate to the EU?
- What data (chemical, physical, and biological) are essential to the characterization and the risk assessment?
- Will the site characterization allow the use of composite samples across areas?
  - What does it gain in terms of information, cost savings, or other benefits?
  - What information might be lost either way?
- How will the data be condensed, statistically?

There are several great planning tools for site characterization with different names; they are very similar and rely upon the same process—methodically plan with the end state in mind. They are effectively based on common sense; however, common sense is often not common practice, and these tools are frequently underutilized. The team encourages systematically planning projects with the involvement of those making site decisions, those collecting data, persons who will use the data, and stakeholders. The team recommends that individuals think of the planning process in this fashion:

- First, define the desired end state of the project and what "site close-out" means to each party involved. Once this is defined, draft a CSM, and remember to refine it throughout the project life cycle.
- Second, define the objectives of the site characterization, the risk assessment, and the risk management decision process.
- Determine what data are essential to inform or reach those decisions.
- Decide (after discussing the matter with those involved in making specific decisions) what data quality level is essential, that is, what level of uncertainty is acceptable or affordable.

7.2.5 Collect Data Essential to Risk Assessment

Ideally, sufficient data should be collected to satisfy multiple data uses—compliance, risk assessment, and remedy development for example. More often than not, the site characterization obtains insufficient data and/or critical insight (information) to inform the risk assessment effectively, forcing the risk assessor to use overly conservative assumptions to achieve the requirement under risk assessment guidance of being demonstrably protective of human health and the environment. Thus, when decisions are made to limit data collection due to cost, schedule, or other reasons, the project team needs to formally capture the decisions. Additionally, they should evaluate the decision in terms of their impact to the risk assessment and risk management decision process.

7.2.6 Analyze to Produce Meaningful Knowledge about Exposure and Risk, Now and in the Future

Risk assessors need to be cognizant of their ultimate audience (stakeholders and end users, as well as risk managers), to design their assessments accordingly, and to communicate their assessments effectively. There is never complete data; thus the assessor should address issues of data quality, accuracy, and precision and discuss the implications of uncertainty on the assessments findings and conclusions. Additionally, the assessor needs to appreciate the site's position in the local landscape and in terms of land use currently, as well as over a reasonable planning horizon.

7.2.7 Clearly Inform Managers about the Risk and How It Was Assessed

Risk assessment is more than mere numbers! Regardless, many non–risk assessors involved in remedial process think that risk assessment is only about applying simple arithmetic to calculate a screening criterion.

Risk assessment is about what is being measured at a site versus what is being used as the standard of comparison. The case studies demonstrate this assertion. Consider the scenarios involving lead—the comparative standards vary over less than an order of magnitude, but the EU can vary over several orders of magnitude (see Table 7-1). Obviously, the combination of various pieces of data coming from the site characterization within the risk assessment is a type of measurement. Thus, the measuring device needs to be well designed and effectively elaborate what the results mean in real terms.

7.2.8 Convey Risk in a Manner Meaningful for the Stakeholder and End User

This chapter has already discussed the importance of risk communication. In the current context, what is important is that risk assessment is a fact-driven exercise built within a context of values ensconced in law and regulation as well as stakeholder and end-user values. Risk assessors and risk managers alike must recognize that they are involved in a fact-intense business, but stakeholders and end users are value(s) driven. Thus, risk assessors and risk managers must wrestle with how to collapse the fact-value gap that exists. Once the data (facts) are available and if the process began with the end in mind, it should be far easier to convey the findings of the risk assessment in a meaningful manner.

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Appendix A

Detailed Information on State Approaches to the Use of Background

DETAILED INFORMATION ON STATE APPROACHES TO THE USE OF BACKGROUND

An expansion of Table 3-3 in Section 3.2.2, "State responses to questions about use of background in risk assessment," Appendix A provides detailed descriptions of the approaches used by several states regarding the use and treatment of background samples in risk assessment.

A.1 ARKANSAS

Arkansas usually defaults to EPA guidelines dealing with surface soil background levels (EPA 2000b or 2002a). In some site-specific cases, a less formal approach is taken by taking a minimum of four background samples (away from the contaminated site) and deriving a value based on the mean +/– 2 standard deviations.

Region 6 Corrective Action Strategy (EPA 2000b)
Appendix C, Page C-7 (High Priority Bright-Line Table)

Contaminant background concentration/range (*mg/kg*)

Aluminum	45000	Copper	20
Arsenic	1.1–16.7	Lead	10–18
Barium	430	Manganese	389–850
Beryllium	0.5–2	Mercury	0.1
Boron	2–100	Nickel	16
Cadmium	0.01–1.0	Silver	0.01–5
Chromium	38	Tin	122
Cobalt	8	Vanadium	66

A.2 MASSACHUSETTS

The determination of representative background levels for a disposal site is an explicit requirement of the "Massachusetts Contingency Plan" (310 Code of Massachusetts Regulations [CMR] 40.0835(4)(f) and 40.0904(2)(b)). Except when MADEP published background levels are used, background should be dealt with on a site-by-site basis and should be medium-specific.

A.2.1 "Background" in the Massachusetts Contingency Plan

> 310 CMR 40.0006: *Background* means those levels of oil and hazardous material that would exist in the absence of the disposal site of concern which are: (a) *ubiquitous and consistently present* in the environment at and in the vicinity of the disposal site of concern; and (b) attributable to geologic or ecologic conditions, atmospheric deposition of industrial process or engine emissions, fill materials containing wood or coal ash, releases to groundwater from a public water supply system, and/or petroleum residues that are incidental to the normal operation of motor vehicles.

The regulatory definition of "background" makes clear that the term is not limited to "pristine" conditions and that MADEP recognizes that historic human activities have resulted in the presence of some chemicals in the environment. Such nonpristine conditions must meet the conditions described in both of the clauses of the definition, however. It is important to note that, under this definition, oil or hazardous material from one release cannot be considered background for another release.

> "It should be assumed that a detected chemical is present above background concentrations unless it can be otherwise demonstrated." (MADEP, *Guidance for Disposal Site Risk Characterization In Support of the Massachusetts Contingency Plan: Interim Final Policy*, 1995, WSC/ORS-95-141)

Site background levels become the cleanup goals of the response action if it is feasible to achieve those levels. Achieving background levels is considered feasible unless:

- The remedial alternative is not technologically feasible (technological feasibility criteria found in 310 CMR 40.0860(5)).
- The costs or risks associated with the remedial alternative would not be justified by the benefits (cost/benefit analysis criteria found in 310 CMR 40.0860(6)).
- Experienced individuals are not available to implement the remedial alternative.
- The alternative would necessitate off-site land disposal, and no facility is available.
- The elimination or control of the source of oil and hazardous materials is not achievable by the person conducting the response action.

Chemicals that are present at levels consistent with background can be removed from the risk characterization process: they are, by definition, at a level of No Significant Risk (310 CMR 40.902(3)). Conversely if a chemical is present at concentrations above background, then it cannot be so eliminated. Thus, background data are one factor used to identify COCs for the risk characterization.

Historically, MADEP has considered the use of published generic background levels to be an option of last resort when obtaining site-specific data was not possible. The following table presents the list of Massachusetts Background Soil Concentrations that may be used in lieu of site-specific background levels. These values were judged by MADEP staff to be sufficiently representative of Massachusetts nonurban (i.e., suburban and rural) locations.

A.2.2 Background Sample Collection and Analysis

Site-specific background determinations are necessary for chemicals not included in the list(s) of generic MADEP background concentrations. Site-specific background determinations may also be made where it is believed that site-specific background may, in fact, be higher or lower than the published Massachusetts values. For many chemicals, including chlorinated organic compounds, expected background levels would be nondetect (ND) and the risk assessor may adopt a background concentration of zero (or ND) without further analysis. Background sample collection and sample analysis methods should be consistent with those for other site-related samples and should be collected concurrently whenever possible to ensure that the analytical results are comparable.

A sufficient number of samples must be taken to allow a meaningful comparison of background concentrations to site concentrations. Generally speaking, more background samples are required under any of the following conditions:

- There is high variation in the concentration of analytes in the background data set (indicated by a coefficient of variation >50).
- Contamination exists in more than one medium.
- Small differences (small minimum detectable relative difference in inferential statistical tests) between site concentrations and backgrounds may be of concern.

When an argument is being presented that remediation of a site is unnecessary because the site concentrations are consistent with background or that a permanent solution has been achieved because site concentrations have been reduced to background concentrations, a sufficient number of background samples must be collected to support this assertion. The specific number of samples needed depends in part upon the method used to compare the results. A number of documents have been prepared by EPA which describe approaches to determining what is an adequate number of samples. A particularly useful publication is the *Guidance for Data Useability in Risk Assessment* (EPA Publication 9285.7-09, 1992).

It is important to remember that not all background samples need to be analyzed for all analytes. To minimize costs and streamline this assessment, analytes that exhibit a low degree of variation require analysis of fewer background samples. Thus, costs can be avoided if only analytes with a high degree of variation are analyzed for in every background sample.

Generic Massachusetts background soil concentrations (mg/kg)

Oil or hazardous material	Concen-tration in "natural" soil	Concentration in soil containing coal ash or wood ash associated with fill material
Acenaphthene	0.5	2
Acenaphthylene	0.5	1
Anthracene	1	4
Aluminum	10,000	10,000
Antimony	1	7
Arsenic	20	20
Barium	50	50
Benzo(a)anthracene	2	9
Benzo(a)pyrene	2	7
Benzo(b)fluoranthene	2	8
Benzo(g,h,i)perylene	1	3
Benzo(k)fluoranthene	1	4
Beryllium	0.4	0.9
Cadmium	2	3
Chromium(Total)	30	40
Chromium(III)	30	40
Chromium(VI)	30	40
Chrysene	2	7
Cobalt	4	4
Copper	40	200
Dibenzo(a,h)anthracene	0.5	1
Fluoranthene	4	10
Fluorene	1	2
Indeno(1,2,3-cd)pyrene	1	3
Iron	20,000	20,000
Lead	100	600
Magnesium	5,000	5,000
Manganese	300	300
Mercury	0.3	1
Methylnaphthalene, 2-	0.5	1
Naphthalene	0.5	1
Nickel	20	30
Phenanthrene	3	20
Pyrene	4	20
Selenium	0.5	1
Silver	0.6	5
Thallium	0.6	5
Vanadium	30	30
Zinc	100	300

Background samples should be collected in locations that are relatively undisturbed, unstained, and unlikely to have been used for handling or storing oil or hazardous materials or to have been affected by oil or hazardous materials migrating to that location. The sampling location should be based upon similarity of the medium and environmental conditions at the background area and the disposal site's conditions.

Background samples should not be collected off site in areas affected by another disposal site. The environmental setting may provide information on where to collect a background sample, such as the upgradient direction for groundwater or the upstream direction of a river. Conversely, the environmental setting may indicate locations where background samples should not be collected, such as a surface area affected by runoff from the disposal site.

If site-specific background concentrations are high relative to typical background levels, a decision to use those data to make a background determination must be justified by other geological or historical information.

As described in Section 2.3 in the main report, many decisions made during the assessment and remediation of disposal sites depend on a comparison of site conditions to background concentrations. Determination of whether site conditions are consistent with background can be reliably made with appropriate statistical techniques.

When comparing these generic background levels to site data, the risk assessor may conclude that the concentrations of an oil or hazardous material is consistent with background conditions if <u>all the site data are equal to or less than</u> the MADEP background level for that chemical. In any case where site concentrations are substantially higher than the MADEP background levels, the risk assessor will bear a relatively heavy burden of proof in using site-specific data to demonstrate consistency with background, and the site-specific evaluation will be closely scrutinized in any MADEP review.

MADEP considers site conditions consistent with background if

- both the median and maximum values for the site samples are less than or equal to the corresponding background values, <u>or</u>
- the median value for the site samples is less than or equal to the background samples median, and the maximum site sample is less than 50% greater than the maximum background concentration, <u>or</u>
- the maximum value for the site samples is less than or equal to the background sample maximum, and the median site sample is less than 50% greater than the background median.

A.2.3 Summary Statistics

Descriptive statistics for the site, including the *number of observations, median*, *minimum*, *maximum*, *mean*, *standard deviation*, and *geometric standard deviation* of each contaminant, should be calculated and presented. It is useful to include the frequency and limits of detection as well.

In the Office of Research and Standards' experience, the use of professional judgment by the risk assessor considering all relevant site information (including historical use of the site, etc.) and simple summary statistics is less likely to lead to erroneous conclusions than the use of a formal, inferential statistical test with small data sets. Generally speaking, the data sets should be comparable in size to provide meaningful comparisons. When making comparisons based on professional judgment, the risk assessor cannot rely on objective statistical measures (such as power and confidence) to validate the conclusions. Therefore, it is important that the thought process employed be described and well documented so that the reader may evaluate whether the conclusions are proper.

The option of summary statistic comparisons has been included for cases when the background and/or site data sets are not large enough for an acceptable inferential statistical test. Nevertheless, adequate sample sizes are needed to make reasonable decisions. The number of samples that is sufficient depends on a variety of factors. It is not possible to specify the optimal sample size a priori; however, these rules of thumb are offered to provide rough indication of what MADEP is likely to consider adequate. To assess both the central tendency and the variation of the background concentrations at a location, a minimum of three must be taken for each contaminated medium. This value is considered a bare minimum for a small, simple release at a small (<3-acre) site. For a slightly larger (<5-acre) but still simple site (in terms of geology and number and distribution of chemicals) where the nature of the contamination is not complex, five samples is considered the minimum. For larger, more complex sites, more background samples would be more likely to provide a defensible result.

- If the risk assessor or site manager believes that an incorrect conclusion is drawn due to statistical uncertainty, the option is always available to reduce that uncertainty through collecting additional background samples and/or performing an inferential statistical test.
- Statistical uncertainty due to inadequate sample size can never be used to justify a conclusion that the site conditions are consistent with background.

A.2.4 Inferential Statistics

The "gold standard" for comparisons of site and background data is the use of a statistical test. Statistical tests using a sample size large enough to provide appropriate power, confidence, and minimal detectable relative difference provide conclusive determinations about the relationship between site concentrations and background levels. A statistical test of the hypothesis that the contaminant levels at the site do not significantly differ from the background levels, if done properly, is the most conclusive evidence of that chemical concentrations at the site are consistent with background levels. Appropriate statistical methodologies are described in further detail in the guidance document.

A.2.5 Summary

The guidelines provided in this report are considered to be a simple and straightforward approach to address the issue of establishing site-specific background values for soil and groundwater media at corrective action sites. More complex parametric and nonparametric statistical testing methods may be considered for use in establishing background concentrations and comparing them to site investigation sampling results. It should be kept in mind that, even if site contaminant concentrations are above both default screening values or cleanup values or even established background values, the options probably still exist for risk-based corrective action strategies (i.e., institutional and engineering controls) to achieve site closure.

A.2.6 Additional References

EPA. 1992. *Guidance for Data Useability in Risk Assessment*. OSWER Directive 9285.7-09A. Washington: Office of Emergency and Remedial Response.

MADEP. 1995. *Guidance for Disposal Site Risk Characterization in Support of the Massachusetts Contingency Plan: Interim Final Policy*. WSC/ORS-95-141.

A.3 NEW JERSEY

In New Jersey, a background site investigation (SI) shall take place pursuant to New Jersey Administrative Code (N.J.A.C.) 7:26E-3.10 requirements, summarized below.

In general, a background soil investigation shall be conducted as follows:

- A minimum of 10 background samples shall be collected from on site or in the region of the site. Two samples shall be collected from each of five locations, with one sample collected at a depth of 0–6 inches and one at a depth of >12 inches at each location.
- Background samples shall be collected at locations unaffected by current and historic site operations as documented by the preliminary assessment, including aerial photographs. Wherever possible, background samples shall be collected from locations which are topographically upgradient and upwind of contaminant sources.
- Background samples shall be collected and analyzed using the same methods as were used for area of concern samples.
- Background samples shall be collected from soil types similar to the area of concern samples.
- The background data set shall be examined for statistical outliers as follows:
  - An outlier is defined as a concentration greater than 1.5 times the range of the 25th–75th percentile, plus the concentration of the 75th percentile. For example, if the 75th percentile concentration in a data set is 9 ppm and the 25th percentile is 3 ppm, subtract 3 from 9 and multiply the result by 1.5. Add the result—9 ppm—to the 75th percentile for a concentration of 18 ppm. Any sample point above 18 ppm would be considered an outlier. The background sample data shall be transformed to natural logarithms before performing the outlier test because it is assumed that natural background chemical concentrations are log normally distributed.
  - Also, an outlier shall not be considered part of background unless the chemical concentration is confirmed with the analysis of an additional sample from the outlier location. If the difference between the original and confirmation sample results is no greater than 20%, the average concentration of the two samples shall be considered the highest background concentration.
- The highest contaminant concentration found in the background samples shall be applied as an upper limit for the contaminant concentrations found on the site. If contaminant concentrations are found at any sampling location on the site exceeding the highest concentration found in the background samples, a remedial investigation (RI) shall be conducted.
- Samples collected for area of concern investigation shall not be averaged for background comparisons.

A related document is the Research Project Summary entitled *Ambient Levels of Metals in New Jersey Soils* (May 2003), which is the basis for the proposed New Jersey arsenic soil standard, found at www.state.nj.us/dep/dsr/research/ambient-levels-metal.pdf.

As for historic fill material SI/RI, it shall take place pursuant to N.J.A.C. 7:26E-3.12 and 7:26E-4.6(b) requirements. "Historic fill material" means nonindigenous material, deposited to raise the topographic elevation of the site, which was contaminated prior to emplacement and in no way connected with the operations at the location of emplacement and which includes, without limitation, construction debris, dredge spoils, incinerator residue, demolition debris, fly ash, or nonhazardous solid waste. Historic fill material does not include any material which is substantially chromate chemical production waste or any other chemical production waste or waste from processing of metal or mineral ores, residues, slag, or tailings. In addition, historic fill material does not include a municipal solid waste landfill site.

Summary of target contaminant concentrations in typical historic fill material (mg/kg)

Contaminant (ppm)	Maximum	Average
Benzo(a)anthracene	160	1.37
Benzo(a)pyrene	120	1.89
Benzo(b)fluoranthene	110	1.91
Benzo(k)fluoranthene	93	1.79
Indeno(1,2,3-cd)pyrene	67	1.41
Dibenz(a,h)anthracene	25	1.24
Arsenic	1,098	13.15
Beryllium	80	1.23
Cadmium	510	11.15
Lead	10,700	574
Zinc	10,900	575

Historic fill database summary table

	Minimum (ppm)	Maximum (ppm)	Average (ppm)	Number of samples	Number > URU CDCSCC[a]	% > URU CDCSCC	Number > RU[b] CDCSCC	% > RU CDCSCC
Benzo(a)anthracene	0.03	160.0	1.37	441	126	29	33	7
Benzo(a)pyrene	0.02	120.0	1.89	431	146	34	146	34
Benzo(b)fluorene	0.02	110.0	1.91	426	118	28	39	9
Benzo(k)fluoranthene	0.02	93.0	1.79	412	101	25	26	6
Indeno(1,2,3-cd)pyrene	0.02	67.0	1.41	397	70	18	18	5
Dibenzo(a,h)anthracene	0.01	25.0	1.24	286	78	27	78	27
Arsenic	0.05	1,098	13.2	369	35	9	35	9
Beryllium	0.01	79.7	1.23	213	21	10	21	10
Cadmium	0.02	510	11.1	236	147	62	5	2
Lead	0.28	10,700	574	538	259	48	119	22
Zinc	2.45	10,900	575	197	80	4	8	4

[a] URU = unrestricted use, CDCSCC = current direct contact soil cleanup criteria.

[b] RU = restricted use.

A.4 WISCONSIN

Please refer to the Wisconsin Department of Natural Resources (2005) document *Guidance for Determining Soil Contaminant Background Levels at Remediated Sites*.

Appendix B

Detailed Case Studies

DETAILED CASE STUDIES

Appendix B provides detailed information collected for each of the case studies discussed in Chapter 4, "Case Studies: Use of Risk Assessment in Risk Management of Contaminated Sites."

B.1 SPRING VALLEY, WASHINGTON

B.1.1 Background Information

Site/Case Study Name(s): Rodman Street and 48th Street, Operable Unit 5 (OU5), Spring Valley Formerly Used Defense Site

Site/Case Study Location: Northwest Washington, D.C.

Regulating Entities and Authorities:
- District of Columbia Department of Health (DCDOH)—Given authority by the Mayor of the District of Columbia. Additionally, an MOU exists between Department of Defense and the District of Columbia.
- EPA Region III—Authority through CERCLA, as amended by the Superfund Amendments and Reauthorization Act.
- USACE—Authority through 10 U.S. Code §§ 2701 et seq. Defense Environmental Restoration Program and its policies and procedures relating to FUDS.

Parties Conducting Investigation/Risk Assessment/Cleanup: The lead agency for the site is USACE. Investigations and removal actions are being performed by the USACE Baltimore District. The baseline risk assessment was performed by EPA Region III.

B.1.2 Site Description

History, Type(s)/Sources of Contamination, Duration of Disposal/Operation: During WWI, the U.S. Government established the American University Experiment Station (AUES) to investigate testing, production, and effects of noxious gases, antidotes, and protective masks. At the time, this was a rural area on the outskirts of Washington, D.C. AUES was located on the present site of American University and used adjoining properties to conduct research, development, testing, and evaluation of chemical warfare material (CWM), including mustard and lewisite agents, adamsite, irritants, and smoke. The research, development, testing, and evaluation of CWM at AUES resulted in CWM, chemicals with CWM-like properties, and related materials being disposed on the various properties that composed AUES. In 1921, all temporary facilities were dismantled. Salvage materials and areas were completed, and the property returned to the landowners.

Interest in buying property for residential use grew, and the properties formerly occupied by the AUES, except the property occupied by American University, were developed for residential housing and named Spring Valley. In 1993, a utility contractor accidentally uncovered buried ordnance at a property in Spring Valley. Following removal of the ordnance, USACE conducted an RI of the entire area within the FUDS boundary. Some 53 areas with potential hazardous items were identified and designated as points of interest (POIs). Subsequent examination of these POIs found arsenic contamination in surface soils. A further examination of the POIs resulted in an extensive post-RI sampling program after the identification of arsenic in surface soil near POI 24.

During the extensive soil sampling program (more than 15,000 samples) performed as part of the engineering evaluation/cost analysis (EE/CA), USACE sampled more than 1,600 sites within the FUDS boundary, based on historical usage. Based on these sample results, USACE is performing a removal action consisting of the excavation and off-site disposal of arsenic affected soil from the properties. Removals are planned for nearly 190 properties, and 51 have been completed as of this writing. Risk across the entire site has been reduced by approximately 60% through excavation and off-site disposal of arsenic-contaminated soils. Two properties with completed removal actions were selected for the Spring Valley case study, one on Rodman Street and another on 48th Street. The property on Rodman Street is located outside of areas where CWM field testing was documented by aerial and ground photographs, testing reports, and other historical documents. Conversely, the property on 48th Street is located in areas where CWM field testing was documented by aerial and ground photographs, testing reports, and other historical documents.

Is the area considered by this case study the whole site, a part of the site, or perhaps an operable unit or analogous categorization? The two properties selected as part of the case study are part of the larger Spring Valley FUDS. The total area of the Spring Valley FUDS is 661 acres, which includes 1,200 private residences, foreign embassies, American University, Wesley Seminary, and numerous commercial properties. The properties are single-family homes located on Rodman Street and 48th Street.

Describe the site(s) under consideration for case study. Location/area/operable unit under consideration for case study (if less than entire site). Size/area under consideration for case study in square feet, location relative to rest of site, and comparability with rest of site. The two residential properties are located on 48th Street and Rodman Street. The properties are each about ½ acre in size and are located in an upper-middle class neighborhood in Washington, D.C. The immediate surrounding area is residential, and the outer surrounding areas are residential and institutional. The properties are two of more than 1,600 sites within the Spring Valley FUDS. The two sites compare well with the other residential lots within the Spring Valley FUDS; however, they are not representative of the commercial/institutional properties (e.g., American University).

B.1.3 Site Status

Investigation Phase	Completion Status
Discovery	No
Preliminary assessment (PA)/SI	No
Phase I, II, or III property assessment	No
RI	No
Baseline risk assessment	While a baseline risk assessment was completed for the FUDS, no baseline risk assessment was completed for the properties on Rodman Street or 48th Street.
EE/CA Report	Yes
FS	No
Remedial design (RD)/RA	No
Remediation	Removal action (as part of the EE/CA)
Post-remediation monitoring	No
Close-out or NFA letter issued	Yes (in progress)

The two properties on Rodman Street and 48th Street were not part of the initial USACE investigations of the Spring Valley FUDS including the baseline risk assessment or RI. The first data on these locations were collected during the sampling to support the EE/CA. This sampling occurred after the completion of the RI.

B.1.4 Risk

At what stage, if any, were risk-based exposure criteria introduced? The evaluation of risk associated with the Spring Valley FUDS project progressed through a series of comprehensive and increasingly focused risk assessment steps. The rigorous risk assessment efforts undertaken were due to the nature, extent, and magnitude of the site contamination and the potential high cost to remediate the site.

Risk assessment activities at the Spring Valley FUDS began following the accidental discovery of the small buried ordnance deposit in January 1993. Following emergency removal of the ordnance, USACE began a two-year RI to determine the extent, magnitude, and risk of residual CWM and related chemicals, developmental materials, and ordnance and explosives that potentially remained at the site.

An initial risk assessment was conducted as part of the initial investigation (USACE 1995), during which 260 random soil samples were collected from 13 areas of the site, including 17 of the 53 identified POIs. The samples were collected at the estimated 1918 ground surface level.

During the initial RI, EPA collected background soil samples and split samples of the original site characterization soil samples to conduct its own independent RA. EPA’s draft RA was completed in 1999, following the evaluation of additional background and site characterization soil samples collected during later stages of the Spring Valley project. The draft baseline risk assessment concluded that there was no unacceptable risk but that hot spots may exist. In conjunction with site characterization soil sampling activities, EPA conducted background sampling to establish site-specific soil screening levels. The background sampling entailed the analysis of 12 split samples collected from background locations within the FUDS boundary during the 1993–1994 RI and 30 samples collected outside the FUDS boundary in 1999. Background arsenic concentrations ranged 0.97–18 mg/kg, with a geometric mean of 5.1 mg/kg. A screening level concentration of 12.6 mg/kg was established based on the 95th percentile of the 42 background samples.

During 1997, concerns from DCDOH that the 1995 RI was not complete led USACE to reevaluate the investigation, findings, and report. Through this effort USACE found that POI 24 had been mislocated. Additional investigation revealed two CWM burial pits. Following removal of materials, EPA and USACE collected soil samples to identify areas of potential contamination on Glenbrook Road near the former burial pits. These properties comprise the Spring Valley project's Operational Unit 3 (OU3). The risk assessment performed for OU3 served as the basis for the follow-on activities in OU4 and 5.

A risk assessment for the Glenbrook Road properties was conducted in 1999–2000 to evaluate the site-specific risks/hazards posed by the chemicals detected at the site to develop human health protective remediation goals for the chemicals determined to pose an unacceptable risk. Details of the risk assessment, as well as the site-specific assumptions and results for the OU3 properties are presented in Appendix B of the *Engineering Evaluation/Cost Analysis, 4801, 4825, and 4835 Glenbrook Road, Spring Valley Operable Unit 3, Washington, D.C.* (USACE, 2000).

The results of the risk assessment for OU3 were used to perform a streamlined risk assessment to support the EE/CA for OU4 and 5, in which the Rodman Street and 48th Street properties are located. The streamlined risk assessment for these properties focused solely on arsenic and selected arsenic remediation end points of 20 mg/kg for accessible soil and 43 mg/kg for inaccessible soil under hardscape (e.g., paving, patios) and landscape (e.g., shrubs, trees) features or where remedial access is too difficult or unsafe. The 20 mg/kg end point was slightly higher than the maximum background concentration (18 mg/kg) and less than the calculated noncancer soil screening level of 23.5 mg/kg for a child resident receptor. The 43 mg/kg end point was allowed on a limited basis and only with the property owner's concurrence.

<u>What was the source of the exposure criterion (criteria)? (reference the document):</u> The sources of the exposure factors in the streamlined risk assessment are documented in the following project documents:

- Appendix B in the *Engineering Evaluation/Cost Analysis, 4801, 4825, and 4835 Glenbrook Road, Spring Valley Operable Unit 3, Washington, D.C.* (USACE, 2000)
- Section 5 (Streamlined Risk Evaluation) in the *Engineering Evaluation/Cost Analysis, Volume I, Spring Valley Operable Units 4 and 5, Washington, D.C.* (USACE, 2003)

In general, the exposure factors that were used are consistent with defaults for residential exposure scenarios that were used in the baseline risk assessment prepared by EPA. A commercial construction worker scenario was also developed.

List the concentrations used for screening and remediation. What level of risk is this intended to represent (e.g., 1/million increased incident of cancer, hazard quotient of "1", etc.)? What land use/exposure scenario does this risk represent? The following table lists the concentration and explains the corresponding risk or hazard level to which the concentration compares:

Concentration of arsenic in soil	**Discussion**
0.43 mg/kg	EPA Region III residential risk-based concentration for soil ingestion (only), based on a 10^{-6} individual excess cancer risk and "standard" residential exposure assumptions; based on default exposure factors corresponding to reasonable maximum exposure (RME) assumptions.
20 mg/kg	"Remediation end point" value for residential receptors, agreed upon by the Spring Valley Partners (USACE, EPA, DCDOH). This concentration is between the maximum project-specific background concentration (18 mg/kg) and a noncancer soil screening level for a "child resident receptor" (23.5 mg/kg).
43 mg/kg	Limited-application remediation end point, to preserve hardscape (e.g., paving, patios) and landscape (e.g., shrubs, trees) features or to be used where remedial access is too difficult or unsafe, based on a 10^{-4} excess cancer risk (EPA's upper boundary of the risk range [OSWER Directive 9355.0-30]).

The objective of the removal actions at these two properties was to reduce the risk of arsenic exposure to human health and the environment. The cleanup objective was to leave the soil with ≤20 mg/kg (20 ppm) of arsenic and to remove all other exposed soils with sampling results above 20 mg/kg. It is important to note that this removal action end point of 20 mg/kg reflects a consensus approach agreed upon by the Spring Valley Partners.

Was guidance available/used as to how to sample the site to use the criterion? (provide reference): In general, the EPA's *Soil Screening Guidance: User's Guide* (1996) and *Soil Screening Levels: Technical Background Document* (1996) were used to design the sampling plan in a manner consistent with the types of screening concentrations used. The project-specific sampling plans are the *Final Work Management Plan for Spring Valley Operable Unit 4* (USACE, 2000) and *Final Work Management Plan for Spring Valley Operable Unit 5* (USACE, 2002)

Was background determined/derived/established? If so, how, and what was the value(s). If not, why not. (Describe methodology for sampling for background, statistical analysis, results, and value selected, including rationale; any referenced sampling guidance followed should be listed): In conjunction with site characterization soil sampling activities, EPA conducted background sampling to establish site-specific soil screening levels. The background sampling entailed the analysis of 12 samples collected from background locations within the FUDS boundary during the 1993–1994 RI and 30 samples collected outside the FUDS boundary in 1999. The samples were collected from four soil associations identified within and outside the FUDS boundary. Samples were collected and analyzed for all metals on the Target Analyte List. The ambient background concentration of arsenic ranged 0.97–18 mg/kg, with a geometric mean of 5.1 mg/kg. A "screening level" concentration of 12.6 mg/kg was established for arsenic, based on the 95th percentile of the 42 background samples. EPA performed a statistical analysis on the concentrations to of metals in soil to determine whether there were any significant differences between soil types and found none.

Were multiple chemicals evaluated for similar/synergistic effect? If so, how was the combined effect of multiple chemicals evaluated? Several chemicals were identified as COPCs in the

EPA's baseline risk assessment and in the USACE risk assessment for OU3. In accord with EPA Region III guidance, the risk screening levels were reduced by a factor of 10 to account for possible additive effects. Four COPCs were identified, all with different target organs whose effects are not additive (e.g., longevity, skin/vascular effects, no observed effects). Results of the OU3 risk assessment showed that arsenic is the primary contributor to unacceptable risk, and only it was carried forward for further consideration.

<u>Was "risk management" other than removal/remediation used (e.g., capping, deed restriction, etc.)? If so, how did that influence analysis of "risk" and provide justification.</u> Excavation/ landfill disposal was selected from six alternatives, which were evaluated based on effectiveness, implementability, and cost: no action, institutional/engineering controls, phytoremediation, soil stabilization, soil washing, and excavation/landfill disposal. A phytoremediation treatability study is being performed at other properties in the Spring Valley FUDS to evaluate the method for properties whose owners desire a less intrusive remediation alternative.

<u>Describe the area over which concentrations averaged, and explain if it changed throughout the site cleanup process. How (if at all) was "point of exposure" identified? Does it change with risk management?</u> Exposure averaged over each lot. Does not change with risk management. The properties on Rodman Street and 48th Street were each considered an EU for purposes of assessing exposure. This basic rule was followed for all properties in Spring Valley FUDS, except for large properties, which were broken down into an approximate ½-acre lots. The exposure area for these two properties did not change throughout the investigation.

<u>How was remediation carried out to meet remediation goals? How was this demonstrated?</u> Each property was surveyed to establish the 20 × 20 foot grids. Grids with concentrations of arsenic >20 mg/kg were excavated to 2 feet bgs. Post-excavation confirmation samples were collected from the center of each grid's remaining sidewalls (6 inches bgs) and from the center of the grid's floor. If the concentration of arsenic was still >20 mg/kg, then the excavation was extended 5 feet laterally and/or an additional 1 foot of soil was excavated vertically, depending on where the elevated arsenic remained. Confirmation samples were collected from the new floor and sidewalls (6 inches bgs for extended walls; 6 inches above floor for deepened floor). Where hard-/landscape features were present within a targeted grid, contingency samples were collected along the edges of the hardscape and within the drip-line radius of the landscape features. Following successful excavation, the grid area was backfilled with clean fill, and topsoil that was analyzed for a variety of chemical parameters and at levels approved by the Spring Valley Partners.

At the 48th Street property 10 of the 10 anticipated grids were excavated; two grids planned for partial removal due to associated tree/shrubs had to be fully excavated due to elevated confirmation samples (53.4 and 106 mg/kg arsenic). A total of 53.35 cubic yards (69.35 tons) was removed from the property. A total of 38 confirmation and three waste disposal characterization samples was collected and analyzed.

At the Rodman Street property 24 grids were excavated instead of the 20 anticipated. The concentration of arsenic in confirmation samples (25.6–76.1 mg/kg) resulted in 5-foot extended excavation into four additional grids, one of which overlapped onto a property on 47th Street. A total of 506 cubic yards (760 tons) of soil was removed. A total of 78 confirmation and 27 waste disposal characterization samples was collected and analyzed.

When (if at all) is "allowable exposure" identified (i.e., "screening level" vs. "PRG" vs. "cleanup level," etc.)? Screening levels were used in the early project phase of the Spring Valley RI and baseline risk assessment to identify COPCs. Results of the OU3 risk assessment, site-specific information such as levels of naturally occurring arsenic, as well as stakeholder input, were used to determine an appropriate cleanup goal.

How, if at all, does the "allowable exposure" change throughout the remediation process? What is the basis (e.g., cost, background exceeds criteria, risk management, etc.)? Does not change.

B.1.5 Sampling

Describe sampling methodology(ies) (i.e., grab sample, sampling grid, composite, random sampling, stratified random sampling, etc.) used at various stages of project:

Stage	Methodology
Discovery	Grab samples
PA/SI	Grab samples
RI	Grab
BRA	Grab
EE/CA	Composite, grid, and grab samples
FS	NA
Remediation	NA
Post-remediation monitoring (verification)	Grab samples

The sampling program for the initial SI (1993–1999) and RI used a traditional grab-sample approach at locations identified as potentially containing contamination. These sampling locations were identified through reviews of historical records. Surface and subsurface sampling was completed. The BRAs (performed by EPA) were based on the sampled collected as part of the RI investigation (USACE 1995).

Based on the findings of the initial investigations (1993–1999) as well early findings of the OU3 work, an expanded area (approximately 91 acres) was investigated. This investigation indicated arsenic concentrations above EPA Region III's risk-based concentrations (RBCs) and above local ambient background concentrations. In consultation with EPA and DCDOH, USACE then undertook an extensive characterization of the remaining Spring Valley FUDS. The two properties selected for the case study are located on Rodman Street and 48th Street in Washington D.C. and are within OU5.

The specific sampling methods examined in this case study are those used for all properties in OU4 and 5. The properties in OU4 and 5 were categorized as within or outside of the Central Testing Area (CTA). The Rodman Street property is outside the CTA, and the 48th Street property is within it. In general, each property received an intensive surface (0–6 inches) sampling program. Sampling at depth was generally limited to one boring per property unless historical data indicated a potential source of contamination in the area.

In general accord with the EPA SSG, each property within the CTA was divided into four equal areas called "quadrants." Six surficial soil samples (subsamples) were collected per quadrant and composited to make one sample for the quadrant for submittal to the analytical laboratory (four samples per site). The subsamples were collected from random locations within the quadrant. Slight variations in the CTA sampling approach were made for properties of more than 2 acres. Samples were not collected where cultural features and/or current site features prevented access to the surface soils (e.g., equipment sheds, patios, gravel roads, etc.). Samples were collected from the first 6 inches of surficial soil. If the concentration of arsenic in any quadrant sample was greater than the screening value, the entire property was grid-sampled on 20-foot centers.

For properties outside of the CTA, the sampling design assumed that this acreage did not contain documented testing areas. Therefore, fewer samples were collected (in general, because of the documented field testing, the CTA included a more focused sampling approach than the non-CTA). Each non-CTA property was divided into two equal halves (essentially the front and back yard for a property). Eight surficial soil samples (subsamples) were collected from each half and composited. Samples were not collected where cultural features and/or current site features prevented access to the surface soils. Samples were collected from the first 6 inches of surficial soil. For properties approximately 2 acres or larger, the property was divided into approximately ½-acre lots. Each of those parcels was then sampled in the same manner as were the properties <2 acres in size as described above.

The procedure used to collect quadrant (or half) samples deviated slightly from the SSG, which calls for six total samples per site, with each sample comprising one subsample from each of the four quadrants. A statistical analysis was performed to ensure that the deviation from the SSG procedure would not compromise attainment of the project decision error goals described in the Waste Management Plan. The changes from the guidance were made to account for site-specific conditions (e.g., potential contamination sources and patterns).

The sampling program for the post-removal confirmation samples is described in a site's project closeout report. The post-excavation sampling program consisted of sidewall and bottom grab samples.

The sampling results for the quadrant composite samples at the 48th Street property were 16.2, 6.6, 17.7, and 18.4 mg/kg. Given that these results were greater than the screening criteria of 12.6 mg/kg, the property was sampled on a 20-foot grid pattern. The results of the grid samples showed several grids with concentrations greater than the removal goal of 20 mg/kg.

The sampling results for the half-lot composite samples at the Rodman Street property were 20.2, and 74.5 mg/kg. Given that these results were greater than the screening criteria of 12.6 mg/kg, the property was sampled on a 20-foot grid pattern. The results of the grid samples showed several grids with concentrations greater than the removal goal of 20 mg/kg.

What value(s) measured (calculated) at the site was compared with the criterion (criteria) at various stages (for example, analytical result for composite sample, highest measurement, an average calculated from all samples, an average representing some other area/volume, a hot spot, a "risk" developed from potential exposure to multiple chemicals with similar effects, etc.):

Stage	Criterion to which concentration of arsenic was compared
Discovery	0.43 mg/kg
PA/SI	0.43 mg/kg
RI	0.43 mg/kg
BRA	The BRA used the EPA Region III RBC of 0.43 mg/kg to selected COPCs. The risk assessment was performed in accord with standard EPA practice and calculated risk for selected receptors using pathways that were consistent with the anticipated current and future use of the property.
EE/CA	12.6 mg/kg for composites and 20 mg/kg for grid samples
FS	NA
Remediation	NA
Post-remediation monitoring (verification)	20 mg/kg (43 mg/kg)

During the initial SI phase, the grab samples were compared to the EPA Region III RBC for arsenic in soil (0.43 mg/kg). During the EE/CA for OU4 and 5, all acreage, residential and nonresidential, was divided into ½-acre (approximate) exposure areas, or sites, for sampling purposes. Six-part composite samples were compared to site screening value of 12.6 mg/kg. The background-based site screening value of 12.6 mg/kg was used as a point of comparison for all of the composite samples.

All of the soil defined by grid samples with concentrations greater than 20 mg/kg was removed. Grab samples on the bottom and sidewalls of the excavation were compared to 20 mg/kg. (In the event that a cultural or natural feature was within an area of contamination, USACE would, at the request of the property owner and regulatory concurrence, not perform a removal in areas of up to 43 mg/kg.)

The remediation end point of 20 mg/kg was a consensus among USACE and the regulatory partners. For comparison purposes, the highest background sample collected was 18 mg/kg and the noncancer soil screening level is 23.5 mg/kg (based on a child resident receptor); 20 mg/kg is a cleanup goal for arsenic in soil that has been adopted by many states (AEHS 1998).

<u>What soil was considered available for exposure?</u> Exposure to surface soil was considered in the streamline risk evaluation in the EE/CA and in the BRA. In accord with standard EPA Region III procedures, the first 6 inches (excluding turf cover) were sampled to examine current exposures. However, during the removal action, the top 2 feet were excavated and disposed off site. While the top 2 feet were not considered as available for standard residential exposure (except for gardening), USACE determined that removal of the top 2 feet would effectively satisfy project objectives and reduce the overall time to complete remediation.

<u>How was the sampling density derived? How did it vary at different stages of the project, and why?</u> The sampling density at the initial stages of the investigation was low. The sampling was specially targeted at areas of suspected contamination rather than targeted at areas over which receptors may be exposed.

The sampling approach for OU4 and 5 EE/CA was designed using *Soil Screening Guidance: User's Guide* (EPA 1996). The sampling approach was focused on characterizing the concentrations of arsenic over areas where receptors may be exposed. The sampling density was derived by examining the potential exposures, receptors, and the suspected pattern/method of contamination. The number of samples per composite sample was determined through Monte Carlo analysis to balance the Type I and Type II error rates using sample sizes of 4–12. The distance between grid samples was determined by examining the probability (80%) of detecting a circular hot spot with a 10-foot radius.

Discuss the relationship (if any) between the "point of exposure," the sampling strategy, and the sampling density. Is the "concentration at the point of exposure" determinable (can it be calculated or derived) from the sampling? If so, how? If not, why not? The point of exposure was determined to be an entire property, with each property being assessed as approximately ½ acre. This ½-acre EU was the area over which the exposure would occur. The receptors evaluated in this EU were residential in nature; however, the sampling strategy was designed to compare the average concentration of arsenic to the upper bound estimate of the range of the background concentration and did not consider a specific exposure scenario. The average concentration of arsenic in an area was determined through the composite samples. If the average concentration (measured with a composite sample from a section of a property) was greater than the upper-bound estimate of the background concentration, then the entire property was sampled on a grid pattern.

B.1.6 Additional References

AEHS (Association for the Environmental Health of Soils). 1998. *Study of State Soil Arsenic Regulations*. www.aehs.com/surveys/arsenic.pdf

USACE (U.S. Army Corps of Engineers). 1995. *Spring Valley Remedial Investigation.*

B.2 EVERGREEN, WASHINGTON

B.2.1 Background Information

Site/Case Study Name(s): Former Evergreen Infiltration Range, Area of Concern (AOC) 4-6, Fort Lewis Agreed Order

Site/Case Study Location: Fort Lewis, Washington

Regulating Entities and Authorities (State/Federal Program, Offices): Washington State Department of Ecology (WSDOE)

Parties Conducting Investigation/Risk Assessment/Cleanup: Fort Lewis Public Works (FLPW) contracted with the U.S. Army Corps of Engineers, Seattle District to perform the site investigation. USACE-Seattle was also tasked with developing the cleanup specifications and managing the remedial contractor. Treatment alternatives were explored by USACE–Engineering Research Development Center (ERDC) through feasability testing for both physical separation and metal stabilization technologies. TPA-CKY was the contractor selected to perform the work, with assistance from Severn Trent Laboratories (STL) Seattle for laboratory support.

Brief Description of History of Site, Type(s) of Contamination: The former Evergreen Infiltration Range was identified from a 1951 aerial photograph and appears to have been in use until 1965. This site was used to condition soldiers to move under live fire and under combat-type situations. Fixed-position machine guns firing into an impact berm provided live-fire training. The impact berm was set back approximately 300 feet from the firing discharge area and was a constructed earthen bank approximately 40 feet high. Bullet slugs and fragments were evident within the berm. The ammunition associated with training during this era was the .30 caliber cartridge.

For the initial characterization, a Triad work strategy was designed to determine whether surface soils contained significant concentrations of metals with the focus on collecting sufficient data for potential future actions (i.e., risk analysis vs. remediation). Sampling data showed that the contaminant driver, lead, was limited to the impact berm and the area immediately behind the berm. The maximum detected lead concentration was 62,500 mg/kg. Antimony and copper were also detected, but only in samples where lead was above the action level of 250 mg/kg. The majority of soil also contained bullet fragments and failed the Toxicity Characteristic Leaching Procedure (TCLP) criteria; therefore, the material was designated as a RCRA hazardous waste.

Nine demolition sites were also identified at this range. A single crater was identified at each demolition site, each approximately 6 feet in diameter. The potential COCs were explosives residues. Sampling results indicated that explosives were not present in these craters. Firing points were also sampled for total metals. Metals concentrations were below action levels. These areas are not discussed in the rest of this document.

Following site characterization the team learned that the property was slated for a Milcon barracks construction project in FY06. Because of the construction schedule, the contaminated property required immediate evaluation of alternatives. Approximately 4,400 cubic yards of lead-impacted soil was estimated as requiring removal.

In accordance with the ITRC guidance *Characterization and Remediation of Soils at Closed Small Arms Firing Ranges* (2003), FLPW pursued the option of reusing the contaminated soil at an active range at the facility instead of disposing of it at a hazardous waste landfill. WSDOE accepted this option if the bullet fragments were removed from the soil and residual soils were treated to reduce leachability of lead to below hazardous waste levels.

Contract plans and specifications were then developed by USACE using a performance-based contracting approach. Performance criteria included removal of lead contamination to achieve cleanup criteria of 250 mg/kg under the WSDOE Model Toxics Control Act (MTCA) guidance. Performance of bullet removal was specified by requiring treated soil portions to contain <0.1% bullet. Treated soil was required to also meet the federal RCRA hazardous waste and state dangerous waste criteria. Recycling of the bullet waste stream was also encouraged.

The contract for the cleanup was awarded to TPA-CKY, an 8(a) MARC contractor with USACE-Seattle in late 2004. Construction began in May 2005 and was completed in July 2005. A power screen was used to generate three waste streams: >1½ inch, 1½–7/16 inch, and <7/16 inch. The 1½-inch gravel waste stream (about 1/3 of the total volume) was clean and was left on site. Bullet fragments in the 1½–7/16-inch waste stream had enough steel that a magnet could be used to remove the fragments. The fragments were sent to a recycling facility and the remaining material left on site. Soils passing the 7/16-inch screen were treated with 4% EnviroBlend®, which was chosen based on the ERDC feasibility study to reduce leachability.

The treated soil was then hauled to an active range on the installation and used to construct berms. The berms were shaped per Fort Lewis Range Control specifications and hydroseeded. Physical location of the berms were surveyed using a geographical informational system and will be retained in the FLPW master planning documents.

<u>Is the area considered by the case study the whole site, a part of the site, or perhaps an operable unit or analogous categorization?</u> The Former Evergreen Infiltration Range is identified as an AOC under the Fort Lewis Agreed Order. Based on the sampling conducted at the site, only part of the former range (the impact berm) was impacted by site activities, required remediation, and is discussed in this case study.

<u>Describe site (or area) under consideration for case study. Location/area/operable unit under consideration for case study (if less than entire site). Size/area under consideration for case study, in square feet, location relative to rest of site, comparability with rest of site.</u> The impact berm is located on the southeast side of Evergreen Avenue, approximately 300 feet from the firing discharge area (see illustration). The berm is approximately 400 feet in length, 40 feet high, and 100 feet between the frontside and backside berm toes. An additional area of contamination in the flat areas in front and behind the berm covers about 21,000 square feet. Based on results from the 2003 site investigation, approximately 4,400 cubic yards of contaminated soil required removal. Ultimately, final removal volume was approximately 6,000 cubic yards. Depths of contamination ranged 0–7 feet bgs depending on location on the berm.

B.2.2 Site Status

Investigation Phase	Completion Status
Discovery	Yes
PA/SI	Yes
Phase I, II, or III Property Assessment	No
RI	No
Baseline Risk Assessment	No
Cleanup Action Plan	Yes. Interim Plan
FS	No
Remediation	Yes. Interim Removal Action
Post-remediation monitoring	No
Close-out or NFA letter issued	No

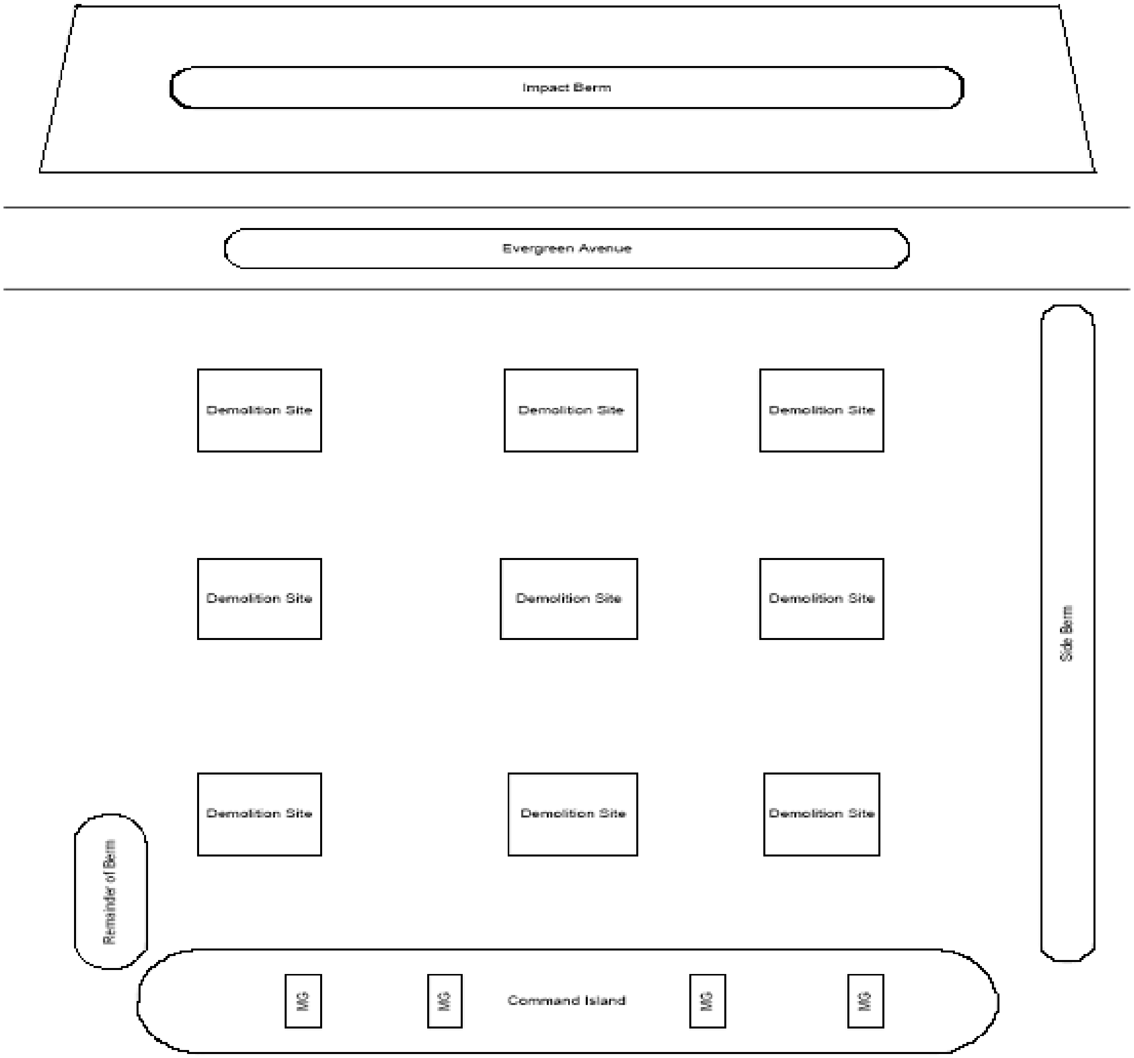


Illustration of the Infiltration Range (not to scale).

B.2.3 Risk

At what stage, if any, were risk-based criteria (e.g. screening levels) introduced? Risk-based criteria were used to develop the sampling program during the SI. Several criteria were considered at the time and included the following:

- WSDOE MTCA cleanup levels for unrestricted land uses (250 mg/kg)
- WSDOE MTCA cleanup levels for industrial properties (1,000 mg/kg for lead)
- WSDOE MTCA three-phase groundwater protection criteria (3,000 mg/kg for lead)
- WSDOE MTCA ecological indicator soil concentrations for protection of terrestrial plants and animals (50 mg/kg for plants, 500 mg/kg for soil biota, 118 mg/kg for wildlife)

To determine the usability of XRF for lead soil sampling, a demonstration of method applicability (DMA) was conducted on the impact berm. The results of the DMA were used to establish decision thresholds around these potential action levels. The data were also used to evaluate the inherent bias of the field-based instrument technology such that an adequate safety factor could be built into the overall decision uncertainty limits.

Based on the uncertainty of XRF values near the action level, collaborative sampling was conducted on XRF equivalent concentrations near the action level to verify appropriate remedial actions were selected. In addition, reporting limits to meet the lowest possible action level of 50 mg/kg were established. Additional information on the development and results of the DMA is presented in the site investigation report (USACE 2004b).

During the development of the Interim Cleanup Action Plan (CAP), it was concluded that the cleanup level for the site would be the action level of 250 mg/kg from MTCA Method A based on the following criteria:

- The interim action involves a limited number of contaminants, in most instances, only lead.
- The cleanup involves a limited choice of cleanup action alternatives.
- The preferred interim action, source removal, is a reliable and proven methodology of accomplishing cleanup standards.
- No MTCA Method B cleanup level for lead is available.

A site-specific terrestrial ecological evaluation (SSTEE) will be required for the final CAP. The risk assessment, in turn, may result in a lower action level for lead. Pending results of the SSTEE, excavation of soils or other remedial action on the Evergreen Infiltration range may be required in the future as part of the final cleanup of the site to achieve the cleanup level for lead determined from the SSTEE. Implementation of the interim action would not preclude future remediation required by a lower action level.

What was the source of the criterion (criteria)? For example, site-specific or published values; cite references for published values (e.g., EPA regional values and state criteria).

Cleanup criteria[a]	**Concentration (lead, in mg/kg)**	**Risk basis**
MTCA Method A cleanup level for unrestricted land uses	250	Preventing unacceptable blood lead levels (child exposure scenario using IEUBK and a unpublished factor of safety)
MTCA cleanup levels for industrial properties	1,000	Direct contact (adult worker exposure) assuming a HQ of 1 or less or a cancer risk of 1×10^{-5}
MTCA three-phase groundwater protection criteria	3,000	Protective of Method A groundwater criteria (based on federal MCL)
MTCA ecological indicator soil concentrations for protection of terrestrial plants	50	Benchmarks published in *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effect on Terrestrial Plants* (Oak Ridge National Laboratory)
MTCA ecological indicator soil concentrations for protection of soil biota	500	Benchmarks published in *Toxicological Benchmarks for Screening Potential Contaminants of Concern for Effect on Terrestrial Plants* (Oak Ridge National Laboratory)
MTCA ecological indicator soil concentrations for protection of wildlife	118	Calculated using the exposure model presented in Table 749-4, assuming a shrew surrogate for mammal predator, American robin for avian predator, and vole for mammal herbivore

[a] WSDOE MTCA, Chapter 173-340 Washington Administrative Code.

Was guidance available/used as to how to sample the site in order to use the criterion? (provide reference)? Primarily, WSDOE *Guidance on Sampling and Data Analysis Methods* (Publication 94-49, January 1995) was used to design the sampling plan with respect to characterizing the site and achieving the cleanup levels. In addition, the following documents were used to design the sampling efforts:

- Air Force Center for Environmental Excellence. 2000. *Technical Protocol for Determining the Remedial Requirements for Soils at Small Arms Firing Ranges*. Technology Transfer Division, prepared by Parsons Engineering.
- Environmental Protection Agency. 1994. *Guidance for the Data Quality Objectives Process*. USEPA QA/G-4.
- Environmental Protection Agency. 1998. *Guidance for Data Quality Assessment.* USEPA QA/G-9.
- Interstate Technology and Regulatory Council. 2003. *Characterization and Remediation of Soils at Closed Small Arms Firing Ranges*.

Was background determined/derived/established? If so, how, and what was the value(s)? If not, why not? (Describe methodology for sampling for background, statistical analysis, results, and value selected, including rationale; any referenced sampling guidance followed should be listed.) Background concentrations were not determined or used during this program.

Were multiple chemicals evaluated for similar/synergistic effect? If so, how was the combined effect of multiple chemicals evaluated? Research on composition for .30 caliber range bullets indicated the primary composition of bullets was 97% lead and <2% antimony, with trace amounts of arsenic, copper, tin, and zinc. The potential impact of these other metals was investigated in the DMA by submitting samples for full suite of metals analysis. The results from these analyses were evaluated to test the hypothesis that lead concentrations would drive decisions regarding this project. Laboratory analysis of collaborative soil samples confirmed that lead was the primary contaminant as other metals were not above MTCA levels when lead was not above criteria. Antimony was the most frequent contaminant after lead above MTCA, with copper being detected in one soil sample.

Were other controls beyond removal/remediation (capping, deed restriction, etc.) used? If so, how did that influence analysis of "risk" and provide justification. Several alternatives were presented in the Interim Cleanup Action, including excavation/hauling, soil washing/particle separation, soil stabilization, chemical extraction, asphalt emulsion batching-encapsulation, and phytoextraction. Of these technologies, excavation/haul, soil washing/particle separation, and soil stabilization were retained for detailed analysis because they were considered the most effective and efficient to implement and they were ones with which local contractors would be most familiar.

Capping was not considered as an alternative because the topography of the site would have required some type of soil handling to implement and FLPW preferred a permanent removal alternative. Deed restrictions were not viable since construction of barracks was already planned on the site. In addition, deed restrictions have not historically been allowable at the base by WSDOE because of concerns over site use control.

How (if at all) was the point of potential contact with contaminated media identified (e.g., depth of soils, area over which exposure is averaged)? Does it change throughout site cleanup process? Does it change with risk management? Washington Administrative Code 173-340-740(6) provides the factors to be considered in establishing a point of compliance for soil. The point of compliance for soil can vary depending on the basis for the soil cleanup levels. For soil cleanup levels based on direct contact, the point of compliance is the upper 15 feet of soil throughout the site. If terrestrial ecological risk is considered, an additional conditional point of compliance is a depth of 6 feet bgs. This required depth remained consistent throughout the cleanup process. However, since contamination was limited to the upper 9 feet, the full risk-based depth was not required to be characterized. The impact berm was defined as the area over which compliance would be measured as a whole.

What is the acceptable contaminant concentration? When (if at all) was it identified and documented (i.e., "screening level" vs. "PRG" vs. "cleanup level," etc.)? The cleanup level of 250 mg/kg was established for this site to protect direct contact for site workers and users. This value was lower than all other risk-based criteria, with the exception of the terrestrial ecological criteria. A site-specific ecological risk assessment was deferred to after cleanup. This criterion was identified in the Interim Cleanup Action Plan and the Remedial Action Management Plan (TPA-CKY 2005).

How, if at all, do the criteria change throughout the remediation process? What is the basis? (cost, background exceeds criteria, risk management, etc.) The criteria did not change throughout the remediation process.

Describe community and/or stakeholder involvement in the decisions made about risk, cleanup, and sampling. The regulator (WSDOE) and the customer (FLPW) were involved as active members of the team throughout all phases of this project. WSDOE and FLPW approved sampling plans, were updated on and approved results of the DMA, and reviewed the SI Report, the treatability study, and the Remedial Action Management Program. During remediation, they attended several site meetings and were updated regularly on the construction progress. In addition, FLPW approved of recommendations for additional excavations as needed in the field. The opinion of the community was formally solicited during the public comment period. No comments were received.

B.2.4 Sampling

Describe sampling methodology(ies) (i.e., grab sample, sampling grid, composite, random sampling, stratified random sampling, etc.) used at various stages of project:

Sampling during SI. Soil sampling was conducted on the berm using field-portable XRF technology and a Triad work strategy. Initially soil grab samples were collected from the area expected to contain contamination during a DMA. Soil samples were collected from 20 sample locations on three areas of the front of the impact berm: the impact zone, below the impact zone, and at the bottom of the berm. The initial grid spacing was set at 10-foot intervals, originating from the center of the berm. Samples were collected at 0–1 and 1–2 foot intervals.

The results of the DMA were used to confirm the suitability of detection limits and ways to manage uncertainty resultant from comparison of XRF to inductively coupled plasma emission spectroscopy data. In addition, the DMA indicated that lead contamination would drive remedial actions and therefore collaborative analysis should be limited to lead.

Following the DMA, a 10-foot systematic sampling grid was used to determine sample positions and locate hot spots along the entire area of the berm and within a trench feature behind the berm. Sample locations were stepped out laterally until field-screening values were below the screening criteria. Samples were planned to be collected at 1-foot intervals to maximum depth dependant on exceedance of the action level or to 15 feet, whichever was shallower. The soil sample depth was based on the maximum depth required to address direct contact risks. However, limitations in the field due to steep slopes and constraint with the hand auger prevented sample collection deeper than 2 feet in almost all locations.

For all sampling in this phase, samples were screening using a No. 10 sieve (2 mm) to remove large bullet fragments from the sample, which would bias the sample results. In accordance with MTCA Chapter 173-340-740(7)(a), compliance with soil cleanup levels is based on total analyses of the soil fraction less than 2 mm in size.

The initial sampling density was evaluated once real-time data from XRF results were obtained for determining whether increased sampling density was required. Additional sampling was deemed unnecessary for determining excavation volumes.

Five samples from the berm were also submitted for analysis of TCLP to determine a correlation with bulk lead concentrations and leaching characteristics.

Sampling during Remediation. Sampling during remediation included bullet fragment removal verification, treatability performance testing, and excavation completion sampling.

Prior to stabilization, the soil was sieved tested to ensure that bullet fragments were removed in accordance with the contract specification of less than 1% by volume. For approximately every ton of soil, a 5 kg treated subsample was collected and sieved with a 6.7 mm sieve. The retained material was hand-searched for bullet material. If the soil did not pass the sieve test, the associated stockpile was to be rescreened.

After screening, the filtered soil was stabilized with approximately 4% Enviroblend additive to soil. Final stabilization was defined as TCLP less than or equal to 5.0 mg/L. Treated material was managed in 100 cubic yard stockpiles. A 30-point composite sample was collected from each stockpile for TCLP lead. If any composite sample failed the TCLP criteria, the stockpile was retreated and retested. Stabilized soil stockpiles were not commingled or transported for disposal until they had passed the TCLP criterion and had been cleared by the USACE project manager.

After excavation of individual designated excavation areas, a grid system was established over the remediation site. Each grid was approximately 30 × 30 foot square, or approximately 900 square feet, and was further divided into nine subgrids. The grid dimension was based on excavation efficiency and reflects a balance between representation of the remediation area and a logical minimum response to discovery of additional contamination. Discrete bag samples were collected randomly from five of the nine subgrids.

These XRF data were used to determine additional areas of sampling and excavation. Since one of the cleanup criteria was that no sample should exceed 500 mg/kg, these areas were immediately excavated. Depending on the distribution of data, areas adjacent to the hot spots were handled in one of the following ways:

- The area was sampled first and additional action was determined based on the additional data. This resulted in some grids having more than five sample results.

or

- If areas were between hot spot samples and therefore likely above 500 mg/kg, these areas were automatically excavated.

For grids that were overexcavated and resampled, the new samples data were used to replace excavated sample results. Once the XRF sample set met the following three cleanup criteria, the operations continued to the post-excavation confirmatory sampling:

- The 95% UCL of mean concentration calculated from sampling data cannot exceed the cleanup level.
- All samples will have measured concentrations less than twice the cleanup level, i.e., 500 mg/kg.
- Less than 10% of the samples can exceed the cleanup level.

Post-excavation confirmatory sampling consisted of submitting archived XRF samples for analysis of lead at a fixed laboratory using EPA Method 6010. The number of samples requiring fixed laboratory analysis was determined based on the distribution of the XRF data. The XRF data were used to calculate the standard deviation and mean for the site. This information was then used with the accepted levels of uncertainty to determine the necessary number of samples required to determine the site was clean. This number of samples (32 total) were then randomly selected from archived bags retained from each grid and submitted for fixed laboratory analysis.

What value(s) measured (calculated) at the site was compared with the criterion (criteria) at various stages? (for example, analytical result for composite sample, highest measurement, values averaged over an area, all values averaged regardless of location, a hot spot, a "risk" developed from potential exposure to multiple chemicals with similar effects, etc.) For soils note the depths of samples used for the comparison:

During the SI. Measured lead concentrations were compared to all potential criteria to evaluate the choice of remedial action levels on remedial options. Volumes above 50, 250, and 1,000 mg/kg were calculated. In addition, detection limits were required to be below 50 mg/kg.

During the Remediation. Measured lead concentrations were compared to the highest measurement and "allowable exposure" based on statistical distribution, as indicated by the following decision criteria:

- The 95% UCL of mean concentration calculated from sampling data cannot exceed the cleanup level (statistical distribution).
- All samples will have measured concentrations less than twice the cleanup level, i.e., 500 mg/kg (highest measurement).
- Less than 10% of the samples can exceed the cleanup level (statistical distribution).

Compliance for these criteria was required to a depth of 15 feet; however, the depth of contamination was limited to the upper 9 feet.

<u>What soil was considered available for exposure?</u> The entire site area was considered available for exposure**.** For soil cleanup levels based on direct contact in Washington State, the point of compliance is the upper 15 feet of soil throughout the site.

<u>How was the sampling density derived? How did it vary at different stages of the project, and why?</u> For the SI, the initial grid spacing was set at 10-foot intervals, based on the reasonable volume of soil that potentially could be excavated for remedial action. One grab sample was taken from each grid.

For the remediation a grid system was established over the remediation site. Each grid was approximately 30 × 30 feet square, or approximately 900 square feet, and was further divided into nine subgrids. One grab sample was obtained from five of the nine subgrids. The grid dimension was based on excavation efficiency and reflects a balance between representation of the remediation area and a logical minimum response to discovery of additional contamination.

<u>Discuss the relationship (if any) between the point of potential contact with the contaminated media, the sampling strategy, and the sampling density. Is the exposure point concentration determinable (can it be calculated or derived) from the sampling? If so, how? If not, why not?</u> For the SI, the sampling strategy and density were primarily based on the need to sufficiently characterize the site for a removal activity. Therefore, the focus was to collect enough data to calculate volumes above selected action levels with sufficient accuracy. In addition, characterization was required in 1-foot intervals since this represented the smallest likely depth of removal. Uncertainties associated with having limited data below 3 feet were handled by having a contingency volumes built into the contract.

For remediation, the impact berm was evaluated and a refined grid size was created based on excavation efficiency and a balance between representation of the remediation area and a logical minimum response to discovery of additional contamination. Confirmation samples were required to statistically abide by the cleanup levels, as established in MTCA.

The strategy did require suitable reporting limits for a future ecological risk assessment. It is anticipated that the density of samples would be sufficient for this purpose.

B.2.5 References

FLPW (Fort Lewis Public Works). 2004. *Interim Cleanup Action Plan, Evergreen Infiltration Range, Fort Lewis, Washington*.

TPA-CKY. 2005. *Final Former Evergreen Infiltration Range Remedial Action Management Plan, Fort Lewis, Washington.* Contract No. DACW67-03-D-1007 CTO002.

USACE. 2004a. *Final Remedial Investigation Work Plan Agreed Order, Fort Lewis, Washington*.

USACE. 2004b. *Site Investigation Report. Remedial Investigation Phase. Former Small Arms Ranges. Evergreen (AOC 4-6.3), Miller Hill (AOC 4-2.2), and Skeet (AOC 4-3), Fort Lewis, Washington*.

B.3 WHITEBRIDGE, CALIFORNIA

B.3.1 Background Information

Site/Case Study Name: Whitebridge Subdivision

Site/Case Study Location: Placer County, California

Regulating Entities and Authorities: California Department of Toxic Substances Control and Placer County Planning Department and Environmental Health Department

Parties Conducting the Investigation, Risk Assessment, and Cleanup: Actium Development Corporation and Montgomery Watson, consultants

History of the Site: The proposed Whitebridge Subdivision is 184 acres in size and is located approximately 2 miles east of the City of Loomis in Placer County, California. From the 1930s to late 1980s, approximately 93 acres of the property was used as a commercial orchard operation. As part of the orchard operation, pesticides, including both inorganic (e.g., lead arsenate) and chlorinated organic pesticides (e.g., DDT) were applied in the orchard area. The remainder of the property was native forest.

Future Land Use: The proposed development will consist of 65 lots ranging approximately 2.3–4.6 acres in size. The development will consist of single-family dwellings with individual septic systems and municipal water supply. Infrastructure will be consistent with that of modern residential developments, including paved streets and underground utilities. Because the development would use septic systems on each lot, the amount of native soil retained on site was crucial to obtaining necessary permits for septic system construction and operation. As a result, the developer wanted to minimize the amount of soils removed.

Motivation for Remediation: Development for residential use

Is the area of concern the entire site? No, of the 184 acres, only half of the property was used as an orchard. The remaining area was open space consisting of trees and underbrush typical of

Sierra foothill native habitat. Sampling confirmed that the open space areas had not been impacted by pesticides.

Describe the site/area under consideration for the study: Pesticide use on the property was confirmed by various investigations conducted 1998–2001, including site reconnaissance, review of county records regarding use of pesticides in the orchard operation, interview of the former property owner/orchard operator, and a phased soil-sampling program. Measurable concentrations of arsenic, lead, and organochlorine-based compounds detected in surface (top 0–12 inches) soil confirmed that these materials were used historically during orchard operations.

The field investigation studies (aerial photograph examination, property owner interview) revealed another area of potential concern, called the "remote filling area." According to the former property owner and orchard operator, this is an area where past handling (mixing and loading) of pesticide materials may have occurred. Soil sampling confirmed the presence of elevated concentrations of lead, arsenic, and certain organochlorine-based compounds (e.g., DDT) in surface soil in this area. The collective results of the multiphased soil-sampling program at the property identified seven COPCs: lead, arsenic, dieldrin, DDT, DDE, endosulfan sulfate, and endrin aldehyde. Although other inorganic elements in addition to lead and arsenic were measured in soil samples, only these two elements were found to be present at concentrations greater than naturally occurring levels in Placer County soils.

B.3.2 Site Status

Investigation Phase	Completion Status
Discovery	Yes
PA/SI	Yes
Phase I, II, or III Property Assessment	No
RI	No
Baseline Risk Assessment	No
Cleanup Action Plan	Yes. Interim Plan
FS	No
Remediation	Yes. Interim Removal Action
Post-remediation monitoring	No
Close-out or NFA letter issued	No

B.3.3 Preliminary Endangerment Assessment

At what stage were risk-based criteria introduced? Risk-based criteria were introduced at the PEA stage as well as the RAW.

What was the source of the criterion (criteria)? Site specific.

If site-specific criteria were used, describe how derived: The PEA screening uses the maximum concentration of each COPC detected during soil sampling. The maximum concentrations are used as EPCs representing the entire site. Screening-level risk assessment equations based on RAGS and using default exposure parameters for residential use are used to calculate risk and hazard for each COC. Ingestion, inhalation, and dermal contact pathways are evaluated. Risk and hazard are then summed for all chemicals to obtain a site-wide total risk and HI.

What level of risk is this intended to represent? To receive an NFA determination at the PEA level, carcinogenic risk must be less than 1×10^{-6}, and HI must be less than 1.

Was guidance available/used on how to sample the site to use the criterion? Typically, DTSC's PEA guidance manual (1999) recommends that a minimum of four samples be collected in areas where chemical releases were most likely to occur. For the Whitebridge site, DTSC became involved after the site was sampled. For lead, DTSC/OEHHA LeadSpread model is used to estimate blood lead levels and compared to a screening level of 10 µg/dL of lead in blood.

PEA Results: Results of the Tier 1 assessment, which are summarized in the following table, indicated reason to believe that certain COPCs may have posed a risk to human health and that further evaluation (Tier 2 assessment) was warranted. More specifically, the results showed that all future receptors (resident child, resident adult, construction worker) and associated exposure pathways should be further evaluated. The assessment also revealed that lead could be eliminated as a COPC for both the future adult resident and construction worker, but not for the future residential child, and that endrin aldehyde and endosulfan sulfate could be eliminated from further risk evaluation for all receptors.

Receptor	Risk	Hazard	Blood lead
Child	3E-04	7.9	15.4
Adult	5E-04	2.9	6.3
Construction worker	2E-05	2.9	3.9

B.3.4 Deterministic Risk Assessment

Because the site failed to achieve the NFA criteria based on the PEA evaluation, a deterministic risk assessment was conducted using the EPA risk assessment guidance.

If site-specific criteria were used, describe how derived: The deterministic risk assessment applied the same risk assessment concepts as the PEA evaluation with the following differences: (1) Statistically derived EPCs were used to represent theoretical human exposure to COPCs in impacted soil instead of maximum measured concentration of each COPC. Consistent with EPA guidance, the 95% UCL of the arithmetic mean of measured concentrations of COPCs in soil were evaluated. (2) The "home-grown produce" (fruits and vegetables) exposure pathway was assessed to more accurately represent the proposed rural residential land use for the proposed Whitebridge Subdivision. And (3) two "areas of concern" were identified and assessed separately. The first area was the 93-acre orchard area, where pesticides were applied for normal agricultural protections. The second area, the approximately 5-acre remote filling area, is where pesticides were mixed and loaded into the spraying equipment. Spray equipment cleaning likely occurred in this area as well. Because of these modifications, the Tier 2 assessment results are considered more accurate than those of the Tier 1 assessment.

What level of risk is this intended to represent? Target risk and HI for unrestricted residential use are 1×10^{-6} and 1, respectively. However, a risk range of 1×10^{-6} to 1×10^{-4} was considered during the risk management evaluation of the site. The deterministic risk assessment was based on EPA RAG documents, CalEPA toxicity criteria, and CalEPA LeadSpread model.

Deterministic Risk Assessment Results. Results from the deterministic risk assessment for the orchard area and the remote fill area indicated that both contain levels of COPCs that may pose unacceptable theoretical human health risks to human health. The assessment revealed that further evaluation of the child and adult residential receptors in both areas and the construction worker in the remote fill area was warranted.

At this stage, remedial goals were to be removal of arsenic-contaminated soils to background arsenic levels (27 mg/kg). Preliminary estimates showed that at least 19,000 cubic yards of soil would need to be removed. As a result, several of the proposed lots would no longer have enough native soils to allow septic systems. To provide additional information to risk managers, the Whitebridge Subdivision consultants did a probabilistic risk assessment.

Orchard Area

Receptor	Risk	Hazard	Blood lead
Child	9E-05	0.90	5.1
Adult	1E-04	0.51	6.3
Construction worker	1E-06	0.20	3.9

Remote Fill Area

Receptor	Risk	Hazard	Blood lead
Child	3E-04	3.1	9.3
Adult	3E-04	1.7	6.3
Construction worker	7E-06	1.0	3.9

B.3.5 Probabilistic Risk Assessment

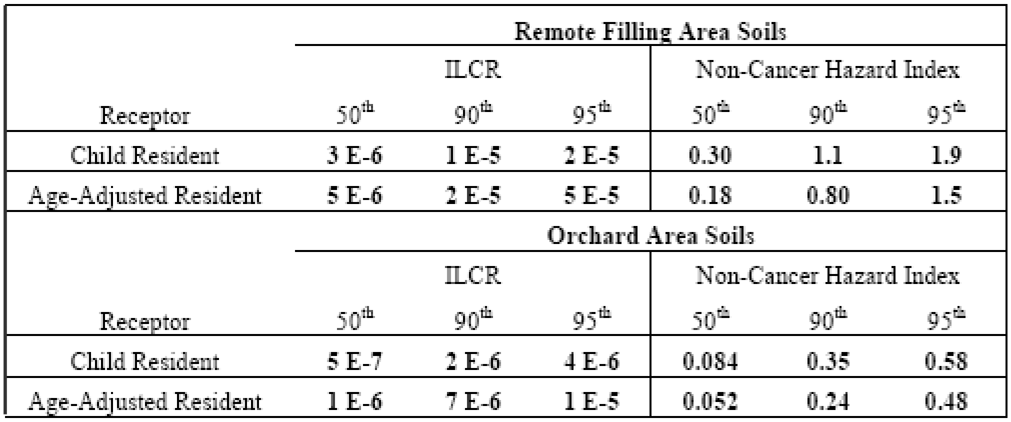
A PRA was performed in accord with EPA guidance (EPA 1997 and EPA 2001b). This form of human health risk assessment is considered by EPA as well as such organizations as the National Academy of Science to provide wider information for risk management decision makers for several reasons:

- A range of exposure and risk estimates is calculated.
- Estimates of variation and uncertainty are quantified.
- The parameters that contribute the majority of risk and exposure can be determined and ranked using sensitivity analyses. Risk drivers are those items in the assessment that account for the majority of the risk. Drivers can be identified for any parameter in the assessment; either a substance (e.g., arsenic), a pathway (e.g., incidental soil ingestion), an exposure assumption (e.g., an assumed duration of exposure), or a particular receptor (e.g., residential child).
- Confidence limits of risk estimates can be derived.
- A wider variety of property-specific information can be included.

Whereas the Tier 3 assessment for the Whitebridge Subdivision retained all exposure pathways, COPCs, and EPCs that were evaluated in the Tier 2 assessment, the additional information afforded by the Tier 3 assessment aided DTSC's decision making.

Probabilistic Risk Assessment Results. The 50th, 90th, and 95th percentiles of the Tier 3 results are provided in the following table to show the range of possible outcomes. The total HIs at the 50th, 90th, and 95th percentiles for both the resident child and adult in Area 1 were less than the noncancer target level of 1.0 and slightly greater than 1.0 in Area 2. The theoretical upper-bound lifetime incremental cancer risk estimates at the 50th, 90th, and 95th percentiles for both the resident child and adult for Area 1 and 2 were within the risk range of 1×10^{-6} to 1×10^{-4}. The risk percentile (e.g., 50th, 90th, 95th, and 99th) applied in risk management decision making is a risk manager decision. In the latest guidance on the role of PRA for risk management decision making, EPA has established the 90th to 99.9th percentiles of the risk distribution as the recommended decision-making range. Within this range, the agency recommends the 95th percentile of the risk distribution as the default percentile for risk management decision making (EPA 2001b). In summary, the Tier 3 results indicate that risks associated with theoretical human exposures to COPCs in the orchard area are acceptable for either residential children or adults. In addition, the assessment also revealed that potential exposures of these receptors to arsenic in the remote filling area may potentially result in unacceptable noncarcinogenic adverse health effects. Arsenic contributes more than 98% of the noncancer risk. Therefore, development of a RBCL for arsenic in the remote fill area was warranted. Because the risks to lead and organochlorine pesticides were at acceptable levels, development of RBCLs for these COPCs was not warranted.

Summary of Tier 3 risk assessment results, Whitebridge Subdivision

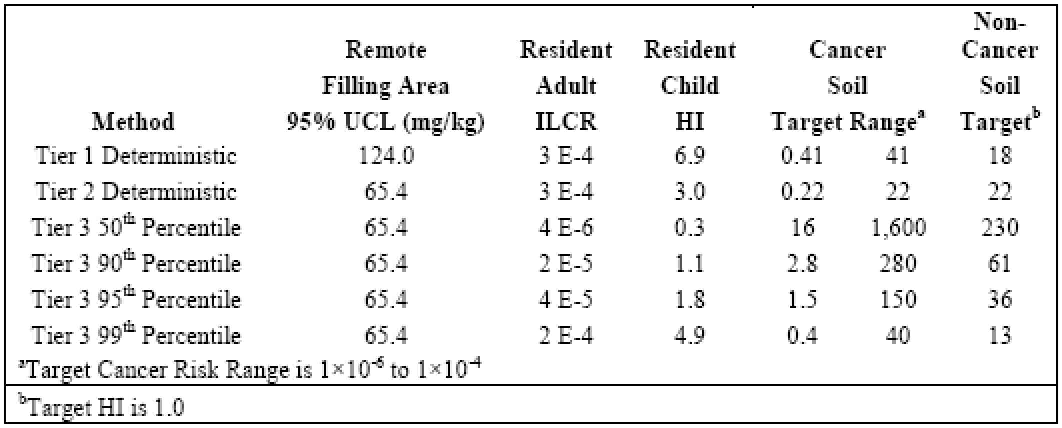


	Remote Filling Area Soils					
	ILCR			Non-Cancer Hazard Index		
Receptor	50th	90th	95th	50th	90th	95th
Child Resident	**3 E-6**	**1 E-5**	**2 E-5**	**0.30**	**1.1**	**1.9**
Age-Adjusted Resident	**5 E-6**	**2 E-5**	**5 E-5**	**0.18**	**0.80**	**1.5**
	Orchard Area Soils					
	ILCR			Non-Cancer Hazard Index		
Receptor	50th	90th	95th	50th	90th	95th
Child Resident	**5 E-7**	**2 E-6**	**4 E-6**	**0.084**	**0.35**	**0.58**
Age-Adjusted Resident	**1 E-6**	**7 E-6**	**1 E-5**	**0.052**	**0.24**	**0.48**

Of the COPCs evaluated in the risk assessment (arsenic, lead, DDT, DDE, endrin, and endosulfan), arsenic was determined to account for the majority of the estimated human health risk. The risk assessment identified that arsenic is the only COPC for which remedial action is warranted to protect the health of future residents in the proposed subdivision.

Risk-Based Cleanup Levels. Because the BRA (Tier 3) concluded that arsenic in the Remote Fill Area may potentially have posed an unacceptable noncarcinogenic health risk to future residents in the Whitebridge Subdivision, mitigative measures were warranted to reduce this risk. Therefore, an arsenic RBCL of 36 mg/kg, which is the 95th percentile probabilistically derived value, is proposed as a health protective remedial action objective for mitigating potential arsenic health risk. The 95th percentile is EPA's recommended default percentile for risk management decisions (EPA 2001b). To verify that 36 mg/kg is health-protective, a Tier 3 BRA of this concentration resulted in an HI of 1.0, and an incremental lifetime cancer risk (ILCR) of 2×10^{-5} showed that 36 mg/kg is health-protective at the 95th percentile. In response to DTSC's request, a range of RBCLs for arsenic in the Remote Fill Area soil has been calculated using the same parameters and assumptions as were applied in the Tier 1, Tier 2, and Tier 3 BRAs. Consistent with regulatory guidance, an HI of 1.0 for theoretical noncancer health effects, and a theoretical upper-bound incremental lifetime cancer risk range of 1×10^{-6} to 1×10^{-4} were applied as "acceptable" risk targets in deriving this range of RBCLs. It should be noted that a target HI of 1.0 for arsenic does not ignore the potential cumulative noncancer risks of other COPCs in Area 2 soil (e.g., lead, DDT). The noncancer toxic end point for arsenic is a unique dermal effect called "blackfoot disease"; this toxic end point and associated mechanisms is not shared by any of the other COPCs in Area 2 soil.

Arsenic target soil concentrations, Whitebridge Subdivision



Method	Remote Filling Area 95% UCL (mg/kg)	Resident Adult ILCR	Resident Child HI	Cancer Soil Target Range[a]		Non-Cancer Soil Target[b]
Tier 1 Deterministic	124.0	3 E-4	6.9	0.41	41	18
Tier 2 Deterministic	65.4	3 E-4	3.0	0.22	22	22
Tier 3 50th Percentile	65.4	4 E-6	0.3	16	1,600	230
Tier 3 90th Percentile	65.4	2 E-5	1.1	2.8	280	61
Tier 3 95th Percentile	65.4	4 E-5	1.8	1.5	150	36
Tier 3 99th Percentile	65.4	2 E-4	4.9	0.4	40	13

[a] Target Cancer Risk Range is 1×10^{-6} to 1×10^{-4}

[b] Target HI is 1.0

To support the conclusion that the RBCL for arsenic is health-protective, three soil samples were collected and evaluated for bioaccessiblity of arsenic. The quantitative risk assessment assumed that the arsenic in soil was 100% bioavailable. Bioaccessibility test results ranged 22%–56%. This added comfort to the risk management decision to allow a cleanup level above background for arsenic at this property.

Was background considered? How was it considered, and what were the values? Seven background samples were collected to establish naturally occurring levels of lead and arsenic at the subject property. Sampling locations were randomly selected within the on-site native forest areas, which are outside the historical orchard area footprint. The historical orchard area and native forest areas were differentiated based on a review of historical aerial photographs. The background sampling locations were reviewed by DTSC during a September 2001 site visit. Consistent with regulatory guidance, the 95% UCL of the arithmetic mean was used to represents the upper range of background levels. In response to DTSC's request for a health risk assessment of background concentrations, a probabilistic assessment of the UCL arsenic concentration was performed. At the 95th percentile level, the 27 mg/kg arsenic background concentration corresponds to a noncancer HI of 0.75 and an ILCR of 2×10^{-5}.

Were multiple chemicals evaluated for similar/synergistic effect? It should be noted that a target HI of 1.0 for arsenic does not ignore the potential cumulative noncancer risks of other COPCs in Area 2 soil (e.g., lead, DDT). The noncancer toxic end point for arsenic is a unique dermal effect called “blackfoot disease”; this toxic end point and associated mechanisms is not shared by any of the other COPCs in Area 2 soil.

How was potential contact with contaminated media identified? Soil was the only media of concern identified at the site. Typically, DTSC considers the upper 10 feet of soil as surface soils for direct contact exposures due to grading and excavation that alter placement of soils for future land use. At Whitebridge samples were collected and analyzed to 2 feet bgs in the orchard area. Contamination did not extend below 12 inches. Contamination in the Remote Fill Area was deeper, extending to 5 feet bgs.

Were other controls beyond removal/remediation (capping, deed restrictions etc.) used? Yes, impacted soils were removed and placed under the new roads accessing the lots within the subdivision. In addition one containment area was placed on one lot. Geotextile membrane was placed on the surface of the containment area, covered with clean soil, and marked to show its location. All areas receiving the contaminated soil were deed-restricted. These risk management measures are considered effective because direct contact via the ingestion, inhalation, or dermal contact pathways is prevented. Arsenic does not readily leach to groundwater in the soils found at Whitebridge.

How, if at all, do the criteria change throughout the remediation process? The criteria of achieving soils concentrations at or below 1×10^{-6} or HI <1 used in the PEA were modified in the deterministic and probabilistic assessments. The criteria became the NCP target risk range of 1×10^{-6} to 1×10^{-4} and HI <1. Using risk assessment methods that provide the most information such as the PRA allowed for a wider base of information on which to base a risk management decision. As a result, less remediation was required.

Describe community and/or stakeholder involvement in the decisions made about risk, cleanup and sampling: Both Placer County and DTSC engage in public participation to obtain input and identify concerns from surrounding property owners and the community. Placer County engaged in an environmental review and subdivision approval process that allowed for public review of environmental impact reports. DTSC sent questionnaires to surrounding property owners and community officials. Fact sheets were distributed announcing the 30-day opportunity for the public to review and comment on the draft removal action workplan and risk assessment documents prior to DTSC’s making risk management decisions about the proposed subdivision.

B.3.6 Sampling

Grab samples were collected from soils during several sampling events beginning in 1998. A total of 88 soil samples has been collected at various locations and depths on the property during five separate sampling events conducted by two consulting firms. Of the 88 samples, 79 samples were collected from surface soil (0–6 inches), four from 12–18 inches bgs, and three at 3 feet bgs. The four samples at 12–18 inches bgs were collected from the remote filling area to investigate the vertical migration of COPCs. The sampling approach at the property has been mostly "purposive" (i.e., samples collected in specific locations for a predetermined purpose). The exception is the October 1999 random sampling event conducted by Wallace-Kuhl & Associates (WKA), which was conducted for the purpose of determining the distribution of COCs in the orchard area as a result of historic farming operations, notably pesticide application (e.g., organochlorine pesticides, arsenical fungicides). During the October 1999 sampling event in the orchard area, 26 samples were collected in the 93-acre footprint of the former orchard. In December 1999, five additional samples were collected in the remote filling area to further investigate elevated soil levels of pesticides identified in the October 1999 sampling. Two samples were collected in May 2000 in the nonorchard area (native forestland area) for the purpose of establishing background levels of arsenic and lead in surface soil. In May/June 2000, 23 additional samples were collected in the vicinity of the remote filling area to further characterize an area with elevated pesticide levels. In January 2001, WKA collected five more samples for background investigation of lead and arsenic. Three additional samples were also collected at that time from the orchard and remote filling areas for an investigation of bioavailability of arsenic in the soils on the property.

The surface soil data confirm past usage of certain organochlorine pesticides (dieldrin, DDT, endrin, endosulfan) and arsenical (lead arsenate) pesticides. Although DDE, DDT, arsenic, and lead were detected throughout the former orchard areas of the property, the concentrations in most areas, except the remote filling area, are well within acceptable levels relative to health risk criteria as defined in the human health risk assessment. Sampling at depths of 12–18 inches bgs in the remote filling area also confirmed that the existing residual pesticide concentrations exist primarily in near-surface soils. To establish background concentrations of naturally occurring elements (arsenic, lead) in property soil, seven soil samples were collected within native woodland areas outside the orchard area footprint. The analytical results indicate minimal if any impact of applied pesticides to nonorchard areas. One sediment sample was collected from an on-site pond. No concentrations above detection levels of chlorinated insecticides (<0.02 mg/kg) or arsenic (<0.5 mg/kg) were found. Although 4.9 mg/kg of lead was measured, this concentration is within the range of the reference background concentrations for lead in soil. Because no elevated levels of COPCs were found in pond sediment, no further evaluation of the pond sediment or pond water was necessary. Also, because of the well-known physical properties of COPCs (e.g., low water solubility, high soil-binding capacity) and well-understood behavior in soil, none of the aforementioned COPCs are expected to undergo runoff from soil into surface water. The lack of finding significant COPC concentrations in the pond sediment supports this conclusion.

<u>Sample Depths Considered Available for Exposure:</u> DTSC considers the upper 10 feet of soil available for direct contact exposure pathways due to the potential for excavation and grading in hilly areas and installation of swimming pools where excess dirt is often used as part of the surrounding landscape.

<u>Is there an occurrence or pattern of attributing risk to a single sample result?</u> No.

How was the sampling density derived? Based on the initial sample results, step-outs and step-downs were made. Also additional samples were collected to better determine background concentrations of arsenic and lead.

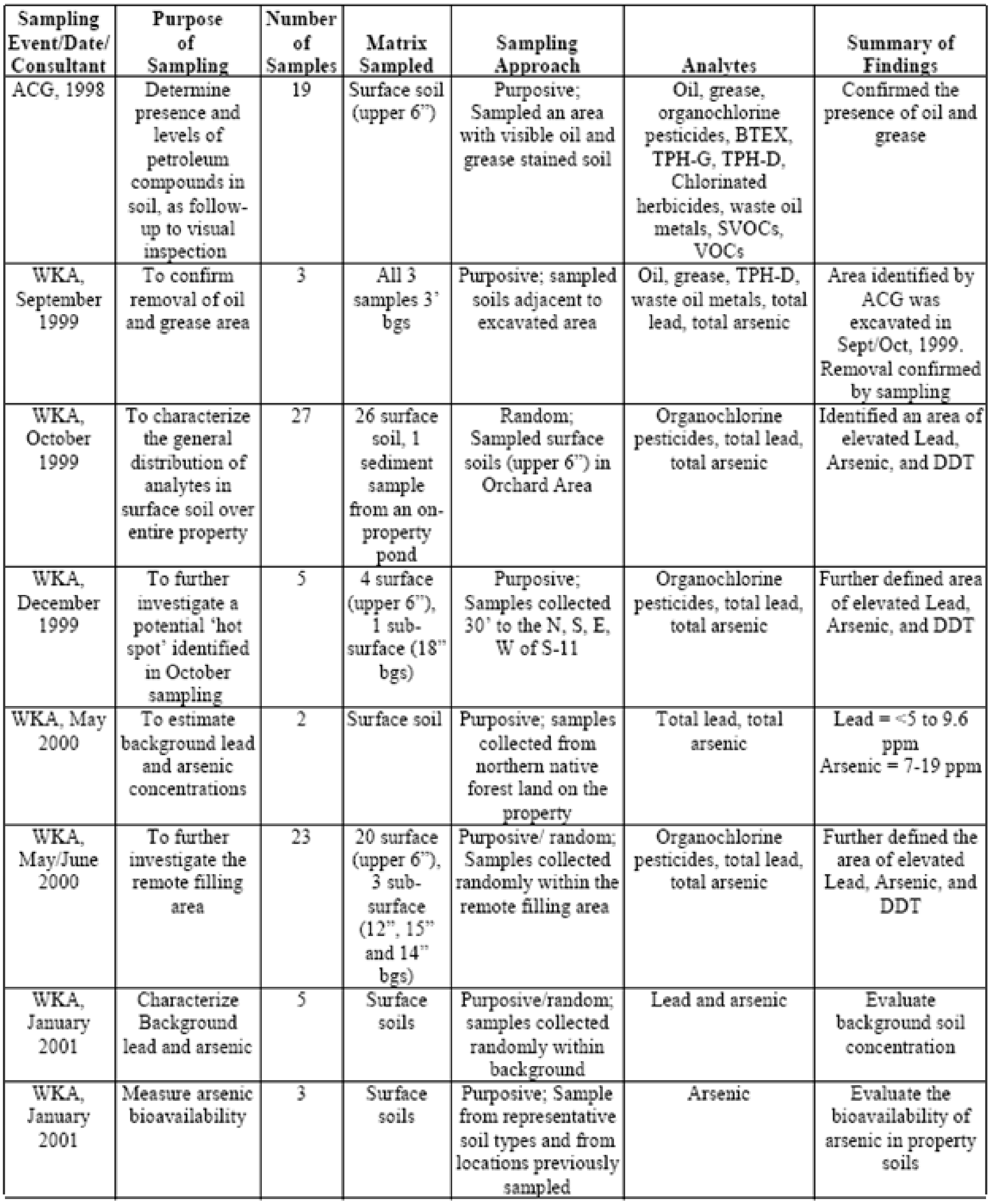
Discuss the relationship between the point of potential contact with the contaminated media, the sampling strategy, and the sampling density. Is the EPC determinable from the sampling? If so, how? The sampling reflects the distribution of potential contaminants across the site. Sample density is greater in areas of higher concentration (e.g., the remote fill area) due to elevated concentrations of COPCs. The EPC for the PEA assessment was the maximum concentration detected for each contaminant on the site regardless of location. The PEA screening evaluation takes a conservative approach in assuming that the maximum concentration is representative for the site. Typically for a PEA, only a few samples are collected. If sufficient numbers of samples are collected, a statistical approach to determine the 95% UCL of the mean is used. For the Whitebridge site, the PEA used the maximum concentrations; the deterministic risk assessment used the 95% UCL of the mean, as did the probabilistic assessment.

B.3.7 Challenges

Ordinarily, a site such as this would come into the DTSC for oversight at the PEA stage of investigation. In this case the property owner and consultant worked with Placer County. The consultant initially submitted just the probabilistic risk assessment to the county. Because the county staff lacked the expertise to evaluate the risk assessment, the county required the property owner to work with DTSC to review the initial document. After the initial review of the probabilistic risk assessment and sampling by DTSC, the property owner under the direction of the county entered into a Voluntary Cleanup Agreement with DTSC to evaluate and remediate the site. Normally, DTSC requires that each stage of the site evaluation be conducted before engaging in the next tier of risk assessment. Most sites are satisfactorily addressed using the deterministic risk assessment approach. If a proponent wishes to do a probabilistic risk assessment, DTSC requires that a workplan be submitted and approved prior to conducting the evaluation. In this case a workplan had not been prepared, nor approved. To provide a transparent assessment with the full range of risk assessments normally required, DTSC required incorporating a PEA evaluation and a deterministic risk assessment. Additionally, DTSC required that 99% of the risk assessment results be shown in addition to those contained in the report.

Additional challenges occurred in communicating the results of the probabilistic risk assessment to the risk managers. While most risk managers are comfortable with the deterministic risk assessments, education was needed to provide a level of understanding that the risk managers felt comfortable with to make decisions about remediation and cleanup goals.

Summary of environmental investigations at the Whitebridge property



Sampling Event/Date/ Consultant	Purpose of Sampling	Number of Samples	Matrix Sampled	Sampling Approach	Analytes	Summary of Findings
ACG, 1998	Determine presence and levels of petroleum compounds in soil, as follow-up to visual inspection	19	Surface soil (upper 6")	Purposive; Sampled an area with visible oil and grease stained soil	Oil, grease, organochlorine pesticides, BTEX, TPH-G, TPH-D, Chlorinated herbicides, waste oil metals, SVOCs, VOCs	Confirmed the presence of oil and grease
WKA, September 1999	To confirm removal of oil and grease area	3	All 3 samples 3' bgs	Purposive; sampled soils adjacent to excavated area	Oil, grease, TPH-D, waste oil metals, total lead, total arsenic	Area identified by ACG was excavated in Sept/Oct, 1999. Removal confirmed by sampling
WKA, October 1999	To characterize the general distribution of analytes in surface soil over entire property	27	26 surface soil, 1 sediment sample from an on-property pond	Random; Sampled surface soils (upper 6") in Orchard Area	Organochlorine pesticides, total lead, total arsenic	Identified an area of elevated Lead, Arsenic, and DDT
WKA, December 1999	To further investigate a potential 'hot spot' identified in October sampling	5	4 surface (upper 6"), 1 sub-surface (18" bgs)	Purposive; Samples collected 30' to the N, S, E, W of S-11	Organochlorine pesticides, total lead, total arsenic	Further defined area of elevated Lead, Arsenic, and DDT
WKA, May 2000	To estimate background lead and arsenic concentrations	2	Surface soil	Purposive; samples collected from northern native forest land on the property	Total lead, total arsenic	Lead = <5 to 9.6 ppm Arsenic = 7-19 ppm
WKA, May/June 2000	To further investigate the remote filling area	23	20 surface (upper 6"), 3 sub-surface (12", 15" and 14" bgs)	Purposive/ random; Samples collected randomly within the remote filling area	Organochlorine pesticides, total lead, total arsenic	Further defined the area of elevated Lead, Arsenic, and DDT
WKA, January 2001	Characterize Background lead and arsenic	5	Surface soils	Purposive/random; samples collected randomly within background	Lead and arsenic	Evaluate background soil concentration
WKA, January 2001	Measure arsenic bioavailability	3	Surface soils	Purposive; Sample from representative soil types and from locations previously sampled	Arsenic	Evaluate the bioavailability of arsenic in property soils

B.3.8 Additional Reference

EPA (Environmental Protection Agency). 1997. *Guiding Principles for Monte Carlo Analysis.* EPA/630/R-97/001. www.epa.gov/NCEA/pdfs/montcarl.pdf

B.4 GRAND STREET MERCURY SITE (GSMS)

B.4.1 Background Information

<u>Site/Case Study Location:</u> 720–732 Grand Street in Hoboken, Hudson County, New Jersey.

<u>Regulating Entities and Authorities (State/Federal Program, Offices):</u> EPA Region II (lead) and NJDEP (support)

<u>Parties Conducting Investigation/Risk Assessment/Cleanup:</u> The lead agency is EPA Region II. The baseline human health risk assessment (April 1997) was prepared for EPA Region II by the previous consultant, Roy F. Weston, Inc. (Weston). Current Consultant is BBL, Inc. Responsible party is General Electric (GE).

<u>History of Site, Type(s) of Contamination:</u> Cooper-Hewitt and GE manufactured mercury vapor lamps at the site. Mercury associated with the manufacture of the vapor lamps is presumed to have been the primary source of mercury contamination throughout the building. Lamps of this type were produced at the site 1910–1965.

Later, the Quality Tool and Die Company manufactured precision tools at the site. In 1990, the owner of Quality Tool and Die Company filed for a cessation of operations under the New Jersey Environmental Cleanup and Responsibility Act. The remediation included removal of a UST and surrounding soil, which contained petroleum hydrocarbons, and covering the parking lot with an asphalt cap. The property was sold to the Grand Street Artists Partnership.

On November 2, 1995, a resident reported mercury contamination on the fourth floor of the building to the Hoboken Board of Health (HBH). On November 8, air monitoring for mercury was performed in two units located on the fourth floor. Mercury was detected in air at levels exceeding EPA standards for mercury. On December 22, 1995, representatives of the Hudson Regional Health Commission (HRHC) and the HBH requested the ATSDR and the New Jersey Department of Health and Senior Services (NJDHSS) to assist in evaluating the public health impact of mercury contamination in a condominium building located at 722 Grand Street in Hoboken. Representatives from the NJDHSS conducted a site visit and air monitoring using a real-time mercury vapor monitoring instrument.

On December 27, 1995, personnel from the HBH and HRHC collected urine samples from 31 people. Samples were analyzed for total mercury, specific gravity, and creatinine by the NJDHSS laboratory. Mercury concentrations in the samples ranged from 3–102 µg/L, and 20 of 29 samples from residents (69%) had mercury concentrations equal to or greater than 20 µg/L, the World Health Organization’s upper limit for normal unexposed adults. Mercury levels in urine samples from six children ranged 7.0–67.3 µg/L; five of these samples contained mercury above 20 µg/L.

On December 29, the HBH, HRHC, and the NJDHSS/ATSDR met with residents to provide them with results of the urine tests and to assist them in interpreting the urine and air mercury results. Based on the levels of contaminants observed, residents were urged to relocate as soon as possible. The ATSDR/NJDHSS completed a health consultation for the GSMS on January 3, 1996. The HBH issued an order which resulted in evacuation of the building and relocation of the residents by EPA. All residents had vacated the building by January 11, 1996.

On January 22, 1996, ATSDR issued a Public Health Advisory proclaiming an imminent public health hazard posed to residents of 722 Grand Street from past, current, and potential future exposures via inhalation, direct dermal contact, and possible ingestion of metallic (elemental) mercury and mercury vapor. ATSDR recommended that the following actions be taken: (1) Dissociate the public as soon as possible from mercury exposure in the 722 Grand Street building. (2) Ensure that residents' belongings would be free of mercury contamination before they were to be removed from the building; such possessions could have continued to expose residents of 722 Grand Street, contaminate other areas, and expose other members of the public.

On March 21, 1996, EPA approved an Action Memorandum to conduct an emergency removal action at the GSMS. On December 23, 1996, EPA proposed the GSMS for inclusion on its NPL. In April 1997, EPA completed a BRA for the GSMS. EPA completed a focused FS in July 1997, which analyzed remedial alternatives for the GSMS. On September 30, 1997, EPA issued a ROD. The major components of the selected remedy include permanent relocation of the former residents of the GSMS and continuation of temporary relocation of the former residents until permanent relocation has been implemented.

Source(s) of Contamination (Hg): Hg vapor lamp manufacturing operations.

Duration of Disposal/Operation (Hg): General Electric Vapor Lamp Company (1911–1939), General Electric Company (1939–1948), Cooper-Hewitt Electric Company (1910–1911 and 1948–1955).

Land Use: The surrounding area is a mix of residential/commercial and industrial properties.

Past/Historical: General Electric Vapor Lamp Company (1911–1939), General Electric Company (1939–1948), Cooper-Hewitt Electric Company (1910–1911 and 1948–1955).

Current: All site buildings have been demolished. All on-site (and off-site) soil excavation activities have been completed.

Future: Most likely residential development, with the first floor being used as a garage to address any potential mercury vapor issues.

Motivation for Remediation (i.e., enforcement, development, property transfer, other, etc.): In January 1996, ATSDR issued a Public Health Advisory that proclaimed "an imminent public health hazard is posed to residents" in the building and recommended that the residents be dissociated from mercury exposure in the building, as well as enforcement and development.

Is/are considered by case study the whole site, a part of the site, or perhaps an operable unit or analogous categorization? On-site soils (parking lot and beneath former building footprint) only.

Describe site (or area) under consideration for case study: GSMS is located at 720–732 Grand Street, Hoboken, New Jersey. The site comprised two buildings and an asphalt-covered parking area. One of the buildings consisted of a five-story former industrial building, which was converted into 16 residential/studio spaces 1993–1995. Fifteen of the 16 conversions were completed prior to identification of site-wide mercury contamination. A four-story adjoining townhouse was slated for residential conversion as well but was never converted. The five-story building was approximately 100 × 150 feet and was constructed of brick masonry with interior wooden structural and flooring components. The surrounding area is a mix of residential and commercial/industrial properties. Hoboken High School is located across the street to the northeast. More than 40,000 residents live within a 1-mile radius of the site.

Location/area/operable unit under consideration for case study (if less than entire site): On-site (parking lot and beneath former building footprint) soils only.

Size/area under consideration for case study, in square feet; location relative to rest of site; comparability with rest of site: ~10,000 square feet soils beneath parking lot and ~14,000 square feet soils beneath buildings.

B.4.2 Site Status

Investigation Phase	Completion Status
Discovery	Yes
PA/SI	Yes
Phase I, II, or III Property Assessment	Yes
RI	Yes
Baseline Risk Assessment	Yes
Cleanup Action Plan	Yes
FS	Yes
Remediation	Yes
Post-remediation monitoring	Yes
Close-out or NFA letter issued	Yes

B.4.3 Risk

At what stage, if any, were risk-based criteria (e.g., screening levels) introduced? RI, Baseline Human Health Risk Assessment (April 1997)

What was the source of the criterion (criteria), for example, site-specific or published values? Cite references for published values (e.g., EPA regional values and state criteria): Noncancer end point—toxicity information available EPA IRIS Toxicity Database as discussed in the BHHRA. Weston prepared this BHHRA for EPA Region II. Prior to on-site/beneath-the-building removal action, an ESD as prepared by BBL.

List the value(s):

- 23 mg/kg (BHHRA)—Based on ingestion and also protective of the inhalation exposure scenario
- 520 (ESD/subsurface) mg/kg—Protective of construction worker scenario

If site-specific criteria were used, describe how derived: N/A

What level of risk is this intended to represent (i.e., 1/million increased incident of cancer, hazard quotient of 1, etc.). List for screening levels and clean-up goals: Hazard quotient of 1.

Was guidance available/used as to how to sample the site to use the criterion? (provide reference):

- *Initial Sampling* (Weston, April 1996): In regard to on-site soils under the parking lot, for sampling locations in certain quadrants where soils were sampled at multiple depths, (e.g., 0–4 foot and 4–8 foot intervals), the shallowest sampling depth (0–4 foot interval) for which data were available was used in the risk assessment (BHHRA). For on-site data from locations in the same quadrants (above) where both discrete and composite sampling results were available, results from discrete samples were used in preference to the composite samples. "It should be noted that the composite samples collected from on-site areas are core composites rather than surface composites, which are more appropriate to evaluate risk through soil ingestion."
- *Most Recent Sampling* (BBL, September 2003): In regard to the footprint of the former industrial building, a 30 × 30 foot sampling grid was used. In general, the on-site soil data consisted of a combination of composite and discrete surficial samples for the 0–2 foot interval and discrete only subsurface samples for the 2–9 foot interval. Note that the top of the groundwater table was approximately 2 feet bgs.

Was background determined/derived/established? If so, how, and what was the value(s). If not, why not. (Describe methodology for sampling for background, statistical analysis, results, and value selected, including rationale; any referenced sampling guidance followed should be listed): No, since mercury was the COC and one would not expect to find elevated levels unless it was discharged. However, due to the presence of historic fill, a deed notice was previously required and will remain in effect due to PAH and priority pollutant metal contamination associated with historic fill. See Section 4.2.7 for NJDEP historic fill (and background) discussion.

Were multiple chemicals evaluated for similar/synergistic effect? If so, how was the combined effect of multiple chemicals evaluated? N/A

Were other controls beyond removal/remediation (capping, deed restriction, etc.) used? If so, how did that influence analysis of "risk" and provide justification? N/A; however, other alternatives were considered, with building demolition and soil excavation being the selected remedy. Again, due to the presence of historic fill, a deed notice was previously required and will remain in effect.

How (if at all) was the point of potential contact with contaminated media identified? (e.g., depth of soils, area over which exposure is averaged) Does it change throughout site cleanup process? Does it change with risk management? Initially, it was direct contact concern from surficial soils. However, once excavation/remediation took place, a subsurface saturated soil number was developed. Impacts to groundwater and vapor intrusion concerns were also considered later in the process.

What is the acceptable contaminant level? When (if at all) was it identified and documented (i.e., "screening level" vs. "PRG" vs. "cleanup level," etc.)? Twenty-three ppm—very early on in the process. Twenty-three ppm represented all three—screening level, PRG, and cleanup level.

How, if at all, do the criteria change throughout the remediation process? What is the basis? (Cost, background exceeds criteria, risk management, etc.) Again, surface number of 23 mg/kg vs. subsurface number of 520 mg/kg. Risk management (different exposure scenario) was the basis.

Describe community and/or stakeholder involvement in the decisions made about risk, cleanup, and sampling: A public meeting was held early on in the process—July 16, 1997. The ROD, ESD, etc. were also available to the public via the local library, Internet, etc. In fact, the site repository is the Hoboken Public Library located at 500 Park Avenue, Hoboken, NJ 07030.

B.4.4 Sampling

Describe sampling methodology (i.e., grab sample, sampling grid, composite, random sampling, stratified random sampling, etc.) used at various stages of project:

Stage	Methodology
Discovery	Combination of composite/discrete for both intervals (0–4 and 4–8 feet)
PA/SI	Combination of composite/discrete for both intervals (0–4 and 4–8 feet)
Phase I/II/III property assessment	N/A
RI	Combination of composite/discrete for both intervals (0–4 and 4–8 feet)
BRA	Combination of composite/discrete for both intervals (0–4 and 4–8 feet)
FS	Combination of composite/discrete for both intervals (0–4 and 4–8 feet)
Remediation	Mainly discrete
Post-remediation monitoring	Mainly discrete
Close-out or NFA letter issued	No

What value(s) measured (calculated) at the site was compared with the criterion (criteria) at various stages (for example, analytical result for composite sample, highest measurement, values averaged over a predetermined area, all values averaged regardless of location, a hot spot, a risk developed from potential exposure to multiple chemicals with similar effects, etc.) For soils note the depths of samples used for the comparison:

Stage	Value compared with criterion
Discovery	Highest value
PA/SI	Highest value
Phase I/II/III property assessment	N/A
RI	Highest value
BRA	Highest value
FS	Highest value
Remediation	Highest value (with averaging)
Post-remediation monitoring	Highest value (with averaging)

What soil was considered available for exposure? Top 2 cm (EPA soil screening document)

Rationale for Other Depth: Again, the remediation goal for mercury in the surface soils (generally 0–2 feet) as described in the ROD is 23 ppm and was developed to be protective for residential populations, including children. As for subsurface soils, which at the site are considered to be soils below the water table (located approximately 4.5–5.5 feet bgs). It is unlikely that residential populations would be exposed under typical, or reasonable, scenarios. The populations most likely to come into contact with these soils consist of utility workers and construction workers.

Is there an occurrence or pattern of attributing risk to a single sample result (the "one sample is a site" issue)? Not at this site. However, for the typical New Jersey site, yes.

How was the sampling density derived? How did it vary at different stages of the project, and why? As stated above, a 30 × 30 foot grid (random) was used. Of course, some samples were biased (within a grid) to visual evidence of mercury, suspect structures, etc. For the most part, sampling density did not vary except for the fact that more samples were required in grids where deeper excavations took place.

Discuss the relationship (if any) between the point of potential contact with the contaminated media, the sampling strategy, and the sampling density. Is the EPC determinable (can it be calculated or derived) from the sampling? If so, how? If not, why not? N/A

B.4.5 Challenges/Summary

This section is provided to allow persons associated most closely with the case study to identify particular problems—technical, regulatory, acceptance by the regulatory agency or public, or other—that they consider worth noting and discussing.

EPA Region II vs. NJDEP comparison table

	EPA Region II	**NJ DEP Site Remediation Program**
BHHRA required?	Yes	No
Risk range—Carcinogenic	1×10^{-4}–1×10^{-6}	1×10^{-6}
HI—Noncarcinogenic	1	1
Surface vs. subsurface distinction	Yes	No
Required depth of delineation	Typically 0–2 feet	To a "clean zone," regardless of depth
Discrete or composite sampling (surficial)	Both	Discrete only
Grid or biased sampling	Grid or combination	Biased only

Reconciling Differences: For example, EPA Region II agreed to collect discrete post-excavation samples at the request of NJDEP. In addition, delineation was accomplished to the most stringent criterion (23 ppm).

In summary, although the GSMS was an EPA (NPL)-lead site, NJDEP worked closely with EPA Region II to ensure compliance with N.J.A.C. Technical Requirements for Site Remediation and ultimately to protect the health of the public. This case study not only compared and contrasted New Jersey's and EPA Region II's approach to risk assessment, but just as importantly the manner in which the risk-based cleanup number(s) are used throughout all investigative as well as remedial phases of the case.

B.4.6 Status Summary

The EPA Region II Office announces the deletion of the Grand Street Mercury Superfund Site from the NPL, which constitutes Appendix B to the NCP, 40 CFR Part 300, which EPA promulgated pursuant to section 105 of CERCLA, as amended. EPA and the State of New Jersey, through the Department of Environmental Protection (NJDEP), have determined that all appropriate response actions have been implemented and no further response actions are required. In addition, EPA and the NJDEP have determined that the remedial action taken at the Grand Street Mercury Site is protective of public health, welfare, and the environment.

Effective Date: September 18, 2007

For further information contact:
Farnaz Saghafi, Remedial Project Manager
U.S. Environmental Protection Agency, Region II
290 Broadway, 19th Floor
New York, New York 10007-1866
(212) 637-4408

B.5 WISCONSIN LUST SITE

B.5.1 Background Information

Site/Case Study Name(s): Operating gasoline filling station/Wisconsin leaking UST (LUST) site

Site/Case Study Location: City of Milwaukee, Wisconsin

Regulating Entities and Authorities (State/Federal Program, Offices): Wisconsin Department of Commerce (Commerce)

Parties Conducting Investigation/Risk Assessment/Cleanup: Regional petroleum distribution/ franchise retail company and its environmental consultant. The company no longer owns the site but remained the RP for the site investigation, remediation, and closure.

Site Description: A failed tank tightness test in February 1993 confirmed petroleum release to the environment. One 4,000-gal diesel fuel and four 6,000–10,000-gal gasoline USTs, dispensers, and product transfer piping were removed and ~900 cubic yards of highly contaminated soil was excavated and landfilled in August 1994. A new three-UST system was installed later that year.

During removal of the former UST system, soil samples were collected at various locations and depths beneath the dispenser islands, along the piping trenches, and from the sidewalls of the tank basin excavation to evaluate the occurrence and magnitude of petroleum contamination remaining in place.

- Type(s) of contamination: Gasoline (and possibly diesel fuel)

- Source(s) of contamination: Holes observed in two of five removed USTs
- Duration of disposal/operation: Unknown release duration

Land Use:

- Past/historical: Gasoline station, probably vacant or farm land before
- Current: Active gasoline station, zoned “Industrial Light 1 (IL1)” for modern industrial use
- Future: Likely to remain zoned “IL1.”

Motivation for Remediation (i.e., enforcement, development, property transfer, other, etc.): To bring the site into statutory compliance with Chapter 292, “Remedial Action,” Wisconsin’s “spills law.”

Is area considered by case study the whole site, a part of the site, or perhaps an operable unit or analogous categorization? Area of concern is <8% of the total station property area.

Describe site (or area) under consideration for case study: location/area/operable unit under consideration for case study (if less than entire site) (size/area under consideration for case study, in sq. ft.; location relative to rest of site; comparability with rest of site: Area of concern is <2,500 square feet, the approximate area under the new “pump island area” (50 × 50 feet). The total station property area is ~31,000 square feet (~7/10 acre). One discrete (~20 g) soil sample collected from the bottom of the north piping/dispenser trench at a depth of 3 feet bgs was analyzed to have a benzene concentration of 13 mg/kg. This soil sample exceeded the benzene concentration and was collected within the depth interval (0–4 ft bgs) established in NR 746, Wisconsin Administrative Code, as posing a potential direct-contact risk to human health. Thus, the sampling location constituted a potential direct-contact hot spot.

The new pump island pad is a transient-use, high-traffic area located in the south-central portion of the site. The site itself is roughly ¼ pie-shaped and is bounded by commercial and light industrial properties to the west and the Milwaukee County Park system’s Menomonee River Parkway lands to the north, south, and east. The property immediately west of the site was a former trucking company but is now undergoing brownfields redevelopment by the City of Milwaukee.

B.5.2 Site Status

Investigation Phase	Completion Status
Discovery	Yes
PA/SI	No
Phase I, II, or III Property Assessment	No
RI	Yes
Baseline Risk Assessment	No
Cleanup Action Plan	No
FS	No
Remediation	Yes
Post-remediation monitoring	No
Close-out or NFA letter issued	Yes

B.5.3 Risk

At what stage, if any, were risk-based criteria (e.g., screening levels) introduced: Close-out or NFA letter issued

What was the source of the criterion (criteria)? For example site specific or published values; cite references for published values (e.g. EPA Regional values and State criteria): NR 746, Wisconsin Administrative Code, Table 2, "Protection of Human Health from Direct Contact with Contaminated Soil"

List the value(s). If site-specific criteria were used, describe how derived. The Table 2 benzene value is 1.1 mg/kg and was derived to be protective of human health from inhalation of volatiles.

What level of risk is this intended to represent? (i.e., 1/million increased incident of cancer, hazard quotient of 1, etc.) List for screening levels and clean-up goals. 10^{-6} (i.e., 1/million) target cancer risk.

Was guidance available/used as to how to sample the site in order to use the criterion? (provide reference): No

Was background determined/derived/established? If so, how, and what was the value(s)? No

If not, why not. (Describe methodology for sampling for background, statistical analysis, results, and value selected, including rationale; any referenced sampling guidance followed should be listed): Benzene is a petroleum volatile organic compound (PVOC) that does not occur as natural background or anthropogenic background (other than possibly in contaminated fill).

Were multiple chemicals evaluated for similar/synergistic effect? If so, how was the combined effect of multiple chemicals evaluated? PAHs were sampled and analyzed in soil samples. Benzo(a)pyrene-equivalent calculations for the seven classified carcinogenic PAHs yielded equivalent concentrations less than Wisconsin's "suggested" residential value (with 10^{-6} risk).

Were other controls beyond removal/remediation (such as capping, deed restriction, etc.) utilized? If so, how did that influence analysis of 'risk' and provide justification? Yes. The site was closed (NFA) with a deed restriction requiring maintenance of the existing soil performance standard (SPS) at the site. Per Wisconsin Department of Natural Resources (WDNR) guidance (PUB-RR-528), the SPS was established to be the 2 or more feet of clean soil backfill that was placed over the benzene hot spot during installation of the new dispenser pad/pump islands.

How (if at all) was the point of potential contact with contaminated media identified? (e.g., depth of soils, area over which exposure is averaged) Does it change throughout site cleanup process? Does it change with risk management? The "point of potential contact" appeared limited to the area of shallow (0–4 feet) soil beneath the new pump island pad, based on low to no detectable benzene concentrations in soil borings installed around the periphery of the pad. The point of potential contact was probably an even smaller area, based on additional sampling conducted in an attempt to show that natural attenuation had lessened the hot spot risk.

What is the acceptable contaminant level? When (if at all) was it identified and documented (i.e., “screening level” vs. “PRG” vs. “cleanup level,” etc.)? Benzene concentrations that are within 4 feet of the ground surface and are less than the NR 746 Table 2 generic level of 1.1 mg/kg pass one of eight “risk” criteria (NR 746.06) used to screen sites for remediation or case closure.

How, if at all, does the criteria change throughout the remediation process? What is the basis? (cost, background exceeds criteria, risk management, etc.): No change

Describe community and/or stakeholder involvement in the decisions made about risk, cleanup and sampling. The RP no longer owns the property and was reluctant to accept an institutional control (i.e., deed restriction) requiring long-term maintenance of the site’s surface pavement as a soil barrier/cover (i.e., the selected SPS) allowing for site closure. The SPS and institutional control would be required until the soil is actively remediated or it can be shown, to the satisfaction of the state, that the residual soil contamination has naturally degraded to levels that do not pose a human health risk.

The RP considered excavating the small volume of hot spot soils from under the new dispenser pad but decided that that was not practical.

Ultimately, the pavement was excluded from the final SPS, thereby releasing the RP of responsibility for maintaining the pavement indefinitely. Per the WDNR SPS guidance, the 2+ feet of clean fill alone was considered adequate for the SPS barrier cover. Maintaining the concrete pavement to City of Milwaukee code requirements is the current owner’s responsibility.

B.5.4 Sampling

Describe sampling methodology(ies) (i.e., grab sample, sampling grid, composite, random sampling, stratified random sampling, etc.) used at various stages of project:

Stage methodology:

- Discovery—Grab (20 g) samples from random locations beneath former dispensers/piping
- RI—Discrete (20 g) samples from split-spoon soil samplers (one sample per split-spoon)
- Remediation—Set of grab samples (various volumes) for waste characterization analysis (including benzene TCLP, flashpoint, lead) for each 300 cubic yards (900 cubic yards total) of contaminated soil excavated and landfilled during tank removal
- Post-remediation monitoring (verification)—Grab (20 g) samples from former tank basin walls and floor (one each) following limited contaminated soil excavation

What value(s) measured (calculated) at the site was compared with the criterion (criteria) at various stages? (for example, analytical result for composite sample, highest measurement, values averaged over a predetermined area, all values averaged regardless of location, a hot spot, a “risk” developed from potential exposure to multiple chemicals with similar effects, etc.) For soils note the depths of samples used for the comparison: Post-remediation monitoring (verification)—13 mg/kg benzene in native silty clay soil at 3 feet bgs in a new piping trench.

What soil was considered available for exposure? Other depth (provide reference): 0–4 feet bgs, the depth interval for which residential receptors and outdoor workers are most likely/commonly exposed to direct-contact risk. The depth interval was negotiated among several Wisconsin environmental and health agencies. The initial depth intervals brought to the code development committee ranged 0–6 inches to no depth limit.

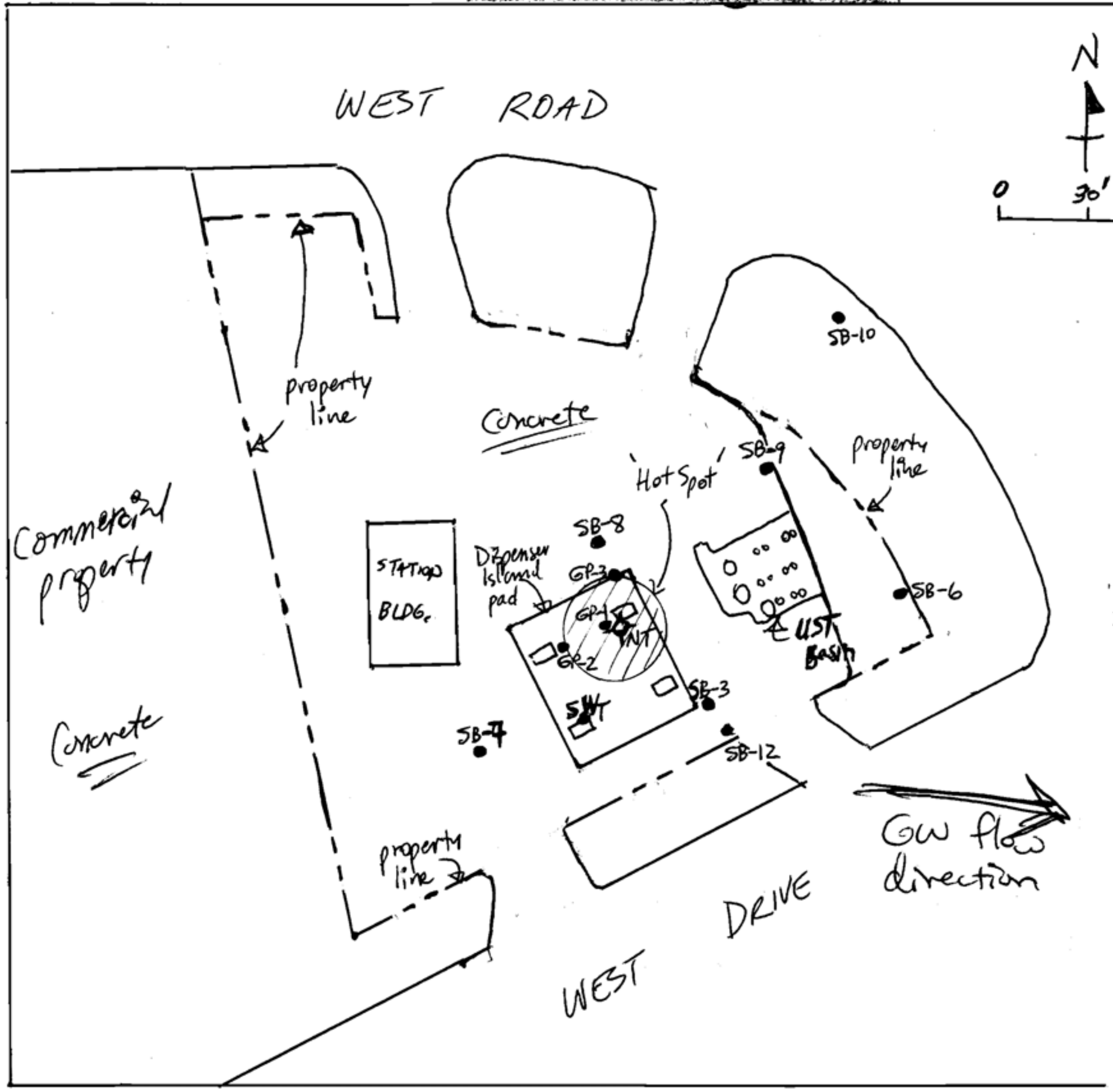
Is there an occurrence or pattern of attributing risk to a single sample result (the "one sample is a site" issue)? Yes. Often, a deed restriction requiring maintenance of a SPS is required by the case manager/regulator as a condition of case (i.e., site) closure, based on a random soil sample or two exceeding a generic direct-contact concentration. An RP will typically request case closure, having concluded that the hot spot sample does not constitute a direct-contact risk because the site is paved. The regulator will usually agree that there is no current risk and will require the deed restriction/SPS to prevent potential future risk. (After this case was closed, Ch. 292, Wisconsin Statutes, was amended to require placement of a site onto the WDNR's geographic information system Registry of Closed Remediation Sites, in lieu of placing a deed restriction on a property's deed.) This is a conservative and "easy" approach for dealing with potential risk; however, it can place a stigma and, more practically, use restrictions on the property that are not warranted. This was the approach taken for this site.

For this site, the RP attempted to drill and collect a soil sample(s) from the original hot spot location to evaluate whether natural attenuation had reduced the benzene concentration to below the generic direct-contact level. The follow-up sample was collected about 3 feet from the original sampling location and from about the same depth interval. The benzene concentration of 0.44 mg/kg was substantially lower than at the original sampling location (13 mg/kg); however, concentrations of other PVOCs (e.g., toluene, ethylbenzene, xylenes) were roughly the same, indicating that the residual contamination and, hence, potential risk may not have substantially diminished.

How was the sampling density derived? How did it vary at different stages of the project, and why? The sampling density (i.e., one discrete sample per location) was established by the RP's consultant to characterize soil quality beneath tank system components (e.g., dispensers, piping joints/elbows, and the tanks themselves) that have been found to be typical petroleum release points at other leaking UST sites. Additional sampling was conducted surrounding the new dispenser island area as part of the overall investigation of degree and extent of contamination across the site.

Discuss the relationship (if any) between the point of potential contact with the contaminated media, the sampling strategy, and the sampling density. Is the exposure point concentration determinable (can it be calculated or derived) from the sampling? If so, how? If not, why not? From a practical standpoint, conducting additional focused sampling to statistically determine the EPC was unrealistic. The additional sampling would have had to be conducted through the existing dispenser pad, which is underlain by fiberglass product piping and electrical lines. Furthermore, the station's fueling operations would likely have had to be shut down for several days, which the current owner was unlikely to allow.

FIGURE 4.3.2.3.1



SOIL SAMPLES COLLECTED BETWEEN 0-4 FEET BELOW GROUND SURFACE

● BENZENE < soil screening level for direct-contact risk (1.1 mg/kg)

⌖ BENZENE > soil screening level for direct-contact risk (1.1 mg/kg)

▨ Estimated area of benzene hot spot'

SOIL SAMPLE	SAMPLE DEPTH (feet)	BENZENE (mg/kg)	HAZARD INDEX (HQ=1)
NT	3	**13**	**0.29**
SWT	3	<0.005	nd
SB-3	2.5-4.5	<0.01	nd
SB-6	0.5-1.5	<1	nd
SB-7	2-4	<0.018	nd
SB-8	2-4	<0.018	nd
SB-9	2-4	<0.019	nd
SB-10	2	<0.018	nd
SB-12	2-4	<0.018	nd
GP-1	2-4	**0.44**	**0.43**
GP-2	2-4	**0.16**	**0.04**
GP-3	2-4	<0.025	**0.27**

nd - not determined

Appendix C

Comparative Case Studies

COMPARATIVE CASE STUDIES

The Risk Assessment Resources Team conducted two comparative case studies, each based on a hypothetical site for which a brief site description, plot plans, sampling locations, and soil analytical results were provided. Appendix C presents the responses to all questions for both case studies in Chapter 5, “State Regulators’ Perspectives: Comparative Case Studies.”

C.1 FIRST COMPARATIVE CASE STUDY

The first comparative case study was begun with a data collection sheet modified from the one used for evaluating the “real” case studies discussed in Appendix B and in the body of this report. However, it soon became apparent that the most efficient mechanism for the comparative case study was to collect specific answers in tables, allowing individual participants to comment on or clarify their answers. This appendix provides the background information, plot plans, data set, and the answers provided by participants, along with any clarification they chose to provide. Chapter 5 of this report presents a refined version of the original answers for most questions posed to participants.

The team asked representatives to complete a review/assessment of a hypothetical project—a former skeet range proposed for development into a six-lot residential neighborhood. The site was sampled at 76 locations for lead. Soil samples were taken from 0–6 and 6–12 inches at each sampling location, and occasionally a third sample was taken 2 feet bgs. EPA Method 6010/6020 was used to analyze samples after fragments were sieved out, and analytical results will be provided following a final review. A plan view of the proposed development—including the sampling locations—and the data set associated with the comparative case study are provided below.

C.1.1 Background Information

Site/Case Study Name(s): Skeet Range Redevelopment Project

Site/Case Study Location: Various (each contributor will assume the project is in his or her own state)

Regulating Entities and Authorities (state/federal program, offices): Various (state-by-state) state programs

Parties Conducting Investigation/Risk Assessment/Cleanup: Private real estate development company

Brief Description of History of Site, Type(s) of Contamination: Area was used as a skeet range from mid 1960s until 2000. Lead is the contaminant of concern.

Land Use:
- Past/Historical: Skeet range.
- Current: Property is not in use, and is essentially an open field. It is not fenced.

- Future: Six-lot residential development is proposed (see attached plan view of proposed lots).

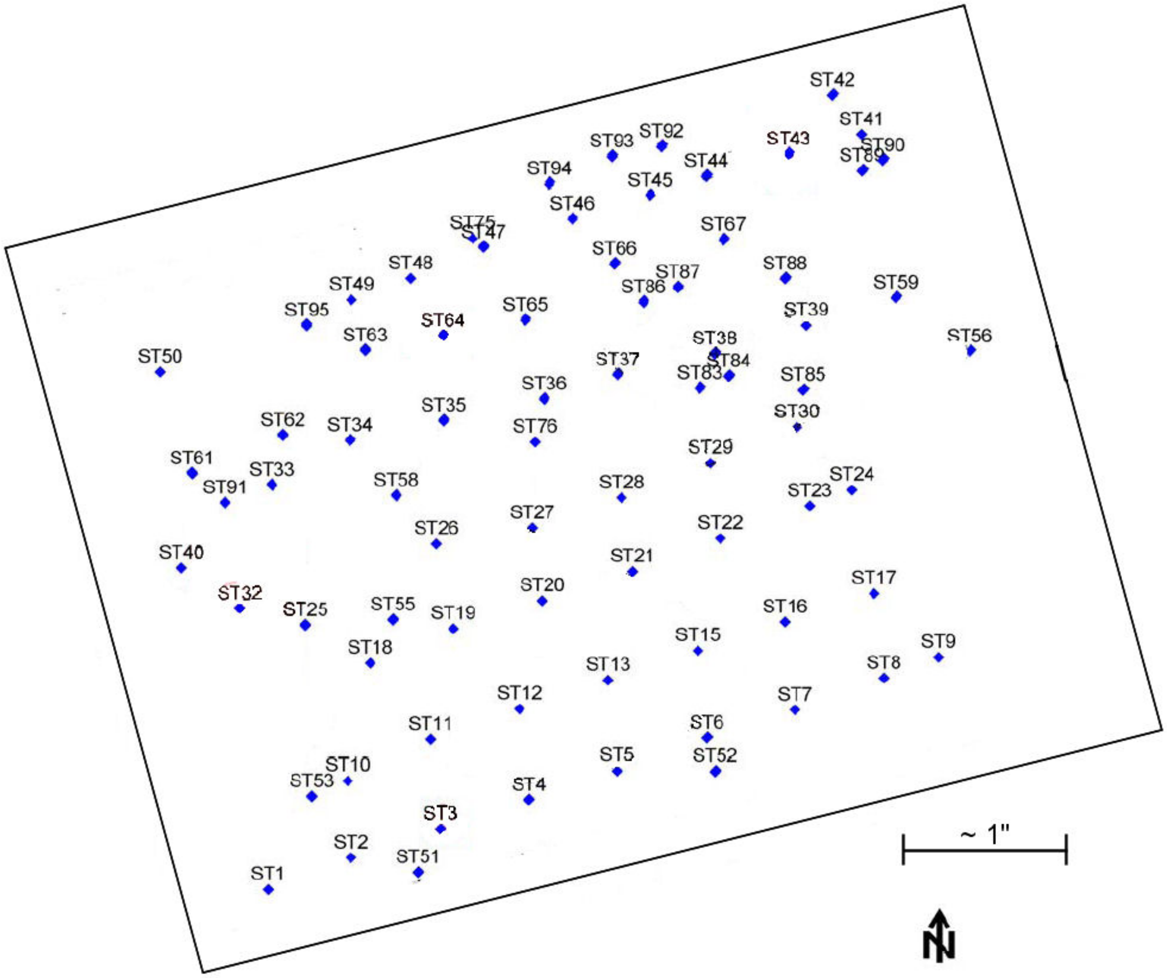
Motivation for Remediation (i.e., enforcement, development, property transfer, other, etc.):
Proposed property development

Skeet Range Case Study Data Set

Sample ID	Lead value (mg/kg)	Depth interval (inches)
ST1S1	20	0–6
ST1S2	26.7	6–12
ST2S1	18	0–6
ST2S2	30.2	6–12
ST3S1	295	0–6
ST3S2	162	6–12
ST3S3	127	12–24
ST4S1	57.2	0–6
ST4S2	35	6–12
ST4S3	40	12–24
ST5S1	29.4	0–6
ST5S2	36.4	6–12
ST6S1 (0–6)	154	0–6
ST6S2 (6–12)	84.9	6–12
ST6S3 (12–24)	85.6	12–24
ST7S1	37	0–6
ST7S2	32	6–12
ST8S1	37.8	0–6
ST8S2	24.8	6–12
ST9S1	45	0–6
ST9S2	25.5	6–12
ST10S1	229	0–6
ST10S2	75.3	6–12
ST11S1	232	0–6
ST11S2	82	6–12
ST12S1	68	0–6
ST12DS1	72	0–6
ST12S2	28	6–12
ST12DS2	32	6–12
ST13S1	51.6	0–6
ST13S2	42.3	6–12
ST15S1	58.2	0–6
ST15S2	46.1	6–12
ST16S1	179	0–6
ST16S2	67.5	6–12
ST17S1	82.5	0–6
ST17S2	23.8	6–12
ST18S1	45	0–6
ST18S2	22.4	6–12
ST19S1	228	0–6
ST19S2	96.5	6–12
ST20S1	54.6	0–6
ST20S2	30.5	6–12
ST21S1	143	0–6
ST21S2	24.1	6–12
ST22S1	246	0–6
ST22DS1	446	0–6
ST22S2	93.1	6–12
ST22DS2	99.7	6–12
ST23S1	179	0–6
ST23S2	65.9	6–12
ST24S1	65.1	0–6
ST24S2	48.2	6–12
ST25S1	623	0–6
ST25S2	162	6–12
ST26S1	169	0–6
ST26S2	95.4	6–12
ST27S1	193	0–6
ST27S2	75.1	6–12
ST28S1	162	0–6
ST28S2	68.7	6–12
ST29S1	131	0–6
ST29S2	72.4	6–12
ST30S1	205	0–6
ST30S2	104	6–12
ST32S1	1750	0–6
ST32S2	698	6–12
ST33S1	1180	0–6
ST33S2	221	6–12
ST34S1	72.7	0–6
ST34S2	85.4	6–12
ST34S1D (0–6)	347	0–6
ST34S2D (6–12)	76	6–12
ST35S1	978	0–6
ST35S2	54.2	6–12
ST35S1D (0–6)	528	0–6
ST35S2D	68.9	6–12
ST36S1	375	0–6
ST36S2	62.4	6–12
ST37S1	918	0–6
ST37S2	116	6–12
ST38S1	401	0–6
ST38S2	144	6–12
ST39S1	149	0–6
ST36S2	38.4	6–12
ST40S1	159	0–6
ST40S2	68.1	6–12
ST41S1	53.3	0–6
ST41S2	20.5	6–12
ST42S1 (0–6)	45.3	0–6

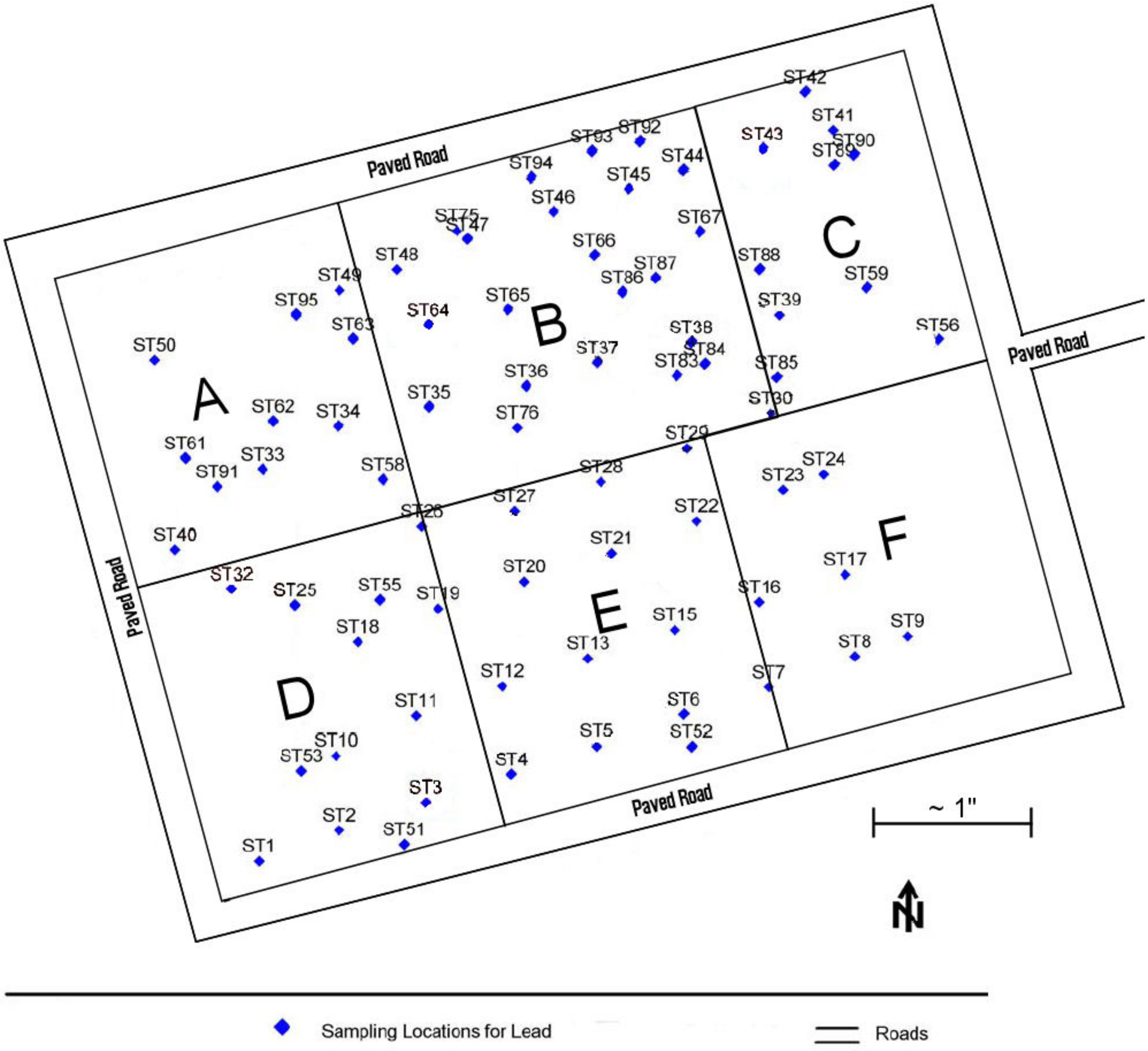
Sample ID	Lead value (mg/kg)	Depth interval (inches)
ST42S1 (6–12)	126	6–12
ST43S1	109	0–6
ST43S2	373	6–12
ST44S1	1170	0–6
ST44S2	142	6–12
ST45S1	1010	0–6
ST45S2	262	6–12
ST46S1	1010	0–6
ST46S2	55.3	6–12
ST46S1D (0–6)	79	0–6
ST46S2D	74	6–12
ST47S1	669	0–6
ST47S2	101	6–12
ST48S1	242	0–6
ST48S2	55.2	6–12
ST49S1	123	0–6
ST49S2	38.4	6–12
ST50S1	24.1	0–6
ST50S2	20.6	6–12
ST51S1	24.6	0–6
ST51S2	18.6	6–12
ST52S1	50.9	0–6
ST52S2	20.5	6–12
ST53S1	104	0–6
ST53S2	18.4	6–12
ST55S1	17.6	0–6
ST55S2	26.1	6–12
ST56S1	54.3	0–6
ST56S2	83.2	6–12
ST58S1	63.6	0–6
ST58S2	77	6–12
ST59S1	112	0–6
ST59S2	156	6–12
ST61S1	45	0–6
ST61S2	45	6–12
ST62S1	534	0–6
ST62S2	157	6–12
ST63S1	184	0–6
ST63S2	172	6–12
ST64S1	409	0–6
ST64S2	325	6–12
ST65S1	93.5	0–6
ST65S2	96.1	6–12
ST65S2D	85.4	6–12
ST66S1	205	0–6
ST66S2	85.9	6–12
ST67S1	886	0–6
ST67S2	106	6–12
ST75S1	212	0–12
ST75S2	85.1	6–12
ST76S1	103	0–12

Sample ID	Lead value (mg/kg)	Depth interval (inches)
ST76S2	42.9	6–12
ST77S1	53.7	0–6
ST77S2	48.7	6–12
ST83S1 (0–6)	204	0–6
ST83S2	39.7	6–12
ST84S1 (0–6)	259	0–6
ST84S2	98	6–12
ST85S1 (0–6)	440	0–6
ST85S2	143	6–12
ST86S1 (0–6)	45	0–6
ST86S2	45	6–12
ST87S1 (0–6)	195	0–6
ST87S2	84	6–12
ST88S1 (0–6)	676	0–6
ST88S2	78	6–12
ST89S1 (0–6)	503	0–6
ST89S2	95.6	6–12
ST90S1 (0–6)	363	0–6
ST90S2	86.7	6–12
ST91S1 (0–6)	343	0–6
ST91S2	101	6–12
ST92S1 (0–6)	339	0–6
ST92S2	96.4	6–12
ST93S1 (0–6)	1280	0–6
ST93S2	90	6–12
ST94S1 (0–6)	166	0–6
ST94S2	96	6–12
ST95S1 (0–6)	310	0–6
ST95S2	98	6–12
Index: D = Duplicate of corresponding sample (i.e., ST12S1 and ST12DS1). Note: Some samples 12–24 inches.		



◆ Sampling Locations for Lead

Scale: 1" = 50'



Scale: 1" ≈ 50'
Lot A, D, E, & F ≈ 8,750 ft ^{2}
Lot B ≈ 11,560 ft ^{2}
Lot C ≈ 6,250 ft ^{2}

C.1.2 Information Collected from Each State Representative

A key objective in undertaking the comparative case study was to capture similarities and differences among participants concerning several key interests of the Risk Assessment Resources Team. Some of those interests were probed through questions such as the following:

- What value is measured/calculated at the site, the highest value or an average, and over what area/volume do you average?

- How is the average developed (simple average, UCL, etc.)?

- What value is measured/calculated to compare against the various risk-based criteria? Does that vary throughout the site cleanup process?

- How are risk-based criteria used throughout the sampling and cleanup process of a project?

- How would you handle the relatively “high” measurements that are commonly reported, especially those “high” measurements that might be surrounded by less remarkable levels of lead?

- Would the “high” measurements be averaged with adjacent samples to provide an estimate of the average level throughout an exposure area (volume), and what would that area (volume) be? Or, would “hot spot removal” be required regardless of surrounding measurements? What is the basis and available guidance?

The results of this comparative case study are presented in a series of summary tables, supplemented by comments from individual state participants.

C.1.3 What Values for Lead Are Used Throughout the Remediation Process?

When contamination is encountered in soil, invariably the first question asked is, “What is the number for that chemical?” That “number” may come from any one of a number of sources, and, as seen in the four case studies of actual projects described previously, may vary with stage of the remediation process or other considerations associated with the project.

State representatives were asked to provide the “number” or “numbers” for lead in soil that would be appropriate throughout the various stages of remediation of the comparative case study. The objective was to determine similarities, sources for the various “numbers,” and when a specific value might change throughout the remediation process. Table C-1 presents the results of this inquiry.

Table C-1. Values for Lead (mg/kg) throughout the course of the remediation process

State	Early	Remedial investigation	Risk	Feasibility study	Remedy monitoring	Confirmation of remedy
Alabama	400	After initial assessment, site-specific input is used and use of the IEUBK Model or the Adult Lead Model is required for those calculations.				
Arkansas	400 or 800 (heavy industrial)	After initial assessment value site specific input is used.				

State	Early	Remedial investigation	Risk	Feasibility study	Remedy monitoring	Confirmation of remedy
California	150 (value of 150 LeadSpread model is basis)	150	150. Might change as a result of risk assessment and/or risk management.	150	150	150
Florida	400	400 mg/kg throughout, based on the IEUBK model, but from here on the IEUBK model could be run with site-specific inputs.				
Georgia—RCRA	400	Based on risk assessment and use of IEUBK and/or Georgia Adult Lead Model.				
Georgia—HSRP	75	After initial assessment, default values of 75 residential/400 nonresidential can be used or site-specific based on IEUBK or Georgia Adult Lead Model. 75 is default regulatory value for state program.				
Massachusetts	300	Under different situations, default values of 100, 300, or 600 mg/kg can be used, or a site-specific risk-based value may be calculated.				
New Jersey	400	400 mg/kg throughout, based on the IEUBK model, but from here on the IEUBK model could be run with site-specific inputs when appropriate.				
Tennessee	400	400	400	400	400	400

Alabama

Up through the Phase III Site Assessment, the same value of 400 mg/kg would be used for the evaluation of each lot using an unrestricted residential scenario. This value would be used up through the BRA phase, at which time 400 mg/kg may continue to be used or a site-specific evaluation using the IEUBK model may be used.

The most current version of the Alabama Risk-Based Corrective Action Guidance Manual: www.adem.state.al.us/LandDivision/Guidance/guidance.htm

The value does not change from the screening to cleanup. It should be noted that this is an unusual circumstance and is unique to lead. Most contaminants have a more conservative screening level, and then the remediation level is typically less conservative due to its being a more site-specific value. The only time the value for lead would differ is if the site wanted to determine an alternate value using the IEUBK model (since this is a residential scenario). This would be unusual, but allowed in Alabama.

California

The values in Table C-1 for this case study remain the same throughout the process because lead is the only COC and only residential use is considered. If there were other COCs and other land uses considered, the "values" would change based on site-specific conditions and proposed land uses.

Georgia

If this site is to be regulated by the RCRA program, then the initial site screening would be done by comparing the maximum concentration detected against the Region 9 residential soil PRG as required by the *Georgia Environmental Protection Division Guidance for Selecting Media Remediation Levels at RCRA Solid Waste Management Units* (www.gaepd.org/Files_PDF/techguide/hwb/swmurisk.pdf). After the initial screening, the RP would need to develop a site-specific risk-based remedial level using the IEUBK model. If this site is to be regulated under the Georgia Hazardous Site Response Act (the state Superfund program), then the initial screening would be done by comparing the maximum detected concentration to the notification concentration for lead contained in the rules for hazardous site response (http://rules.sos.state.ga.us/cgi-bin/page.cgi?g=GEORGIA_DEPARTMENT_OF_NATURAL_RESOURCES/ENVIRONMENTAL_PROTECTION/HAZARDOUS_SITE_RESPONSE/index.html&d=1), which is 400 mg/kg. If the site were then listed on the Hazardous Site Inventory, then either the site would need to be remediated to the default residential value for lead, 75 mg/kg, or a site-specific remedial level would need to be developed using the IEUBK model.

Massachusetts

The Method 1 standard for lead in soils (300 mg/kg) is adopted from the "Land Application of Sludge and Septage" regulations (310 CMR 32). However, if it is feasible to go beyond the minimum requirement of eliminating significant risk, there is a statutory obligation to do so (310 CMR 40.0860(5)). The generic background concentration for lead in soils is 100 mg/kg, unless coal or wood ash is present, in which case the generic background concentration is 600 mg/kg.

C.1.4 Are Lots Evaluated Individually or All Together as One Unit?

The first comparative case study presented 170 measurements of lead in soil distributed across approximately 1.2 acres, along with a plan for development that would eventually provide six residential lots. The values one would calculate as averages would be different depending on whether one considers the six proposed residential lots together or separately. In large measure this question was asked to surface differences in how the data would be processed: would all 170 data points be linked together, or would the data points on each proposed lot be linked together?

Table C-2. How are data evaluated—by lot or all together?

State	Individual lots	All 6 lots together	Notes
Alabama	X		Under a "current conditions" scenario where the exposure scenarios are the same and the property is owned by one person, that entire area would be considered one exposure area. However, in this case, it has been defined that the area will be owned in the future by separate entities. This causes the risk to be evaluated based on a "future use" scenario. Each lot will be treated as a separate exposure area (or "exposure domain" as Alabama refers to it).

State	Individual lots	All 6 lots together	Notes
Arkansas		X	Note: All six together would be typical, but individually might be accepted in Brownfield Program.
California	X		Individually, since lots are legally described.
Florida	X		
Georgia—RCRA		X	Properties would be considered one SWMU.
Georgia—HSRP		X	The properties would be considered one site since there is one source of a release.
Massachusetts	X		Every data point is evaluated in hot spot evaluation.
New Jersey	X		
Tennessee	X		Each lot would be considered an exposure area.

Alabama

The future risk would be the driver, so each lot would be evaluated and remediated based on six separate evaluations, one evaluation for each lot.

California

In this case the six lots are legally created and would be treated as individual EUs. If the property were undeveloped and the six lots were "proposed," we would look at the entire property as a unit. We would look for potential hot spots that should be remediated to achieve health-protective criteria so that the property meets unrestricted use criteria no matter where the lot lines are finally drawn.

Georgia

If the site is to be regulated under the RCRA program, then the firing range would be considered one SWMU and handled as one. If the site is to be regulated under the Hazardous Site Response Act, then the properties would be considered one "site" since they are contaminated by the same source and again handled together.

Massachusetts

Each sample is considered a "site" for the purposes of the hot spot evaluation (see Table 3-1 in the main text). In the absence of hot spots, each lot is considered separately, as the preponderance of exposure for each receptor is going to be from respective lot.

C.1.5 How Is EU Determined?

Risk assessment focuses on identifying the time-variable level of exposure that—if sufficient—would cause an adverse response. Central to this approach is the development of an exposure scenario that would create any exposure in the first place. In the comparative case study, a residential setting was selected, and exposure to shallow soil was the focus as a way of simplifying the analysis and comparison of responses.

In risk assessment terminology, exposures to shallow soil are evaluated throughout an area, typically called an "EU." The responses to the question, "How is the EU determined?" are provided in Table C-3.

Table C-3. How is the EU determined?

State	Notes
Alabama	Site specific
Arkansas	Site specific
California	Site specific
Florida	¼ acre = default lot size
Georgia—RCRA	Site specific
Georgia—HSRP	Averages not allowed
Massachusetts	Lot size
New Jersey	Lot size
Tennessee	Site specific

California

In this case the six lots are legally created and would be treated as individual EUs. If the property were undeveloped and the six lots were "proposed," we would look at the entire property as a unit. We would look for potential hot spots that should be remediated to achieve health-protective criteria so that the property meets unrestricted use criteria no matter where the lot lines are finally drawn.

Georgia

If this site is to be regulated under the RCRA program, the EU would be determined based on the current and future receptors exposed at this SWMU. In most cases, there is a tendency to consider one SWMU a single EU. If the properties is to be regulated under the Hazardous Site Response Act, this point becomes moot since all remedial levels are considered "bright lines" that must be met at all locations throughout the site.

Massachusetts

See Massachusetts' response in previous section (Table C-2).

C.1.6 Is Horizontal Averaging Allowed?

As a follow-up to the question about EUs, it was of interest to evaluate how horizontal averaging—which for purposes of risk assessment should logically occur throughout the area of an EU—was practiced. The responses to the question, "Is horizontal averaging allowed?" are presented in Table C-4.

Table C-4. Is horizontal averaging allowed?

State	Yes	No	Method
Alabama	X		95% UCL about the mean measured over the site-specific EU.
Arkansas	X		
California	X		Lots evaluated individually. Excavation proceeds until 95% UCL of the mean concentration for each lot is less than the remedial goal.
Florida	X		95% UCL averaged over ¼ acre for a default residential lot.
Georgia—RCRA	X		Averaged over solid waste management unit.
Georgia—HSRP		X	
Massachusetts	X		Median or 95% UCL (provided there are enough data points).
New Jersey	X		During the remedial investigation phase (only) pursuant to 7:26E-4.8(c) 3i.
Tennessee	X		Over "contamination"—not a set area/dimension.

California

California allows "horizontal averaging" by using the 95% UCL of the mean of data collected following remediation. If the 95% UCL is less then the remedial goal, the property is considered remediated. In this case the six lots are legally created and would be treated as individual EUs. If the property were undeveloped and the six lots were "proposed," we would look at the entire property as a unit. We would look for potential hot spots that should be remediated to achieve health-protective criteria so that the property meets unrestricted use criteria no matter where the lot lines are finally drawn.

Georgia

If this site is to be regulated under the RCRA program, the EU would be determined based on the current and future receptors exposed at this SWMU. An EPC consisting of a representative average would be developed and compared to any remedial goal. If the properties are to be regulated under the Hazardous Site Response Act, area averaging is not allowed, and the remedial levels are considered "bright lines" that must be met at all locations throughout the site.

Massachusetts

Typically the EPC would be the arithmetic average of the contaminant concentration, although consideration should be given to using the maximum concentration reported or an upper percentile of the range of concentrations reported when the site data may not be adequate, when evaluating acute exposures, when evaluating chemicals associated with lethal or severe health effects, or when performing screening assessments (310 CMR 40.0926(3)). Generally, for surface soil exposures, the arithmetic mean soil concentration in an exposure area may be used as the EPC estimate. The accuracy of this method depends on three underlying assumptions:

- Over time, soil concentrations remain constant.
- The detected concentrations represent a uniform or random distribution of soil samples over the exposure area.
- Over time, exposure is equally likely at any location within the exposure area.

If these assumptions hold true, the arithmetic mean concentration in the exposure area will represent the arithmetic mean concentrations with which a person comes into contact over time.

In other words, the spatial average may be used as a surrogate for the temporal average. There are cases, however, when the second and/or third assumptions do not hold true. Sampling locations are not always distributed evenly over the site, and exposure frequencies are often higher in some areas than others. In these cases, a weighted average of the detected concentrations should be used.

C.1.7 How Are Shallow and Deep Soil Defined?

In the context of exposure to contaminated soil, there is some interval near the surface where one should sample to evaluate if the level of exposure exceeds or is less than a soil exposure criterion. At the same time, there is some depth beyond which soil is unlikely to be brought to the surface; thus, it would not reasonably—if ever—be available for direct exposure. Both of these dimensions depend on human behavior and construction activities that would bring deep soil to the surface and are not related to any level of contamination.

State representatives were asked how, if at all, “shallow” and “deep” soil are differentiated. Table C-5 provides the answers to this question.

Table C-5. Definitions of shallow and deep soil

State	Shallow	Deep
Alabama	0–12 inches	12 inches to water table
Arkansas	0–12 inches	12 inches to water table
California	10 feet available (defined by concentration)	Below 10 feet
Florida	0–6 inches	24 inches to water table
Georgia—RCRA	0–12 inches	12 inches to water table
Georgia—HSRP	0–24 inches	24 inches to water table
Massachusetts	0–1 foot (imminent hazard [IH]) 0–3 feet (residential) 0–15 feet (construction)	36–180 inches
New Jersey	0–6 inches initial characterization soil samples (except VOCs) pursuant to 7:26E-3.6(a)3.	No limit
Tennessee	0–2 inches (surficial) 0–24 inches (possible contact hazard)	Not defined

Alabama

The direct contact exposure pathway was evaluated for the surficial soils defined as 0–12 inches bgs. This was used for screening and remediation purposes. All surficial soils (0–12 inches bgs) would be evaluated.

California

California considers the upper 10 feet of soil to be available for direct contact pathways. The 10-foot criterion was established to accommodate potentially extensive grading on large parcels and excavations on small parcels such as installing swimming pools. During the grading and excavation operations, soils that were at deeper levels could be brought to the surface and become part of the post grading/excavation surface topography.

Georgia

If this site is to be regulated under the RCRA program, surface soil is assumed to be 0–1 foot, and subsurface soil would be 1 foot to the top of the water table. If the properties are to be regulated under the Hazardous Site Response Act, surface soil is defined as 0–2 feet, and subsurface soil is 2 feet to the top of the water table.

Massachusetts

Massachusetts categorizes soils by depth as well as accessibility. IH evaluations focus on only the actual current exposures. The top 12 inches of soil is considered readily accessible (310 CMR 40.0953(2)). In non-IH situations, the top 36 inches is considered accessible. Construction workers often dig excavations or trenches that can easily reach depths of 180 inches (15 feet). This is considered a reasonable future use, however, and would not be considered in an IH evaluation (310 CMR 0933(9)).

C.1.8 Is Vertical Averaging Allowed?

Every soil sample has a volume. Most soil samplers extract a sample from at least the top few inches, and so by definition some modest averaging is accomplished in the vertical dimension. However, as discussed just previously, most state programs recognize a difference between shallow and deep soil regarding the conditions that would produce an unwarranted level of exposure. That recognition is manifest in some programs by identifying discrete depth zones within which an "average" value is appropriate, and by identifying zones across which an "average" value is not appropriate.

Table C-6 provides responses to the question, "Is vertical averaging allowed?"

Table C-6. Is vertical averaging allowed?

State	Yes	No	Comments
Alabama	X		0–12 inches OK
Arkansas	X		Discrete zones
California	X		Site specific
Florida	X		0–6 inches 6 inches–2 feet 2–4 feet and every 2 feet thereafter
Georgia—RCRA	X		In most cases, data are separated into surface and subsurface soil
Georgia—HSRP		X	
Massachusetts	X		0–1 feet IH
	X		0–3 feet for residential (non-IH)
	X		0–15 feet for construction
New Jersey		X	
Tennessee		X	

California

California evaluates the use of vertical averaging on a site-by-site basis.

Georgia

If this site is to be regulated under the RCRA program, vertical averaging may be allowed on a site-by-site basis; however, it is preferred to separate soils into surface and subsurface soils. If the properties are to be regulated under the Hazardous Site Response Act, vertical averaging will not be allowed.

Massachusetts

Consistent with the definition of shallow soil (see Section C.1.7), vertical averaging is allowed down to 3 feet in a residential scenario and to 15 feet in a construction scenario.

C.1.9 Are Composites Allowed?

Composite sampling provides a physical approach to determining an average value throughout an area or volume. While it has the disadvantage of not allowing a statistical determination of variance, it has use. In many circles compositing is discouraged and perhaps not allowed because it might "miss" something. In other circumstances it is encouraged.

State participants were asked about compositing samples; Table C-7 provides their responses.

Table C-7. Are composites allowed?

State	Yes/No	Comment
Alabama	Yes	A minimum of five multiincrement samples each composed of a minimum of 30 increments may be used. This procedure enables the Central Limit Theorem to be invoked, which then makes it appropriate to calculate a 95% UCL about the true mean. See Appendix A of the Alabama Risk-Based Corrective Action Guidance Manual (www.adem.state.al.us/)
Arkansas	Yes	Site-specific determination.
California	Maybe	Not for risk or confirmation.
Florida	No	Vertical composites are allowed within specified intervals: 0–6 inches, 6 inches–2 feet, 2–4 feet, and every 2 feet thereafter.
Georgia—RCRA	Maybe	Site by site determination.
Georgia—HSRP	No	
Massachusetts	Yes	Although allowed, not preferred.
New Jersey	No	
Tennessee	Yes	

Alabama

In those media that are amenable to the collection of multiincrement samples (i.e., soils, sediments) a minimum of 5 multiincrement samples each composed of 30–100 increments may be used instead of the method as described in Guideline #1. A sample mean and standard deviation can be calculated for the five data points for each COPC. Consequently, since the sample design is equivalent to collecting 150–500 discrete samples, the central limit theorem (CLT) may be invoked. The CLT may be invoked when the distribution of an average tends to be normal, even when the distribution from which the average is computed is decidedly nonnormal. As a result of the CLT, parametric statistics are then appropriate for use in the calculation of the 95% UCL of the true mean. The department recognizes the use of the student's t-test in such cases.

California

Compositing is usually not allowed for characterizing sites. Discrete sample results enable delineation of impacted areas for assessing risk and potential remediation. Composite samples can be useful for characterizing stockpiles of soil for disposal or reuse options.

Georgia

Composite samples may be allowed on a case-by-case basis if the site is regulated under the RCRA program. If the properties are regulated under the Hazardous Site Response Act, composite sample cannot be used when certifying compliance with a remedial level since the remedial levels are considered “bright lines” that must be met at all locations throughout the site.

Massachusetts

The concentration of a composite soil sample may be used to approximate the arithmetic average of the subsample concentrations. The use of composites can provide an arithmetic mean concentration of several locations at the same cost as analyzing an individual sample. However, the concentration detected in a composite is representative of the average concentration of subsamples only if (1) the subsamples are representative of the exposure area, (2) the composite sample is well mixed, and (3) the process of compositing does not result in analyte loss.

C.1.10 Handling of Duplicate Samples

Soil contamination is variable. If the small amount of soil actually used for chemical analysis were examined closely—as under a high-power microscope—one might discern pockets of soil with relative abundances of chemicals and pockets with relative absences of chemicals. A “sample” of each would give a dramatically different result. Samples collected from next to one another and samples collected from different depth intervals would also provide different results.

Within the data set for the comparative case study were duplicate samples. These duplicates gave rise to different results. The state responders were asked how they would address and use these different results. Table C-8 provides their responses.

Table C-8. Handling of duplicate samples

State	Comment
Alabama	Duplicates were averaged.
Arkansas	Not averaged.
California	Hot spots discussed. Duplicates not used other than for QA/QC.
Florida	Duplicates were averaged.
Georgia—RCRA	Duplicates were averaged.
Georgia—HSRP	Not relevant—all samples considered individually.
Massachusetts	Hot spots discussed. Use average of all detected concentrations (exclude nondetects unless all are nondetects).
New Jersey	Not averaged; highest of split.
Tennessee	Averaged.

California

Duplicate sample results are used as part of the QA/QC program for a site along with other standard laboratory reporting. Duplicate sample results ideally should be nearly the same. If they are not, it may be a reflection of variation within the sampling locations or issues with laboratory analysis. As such duplicate sample results are evaluated on a case-by-case basis for each site to aid in determining the next steps.

Georgia

If the site is regulated under the RCRA program, duplicate samples are handled on a case-by-case basis but are normally averaged. If the properties are to be regulated under the Hazardous Site Response Act, each of the duplicates will be considered separately when certifying compliance with a remedial level since the remedial levels are considered “bright lines” that must be met at all locations throughout the site.

Massachusetts

Duplicate samples with a detected concentration can be averaged.

C.1.11 Can a Sample Be (Considered?) a Site?

This question was asked to probe the various approaches to soil variation and also to test the faith expressed in risk assessment. Clearly, risk assessment for shallow soil contamination in a residential setting would approach a number of measurements to be averaged—theoretically all measurements throughout the identified EU. However, soil contamination can be highly variable. This variation tests the faith of anyone who would want to average values for fear that contamination identified by significantly higher measurements is indicative of something more pervasive or extensive. Thus, the concern that “something might have been missed” comes into play.

The question, “Can a sample be (considered?) a site?” is something of a surrogate question for probing approaches to addressing variation of soil contamination and also for probing the common practice of identifying hot spots. Two things seem expected from risk assessment on this subject. First, early on in the investigation, a single measurement—especially if it is one of only a handful of measurements—would be sufficient to consider a sample a “site,” or at least a condition meriting more sampling. Second, as more measurements are made, it would seem that some logical groupings of data—as across an EU—would dictate the analysis and response to individual high measurements.

Table C-9 provides responses to the question, “Can a sample be considered a site?”—which asked for answers at various stages of the site cleanup process.

Table C-9. Can a sample be considered a site?

State	Early	Remedial investigation	Risk	Feasibility study	Remedy monitoring	Confirmation of remedy
Alabama	Yes	No	No	No	No	No
Arkansas	Yes	No	No	No	No	No
California	Yes	No	No	No	No	No
Florida	Yes	No—needs delineation	No	No	No	No
Georgia—RCRA	Yes	Probably not	Probably not	Probably not	Probably not	Probably not
Georgia—HSRP	Yes—program standards are enforced as a brightline	Yes	Yes	Yes	Yes	Yes
Massachusetts	Yes—when a hot spot is considered to constitute a site	Yes	Yes	Yes	Yes	Yes
New Jersey	Yes	No	No	No	Yes	Yes
Tennessee	Yes	No	No	No	Yes	Yes

Alabama

Yes, for the screening process; no, for the remediation process, although if the facility would like to use the screening approach, it may do so.

The EPC is considered to be the maximum value within the exposure domain (in this case each lot) for the screening process and would be considered to be the 95% UCL about the mean for the remediation process.

California

In theory, a sample could become a site during the initial screening step because we use the maximum concentration as the EPC. During the risk assessment and confirmation sampling process, we typically use the 95% UCL of the mean for EPCs and comparison to remedial goals. Site-specific hot spot analysis is performed by looking at the highest concentrations to determine whether more sampling is required to determine whether the initial "sample" is an indicator of a problem area, particularly if sampling density is low in the vicinity of the initial sample. For remediation, an extremely high value may indicate that additional remediation is needed in that location. To evaluate this possibility, more samples could be taken in the vicinity of this sample. If sample results are high, more remediation may occur.

Georgia

If this site is regulated by the RCRA program, then the initial site screening will be done by comparing the maximum concentration detected against the Region 9 residential soil PRG as required by the *Georgia Environmental Protection Division Guidance for Selecting Media Remediation Levels at RCRA Solid Waste Management Units*. After the initial screening, the responsible party could develop an EPC for each SWMU and use that concentration when determining whether corrective action is needed. If this site is regulated under the Georgia

Hazardous Site Response Act, all locations within the site will need to be at or below the remedial level developed.

Massachusetts

A hot spot (defined at 310 CMR 40.0006) is always considered a “site” requiring its own remedy. In a Method 1 risk analysis, a single EPC (not necessarily a single sample, since vertical averaging is allowed) above Method 1 standards is enough to disqualify a conclusion of “no significant risk.”

C.1.12 Are Field Methods OK?

A number of technologies have been and continue to be developed to make real-time or field measurements. In the context of the current comparative case study—where lead in soil was of interest—the state responders were asked whether field analytical methods would provide data that could be incorporated into the various stages of a remediation project.

Site cleanup is typically a difficult, expensive, and often contentious undertaking. In this environment every data point can come under scrutiny, and field analytical methods have been viewed as inferior to traditional laboratory analysis, largely because of the legal defensibility of traditional methods.

State representatives were asked about the acceptability of field analytical methods for the comparative case study. Table C-10 presents their responses.

Table C-10. Are field methods OK?

State	Early	Remedial investigation	Risk	Feasibility study	Remedy monitoring	Confirmation of remedy
Alabama	OK. Needs to be correlated with lab results.	OK	OK	OK	OK	OK
Arkansas	OK	OK	OK	OK	OK	OK
California	Conditionally, if DQOs are met by method.	Conditionally, if DQOs are met by method.	If detection limits are less than health protective screening criteria.		Conditionally, if DQOs are met by method.	Conditionally, if DQOs are met by method.
Florida	OK	XRF for lead allowed after lab confirmation/acceptable correlation.	After laboratory confirmation.	After laboratory confirmation.		After lab confirmation.
Georgia—RCRA[a]	No	Probably	Probably	Probably	Probably	Probably
Georgia—HSRP[a]	No	Maybe	Maybe	Maybe	Maybe	No
Massachusetts—Field lab[b]	Maybe	Maybe	Maybe	Maybe	Maybe	Maybe
Massachusetts—Field screening[b]	Maybe	No	No	No	No	No
New Jersey	No	Yes, if certified methods used with lab confirmation.	Possibly	Possibly	Possibly	Possibly

[a] Maybe in Georgia = May be OK for locating lab samples.
[b] Maybe in Massachusetts = Needs to have adequate QA/QC defined AND correlation with select lab results.

Alabama

Field analytical methods may be used for all phases as long as a proper QA/QC procedure is followed by splitting samples with a laboratory.

California

California allows the use of mobile laboratories if they meet certification requirements and are able to evaluate samples using methods with detection limits that are less than health-protective criteria. Field instruments can also be used with the same conditions and after demonstrating that the field instrument results are consistent with laboratory analysis results.

Georgia

Under both programs field methods could be used to aid in the selection of sample locations to send for fixed laboratory analysis. Field results could not be used for certifying compliance with remedial levels.

Massachusetts

MADEP believes that screening methods can be useful at decision points that are related to the delineation of contamination but are often not apropos with regard to the characterization of contamination. Two goals of analytical measurement, estimating EPCs and comparing site concentrations to background levels, always require complete characterization of contamination, which cannot be accomplished using screening techniques alone. Therefore, it is MADEP's opinion that screening techniques are applicable to neither the estimation of EPCs nor the comparison of site concentrations to background but can be useful in determining the extent of contamination.

C.1.13 What Is (Are) the EPC(s) for the Comparative Site Case Study?

The EPC is the estimated or projected value compared with a numerical exposure criterion to determine whether a significant risk or hazard exists. How the EPC is determined requires site sampling data and some calculation or determination. Table C-11 presents the responses to this question.

California

California considers the upper 10 feet of soil to be "surface" soils, so we would look at that volume as potential exposure media for direct contact, fugitive dust, etc. pathways. Characterization end points are typically different from cleanup end points. To characterize the horizontal and vertical extent of contamination, we typically ask to characterize to background for metals and nondetect for organics. Nondetect criteria means that the analysis detection limit is below health-protective thresholds.

To determine EPC for preliminary screening, California typically uses the maximum concentration to represent the EU, which is typically the site. In this case the six lots have been legally created for development, so we would look at each lot as an EU. We would also look at the site as a whole (all lots, particularly if they are undeveloped). If the lots were developed, we would look only at individual lots as EUs (i.e., similar to the Spring Valley investigation and remediation for individual parcels). To start, we would look at the contamination profile, in this case the 0–6 inch and 6–12 inch strata to determine the areas of each layer that exceed criteria, determine whether they overlap (and they do in this case), and then proceed to make risk management decisions about remediation. In this case we have numerous data points for each strata in each lot (except for parcel F), so we would consider using the 95% UCL of the mean for each stratum in each lot as the EPC. This has been done using Florida UCL. Where there were fewer than 10 data points, the maximum concentration was used (e.g., Lot F and all lots at 12–24 inches).

Table C-11. Exposure point concentration(s) for first comparative case study (mg/kg)

State	Lot A			Lot B			Lot C			Lot D			Lot E			Lot F			Across all lots		
	0–6"	6–12"	12–24"	0–6"	6–12"	12–24"	0–6"	6–12"	12–24"	95 0–6"	6–12"	12–24"	0–6"	6–12"	12–24"	0–6"	6–12"	12–24"	0–6"	6–12"	12–24"
AL	412			480			350			493			134			132					
	95% Chebyshev, as recommended by ProUCL			95% Chebyshev, as recommended by ProUCL			95% Chebyshev, as recommended by ProUCL			95% Chebyshev, as recommended by ProUCL			95% Chebyshev, as recommended by ProUCL			95% Chebyshev, as recommended by ProUCL					
AR	Did not calculate an EPC. Used all data points above 400 mg/kg in 0–6 inch horizon.																				
CA	760	182		773	129		638	258		857	221	127	181	67	86	179	68	68			
	95% UCL using FL UCL (www.dep.state.fl.us/waste/categories/wc/pages/ProgramTechnicalSupport.htm) except for Lot F; with fewer than 10 samples, the highest value was used.[a]																				
FL	760	182		773	129		638	258		857	221	127	181	67	86	179	68	68			
	95% UCL using FL UCL (www.dep.state.fl.us/waste/categories/wc/pages/ProgramTechnicalSupport.htm) except for Lot F; with fewer than 10 samples, the highest value was used.																				
GA-RCRA	281			281			281			281			281			281					
	Pro UCL			Pro UCL			Pro UCL			Pro UCL			Pro UCL			Pro UCL					
	Since the entire firing range is considered one SWMU and therefore one exposure area, the EPC is the 95% UCL of all sample results for the entire site separated into surface soil and subsurface soil.																				
GA-HSRP	An exposure point concentration is not derived, and all sample results are individually compared to the cleanup concentration.																				
MA	193.4			284.4			185.5			200			78.8			70.3					
	Averages over the top 3 feet of the soil.																				
NJ	NJ does not use baseline risk assessment; all points above 400 mg/kg would require delineation and remediation (eliminate exposure) pursuant to 7:26E (Technical Requirements For Site Remediation N.J.A.C. 7:26E).																				
TN	289	98	NA	465	104	NA	250	120	NA	289	116	127	110	50	NA	98	43	NA	289	93	NA
	Simple average.																				

[a] The California representative used the same statistical package as Florida, resulting in the same values for each lot.

Georgia

Under the Hazardous Site Response Program, certifying this site for compliance with the residential standards would require removal or decontamination of all lead above 75 mg/kg or development of a site-specific residential cleanup value using the IEUBK model. If it is assumed that there is no groundwater contamination and that the detection limit for the groundwater samples is 5 µg/L, then the results of the IEUBK model would be 332 mg/kg. However, a soil leachability concentration would need to be developed using either laboratory analysis (Synthetic Precipitation leaching Procedure [SPLP] or TCLP testing) or modeling, and the lower of the leachability value or 332 mg/kg would be the residential cleanup value. If we assume the leach value to be >332 mg/kg, then any sample point where lead was detected >332 mg/kg would need to be removed or decontaminated, and confirmation sampling would be required. If the leachability concentration was <332 mg/kg, then all soil above that concentration would need to be removed.

Under the RCRA program, a site-specific risk assessment would be required since there are concentrations above the Region 9 PRG residential soil screening value of 400 mg/kg. This site could use the IEUBK model as discussed in the paragraph above. The EPC would depend on what current and future receptors were identified at the site.

Massachusetts

The hot spot analysis was first performed. While samples ST32 and ST25 are more than 10 times higher than the surrounding samples ST55, ST18, and ST32, there is no reason to believe that there would be “greater exposure potential” at these two sample sites. Therefore, no hot spots were identified, and the EPC can be calculated as described below.

Duplicates are averaged, or the maximum of the duplicates was used (in the cases where one duplicate measured ND). The average for each sample location was then calculated based on all data for that location (0–36 inches is considered accessible in Massachusetts; e.g., samples ST4S1, ST4S2, and ST4S3 were averaged and counted as one data point, while samples ST2S1 and ST2S2 were also averaged and also counted as one data point).

Finally, the average across all data points in each lot (the EU) is then calculated. The EPCs thus calculated were all below the Method 1 standard of 300 mg/kg.

New Jersey

Slight/marginal exceedances—namely, the 401 (ST38S1) and 409 (ST64S1) mg/kg results—would probably not require further evaluation, remediation, etc.

Again, with a residential reuse the number of 400 mg/kg is applied throughout the soil column—initially for delineation and then for remediation. If not all contamination is remediated, then an engineering control (cap) with deed notice would be required.

Unless remediation were to take place to the present “clean zones,” horizontal delineation (see below) would be necessary to limit (hopefully) the area to be remediated/excavated.

- Lot A—Vertical delineation complete. Horizontal delineation necessary at ST62 (534) and ST33 (1,180).
- Lot B—Vertical delineation complete. Horizontal delineation necessary at ST93 (1,280), ST47 (669), ST46 (1,010), ST45 (1,010), ST44 (1,170), ST35 (978), ST37 (918), and ST67 (886).
- Lot C—Vertical delineation complete. Horizontal delineation necessary at ST85 (440), ST89 (503), and ST88 (676).
- Lot D—Vertical delineation necessary at ST32 (1,750/698). Horizontal delineation necessary at ST25 (623).
- Lot E—Vertical delineation complete. Horizontal delineation necessary at ST22 (446).
- Lot F—Vertical delineation and horizontal delineation complete. Although one may question why the lack of samples in the eastern portion of this lot, NFA appears to be appropriate.

After delineation (mentioned above) takes place and the extent of impacted soil is better known, then decisions can be in regard to remediation (excavation with post-excavation sampling or alternatively to a “clean-zone”).

Therefore, the succinct answer for Supplemental Question #1 is that for each lot every data point is considered separately.

C.1.14 What Soils Would Merit Risk Management?

Following the previous question about EPCs, participants were asked to identify what soils—if any—would merit risk management. These answers were collected as illustrations (areas identified on the plat map) as well as verbal descriptions. Illustrations depicting the areas meriting risk management are presented in the text. Text answers are presented below.

Alabama

Alabama would not dictate a risk management but would, rather, require that the final exposure be less than the criteria. The method for achieving that would be agreed to but not specified.

California

See figures for 0–6 and 6–12 inches bgs for “lines” of risk management. This assumes that the equipment doing the risk management can do 6-inch surface scrapes, which may not be realistic. Following excavation of both strata volumes, confirmation samples would be collected from the floor and sidewalls. We would look at the 95% UCL of the mean to compare to the action level, which in this case is about 150 mg/kg based on LeadSpread 7.

Georgia

For the RCRA Program the lots would be considered one regulated unit and a 95% UCL could be used as an EPC. Based on the data set, all of the sample results from 0–12 inches would be used to develop the EPC for surface soil. Since there is only one sample from 12–24 inches and its concentration is below the screening value of 400 mg/kg, then that media would drop out of the risk assessment, and no remedial levels would be developed for subsurface soil. The surface soil EPC would then be compared to the remedial level using the IEUBK model since there is a future residential child receptor. Assuming no lead in groundwater with a detection limit of 5 µg/L, that risk management level would be 332 mg/kg lead. If the EPC was >332 mg/kg, then any sample locations that exceed 332 mg/kg would require corrective action.

Under the Hazardous Site Response Program, all points where the concentration exceeds the remedial level would need to be either removed or decontaminated.

Massachusetts

Since all EPCs were below the Method 1 standards, no risk management would be required due to a Method 1 risk assessment.

New Jersey

Lots/areas requiring risk management—the response would be the sample points identified above would most likely require remediation, but only after delineation takes place to better define the extent lead-impacted (i.e., >400 ppm) soil.

Tennessee

For the purposes of this survey, TDEC assumes the pellets are no longer leaching significant lead and the large areas in lots A, D, and F are not sampled because field determinations have adequately shown them as clean (e.g., previous removals or lack of lead pellets).

The cleanup goal and the screening level for this site would both be 400 mg/kg in soil. The 400 mg/kg cleanup goal is the result of IEUBK methodology from EPA. This model with its corresponding guidance recommends a mathematical average of lead concentrations to calculate the EPC. If the site contaminant were virtually any other constituent, the EPC would be a 95% UCL of the mean calculated in a manner consistent with the distribution of the sampling results.

TDEC would require the remediation of Lot B. It is the only lot that exceeds the 400 mg/kg threshold. Remediation could include removals, placement under buildings, or any technically and economically feasible remedial action. However, on residential properties TDEC would likely urge for the removal of contaminated materials because deed notices and other controls are not as effective on residential property and are much harder to monitor and enforce.

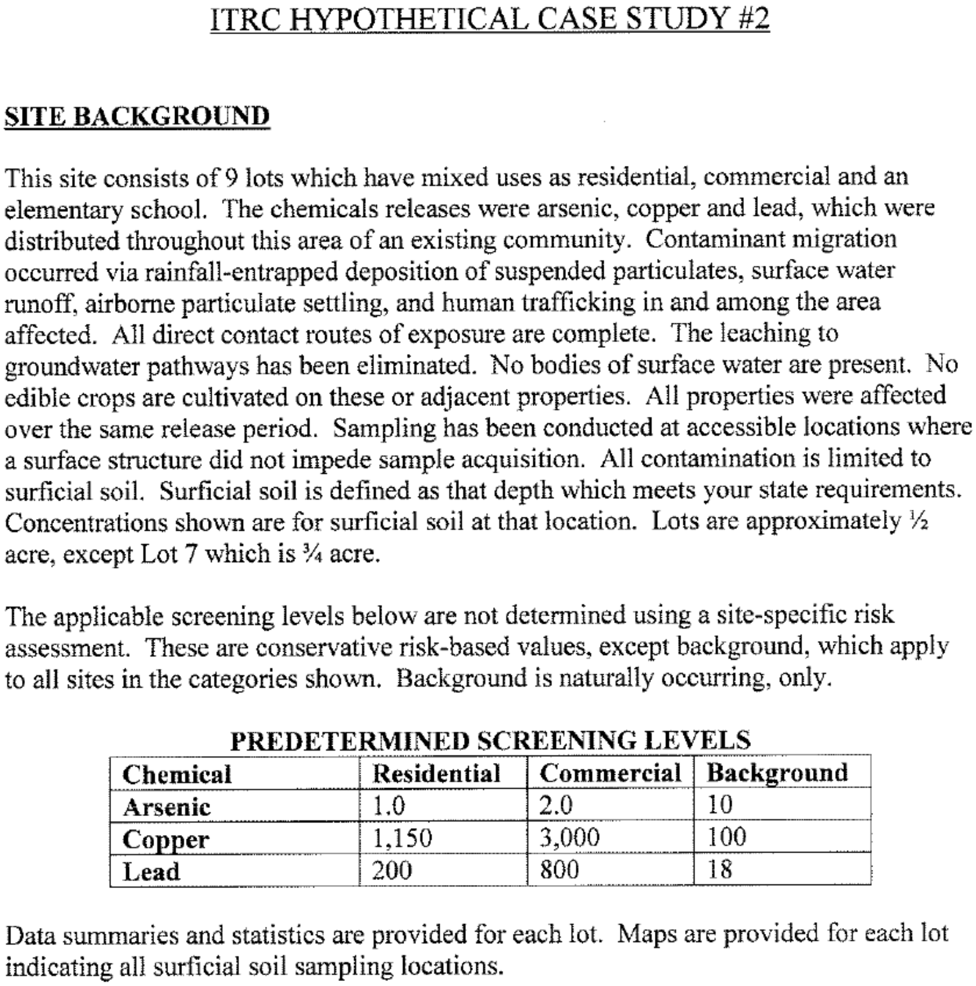
Reference

EPA. 2007. *Estimating the Soil Lead Concentration Term for the IEUBK Model.* OSWER 9200.1-78. Washington, D.C.: Office of Solid Waste and Emergency Response.

C.2 SECOND COMPARATIVE CASE STUDY

The second comparative case study was conducted to supplement the first comparative case study. The Risk Assessment Resources Team recognized that several fundamental questions routinely faced by risk assessment professionals were not addressed in the first comparative case study but could be probed with a follow-up effort.

Participants in the second comparative case study included four responders who participated in the first (Alabama, California, Florida, and Massachusetts), as well as several new participants (Alaska, Arizona, and a team or responders made up of representatives from the Army, Navy, and Air Force). This appendix includes the basic data package and questionnaire, as well as the original submittal from each respondent. The information from each respondent was processed into a summary table presented in Chapter 5 of the main report.



ITRC HYPOTHETICAL CASE STUDY #2

SITE BACKGROUND

This site consists of 9 lots which have mixed uses as residential, commercial and an elementary school. The chemicals releases were arsenic, copper and lead, which were distributed throughout this area of an existing community. Contaminant migration occurred via rainfall-entrapped deposition of suspended particulates, surface water runoff, airborne particulate settling, and human trafficking in and among the area affected. All direct contact routes of exposure are complete. The leaching to groundwater pathways has been eliminated. No bodies of surface water are present. No edible crops are cultivated on these or adjacent properties. All properties were affected over the same release period. Sampling has been conducted at accessible locations where a surface structure did not impede sample acquisition. All contamination is limited to surficial soil. Surficial soil is defined as that depth which meets your state requirements. Concentrations shown are for surficial soil at that location. Lots are approximately ½ acre, except Lot 7 which is ¾ acre.

The applicable screening levels below are not determined using a site-specific risk assessment. These are conservative risk-based values, except background, which apply to all sites in the categories shown. Background is naturally occurring, only.

PREDETERMINED SCREENING LEVELS

Chemical	Residential	Commercial	Background
Arsenic	1.0	2.0	10
Copper	1,150	3,000	100
Lead	200	800	18

Data summaries and statistics are provided for each lot. Maps are provided for each lot indicating all surficial soil sampling locations.

ITRC HYPOTHETICAL CASE STUDY QUESTIONS

State Name, or Agency Name	
Name of Participant	

1. Approaches to Data Use	a. Can lots having similar land use, e.g., residential, be treated aggregately or must they be evaluated separately?	
	b. If contaminant release/deposition/migration had instead occurred over 50 lots instead of 9, would you treat lots aggregately or individually? Why?	
	c. Does grouping or segregation (which ever you do) of the 9 Lots depend upon the stage of evaluation?	Initial Screening: Yes / No Calculating EPC: Yes / No Conducting Risk Assessment: Yes / No
	d. State whether the value used for the initial screening of chemicals is the maximum concentration, the arithmetic average, or the 95% UCL.	
	e. On the attached data sheets, circle the Lot number for those lots which failed initial screening, and the chemical name(s) which failed.	
	f. If lots are evaluated individually, please circle the method used to determine, and value of the EPC.	
	g. Can more than one exposure unit be determined within any of these 9 Lots?	
	h. Had all the samples within a lot been composited in equal volume aliquots, would you use the average concentration shown for the EPC?	
2. Data Needs	a. Indicate on the Lot Maps which lots have an inadequate sampling density to meet the data quality requirements for a risk assessment.	
	b. State the density or frequency of sampling required, and mark the area on the map needing further sampling as "S".	
	c. Indicate on the Lot Map whether additional sampling is dependent upon the concentration of an adjacent sample, land use, or other.	
3. Risk Assessment	a. Please write RA under each Lot No. on the Data Sheets for those lots eligible to conduct a site-specific risk assessment.	
	A reverse risk assessment has been conducted which shows the following site-specific concentrations at the indicated ELCR or hazard index. Does any chemical on any lot now become eliminated from any further consideration? Please state which Lots based on which chemical.	

	Residential		Commercial	
Chemical	10^{-6}	HI = 1	10^{-6}	HI = 1

<table>
<tr><td></td><td><table>
<tr><td>Arsenic</td><td>12</td><td>33</td><td>48</td><td>390</td></tr>
<tr><td>Copper</td><td>▨</td><td>3,100</td><td>▨</td><td>5,800</td></tr>
<tr><td>Lead *</td><td colspan="2">400</td><td colspan="2">1,000</td></tr>
</table>
*Based on achieving target blood lead level by pharmacokinetic modeling.</td><td></td></tr>
<tr><td></td><td>b. Using the table above, please calculate the cumulative health risk and hazard for those lots which exceeded the applicable cleanup levels. Write in on Data Sheets under Lot No.</td><td></td></tr>
<tr><td></td><td>c. Were all chemicals included, even if eliminated in the initial screening or screening against the EPC?</td><td></td></tr>
<tr><td></td><td>d. Was the non-carcinogenic arsenic contribution to the hazard quotient included?</td><td></td></tr>
<tr><td></td><td>e. Was lead considered separately or combined by some method for contribution to the overall health hazard?</td><td></td></tr>
<tr><td></td><td>f. Federal guidance suggests that arsenic and lead have greater than additive effects on neurological toxicity. How would you account for this:</td><td>(i) quantitatively in the risk characterization calculation;
(ii) qualitatively in the uncertainty section;
(iii) use this information in setting risk management decision and final cleanup goals;</td></tr>
<tr><td></td><td></td><td>(iv) other:</td></tr>
<tr><td></td><td>g. Do you account for the contribution of background levels in the risk characterization? Indicate if the level of risk due to background is:</td><td>(i) quantitated and combined with the risk estimate due to the contaminant release;
(ii) is quantitated and not included with the overall risk estimate, but used in risk management decision-making;
(iii) discussed qualitatively in the uncertainty section only;
(iv) other:</td></tr>
<tr><td>3. Risk Management Decisions</td><td>a. For those lots having the EPC in exceedance of the site-specific cleanup level, do you remediate the whole lot for that chemical or just portions? If portions, circle the areas on Lot Maps as "R".</td><td></td></tr>
<tr><td></td><td>b. Is the remediation different had the site-specific risk assessment not been conducted?</td><td></td></tr>
<tr><td></td><td>c. What elements of this site would you require to be discussed in the uncertainty section of the risk assessment, and would any elements result in a determination of a more stringent cleanup level for 1 or more chemicals?</td><td></td></tr>
<tr><td></td><td>d. How was the school lot treated differently in this scenario?</td><td></td></tr>
</table>

Lot No.	As	Cu	Pb
5	160	1800	77
	78	1,400	520
	140	2,000	230
	24	190	41
	45	500	100
	35	370	60
	14	140	43
	35	410	62
	21	840	70
	83	790	80
	27	410	68
	74	1,200	99
	23	560	47
	24	100	26
	140	1,700	220
	19	280	70
	19	150	47
	68	1,700	150
	170	1,700	220
	14	150	79
	7	180	29
	30	400	130
	74	1,600	130
	76	1,200	230
	94	1,900	480
	19	220	37
	120	1,300	1,100
	109	1,900	1,613
	15	100	54
	18	270	50
N	30	30	30
Max conc	170	2000	1613
Min conc	7	100	26
Aver conc	59	849	205
95% UCL	78	1,141	826

Lot No.	As	Cu	Pb
6	5	43	25
	80	660	140
	75	1,700	71
	15	140	34
	110	1,200	150
	65	825	120
	120	1,900	240
	62	2,200	210
	13	685	72
	8.2	170	39
	17	870	35
	9.9	79	64
	54	200	160
	19	570	81
	120	2,500	250
	87	1,500	100
	86	1,700	100
	100	1,800	170
	43	740	75
	115	2,900	71
	150	2,600	92
	36	790	140
	200	3,700	430
	77	1,100	200
	54	1,200	120
	76	760	135
	35	1,700	350
	62	1,300	180
	12	230	130
	110	1,300	110
	10	285	30
	7.2	150	28
	32	240	76
	130	1,400	84
N	34	34	34
Max conc	200	3700	430
Min conc	5	43	25
Aver conc	65	1,151	127
95% UCL	84	1,521	156

Lot No.	As	Cu	Pb
7	76	1300	120
	86	1,300	130
	110	2,600	184
	37	1,300	76
	36	730	77
	66	2,000	800
	65	230	46
	58	360	220
	89	1,500	100
	65	1,550	82
	69	2,700	150
	160	2,400	220
	64	220	95
	91	2,600	160
	73	1,100	88
	39	690	94
	180	2,700	190
	100	1,800	300
	13	910	45
	130	2,300	140
	57	340	69
	70	430	67
	69	960	160
	165	2,250	205
	68	1,000	200
	84	670	310
	79	1,200	88
	28	430	69
	32	200	73
	92	720	150
	120	2,700	250
	69	260	55
	39	430	34
	79	1,000	97
	68	1,300	130
	66	325	110
	71	6,400	320
	49	180	41
	69	1,400	140
	51	2,700	250
	27	745	76
	60	590	190
	73	300	200
	56	1,300	150
	33	340	79
	23	260	48
	61	380	110
	36	140	54
	93	1,200	210
	30	370	67
	59	140	75
	37	1,200	100
N	52	52	52
Max conc	180	6400	800
Min conc	13	140	34
Aver conc	70	1,195	144
95% UCL	78	1,468	168

Lot No.	As	Cu	Pb
8	55	520	750
	51	1,600	98
	65	1,350	120
	23	20	63
	7.9	110	28
	210	2,900	340
	38	270	225
	9.1	64	72
	43	870	99
	38	580	83
	90	1,100	130
	100	1,600	130
	32	340	67
	33	790	62
	160	3,400	180
	130	1,500	120
	28	850	83
	37	180	170
	74	290	67
	18	150	59
	250	3,500	440
	130	2,800	380
	60	410	140
	94	990	300
	280	1,500	620
	120	1,300	110
	38	130	87
	120	220	760
	79	1,300	60
	58	750	68
	370	4,800	680
	41	695	303
	59	1,800	160
	66	340	790
N	34	34	34
Max conc	370	4800	790
Min conc	7.9	20	28
Aver conc	88	1,148	231
95% UCL	114	1,575	403

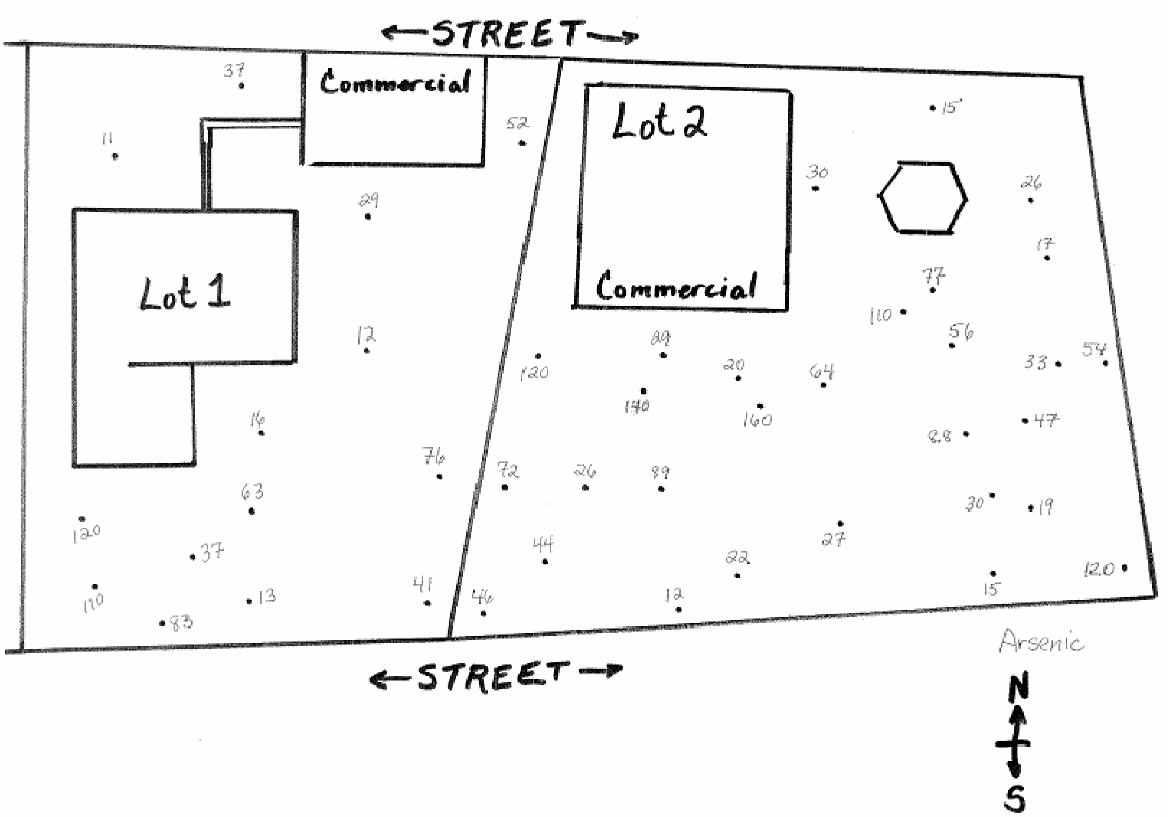
Lot No.	As	Cu	Pb
9	7	7	9
	160	8	180
	15	200	58
	10	210	34
	10	1,700	110
	110	2,400	170
	5	37	13
	6	84	35
	69	1,600	230
	39	900	72
	16	880	83
	12	140	22
	11	110	31
	65	950	180
	21	340	75
	58	580	96
	43	96	65
	45	32	95
N	18	18	18
Max conc	160	2400	230
Min conc	5	7	9
Aver conc	39	571	87
95% UCL	61	1,067	113

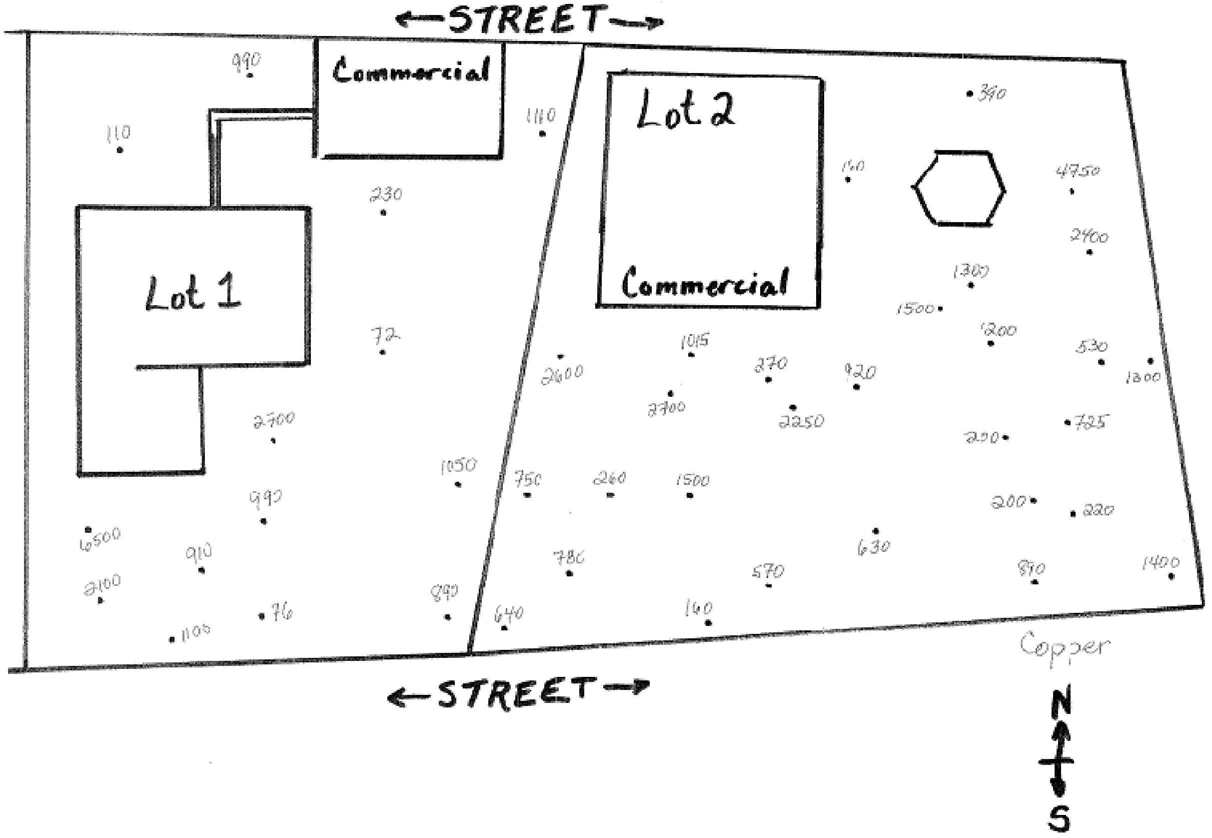
Lot No.	As	Cu	Pb
1	11	110	17
	37	990	81
	52	1110	100
	29	230	82
	12	72	69
	16	2700	94
	76	1050	260
	63	990	470
	37	910	130
	120	6500	210
	110	2100	1200
	83	110	230
	13	76	55
	41	890	130
N	14	14	14
Max conc	120	6500	1200
Min conc	11	72	17
Aver conc	50	1,274	223
95% UCL	67	2436	381

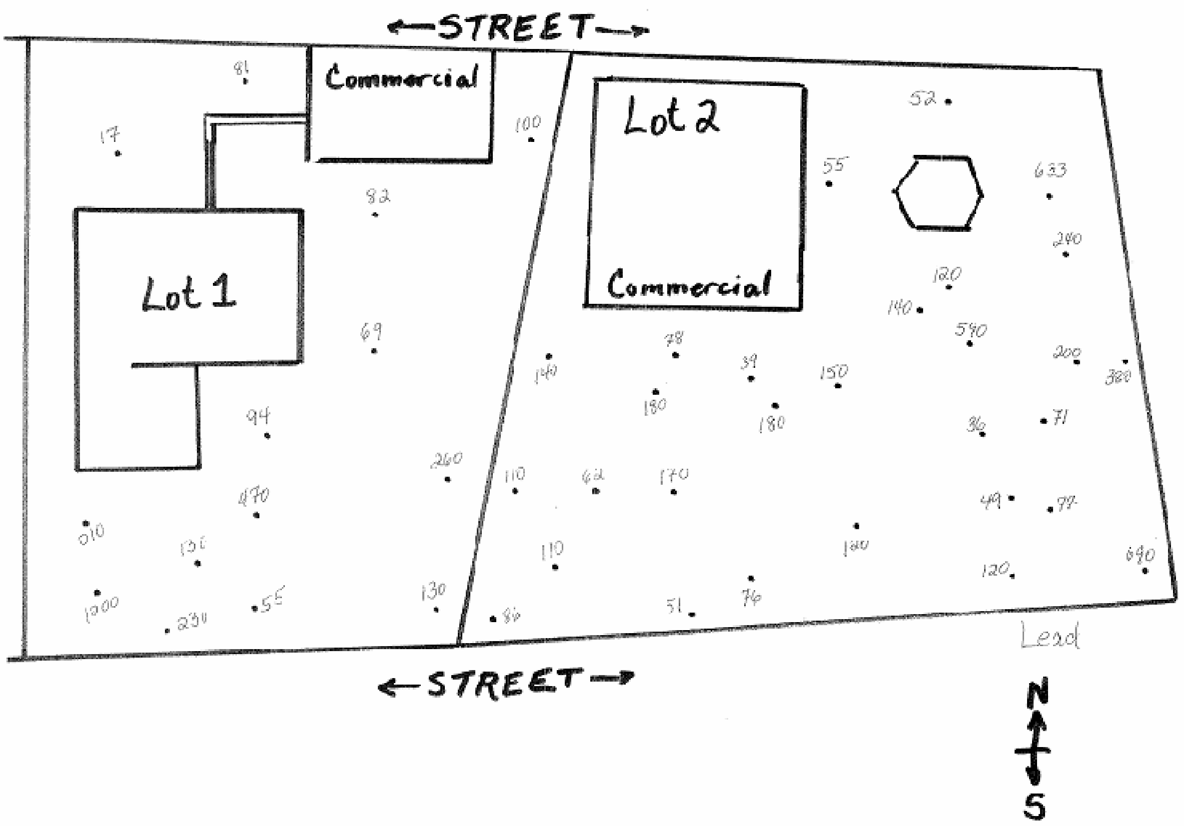
Lot No.	As	Cu	Pb
2	15	390	52
	30	160	55
	120	2600	140
	26	4750	633
	17	2400	240
	77	1300	120
	110	1500	140
	29	1015	78
	140	2700	180
	20	270	39
	160	2250	180
	64	920	150
	56	1200	590
	33	530	200
	54	1300	380
	47	725	71
	8.8	200	36
	72	750	110
	26	260	62
	89	1500	170
	30	200	49
	19	220	77
	120	1400	690
	15	890	120
	27	630	120
	22	570	76
	12	160	51
	44	780	110
	46	640	86
N	29	29	29
Max conc	160	4750	690
Min conc	8.8	160	36
Aver conc	53	1,111	173
95% UCL	68	1,482	234

Lot No.	As	Cu	Pb
3	120	5500	470
	110	880	12
	56	1,600	430
	210	3,000	2,000
	10	200	45
	91	2,000	240
	13	590	280
	37	620	120
	5.5	200	210
	56	160	1,241
	17	78	130
	48	460	65
	29	500	100
	11	160	100
	46	180	77
	39	630	8,350
N	16	16	16
Max conc	210	5500	8,350
Min conc	5.5	78	12
Aver conc	56	1,047	867
95% UCL	87	1,825	3,658

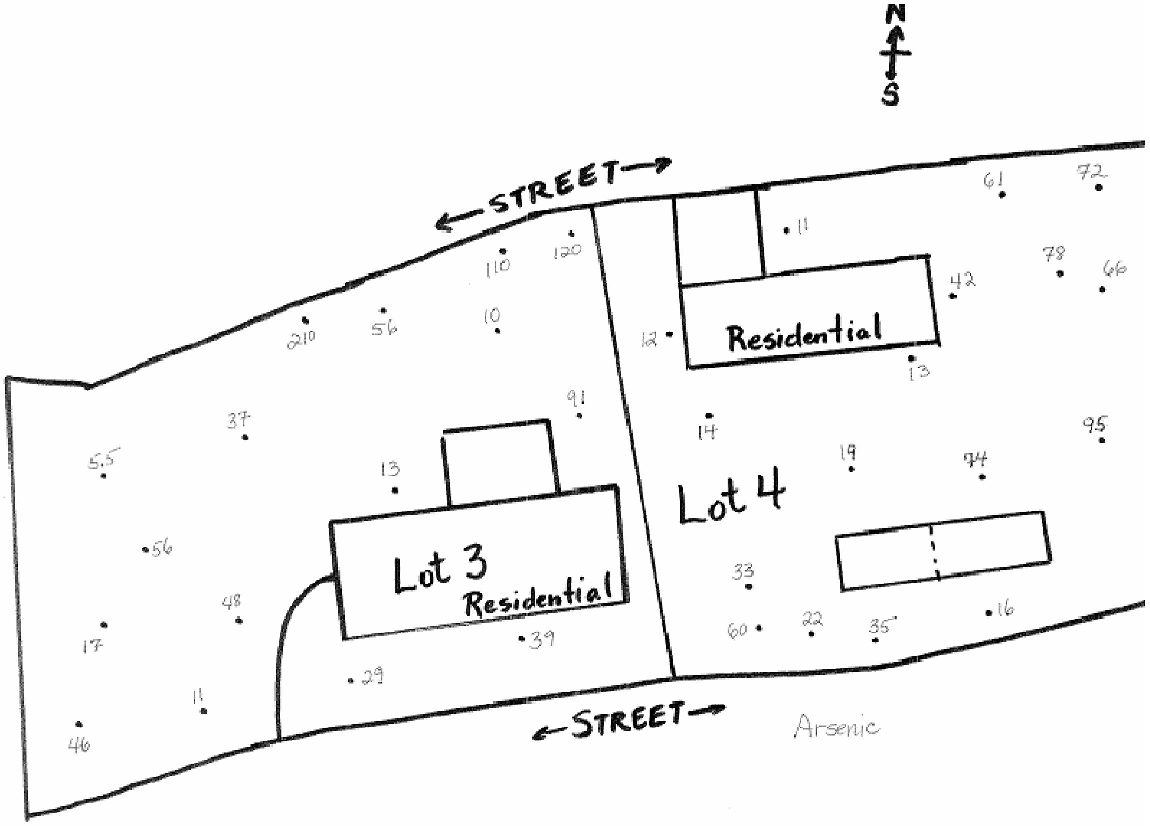
Lot No.	As	Cu	Pb
4	11	120	61
	12	120	33
	42	330	120
	13	420	180
	14	220	38
	19	325	195
	74	940	445
	33	1,100	160
	60	430	690
	22	360	57
	35	540	150
	16	430	49
	61	980	69
	72	1,400	110
	78	1,600	270
	66	1,300	260
	95	1,300	815
N	17	17	17
Max conc	95	1,600	815
Min conc	11	120	33
Aver conc	43	701	218
95% UCL	54	989	335


←STREET→
Commercial
Lot 1
Lot 2
Commercial
37
11
52
29
12
16
63
120
37
110
13
83
76
41
46
72
26
89
44
12
22
27
15
120
30
19
47
8.8
33
54
56
110
77
17
26
30
15
89
20
64
120
140
160
←STREET→
Arsenic
N
S

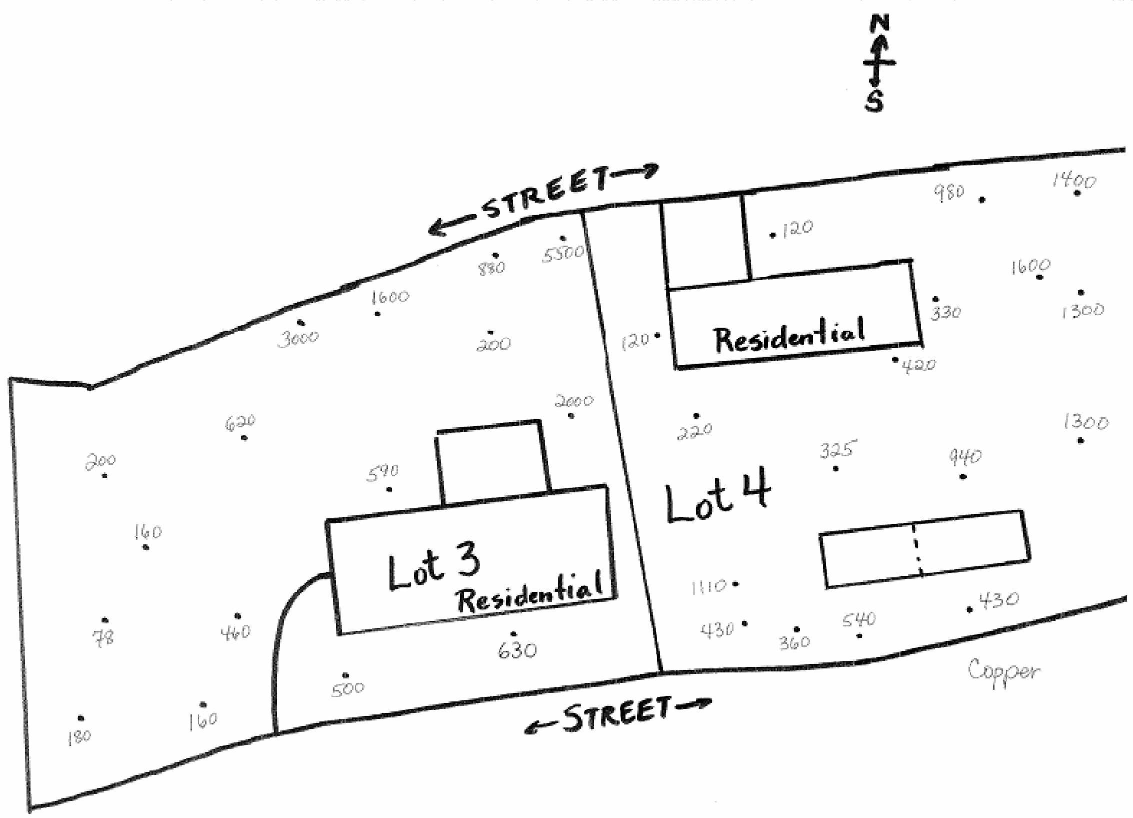

←STREET→
Commercial
Lot 1
Lot 2
Commercial
990
110
1110
230
72
2700
990
6500
910
2100
1100
76
890
1050
640
750
260
1500
780
160
570
630
200
220
890
1400
200
725
1300
530
1200
1500
1300
2400
4750
390
160
1015
2600
2700
270
2250
920
←STREET→
Copper
N
S

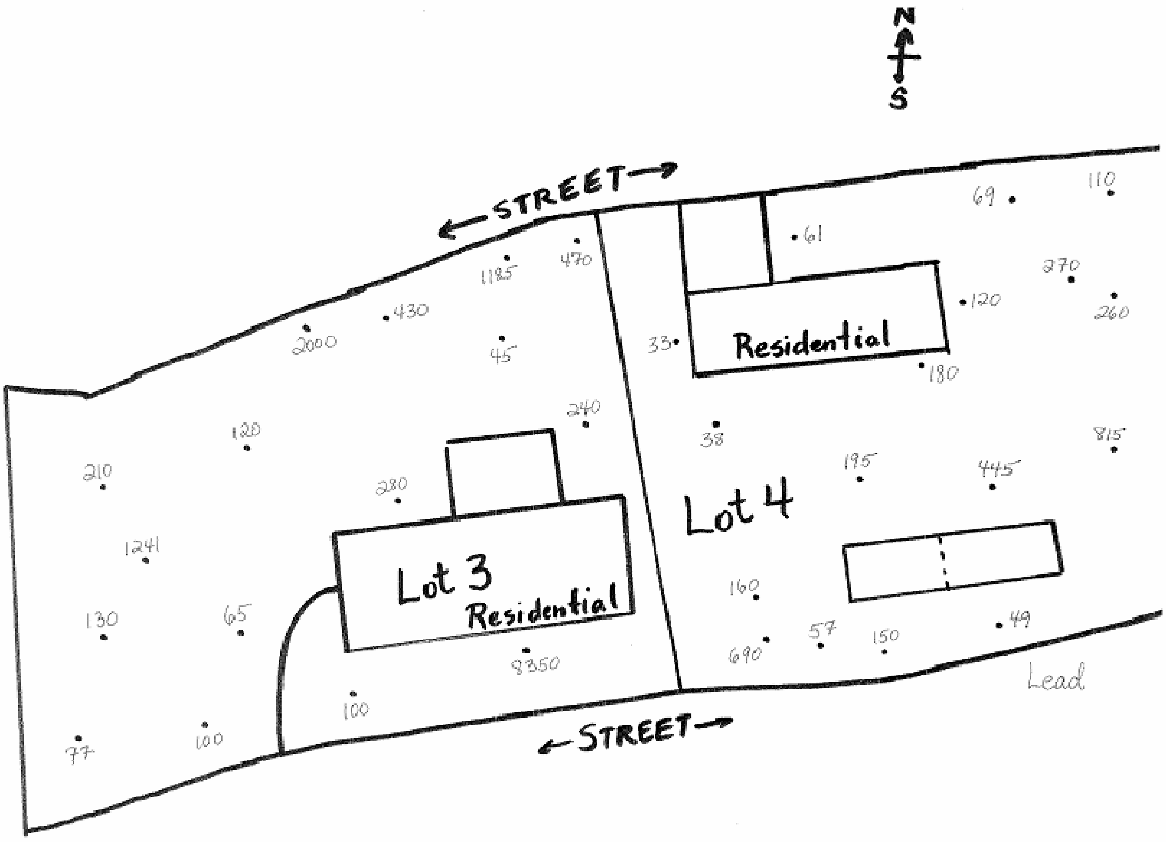


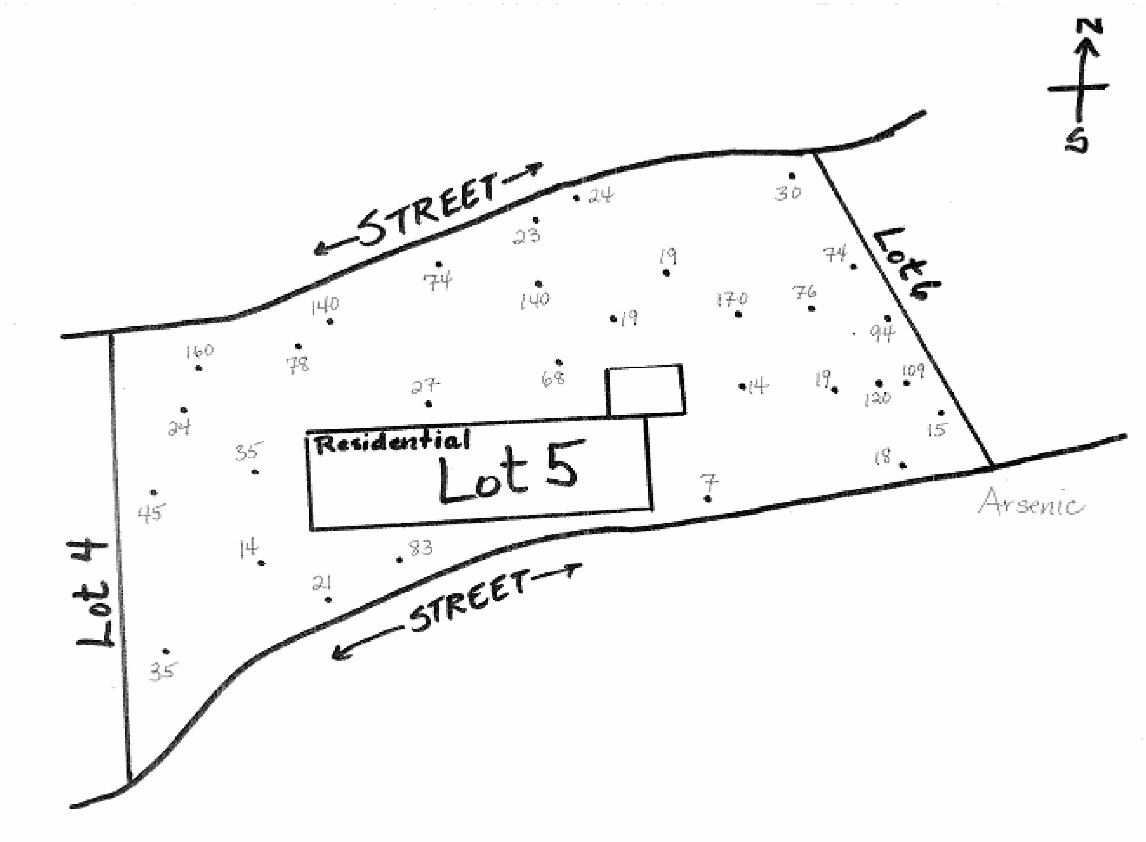
Lead

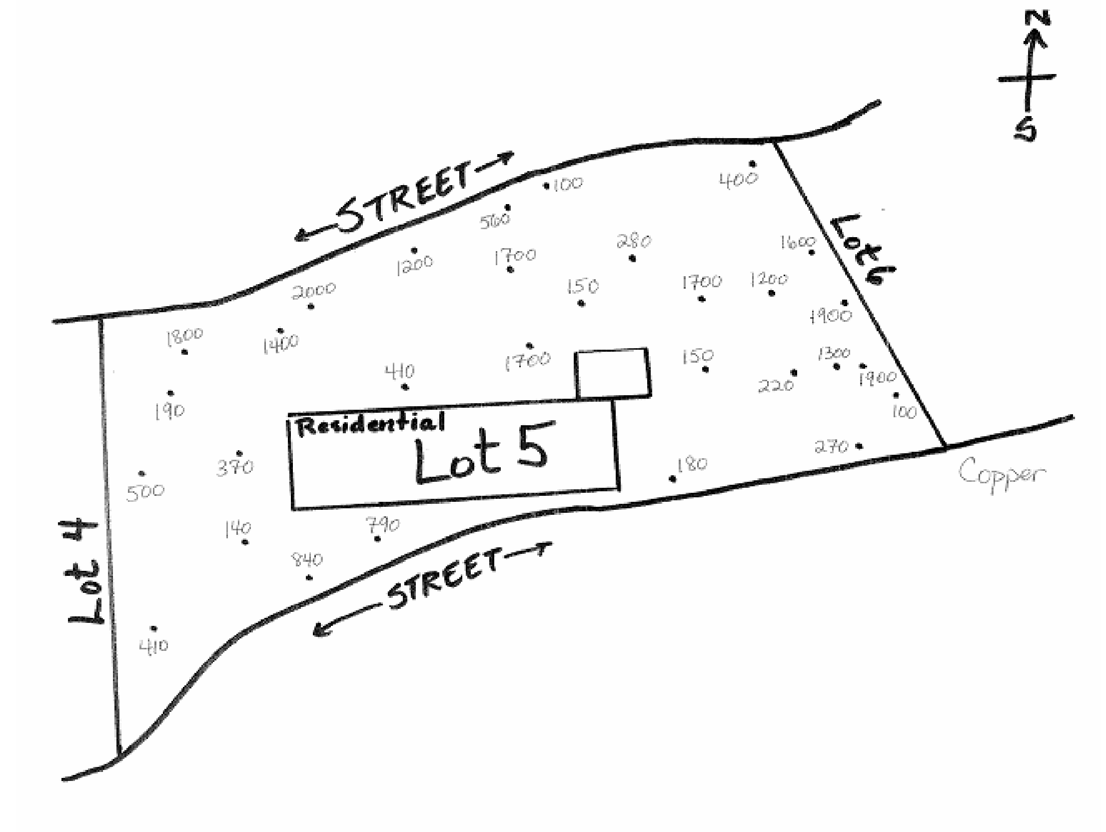


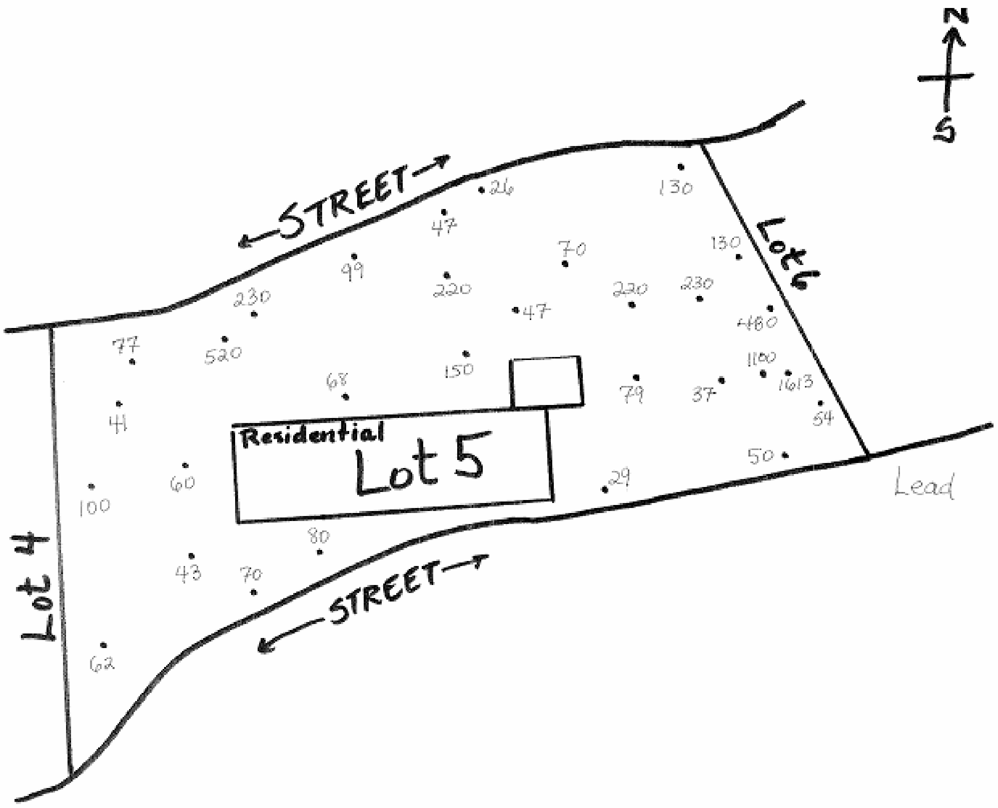
Arsenic

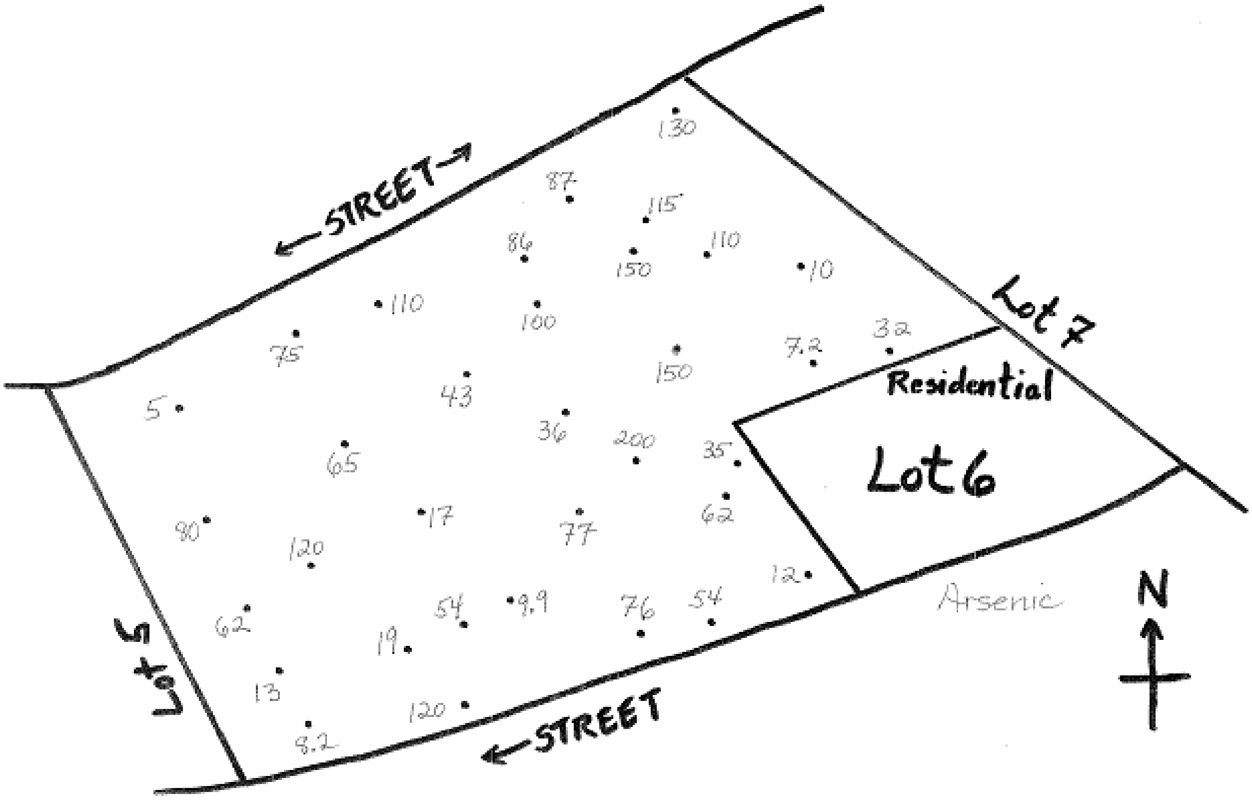

N
S
STREET
STREET
Residential
Lot 3
Residential
Lot 4
5500
880
1600
3000
200
2000
620
200
590
160
78
460
630
500
180
160
120
980
1400
1600
330
1300
120
420
220
325
940
1300
1110
430
360
540
430
Copper

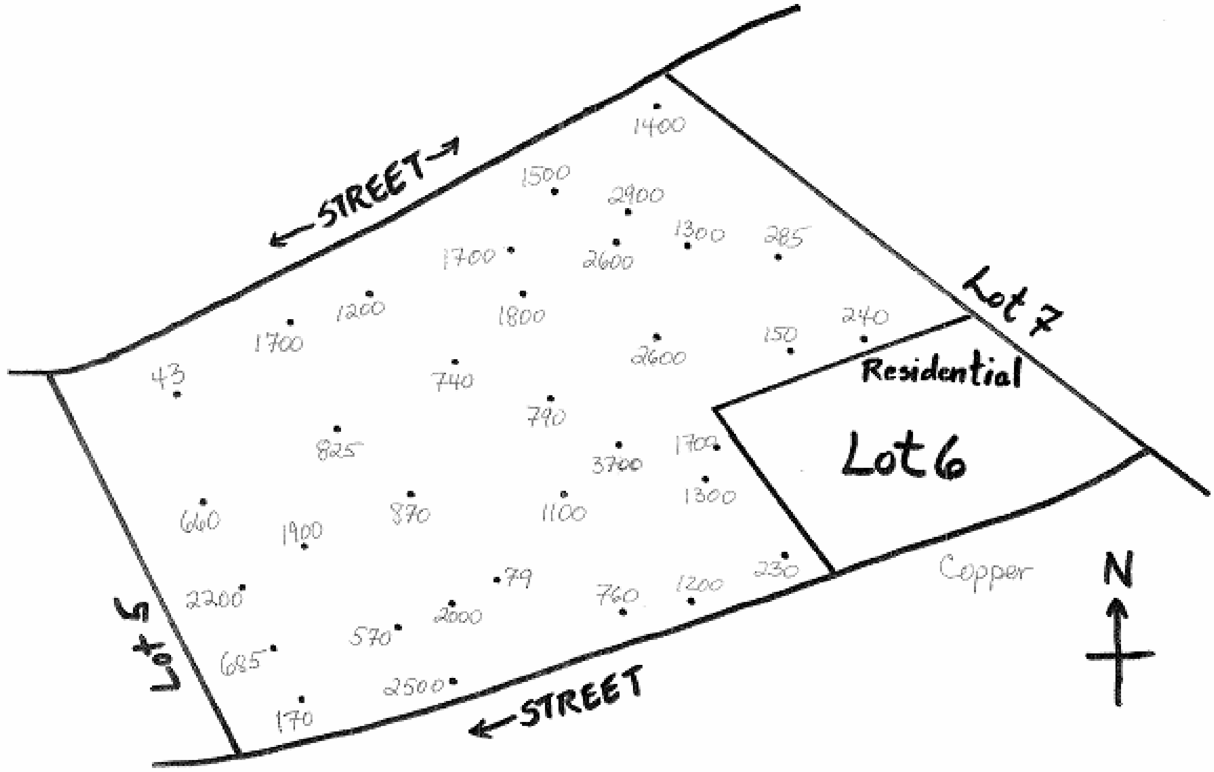

N
S
STREET
STREET
Residential
Lot 3
Residential
Lot 4
470
1185
430
2000
45
240
120
210
280
1241
130
65
8350
100
77
100
61
69
110
270
120
260
33
180
38
815
195
445
160
690
57
150
49
Lead

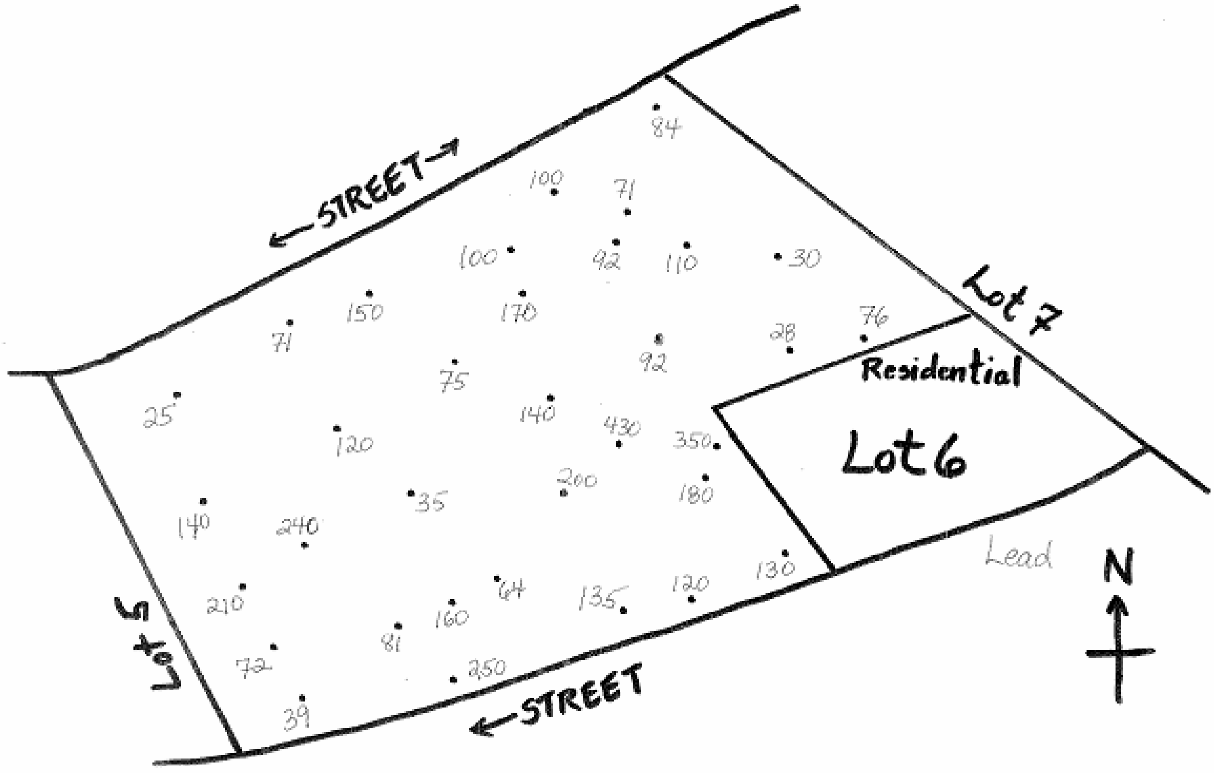

N
S
STREET
Lot 6
30
24
23
74
19
74
140
140
19
170
76
94
160
78
27
68
14
19
109
120
24
Residential
Lot 5
15
35
18
45
7
Arsenic
Lot 4
14
83
21
STREET
35

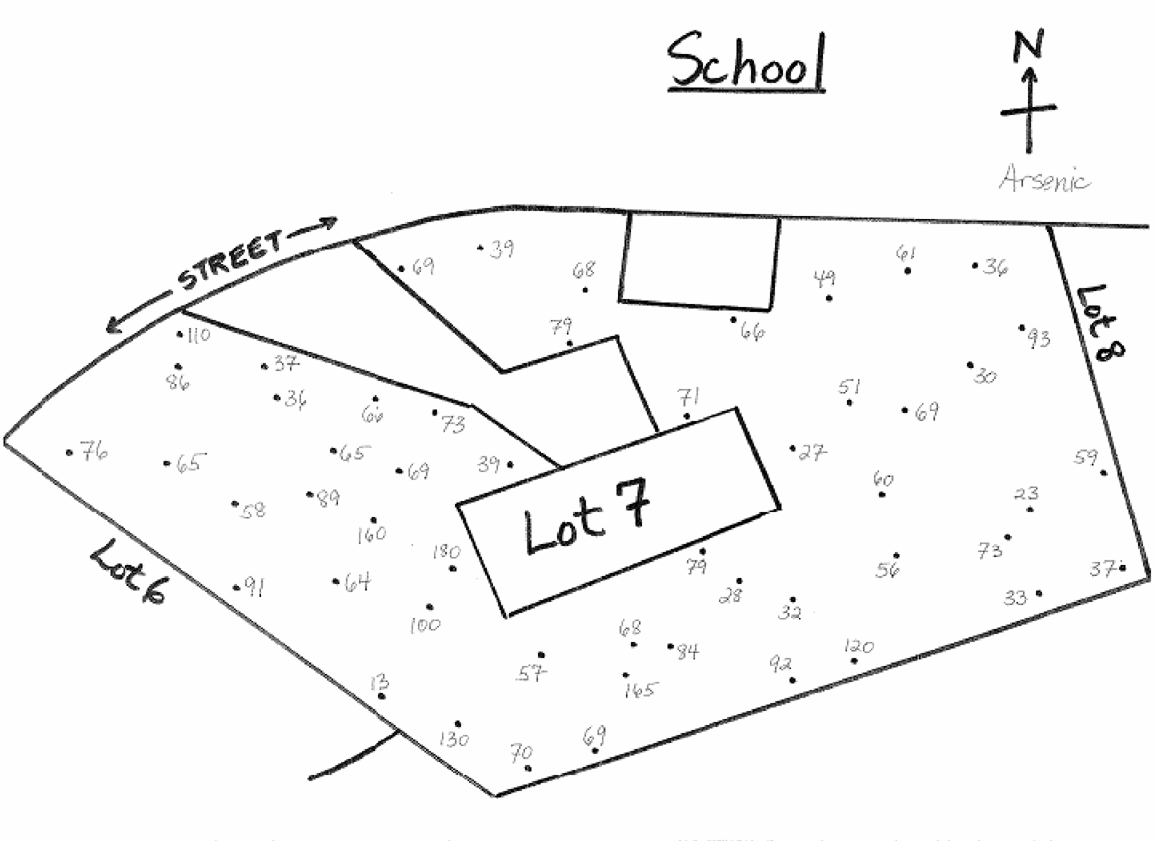

N
S
STREET
Lot 6
100
400
560
280
1600
1200
1700
150
1700
1200
2000
1900
1800
1400
410
1700
150
1300
220
1900
190
100
Residential
Lot 5
370
270
500
180
Copper
Lot 4
140
790
840
STREET
410

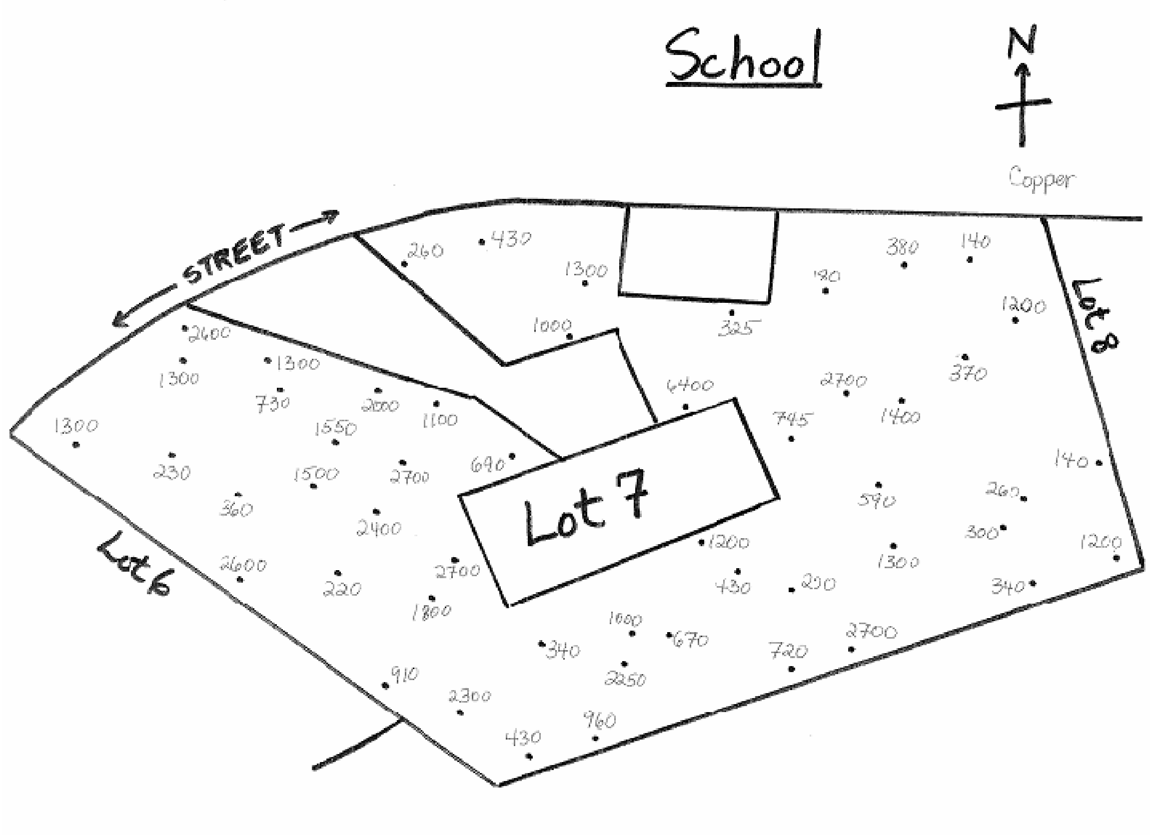

N
S
←STREET→
•26
130
47
Lot6
130
70
99
220
220
230
230
•47
460
77
520
150
1100
1613
68
79
37
54
41
Residential
Lot 5
50
60
100
29
Lead
80
43
70
←STREET→
Lot 4
62

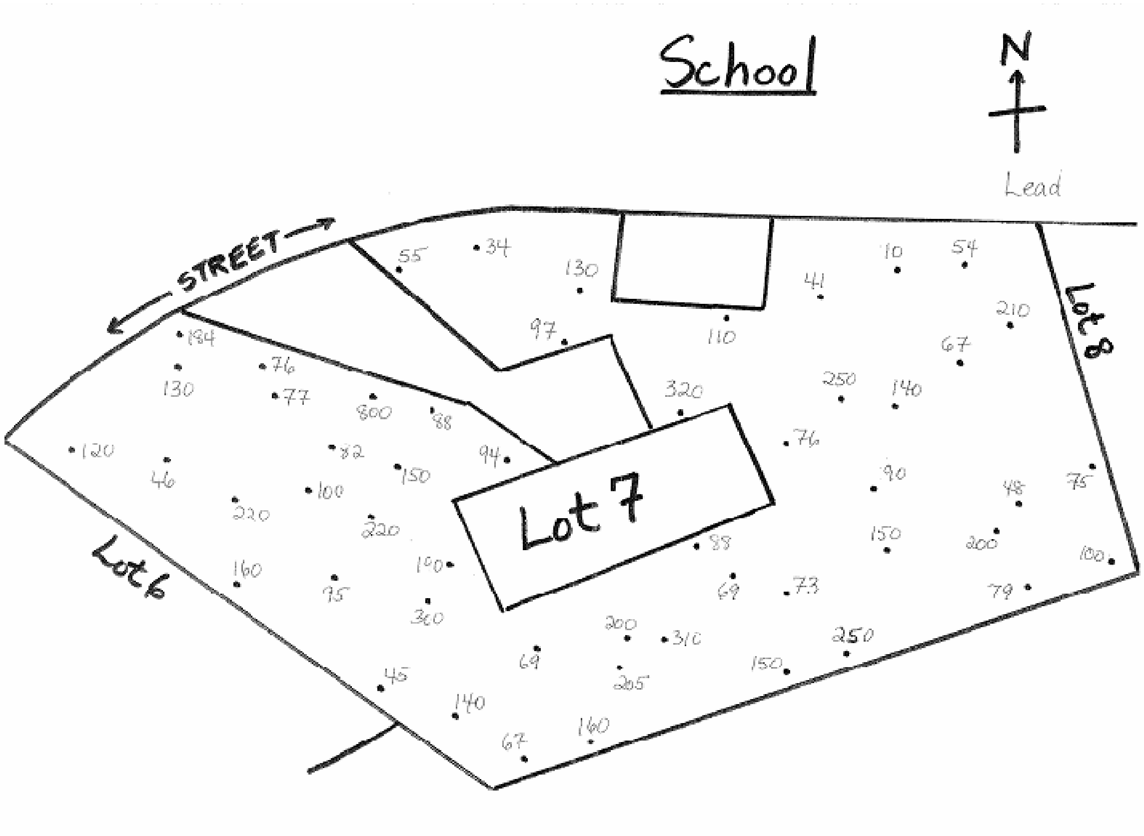

130
←STREET→
87
115
86
110
150
•10
•110
100
Lot 7
75
32
7.2
150
Residential
5
43
36
200
35
Lot6
65
•17
77
62
80
120
12
Arsenic
N
62
54
•9.9
76
54
19
Lot 5
13
120
8.2
←STREET

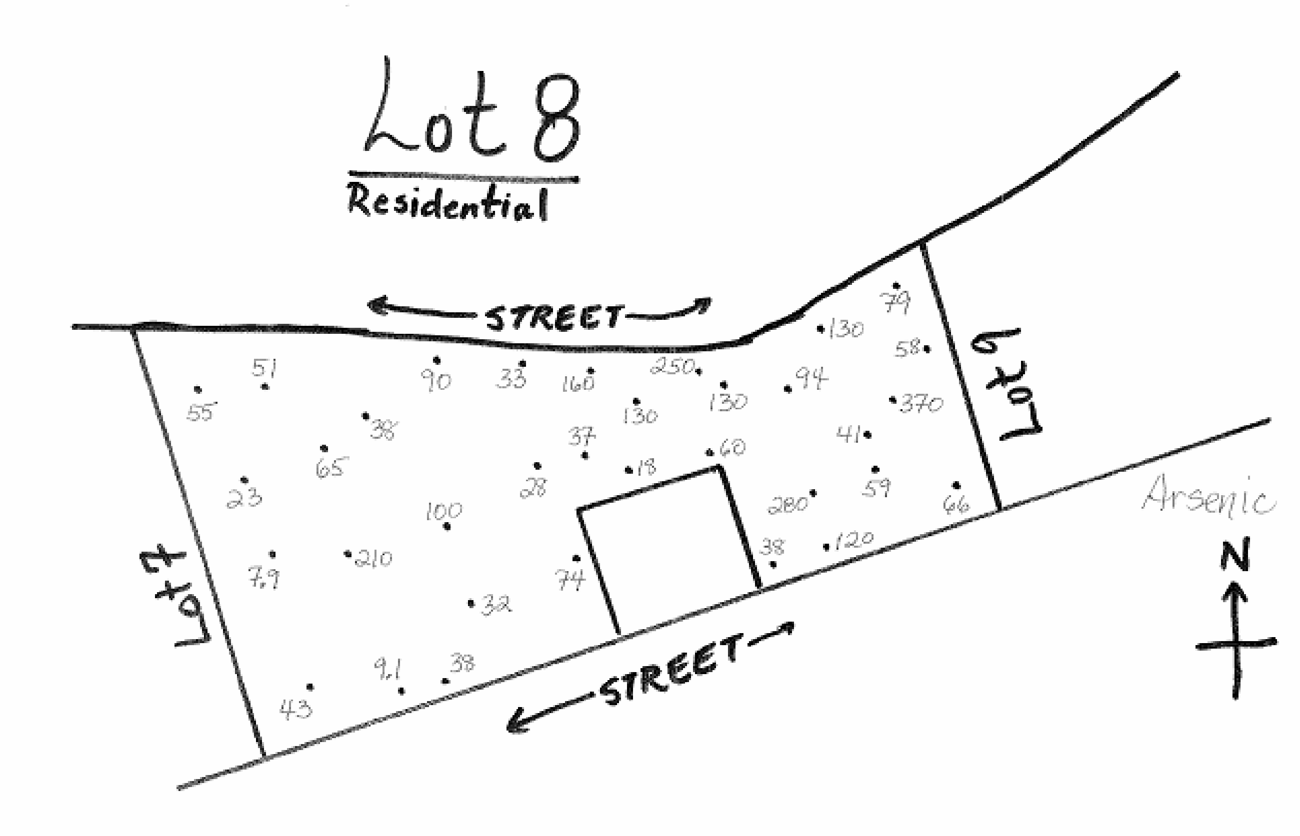

←STREET→
1400
1500
2900
1300
285
1700
2600
1200
1800
1700
150
240
Lot 7
43
740
2600
Residential
790
825
3700
1700
Lot 6
1300
660
1900
870
1100
2200
79
760
1200
230
Copper
N
Lot 5
2000
570
685
2500
170
←STREET

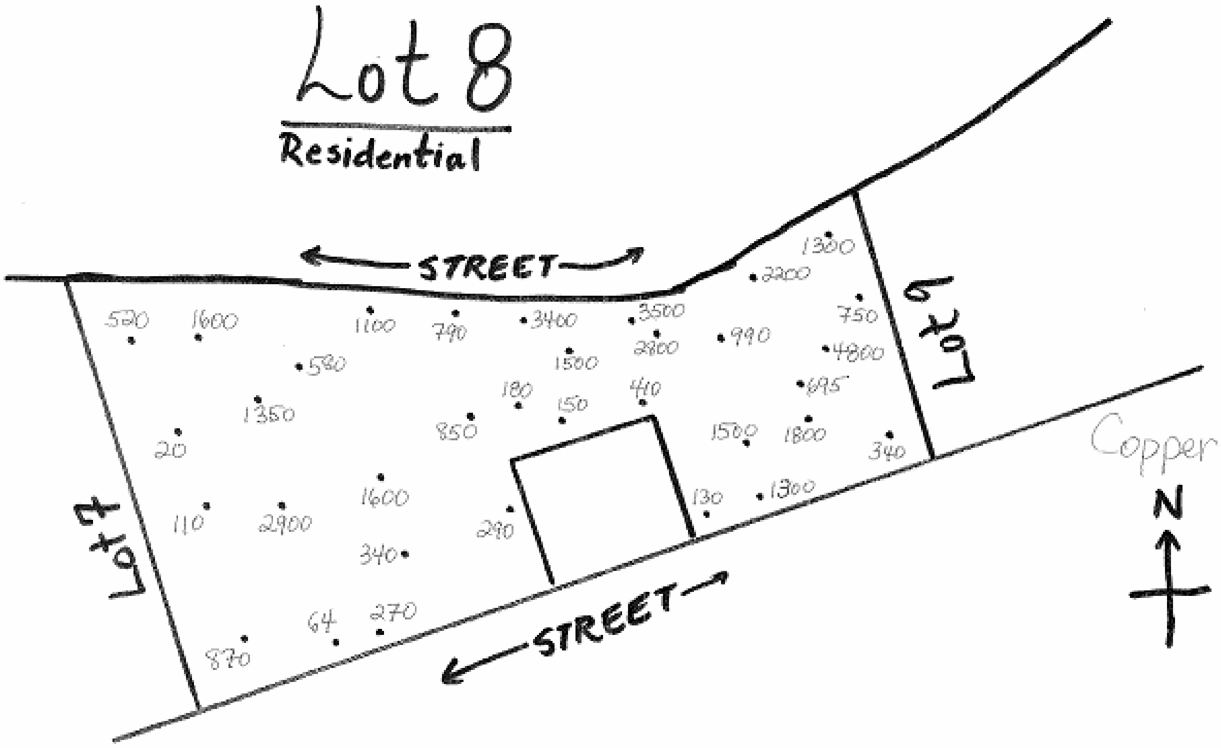

←STREET→
84
100
71
100
92
110
30
150
170
71
28
76
Lot 7
92
Residential
75
25
140
120
430
350
Lot 6
200
180
35
140
240
Lead
N
210
64
135
120
130
160
81
Lot 5
72
250
39
←STREET

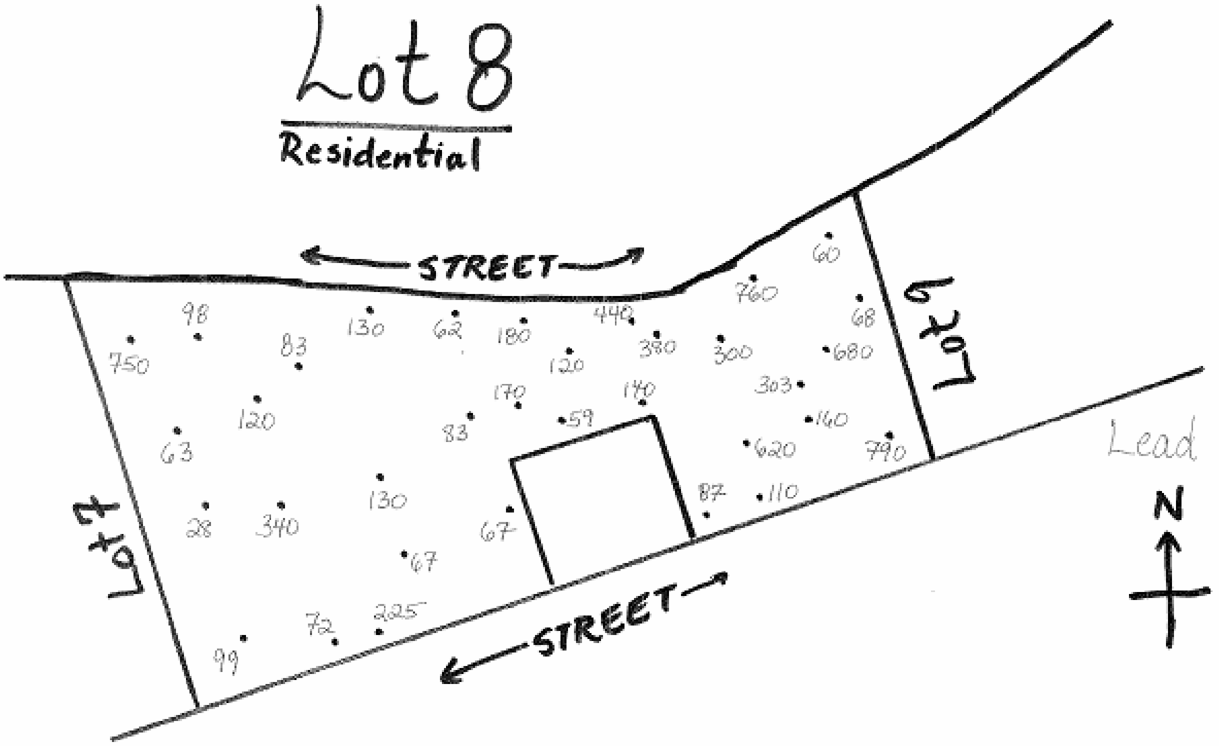

School
N
Arsenic
STREET
Lot 8
Lot 7
Lot 6
69
39
68
49
61
36
110
37
86
34
66
73
79
66
93
30
71
51
69
76
65
65
69
39
27
60
59
58
89
160
180
23
73
79
56
37
91
64
28
32
33
100
68
84
120
57
92
165
13
130
70
69

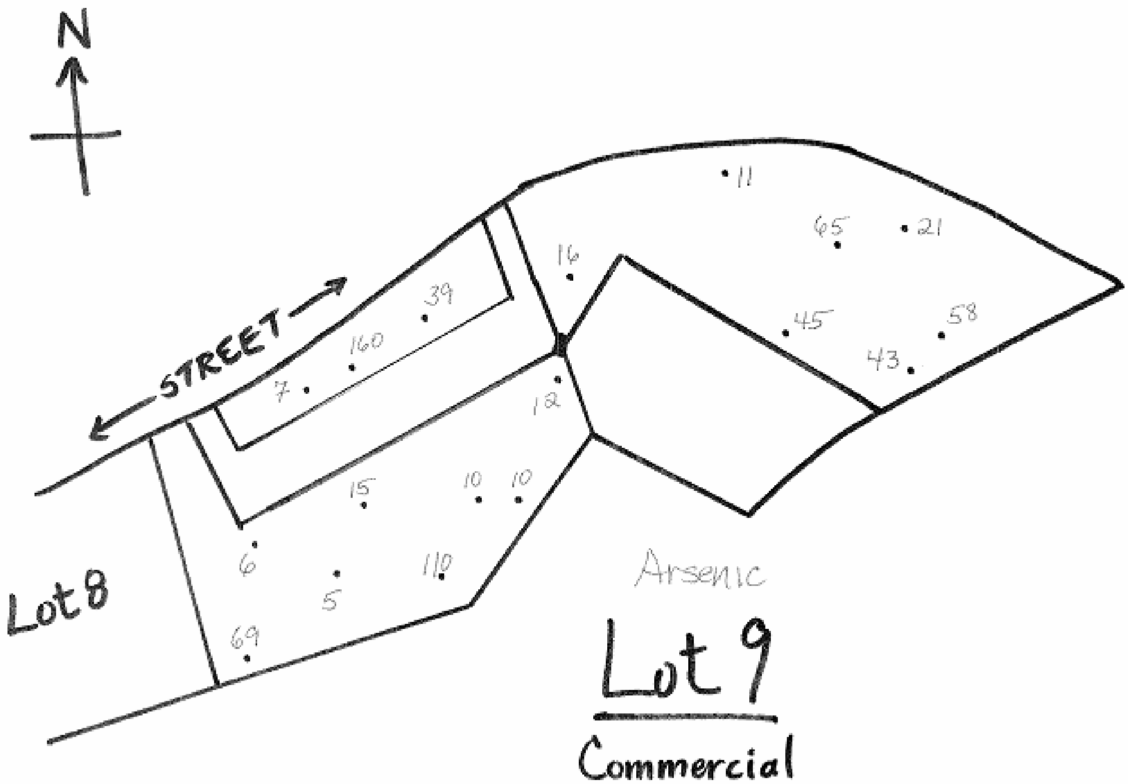

School
N
Copper
STREET
Lot 8
Lot 7
Lot 6
260
430
1300
380
140
180
1200
2600
1000
325
1300
1300
730
2000
1100
1550
6400
2700
745
1400
370
1300
230
1500
2700
690
140
360
2400
590
260
300
1200
2600
220
2700
1200
430
200
1300
340
1200
1800
1000
670
2700
340
720
2250
910
2300
960
430

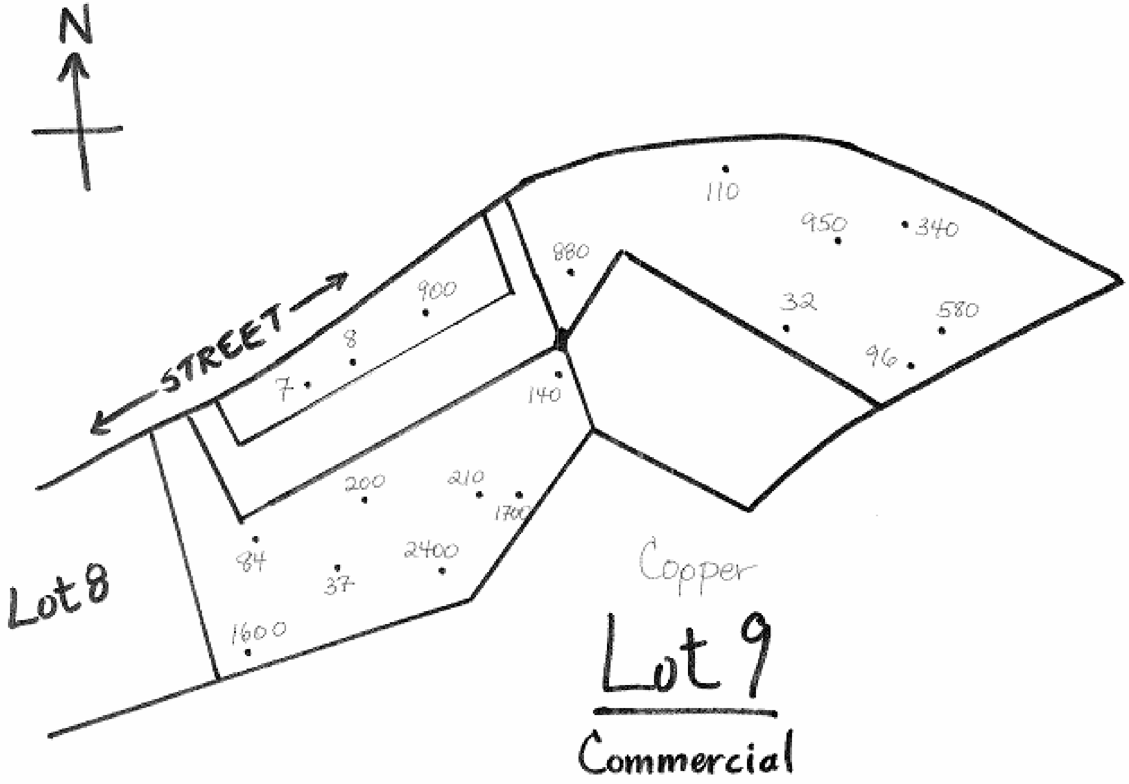

School
N
Lead
STREET
Lot 8
Lot 7
Lot 6
55
34
130
10
54
41
210
97
110
67
184
76
130
77
800
88
250
140
320
120
82
94
76
46
150
100
90
48
75
220
220
150
200
100
160
100
88
95
69
73
79
300
200
310
250
69
150
45
205
140
160
67

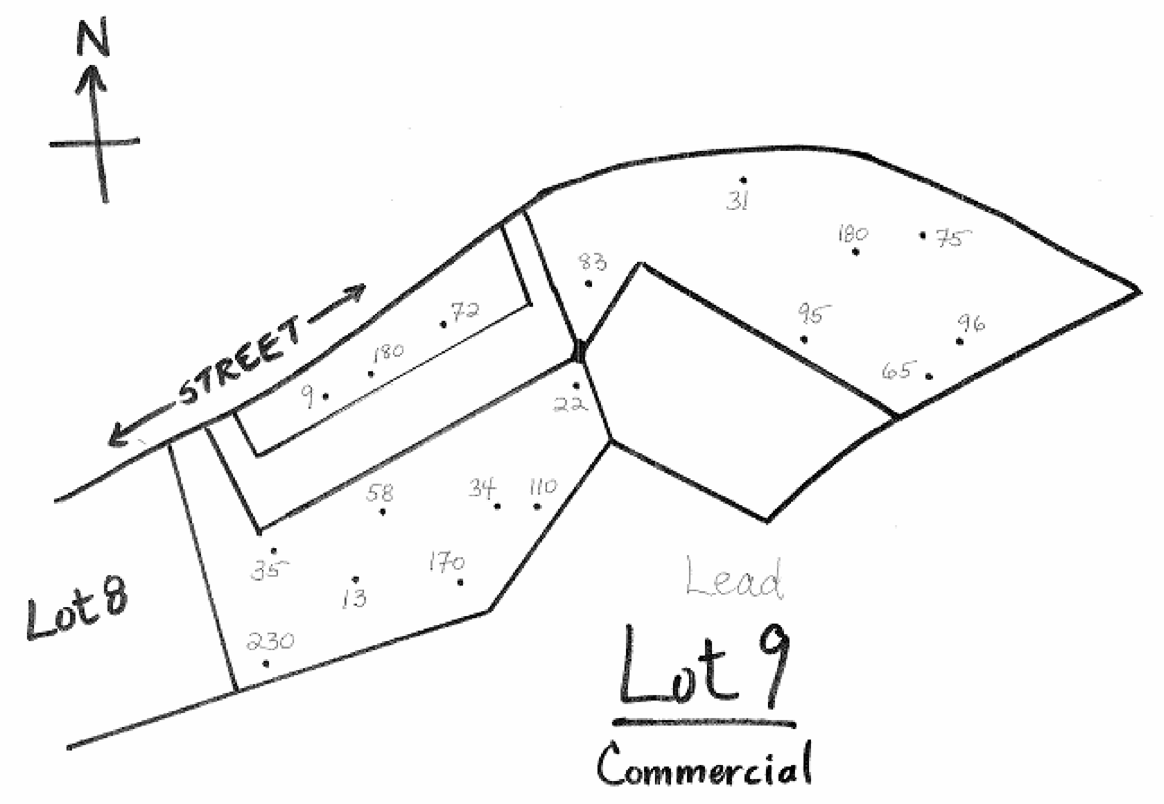

Lot 8
Residential
STREET
Lot 9
Lot 7
Arsenic
N
79
130
58
51
90
33
160
250
94
55
130
130
370
38
37
41
65
18
60
23
28
59
100
280
66
38
120
7.9
210
74
32
9.1
38
43


Lot 8
Residential
STREET
STREET
Lot 7
Lot 9
Copper
N
1300
2200
520
1600
1100
790
3400
3500
750
2800
990
4800
580
1500
180
150
410
695
1350
850
1500
1800
20
340
1600
130
1300
110
2900
290
340
64
270
870

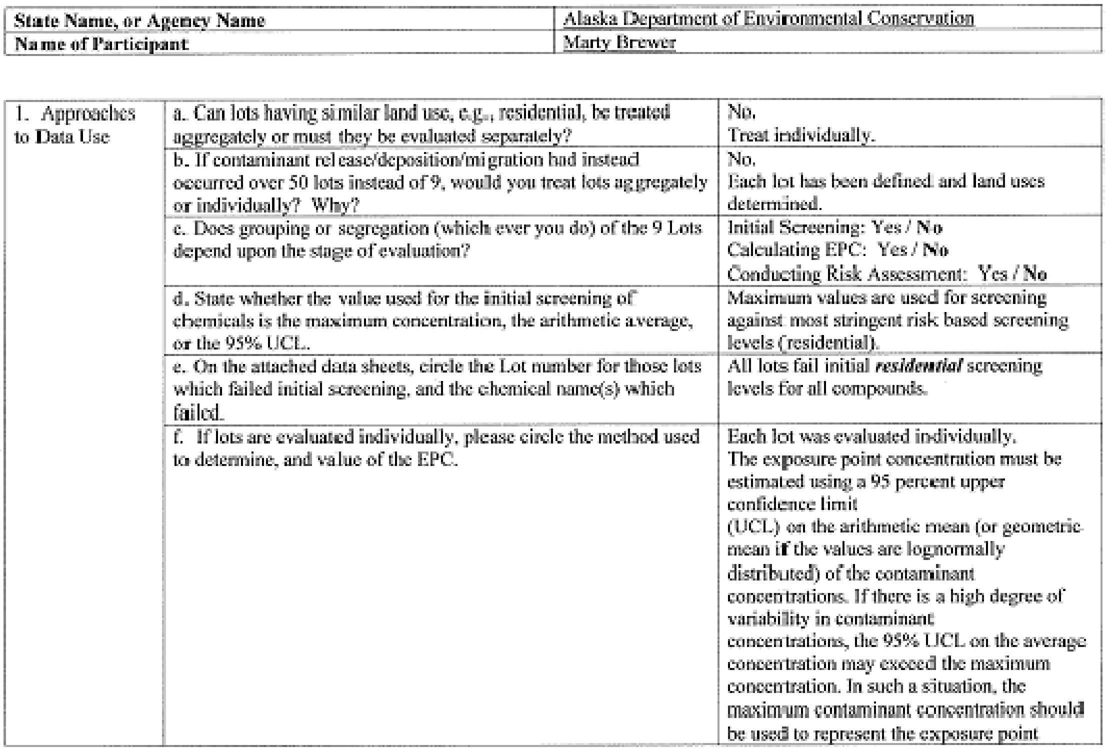

Lot 8
Residential
STREET
STREET
Lot 7
Lot 9
Lead
N
60
760
98
130
62
180
440
68
750
83
120
380
300
680
303
170
140
120
83
59
160
63
620
790
87
110
130
28
340
67
67
72
225
99


N
STREET
Lot 8
11
65
21
16
39
160
7
45
58
43
12
15
10
10
6
5
110
69
Arsenic
Lot 9
Commercial


N
STREET
Lot 8
110
950
340
880
900
8
7
32
580
96
140
200
210
1700
84
37
2400
1600
Copper
Lot 9
Commercial



C.2.1 Second Comparative Case Study—Alaska Respondent



State Name, or Agency Name	Alaska Department of Environmental Conservation
Name of Participant	Marty Brewer

1. Approaches to Data Use	a. Can lots having similar land use, e.g., residential, be treated aggregately or must they be evaluated separately?	No. Treat individually.
	b. If contaminant release/deposition/migration had instead occurred over 50 lots instead of 9, would you treat lots aggregately or individually? Why?	No. Each lot has been defined and land uses determined.
	c. Does grouping or segregation (which ever you do) of the 9 Lots depend upon the stage of evaluation?	Initial Screening: Yes / **No** Calculating EPC: Yes / **No** Conducting Risk Assessment: Yes / **No**
	d. State whether the value used for the initial screening of chemicals is the maximum concentration, the arithmetic average, or the 95% UCL.	Maximum values are used for screening against most stringent risk based screening levels (residential).
	e. On the attached data sheets, circle the Lot number for those lots which failed initial screening, and the chemical name(s) which failed.	All lots fail initial ***residential*** screening levels for all compounds.
	f. If lots are evaluated individually, please circle the method used to determine, and value of the EPC.	Each lot was evaluated individually. The exposure point concentration must be estimated using a 95 percent upper confidence limit (UCL) on the arithmetic mean (or geometric mean if the values are lognormally distributed) of the contaminant concentrations. If there is a high degree of variability in contaminant concentrations, the 95% UCL on the average concentration may exceed the maximum concentration. In such a situation, the maximum contaminant concentration should be used to represent the exposure point

		concentration.
	g. Can more than one exposure unit be determined within any of these 9 Lots?	No. However, adjacent land use may be considered in risk management decisions. For instance a commercial lot adjacent to a residential lot may meet commercial risk levels, but it might warrant further risk management consideration in relation to adjacent lots.
	h. Had all the samples within a lot been composited in equal volume aliquots, would you use the average concentration shown for the EPC?	No. ADEC does not allow compositing for risk assessment.
2. Data Needs	a. Indicate on the Lot Maps which lots have an inadequate sampling density to meet the data quality requirements for a risk assessment.	It is assumed that all the UCLs calculated are statistically valid and therefore may be used as the EPC.
	b. State the density or frequency of sampling required, and mark the area on the map needing further sampling as "S".	Additional data identifying extent of contamination above screening levels. Step out sampling required from each sample point exceeding risk screening levels or background.
	c. Indicate on the Lot Map whether additional sampling is dependent upon the concentration of an adjacent sample, land use, or other.	Sampling should identify the source and extent of contamination (as determined by residential screening levels).
3. Risk Assessment	a. Please write RA under each Lot No. on the Data Sheets for those lots eligible to conduct a site-specific risk assessment.	All.
	A reverse risk assessment has been conducted which shows the following site-specific concentrations at the indicated ELCR or hazard index. Does any chemical on any lot now become eliminated from any further consideration? Please state which Lots based on which chemical.	Copper for lot 4, 6 & 9 is below the calculated residential risk based screening level. However, given cumulative risk considerations, it is not recommended that it be dropped as a COPC.

	Residential		Commercial	
Chemical	10^{-6}	HI = 1	10^{-6}	HI = 1
Arsenic	12	33	48	390
Copper	▨	3,100	▨	5,800
Lead *	400		1,000	

*Based on achieving target blood lead level by pharmacokinetic modeling.

	b. Using the table above, please calculate the cumulative health risk and hazard for those lots which exceeded the applicable cleanup levels. Write in on Data Sheets under Lot No.	See attached calculations.
	c. Were all chemicals included, even if eliminated in the initial screening or screening against the EPC?	No chemicals were eliminated.
	d. Was the non-carcinogenic arsenic contribution to the hazard quotient included?	Yes. Both carcinogenic & non-carcinogenic effects should be considered.
	e. Was lead considered separately or combined by some method for contribution to the overall health hazard?	Lead is considered separately.
	f. Federal guidance suggests that arsenic and lead have greater than additive effects on neurological toxicity. How would you account for this:	(i) quantitatively in the risk characterization calculation; **(ii)** qualitatively in the uncertainty section; **(iii)** use this information in setting risk management decision and final cleanup goals; (iv) other:
	g. Do you account for the contribution of background levels in the risk characterization? Indicate if the level of risk due to background is:	(i) quantitated and combined with the risk estimate due to the contaminant release; **(ii)** is quantitated and not included with the

		overall risk estimate, but used in risk management decision-making; (iii) discussed qualitatively in the uncertainty section only; (iv) other:
3. Risk Management Decisions	a. For those lots having the EPC in exceedance of the site-specific cleanup level, do you remediate the whole lot for that chemical or just portions? If portions, circle the areas on Lot Maps as "R".	Risk management decision to either remediate "hot spots" or the entire lot.
	b. Is the remediation different had the site-specific risk assessment not been conducted?	Possibly. Remediation might attempt to go after hotspots which would require additional sampling. Alternatively, a UCL could have been used to remediate the entire lot.
	c. What elements of this site would you require to be discussed in the uncertainty section of the risk assessment, and would any elements result in a determination of a more stringent cleanup level for 1 or more chemicals?	A discussion of sampling rationale should be included to indicate if the sampling was random or was source identification and extent the objective. Calculation of lead risks separately from other COCs warrants discussion especially in lieu of the more than additive effects between lead and arsenic. Risk management decisions should evaluate the risk the contribution of each contaminant as well as cumulative risk at each lot especially where lead and arsenic are collocated. A discussion of background is also needed although it appears that site concentrations are most all above background. Potential migration of contaminants should also be considered via tracking or dust blown. There is also the uncertainty of the depth of contamination and what potential risk that may pose. The COCs are not volatile so there is that less of a concern about contaminants at depth. However, the potential for contaminant uptake into edible plants should not be discounted even though it is not considered a current exposure pathway.
	d. How was the school lot treated differently in this scenario?	Childhood exposure factors. Use of the Childhood Lead Model as apposed to the Adult Lead Model.

	Site1 EPC	Site2 EPC	Site3 EPC	Site4 EPC	Site5 EPC	Site6 EPC	Site7 EPC	Site8 EPC	Site9 EPC
Arsenic	67	68	87	54	78	84	78	114	61
Copper	2436	1482	1825	989	1141	1521	1468	1575	1067
Lead	381	234	3658	335	026	156	168	403	113

Residential	**Direct Contact Non-Cancer Risk**								
Arsenic	2.030303	2.00000000	2.636364	1.636364	2.363636364	2.6464646	2.3636364	3.45451545	1.848485
Copper	0.7858065	0.47806452	0.58871	0.319032	0.368064516	0.4906452	0.4735484	0.50806452	0.344194
Lead	NA								
HI	3		3	2	3		3	4	

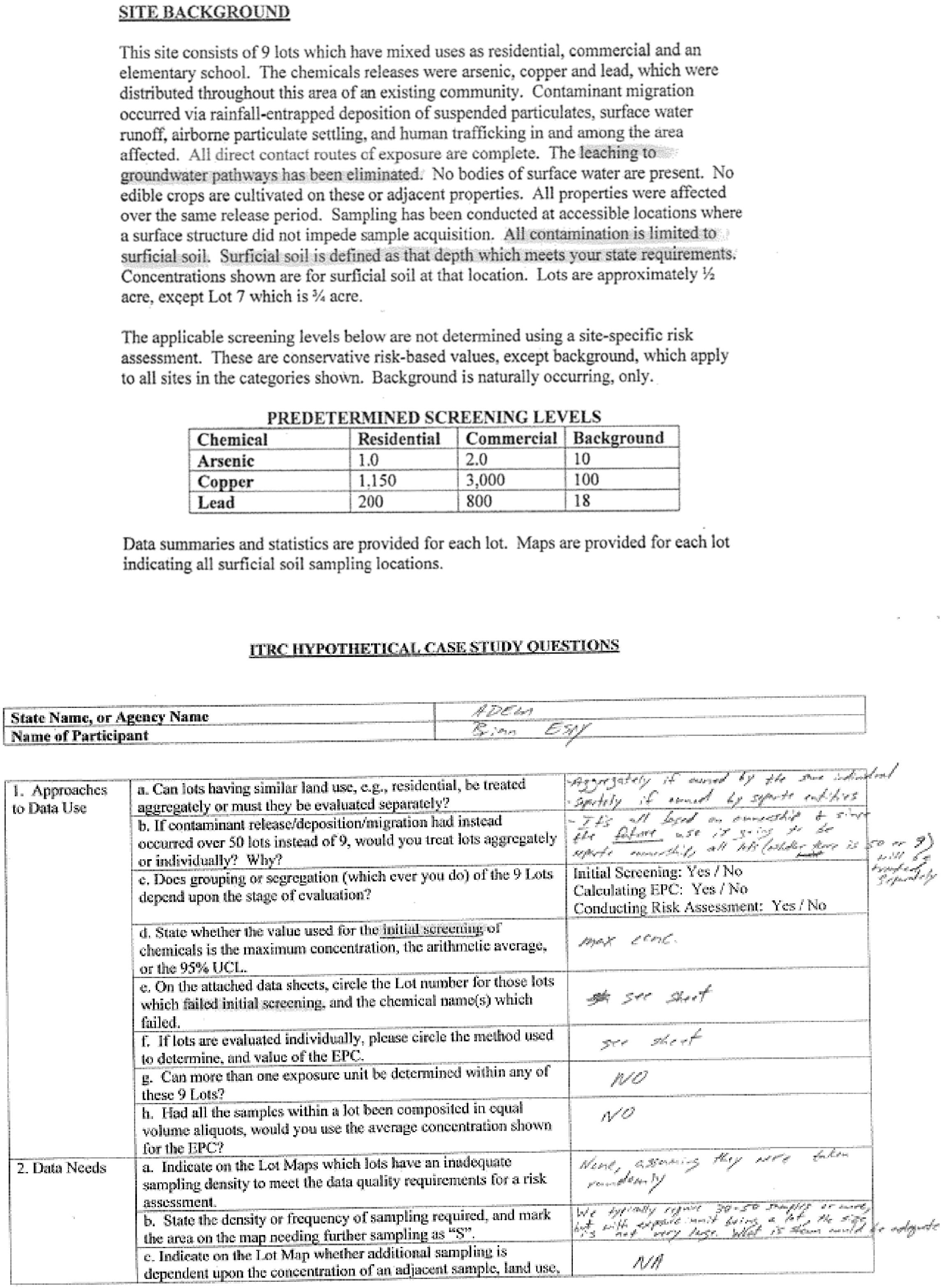
Industrial/Commercial Lot All other lots considered residential

Residential	**Direct Contact Cancer Risk**								
Arsenic	6.E-05	6.E-05	7.E-05	5.E-05	7.E-06	7 E-05	7.E-05	1.E-04	5.E-05
Copper	NA								
Lead									
ELCR	6.E-05	6.E-05	7.E-05	5.E-05	7.E-06	7 E-05	7.E-05	1.E-04	5.E-05

Ind/Com	**Direct Contact Non-Cancer Risk**								
Arsenic	0.1717949	0.17435897	NA	NA	NA	NA	NA	NA	0.15641
Copper	0.42	0.25551724	NA	NA	NA	NA	NA	NA	0.183966
Lead	NA	NA	NA	NA	NA	NA	NA	NA	NA
HI	0.6	0.4							0.3

Ind/Com	**Direct Contact Cancer Risk**								
Arsenic	1.E-05	1.E-05	NA	NA	NA	NA	NA	NA	1.E-05
Copper	NA	NA	NA	NA	NA	NA	NA	NA	NA
Lead			NA	NA	NA	NA	NA	NA	
ELCR	1.E-05	1.E-05							1.E-05

C.2.2 Second Comparative Case Study—Alabama Respondent



SITE BACKGROUND

This site consists of 9 lots which have mixed uses as residential, commercial and an elementary school. The chemicals releases were arsenic, copper and lead, which were distributed throughout this area of an existing community. Contaminant migration occurred via rainfall-entrapped deposition of suspended particulates, surface water runoff, airborne particulate settling, and human trafficking in and among the area affected. All direct contact routes of exposure are complete. The leaching to groundwater pathways has been eliminated. No bodies of surface water are present. No edible crops are cultivated on these or adjacent properties. All properties were affected over the same release period. Sampling has been conducted at accessible locations where a surface structure did not impede sample acquisition. All contamination is limited to surficial soil. Surficial soil is defined as that depth which meets your state requirements. Concentrations shown are for surficial soil at that location. Lots are approximately ½ acre, except Lot 7 which is ¾ acre.

The applicable screening levels below are not determined using a site-specific risk assessment. These are conservative risk-based values, except background, which apply to all sites in the categories shown. Background is naturally occurring, only.

PREDETERMINED SCREENING LEVELS

Chemical	Residential	Commercial	Background
Arsenic	1.0	2.0	10
Copper	1,150	3,000	100
Lead	200	800	18

Data summaries and statistics are provided for each lot. Maps are provided for each lot indicating all surficial soil sampling locations.

ITRC HYPOTHETICAL CASE STUDY QUESTIONS

State Name, or Agency Name	ADEM
Name of Participant	Brian Espy

1. Approaches to Data Use	a. Can lots having similar land use, e.g., residential, be treated aggregately or must they be evaluated separately?	Aggregately if owned by the same individual separately if owned by separate entities
	b. If contaminant release/deposition/migration had instead occurred over 50 lots instead of 9, would you treat lots aggregately or individually? Why?	- It's all based on ownership & since the future use it's going to be separate ownership, all lots (whether there is 50 or 9) will be treated separately
	c. Does grouping or segregation (which ever you do) of the 9 Lots depend upon the stage of evaluation?	Initial Screening: Yes / No Calculating EPC: Yes / No Conducting Risk Assessment: Yes / No
	d. State whether the value used for the initial screening of chemicals is the maximum concentration, the arithmetic average, or the 95% UCL.	max conc.
	e. On the attached data sheets, circle the Lot number for those lots which failed initial screening, and the chemical name(s) which failed.	see sheet
	f. If lots are evaluated individually, please circle the method used to determine, and value of the EPC.	see sheet
	g. Can more than one exposure unit be determined within any of these 9 Lots?	NO
	h. Had all the samples within a lot been composited in equal volume aliquots, would you use the average concentration shown for the EPC?	NO
2. Data Needs	a. Indicate on the Lot Maps which lots have an inadequate sampling density to meet the data quality requirements for a risk assessment.	None, assuming they were taken randomly
	b. State the density or frequency of sampling required, and mark the area on the map needing further sampling as "S".	We typically require 30-50 samples or more, but with exposure unit being a lot the size it's not very large. What is shown would be adequate
	c. Indicate on the Lot Map whether additional sampling is dependent upon the concentration of an adjacent sample, land use,	NA

	or other.	
3. Risk Assessment	a. Please write RA under each Lot No. on the Data Sheets for those lots eligible to conduct a site-specific risk assessment.	see data sheet
	A reverse risk assessment has been conducted which shows the following site-specific concentrations at the indicated ELCR or hazard index. Does any chemical on any lot now become eliminated from any further consideration? Please state which Lots based on which chemical.	Note: For the RA, AL utilized the 95% UCL → Yes, Pb is the only one evaluated based on individual risk since a different set of criteria is used to determine a "safe" level. As & Cu must be evaluated based on cumulative risk ∴ see 3b. (Yes, I know As is the only carcinogen using the ELCR first but I thought that info might be helpful.) Pb eliminated beyond screening -Lot 1 -Lot 4 -Lot 6 -Lot 7

~~HI~~ → HQ →

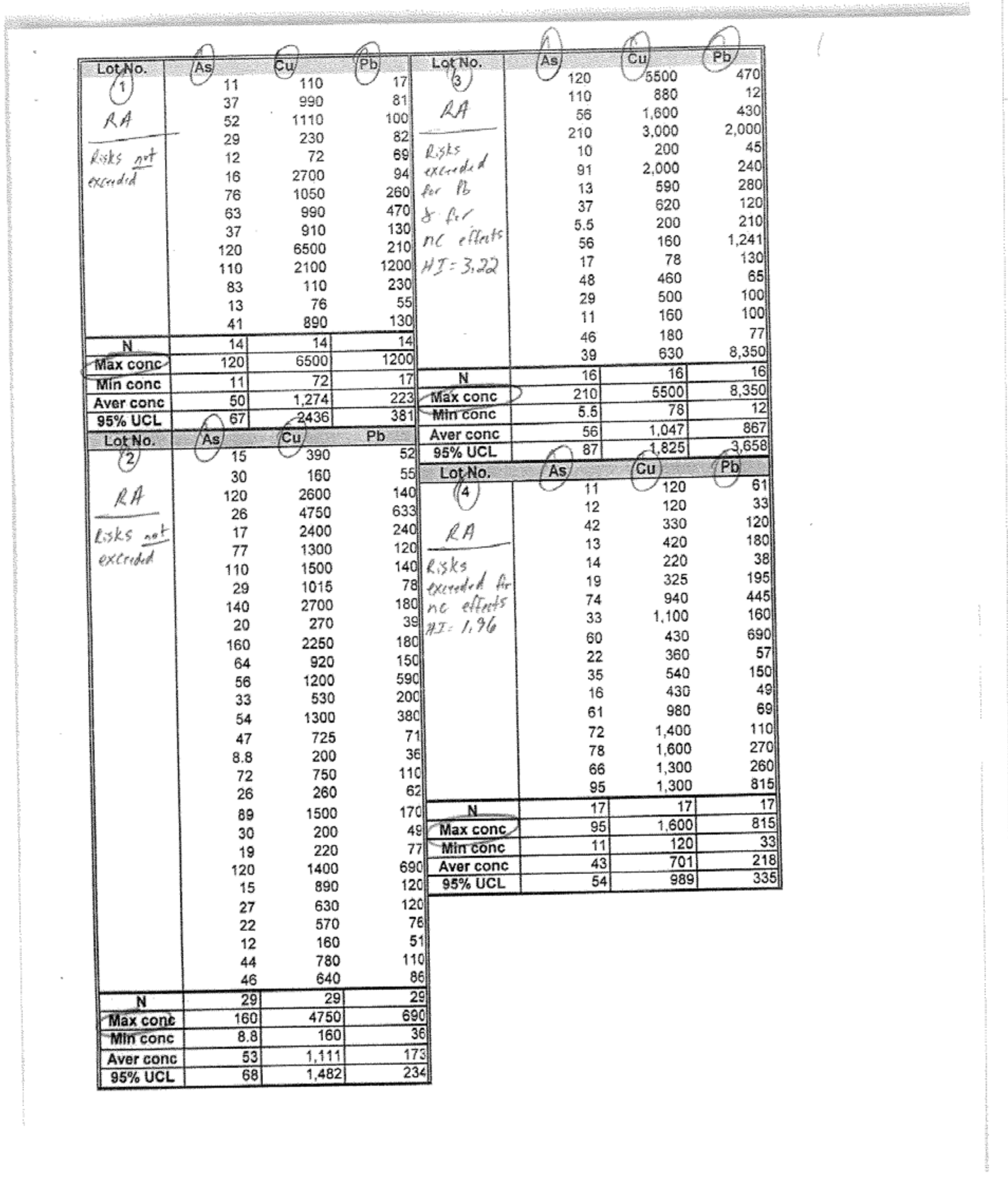
	Residential		Commercial	
Chemical	10^{-6}	HQ= 1	10^{-6}	HQ= 1
Arsenic	12	33	48	390
Copper	▨	3,100	▨	5,800
Lead *	400		1,000	

*Based on achieving target blood lead level by pharmacokinetic modeling.

	b. Using the table above, please calculate the cumulative health risk and hazard for those lots which exceeded the applicable cleanup levels. Write in on Data Sheets under Lot No.	AL Risk levels ELCR = 1E-05 HI = Σ HQ = 1.0
	c. Were all chemicals included, even if eliminated in the initial screening or screening against the EPC?	3 chemicals were screened and they were left out of the cumulative risk calculations. All other chemicals were included
	d. Was the non-carcinogenic arsenic contribution to the hazard quotient included?	The HQ calculated from the As contributed to the HI (confusing question)
	e. Was lead considered separately or combined by some method for contribution to the overall health hazard?	separately
	f. Federal guidance suggests that arsenic and lead have greater than additive effects on neurological toxicity. How would you account for this:	(i) quantitatively in the risk characterization calculation; [✓ (ii)] qualitatively in the uncertainty section; [✓ (iii)] use this information in setting risk management decision and final cleanup goals;

		(iv) other:
	g. Do you account for the contribution of background levels in the risk characterization? Indicate if the level of risk due to background is:	(i) quantitated and combined with the risk estimate due to the contaminant release; [✓ (ii)] is quantitated and not included with the overall risk estimate, but used in risk management decision-making; (iii) discussed qualitatively in the uncertainty section only; (iv) other:
3. Risk Management Decisions	a. For those lots having the EPC in exceedance of the site-specific cleanup level, do you remediate the whole lot for that chemical or just portions? If portions, circle the areas on Lot Maps as "R".	You remediate so that the "whole lot" has an EPC that is considered safe for the intended land-use. This could mean the whole lot or just portions, it's up to the facility.
	b. Is the remediation different had the site-specific risk assessment not been conducted?	yes
	c. What elements of this site would you require to be discussed in the uncertainty section of the risk assessment, and would any elements result in a determination of a more stringent cleanup level for 1 or more chemicals?	the info provided in 3.e. and 3.f.
	d. How was the school lot treated differently in this scenario?	It was treated the same as any residential location.

C.2.3 Second Comparative Case Study—Arizona Respondent



Lot No.	As	Cu	Pb
1 RA Risks not exceeded	11	110	17
	37	990	81
	52	1110	100
	29	230	82
	12	72	69
	16	2700	94
	76	1050	260
	63	990	470
	37	910	130
	120	6500	210
	110	2100	1200
	83	110	230
	13	76	55
	41	890	130
N	14	14	14
Max conc	120	6500	1200
Min conc	11	72	17
Aver conc	50	1,274	223
95% UCL	67	2436	381

Lot No.	As	Cu	Pb
2 RA Risks not exceeded	15	390	52
	30	160	55
	120	2600	140
	26	4750	633
	17	2400	240
	77	1300	120
	110	1500	140
	29	1015	78
	140	2700	180
	20	270	39
	160	2250	180
	64	920	150
	56	1200	590
	33	530	200
	54	1300	380
	47	725	71
	8.8	200	36
	72	750	110
	26	260	62
	89	1500	170
	30	200	49
	19	220	77
	120	1400	690
	15	890	120
	27	630	120
	22	570	76
	12	160	51
	44	780	110
	46	640	86
N	29	29	29
Max conc	160	4750	690
Min conc	8.8	160	36
Aver conc	53	1,111	173
95% UCL	68	1,482	234

Lot No.	As	Cu	Pb
3 RA Risks exceeded for Pb & for nc effects HI=3,22	120	5500	470
	110	880	12
	56	1,600	430
	210	3,000	2,000
	10	200	45
	91	2,000	240
	13	590	280
	37	620	120
	5.5	200	210
	56	160	1,241
	17	78	130
	48	460	65
	29	500	100
	11	160	100
	46	180	77
	39	630	8,350
N	16	16	16
Max conc	210	5500	8,350
Min conc	5.5	78	12
Aver conc	56	1,047	867
95% UCL	87	1,825	3,658

Lot No.	As	Cu	Pb
4 RA Risks exceeded for nc effects HI= 1,96	11	120	61
	12	120	33
	42	330	120
	13	420	180
	14	220	38
	19	325	195
	74	940	445
	33	1,100	160
	60	430	690
	22	360	57
	35	540	150
	16	430	49
	61	980	69
	72	1,400	110
	78	1,600	270
	66	1,300	260
	95	1,300	815
N	17	17	17
Max conc	95	1,600	815
Min conc	11	120	33
Aver conc	43	701	218
95% UCL	54	989	335

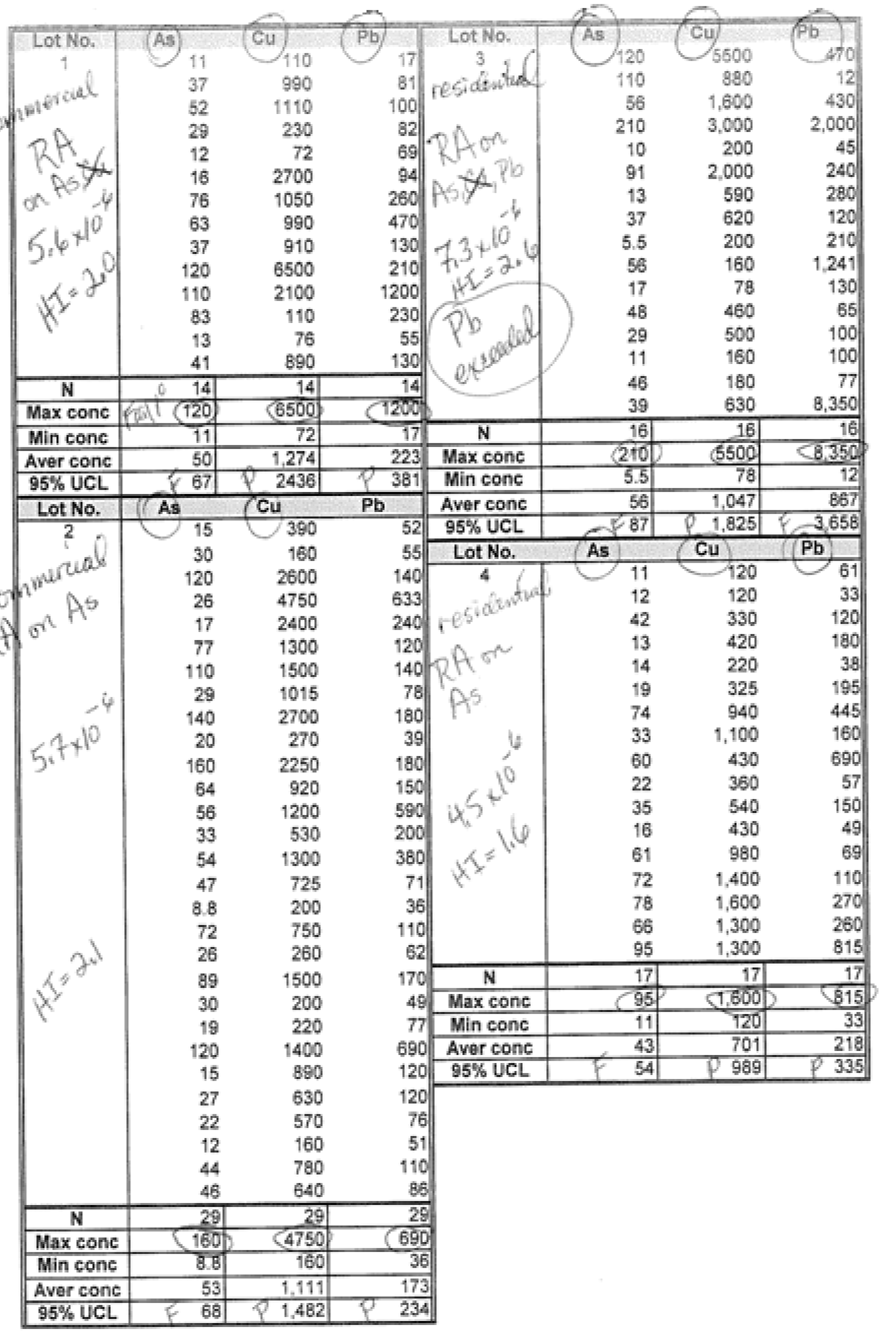
Lot No.	As	Cu	Pb
5	160	1800	77
	78	1,400	520
RA	140	2,000	230
	24	190	41
Risks exceeded for Pb & for nc effects HI = 2.73	45	500	100
	35	370	60
	14	140	43
	35	410	62
	21	840	70
	83	790	80
	27	410	68
	74	1,200	99
	23	560	47
	24	100	26
	140	1,700	220
	19	280	70
	19	150	47
	68	1,700	150
	170	1,700	220
	14	150	79
	7	180	29
	30	400	130
	74	1,600	130
	76	1,200	230
	94	1,900	480
	19	220	37
	120	1,300	1,100
	109	1,900	1,613
	15	100	54
	18	270	50
N	30	30	30
Max conc	170	2000	1613
Min conc	7	100	26
Aver conc	59	849	205
95% UCL	78	1,141	826

Lot No.	As	Cu	Pb
6	5	43	25
	80	660	140
LA	75	1,700	71
	15	140	34
Risks exceeded for nc effects HI = 3.04	110	1,200	150
	65	825	120
	120	1,900	240
	62	2,200	210
	13	685	72
	8.2	170	39
	17	870	35
	9.9	79	64
	54	200	160
	19	570	81
	120	2,500	250
	87	1,500	100
	86	1,700	100
	100	1,800	170
	43	740	75
	115	2,900	71
	150	2,600	92
	36	790	140
	200	3,700	430
	77	1,100	200
	54	1,200	120
	76	760	135
	35	1,700	350
	62	1,300	180
	12	230	130
	110	1,300	110
	10	285	30
	7.2	150	28
	32	240	76
	130	1,400	84
N	34	34	34
Max conc	200	3700	430
Min conc	5	43	25
Aver conc	65	1,151	127
95% UCL	84	1,521	156

Lot No.	As	Cu	Pb
7	76	1300	120
	86	1,300	130
RA	110	2,600	184
	37	1,300	76
Risks exceeded for nc effects HI=2.84	36	730	77
	66	2,000	800
	65	230	46
	58	360	220
	89	1,500	100
	65	1,550	82
	69	2,700	150
	160	2,400	220
	64	220	95
	91	2,600	160
	73	1,100	88
	39	690	94
	180	2,700	190
	100	1,800	300
	13	910	45
	130	2,300	140
	57	340	69
	70	430	67
	69	960	160
	165	2,250	205
	68	1,000	200
	84	670	310
	79	1,200	88
	28	430	69
	32	200	73
	92	720	150
	120	2,700	250
	69	260	55
	39	430	34
	79	1,000	97
	68	1,300	130
	66	325	110
	71	6,400	320
	49	180	41
	69	1,400	140
	51	2,700	250
	27	745	76
	60	590	190
	73	300	200
	56	1,300	150
	33	340	79
	23	260	48
	61	380	110
	36	140	54
	93	1,200	210
	30	370	67
	59	140	75
	37	1,200	100
N	52	52	52
Max conc	180	6400	800
Min conc	13	140	34
Aver conc	70	1,195	144
95% UCL	78	1,468	168

Lot No.	As	Cu	Pb
8	55	520	750
	51	1,600	98
RA	65	1,350	120
	23	20	63
Risks exceeded for Pb & for nc effects HI=3.96	7.9	110	28
	210	2,900	340
	38	270	225
	9.1	64	72
	43	870	99
	38	580	83
	90	1,100	130
	100	1,600	130
	32	340	67
	33	790	62
	160	3,400	180
	130	1,500	120
	28	850	83
	37	180	170
	74	290	67
	18	150	59
	250	3,500	440
	130	2,800	380
	60	410	140
	94	990	300
	280	1,500	620
	120	1,300	110
	38	130	87
	120	220	760
	79	1,300	60
	58	750	68
	370	4,800	680
	41	695	303
	59	1,800	160
	66	340	790
N	34	34	34
Max conc	370	4800	790
Min conc	7.9	20	28
Aver conc	88	1,148	231
95% UCL	114	1,575	403

Lot No.	As	Cu	Pb
9	7	7	9
	160	8	180
	15	200	58
RA	10	210	34
	10	1,700	110
Risks not exceeded	110	2,400	170
	5	37	13
	6	84	35
	69	1,600	230
	39	900	72
	16	880	83
	12	140	22
	11	110	31
	65	950	180
	21	340	75
	58	580	96
	43	96	65
	45	32	95
N	18	18	18
Max conc	160	2400	230
Min conc	5	7	9
Aver conc	39	571	87
95% UCL	61	1,067	113



Lot No.	As	Cu	Pb
1 Commercial RA on As 5.6x10^{-6} HI=2.0	11	110	17
	37	990	81
	52	1110	100
	29	230	82
	12	72	69
	16	2700	94
	76	1050	260
	63	990	470
	37	910	130
	120	6500	210
	110	2100	1200
	83	110	230
	13	76	55
	41	890	130
N	14	14	14
Max conc	Fail 120	6500	1200
Min conc	11	72	17
Aver conc	50	1,274	223
95% UCL	F 67	P 2436	P 381

Lot No.	As	Cu	Pb
2 commercial RA on As 5.7x10^{-6} HI=2.1	15	390	52
	30	160	55
	120	2600	140
	26	4750	633
	17	2400	240
	77	1300	120
	110	1500	140
	29	1015	78
	140	2700	180
	20	270	39
	160	2250	180
	64	920	150
	56	1200	590
	33	530	200
	54	1300	380
	47	725	71
	8.8	200	36
	72	750	110
	26	260	62
	89	1500	170
	30	200	49
	19	220	77
	120	1400	690
	15	890	120
	27	630	120
	22	570	76
	12	160	51
	44	780	110
	46	640	86
N	29	29	29
Max conc	160	4750	690
Min conc	8.8	160	36
Aver conc	53	1,111	173
95% UCL	F 68	P 1,482	P 234

Lot No.	As	Cu	Pb
3 residential RA on As, Pb 7.3x10^{-6} HI=2.6 Pb exceeded	120	5500	470
	110	880	12
	56	1,600	430
	210	3,000	2,000
	10	200	45
	91	2,000	240
	13	590	280
	37	620	120
	5.5	200	210
	56	160	1,241
	17	78	130
	48	460	65
	29	500	100
	11	160	100
	46	180	77
	39	630	8,350
N	16	16	16
Max conc	210	5500	8,350
Min conc	5.5	78	12
Aver conc	56	1,047	867
95% UCL	F 87	P 1,825	F 3,658

Lot No.	As	Cu	Pb
4 residential RA on As 4.5x10^{-6} HI=1.6	11	120	61
	12	120	33
	42	330	120
	13	420	180
	14	220	38
	19	325	195
	74	940	445
	33	1,100	160
	60	430	690
	22	360	57
	35	540	150
	16	430	49
	61	980	69
	72	1,400	110
	78	1,600	270
	66	1,300	260
	95	1,300	815
N	17	17	17
Max conc	95	1,600	815
Min conc	11	120	33
Aver conc	43	701	218
95% UCL	F 54	P 989	P 335

1 1150 200

residential

RA on As, Pb

Pb exceeded

6.5×10^{-6}

HI = 2.4

Lot No.	As	Cu	Pb
5	160	1800	77
	78	1,400	520
	140	2,000	230
	24	190	41
	45	500	100
	35	370	60
	14	140	43
	35	410	62
	21	840	70
	83	790	80
	27	410	68
	74	1,200	99
	23	560	47
	24	100	26
	140	1,700	220
	19	280	70
	19	150	47
	68	1,700	150
	170	1,700	220
	14	150	79
	7	180	29
	30	400	130
	74	1,600	130
	76	1,200	230
	94	1,900	480
	19	220	37
	120	1,300	1,100
	109	1,900	1,613
	15	100	54
	18	270	50
N	30	30	30
Max conc	170	2000	1613
Min conc	7	100	26
Aver conc	59	849	205
95% UCL	F 78	P 1,141	F 826

residential

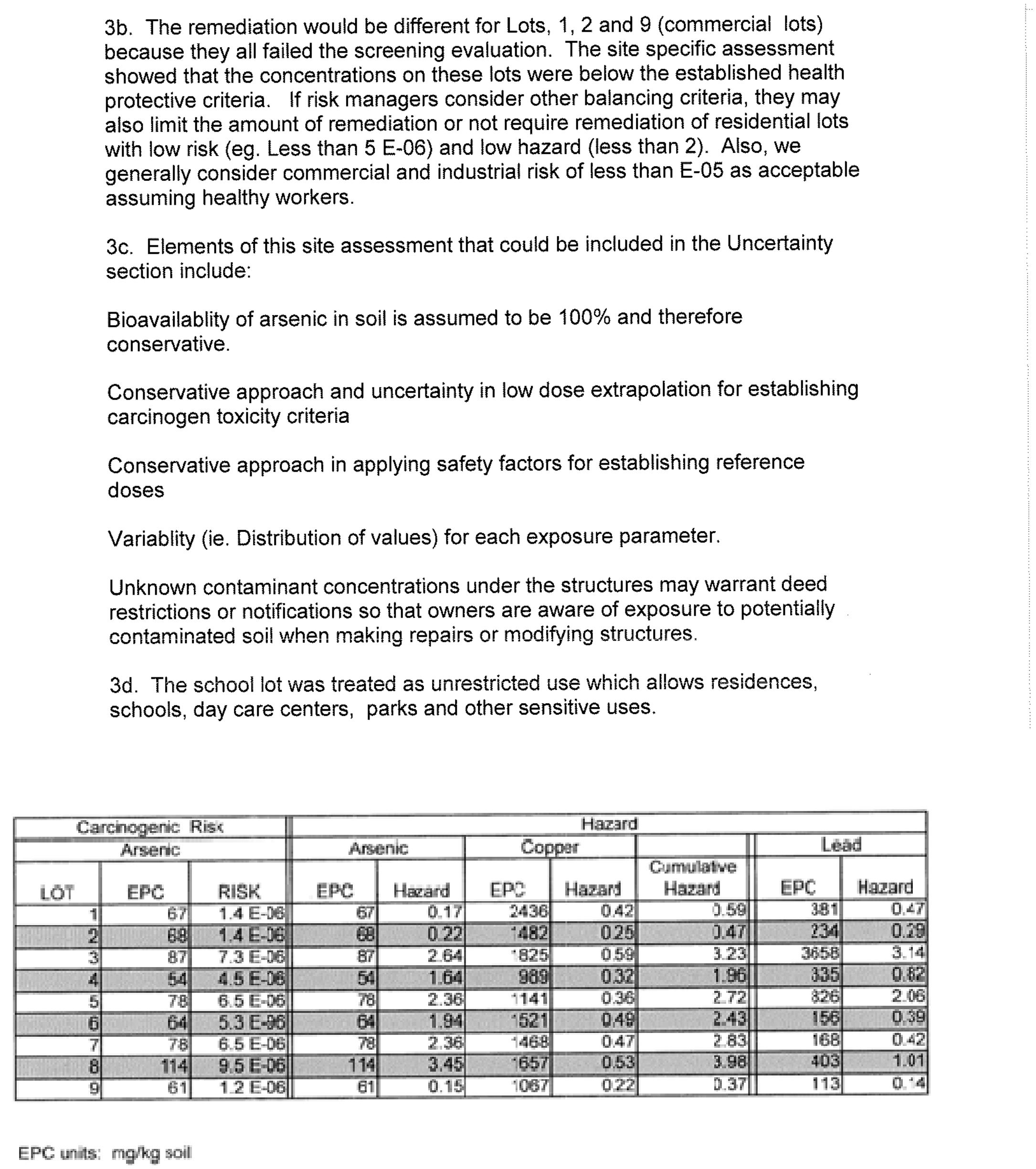
RA on As ~~Cu~~

7.0×10^{-6}

HI = 2.5

Lot No.	As	Cu	Pb
6	5	43	25
	80	660	140
	75	1,700	71
	15	140	34
	110	1,200	150
	65	825	120
	120	1,900	240
	62	2,200	210
	13	685	72
	8.2	170	39
	17	870	35
	9.9	79	64
	54	200	160
	19	570	81
	120	2,500	250
	87	1,500	100
	86	1,700	100
	100	1,800	170
	43	740	75
	115	2,900	71
	150	2,600	92
	36	790	140
	200	3,700	430
	77	1,100	200
	54	1,200	120
	76	760	135
	35	1,700	350
	62	1,300	180
	12	230	130
	110	1,300	110
	10	285	30
	7.2	150	28
	32	240	76
	130	1,400	84
N	34	34	34
Max conc	200	3700	430
Min conc	5	43	25
Aver conc	65	1,151	127
95% UCL	F 84	P 1,521	P 156

C.2.4 Second Comparative Case Study—California Respondent



3b. The remediation would be different for Lots, 1, 2 and 9 (commercial lots) because they all failed the screening evaluation. The site specific assessment showed that the concentrations on these lots were below the established health protective criteria. If risk managers consider other balancing criteria, they may also limit the amount of remediation or not require remediation of residential lots with low risk (eg. Less than 5 E-06) and low hazard (less than 2). Also, we generally consider commercial and industrial risk of less than E-05 as acceptable assuming healthy workers.

3c. Elements of this site assessment that could be included in the Uncertainty section include:

Bioavailablity of arsenic in soil is assumed to be 100% and therefore conservative.

Conservative approach and uncertainty in low dose extrapolation for establishing carcinogen toxicity criteria

Conservative approach in applying safety factors for establishing reference doses

Variablity (ie. Distribution of values) for each exposure parameter.

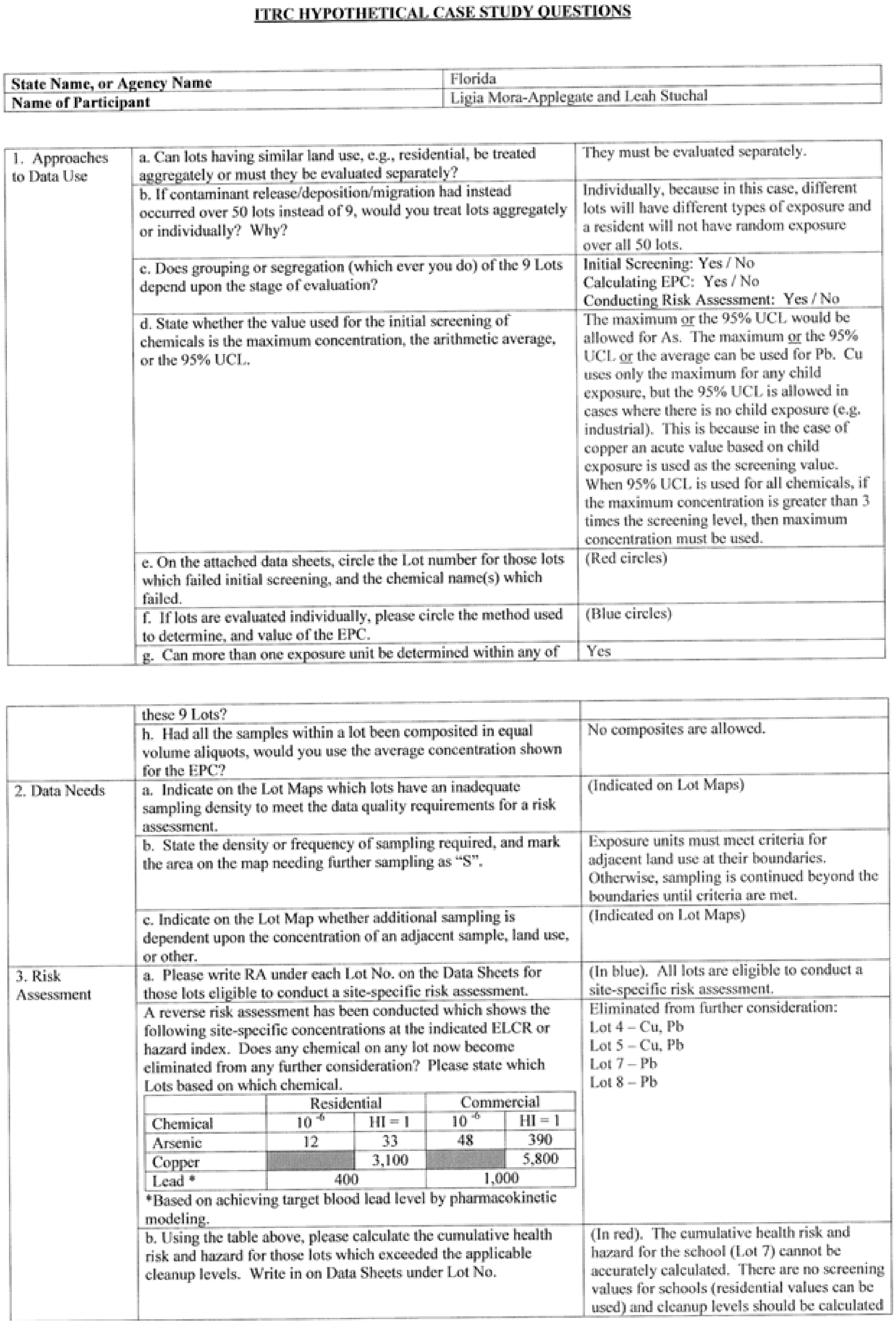
Unknown contaminant concentrations under the structures may warrant deed restrictions or notifications so that owners are aware of exposure to potentially contaminated soil when making repairs or modifying structures.

3d. The school lot was treated as unrestricted use which allows residences, schools, day care centers, parks and other sensitive uses.

Carcinogenic Risk			Hazard						
Arsenic			Arsenic		Copper			Lead	
LOT	EPC	RISK	EPC	Hazard	EPC	Hazard	Cumulative Hazard	EPC	Hazard
1	67	1.4 E-06	67	0.17	2436	0.42	0.59	381	0.47
2	68	1.4 E-06	68	0.22	1482	0.25	0.47	234	0.29
3	87	7.3 E-06	87	2.64	1825	0.59	3.23	3658	3.14
4	54	4.5 E-06	54	1.64	989	0.32	1.96	335	0.82
5	78	6.5 E-06	78	2.36	1141	0.36	2.72	826	2.06
6	64	5.3 E-06	64	1.94	1521	0.49	2.43	156	0.39
7	78	6.5 E-06	78	2.36	1468	0.47	2.83	168	0.42
8	114	9.5 E-06	114	3.45	1657	0.53	3.98	403	1.01
9	61	1.2 E-06	61	0.15	1067	0.22	0.37	113	0.14

EPC units: mg/kg soil

C.2.5 Second Comparative Case Study—Florida Respondent



ITRC HYPOTHETICAL CASE STUDY QUESTIONS

State Name, or Agency Name	Florida
Name of Participant	Ligia Mora-Applegate and Leah Stuchal

<table>
<tr><td rowspan="8">1. Approaches to Data Use</td><td>a. Can lots having similar land use, e.g., residential, be treated aggregately or must they be evaluated separately?</td><td>They must be evaluated separately.</td></tr>
<tr><td>b. If contaminant release/deposition/migration had instead occurred over 50 lots instead of 9, would you treat lots aggregately or individually? Why?</td><td>Individually, because in this case, different lots will have different types of exposure and a resident will not have random exposure over all 50 lots.</td></tr>
<tr><td>c. Does grouping or segregation (which ever you do) of the 9 Lots depend upon the stage of evaluation?</td><td>Initial Screening: Yes / No
Calculating EPC: Yes / No
Conducting Risk Assessment: Yes / No</td></tr>
<tr><td>d. State whether the value used for the initial screening of chemicals is the maximum concentration, the arithmetic average, or the 95% UCL.</td><td>The maximum <u>or</u> the 95% UCL would be allowed for As. The maximum <u>or</u> the 95% UCL <u>or</u> the average can be used for Pb. Cu uses only the maximum for any child exposure, but the 95% UCL is allowed in cases where there is no child exposure (e.g. industrial). This is because in the case of copper an acute value based on child exposure is used as the screening value. When 95% UCL is used for all chemicals, if the maximum concentration is greater than 3 times the screening level, then maximum concentration must be used.</td></tr>
<tr><td>e. On the attached data sheets, circle the Lot number for those lots which failed initial screening, and the chemical name(s) which failed.</td><td>(Red circles)</td></tr>
<tr><td>f. If lots are evaluated individually, please circle the method used to determine, and value of the EPC.</td><td>(Blue circles)</td></tr>
<tr><td>g. Can more than one exposure unit be determined within any of these 9 Lots?</td><td>Yes</td></tr>
<tr><td>h. Had all the samples within a lot been composited in equal volume aliquots, would you use the average concentration shown for the EPC?</td><td>No composites are allowed.</td></tr>
<tr><td rowspan="3">2. Data Needs</td><td>a. Indicate on the Lot Maps which lots have an inadequate sampling density to meet the data quality requirements for a risk assessment.</td><td>(Indicated on Lot Maps)</td></tr>
<tr><td>b. State the density or frequency of sampling required, and mark the area on the map needing further sampling as "S".</td><td>Exposure units must meet criteria for adjacent land use at their boundaries. Otherwise, sampling is continued beyond the boundaries until criteria are met.</td></tr>
<tr><td>c. Indicate on the Lot Map whether additional sampling is dependent upon the concentration of an adjacent sample, land use, or other.</td><td>(Indicated on Lot Maps)</td></tr>
<tr><td rowspan="3">3. Risk Assessment</td><td>a. Please write RA under each Lot No. on the Data Sheets for those lots eligible to conduct a site-specific risk assessment.</td><td>(In blue). All lots are eligible to conduct a site-specific risk assessment.</td></tr>
<tr><td>A reverse risk assessment has been conducted which shows the following site-specific concentrations at the indicated ELCR or hazard index. Does any chemical on any lot now become eliminated from any further consideration? Please state which Lots based on which chemical.
<table>
<tr><td></td><td colspan="2">Residential</td><td colspan="2">Commercial</td></tr>
<tr><td>Chemical</td><td>10^{-6}</td><td>HI = 1</td><td>10^{-6}</td><td>HI = 1</td></tr>
<tr><td>Arsenic</td><td>12</td><td>33</td><td>48</td><td>390</td></tr>
<tr><td>Copper</td><td>▨</td><td>3,100</td><td>▨</td><td>5,800</td></tr>
<tr><td>Lead *</td><td colspan="2">400</td><td colspan="2">1,000</td></tr>
</table>
*Based on achieving target blood lead level by pharmacokinetic modeling.</td><td>Eliminated from further consideration:
Lot 4 – Cu, Pb
Lot 5 – Cu, Pb
Lot 7 – Pb
Lot 8 – Pb</td></tr>
<tr><td>b. Using the table above, please calculate the cumulative health risk and hazard for those lots which exceeded the applicable cleanup levels. Write in on Data Sheets under Lot No.</td><td>(In red). The cumulative health risk and hazard for the school (Lot 7) cannot be accurately calculated. There are no screening values for schools (residential values can be used) and cleanup levels should be calculated</td></tr>
</table>

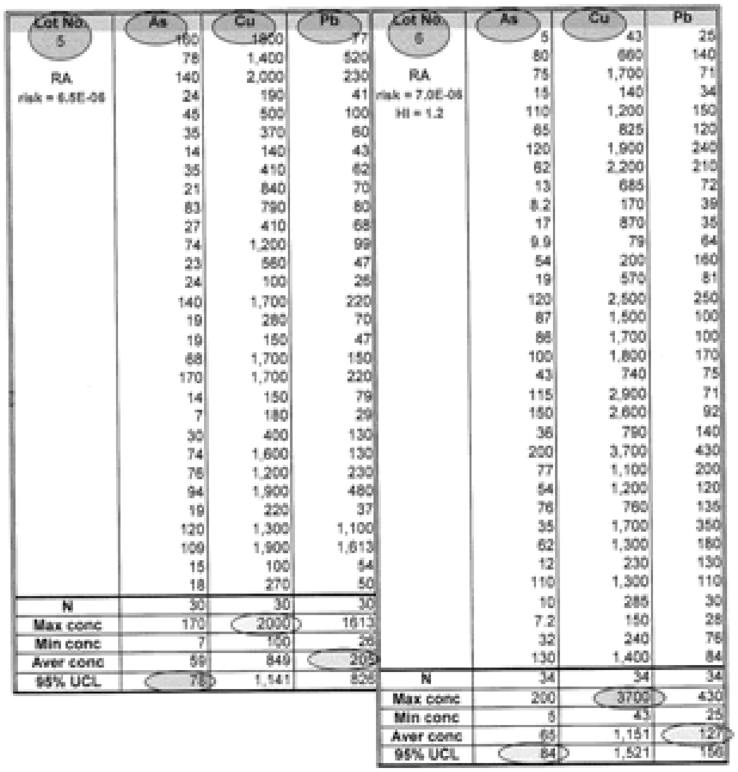
		on a site-specific basis.
	c. Were all chemicals included, even if eliminated in the initial screening or screening against the EPC?	No. Each chemical has a different target organ/effect so the cumulative health risk or hazard was not combined.
	d. Was the non-carcinogenic arsenic contribution to the hazard quotient included?	No
	e. Was lead considered separately or combined by some method for contribution to the overall health hazard?	Separately
	f. Federal guidance suggests that arsenic and lead have greater than additive effects on neurological toxicity. How would you account for this:	(i) quantitatively in the risk characterization calculation; (ii) qualitatively in the uncertainty section; (iii) use this information in setting risk management decision and final cleanup goals; (iv) other: If a chemical is a carcinogen, then non-carcinogenic effects are dropped.
	g. Do you account for the contribution of background levels in the risk characterization? Indicate if the level of risk due to background is:	(i) quantitated and combined with the risk estimate due to the contaminant release; (ii) is quantitated and not included with the overall risk estimate, but used in risk management decision-making; to eliminate it as a chemical of concern if the concentration is less than site-specific natural background. (iii) discussed qualitatively in the uncertainty section only; (iv) other:
3. Risk Management Decisions	a. For those lots having the EPC in exceedance of the site-specific cleanup level, do you remediate the whole lot for that chemical or just portions? If portions, circle the areas on Lot Maps as "R".	Portions. Areas with the highest concentrations are remediated until the EPC for each chemical in each lot is below the site-specific cleanup level ("virtual remediation").
	b. Is the remediation different had the site-specific risk assessment not been conducted?	The lots would still be remediated in portions, but the chemicals in lots eliminated due to the site-specific risk assessment in question 3a would then be included.
	c. What elements of this site would you require to be discussed in the uncertainty section of the risk assessment, and would any elements result in a determination of a more stringent cleanup level for 1 or more chemicals?	No element discussed in the uncertainty section would result in a more stringent cleanup level for this site.
	d. How was the school lot treated differently in this scenario?	A site-specific risk assessment would be conducted that included the average body weight, surface area, and exposure duration at the school for children of elementary school age. The lower of site-specific levels protective of elementary school children or teachers would be used.

Lot No.	As	Cu	Pb
1	11	110	17
	37	990	81
RA	52	1110	100
risk = 1.4E-06	29	230	82
	12	72	69
	16	2700	94
	76	1050	260
	63	990	470
	37	910	130
	120	6500	210
	110	2100	1200
	83	110	230
	13	76	55
	41	890	130
N	14	14	14
Max conc	120	6500	1200
Min conc	11	72	17
Aver conc	50	1,274	223
95% UCL	67	2436	381

Lot No.	As	Cu	Pb
2	15	390	52
	30	160	55
RA	120	2600	140
risk = 1.4E-06	26	4750	633
	17	2400	240
	77	1300	120
	110	1500	140
	29	1015	78
	140	2700	180
	20	270	39
	160	2250	180
	64	920	150
	56	1200	590
	33	530	200
	54	1300	380
	47	725	71
	8.8	200	36
	72	750	110
	26	260	62
	89	1500	170
	30	200	49
	19	220	77
	120	1400	690
	15	890	120
	27	630	120
	22	570	76
	12	160	51
	44	780	110
	46	640	86
N	29	29	29
Max conc	160	4750	690
Min conc	8.8	160	36
Aver conc	53	1,111	173
95% UCL	68	1,482	234

Lot No.	As	Cu	Pb
3	120	5500	470
	110	880	12
RA	56	1,600	430
risk = 7.3E-06	210	3,000	2,000
HI = 1.8	10	200	45
	91	2,000	240
	13	590	280
	37	620	120
	5.5	200	210
	56	160	1,241
	17	78	130
	48	460	65
	29	500	100
	11	160	100
	46	180	77
	39	630	8,350
N	16	16	16
Max conc	210	5500	8,350
Min conc	5.5	78	12
Aver conc	56	1,047	867
95% UCL	87	1,825	3,658

Lot No.	As	Cu	Pb
4	11	120	61
	12	120	33
RA	42	330	120
risk = 4.5E-06	13	420	180
	14	220	38
	19	325	195
	74	940	445
	33	1,100	160
	60	430	690
	22	360	57
	35	540	150
	16	430	49
	61	980	69
	72	1,400	110
	78	1,600	270
	66	1,300	260
	95	1,300	815
N	17	17	17
Max conc	95	1,600	815
Min conc	11	120	33
Aver conc	43	701	218
95% UCL	54	989	335



Lot No.	As	Cu	Pb
5	160	1,800	77
	78	1,400	520
RA	140	2,000	230
risk = 6.5E-06	24	190	41
	45	500	100
	35	370	60
	14	140	43
	35	410	62
	21	840	70
	83	790	80
	27	410	68
	74	1,200	99
	23	560	47
	24	100	26
	140	1,700	220
	19	280	70
	19	150	47
	68	1,700	150
	170	1,700	220
	14	150	79
	7	180	29
	30	400	130
	74	1,600	130
	76	1,200	230
	94	1,900	480
	19	220	37
	120	1,300	1,100
	109	1,900	1,613
	15	100	54
	18	270	50
N	30	30	30
Max conc	170	2000	1613
Min conc	7	100	26
Aver conc	59	849	205
95% UCL	78	1,141	826

Lot No.	As	Cu	Pb
6	5	43	25
	80	660	140
RA	75	1,700	71
risk = 7.0E-06	15	140	34
HI = 1.2	110	1,200	150
	65	825	120
	120	1,900	240
	62	2,200	210
	13	685	72
	8.2	170	39
	17	870	35
	9.9	79	64
	54	200	160
	19	570	81
	120	2,500	250
	87	1,500	100
	86	1,700	100
	100	1,800	170
	43	740	75
	115	2,900	71
	150	2,600	92
	36	790	140
	200	3,700	430
	77	1,100	200
	54	1,200	120
	76	760	135
	35	1,700	350
	62	1,300	180
	12	230	130
	110	1,300	110
	10	285	30
	7.2	150	28
	32	240	76
	130	1,400	84
N	34	34	34
Max conc	200	3700	430
Min conc	5	43	25
Aver conc	65	1,151	127
95% UCL	84	1,521	156

Lot No. 7	As	Cu	Pb
	76	1300	120
	86	1,300	130
RA	110	2,600	184
unknown	37	1,300	76
	36	730	77
	66	2,000	800
	65	230	46
	58	360	220
	89	1,500	100
	65	1,550	82
	69	2,700	150
	160	2,400	220
	64	220	95
	91	2,600	160
	73	1,100	88
	39	690	94
	180	2,700	190
	100	1,800	300
	13	910	45
	130	2,300	140
	57	340	69
	70	430	67
	69	960	160
	165	2,250	205
	68	1,000	200
	84	670	310
	79	1,200	88
	28	430	69
	32	200	73
	92	720	150
	120	2,700	250
	69	260	55
	39	430	34
	79	1,000	97
	68	1,300	130
	66	325	110
	71	6,400	320
	49	180	41
	69	1,400	140
	51	2,700	250
	27	745	76
	60	590	190
	73	300	200
	56	1,300	150
	33	340	79
	23	260	48
	61	380	110
	36	140	54
	93	1,200	210
	30	370	67
	59	140	75
	37	1,200	100
N	52	52	52
Max conc	180	6400	800
Min conc	13	140	34
Aver conc	70	1,195	144
95% UCL	78	1,468	168

Lot No. 8	As	Cu	Pb
	55	520	760
	51	1,600	98
RA	65	1,350	120
risk = 9.5E-06	23	20	63
HI = 1.5	7.9	110	28
	210	2,900	340
	38	270	225
	9.1	64	72
	43	870	99
	38	580	83
	90	1,100	130
	100	1,600	130
	32	340	67
	33	790	62
	160	3,400	180
	130	1,500	120
	28	850	83
	37	180	170
	74	290	67
	18	150	59
	250	3,500	440
	130	2,800	380
	60	410	140
	94	990	300
	280	1,500	620
	120	1,300	110
	38	130	87
	120	220	760
	79	1,300	60
	58	750	68
	370	4,800	680
	41	695	303
	59	1,800	160
	66	340	790
N	34	34	34
Max conc	370	4800	790
Min conc	7.9	20	28
Aver conc	88	1,148	231
95% UCL	114	1,575	403

Lot No. 9	As	Cu	Pb
	7	7	9
	160	8	180
RA	15	200	58
risk = 1.3E-06	10	210	34
	10	1,700	110
	110	2,400	170
	5	37	13
	6	84	35
	69	1,600	230
	39	900	72
	16	880	83
	12	140	22
	11	110	31
	65	950	180
	21	340	75
	58	580	96
	43	96	65
	45	32	95
N	18	18	18
Max conc	160	2400	230
Min conc	5	7	9
Aver conc	39	571	87
95% UCL	61	1,067	113


←STREET→
Commercial
Lot 1
Lot 2
Commercial
R
R
R
R
R
37
11
52
29
12
16
63
120
110
37
13
83
76
41
15
30
26
17
77
110
56
54
33
89
20
64
120
140
160
47
2.8
72
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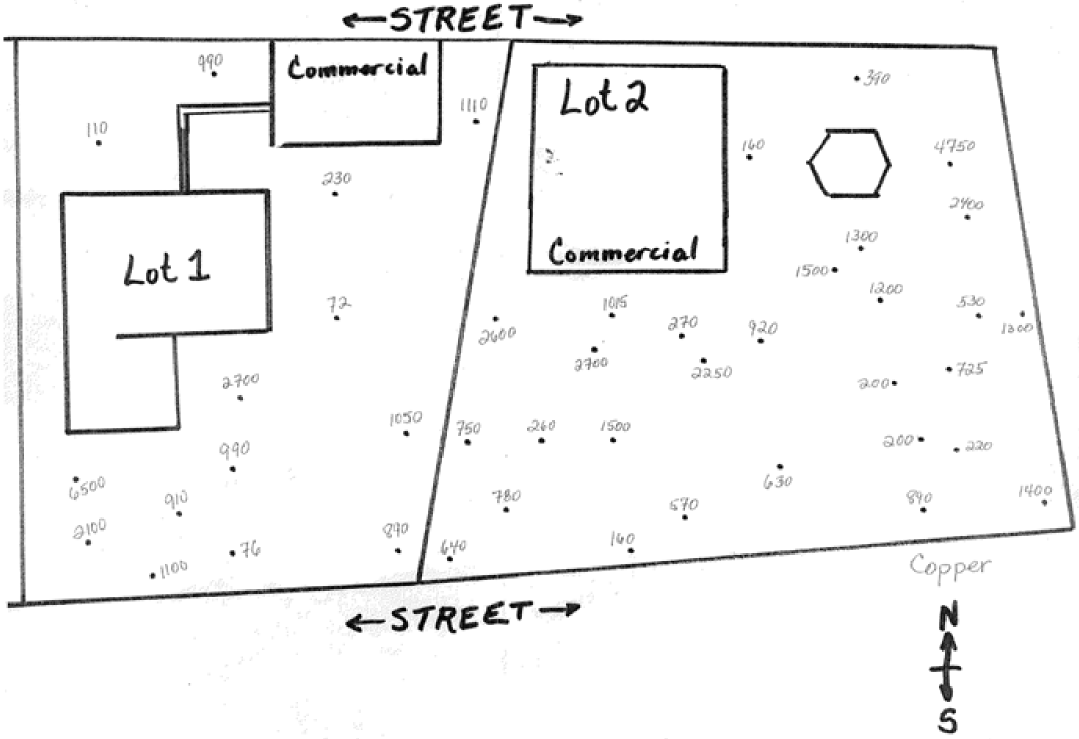
89
30
19
27
44
22
12
46
15
120
←STREET→
Arsenic
N
S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Commercial
Lot 1
Lot 2
Commercial
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110
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2700
990
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2100
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1100
76
1050
870
390
160
4750
2400
1300
1500
1200
1015
2600
270
920
530
1300
2700
2250
200
725
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1500
200
220
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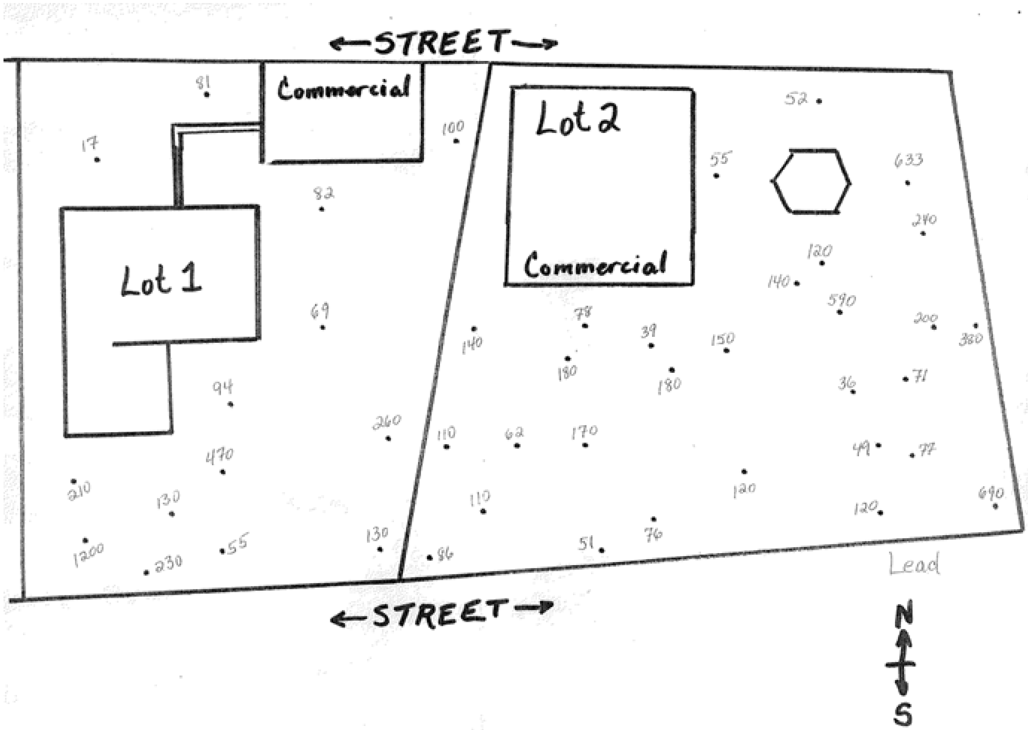
780
570
890
1400
640
160
←STREET→
Copper
N
S



←STREET→
Commercial
Lot 1
Lot 2
Commercial
←STREET→
Lead
N
S
81
17
100
82
69
94
260
470
210
130
1200
230
55
130
52
55
633
240
120
140
590
200
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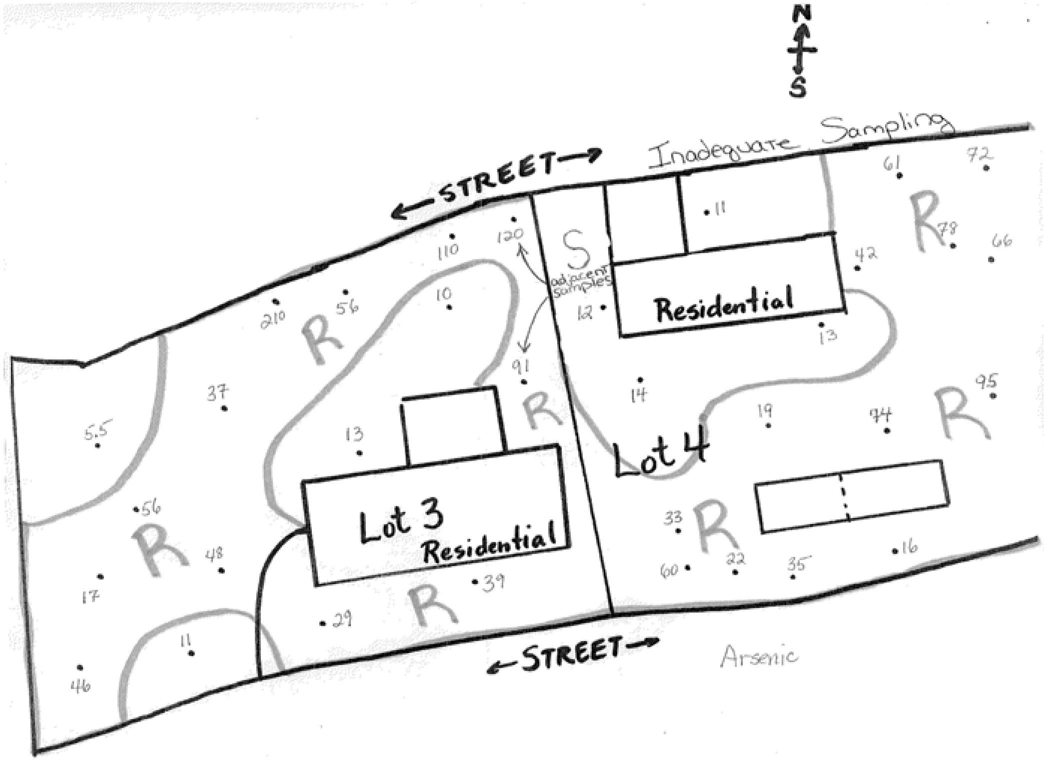
690
86
51
76



N
S
Inadequate Sampling
←STREET→
S
adjacent samples
Residential
Lot 3
Residential
Lot 4
R
R
R
R
R
R
←STREET→
Arsenic
110
120
11
61
72
78
66
42
210
56
10
12
13
91
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5.5
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11
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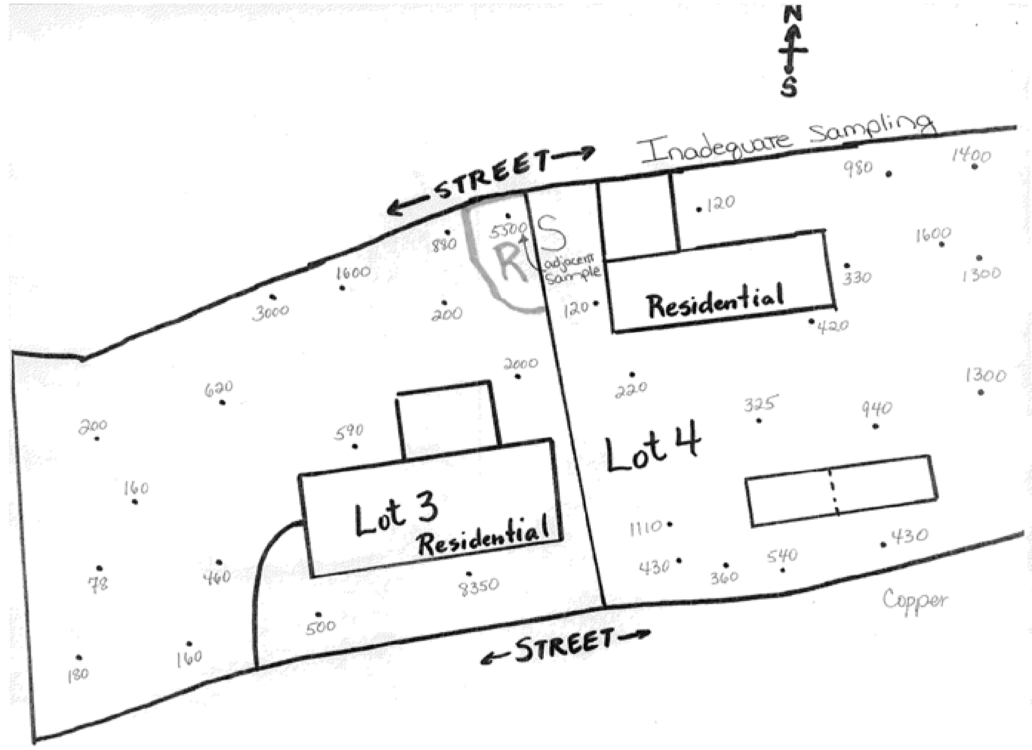
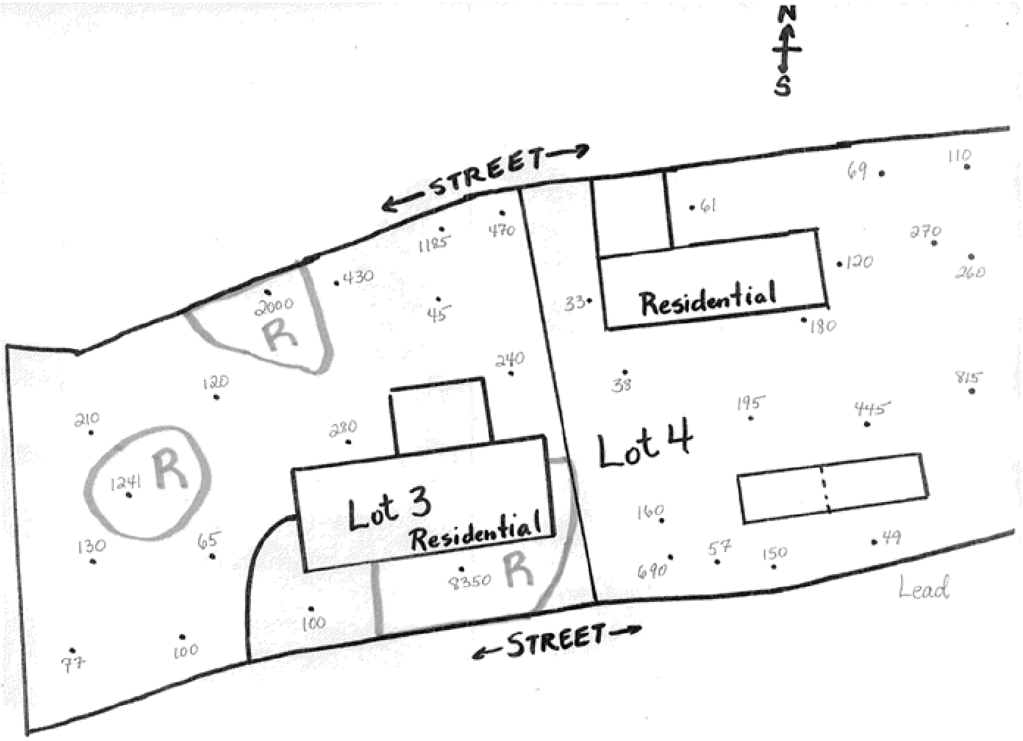

N
S
STREET
Inadequate Sampling
980
1400
120
1600
1300
330
420
Residential
5500
S
R
Adjacent Sample
880
1600
3000
200
120
2000
620
200
590
220
325
940
1300
Lot 4
160
Lot 3
Residential
1110
430
540
430
78
460
8350
360
Copper
500
STREET
180
160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S
STREET
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61
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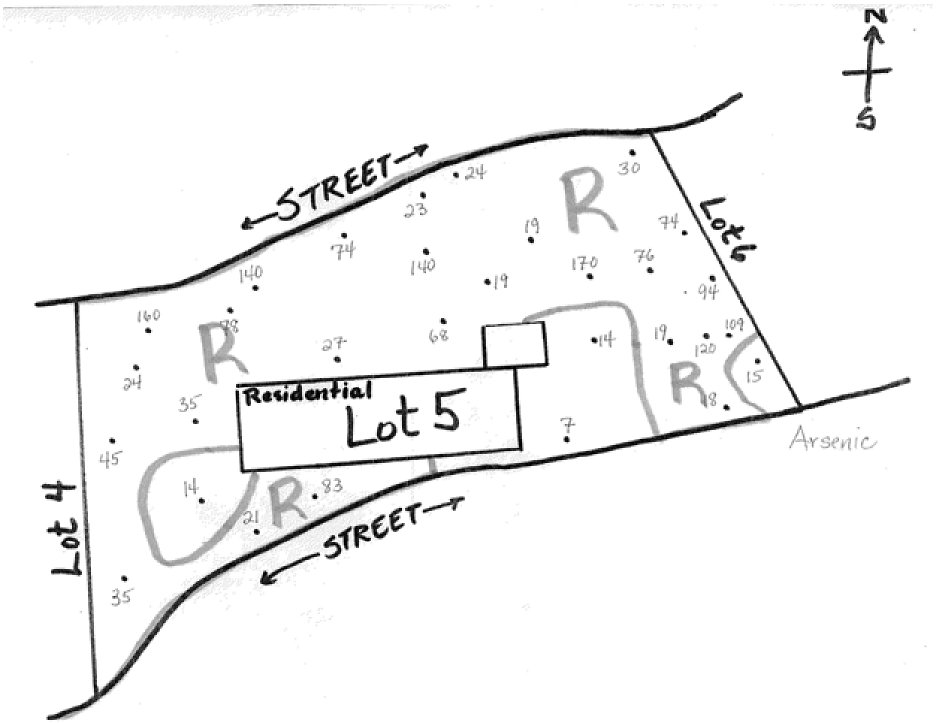
270
120
260
2000
R
45
33
Residential
180
240
38
815
120
195
445
210
220
Lot 4
1241
R
Lot 3
Residential
160
130
65
57
150
49
8350
R
690
Lead
100
STREET
77
100


N
S
STREET
STREET
Lot 4
Lot 6
Residential
Lot 5
R
R
R
R
Arsenic
24
30
23
19
74
74
140
140
19
170
76
94
160
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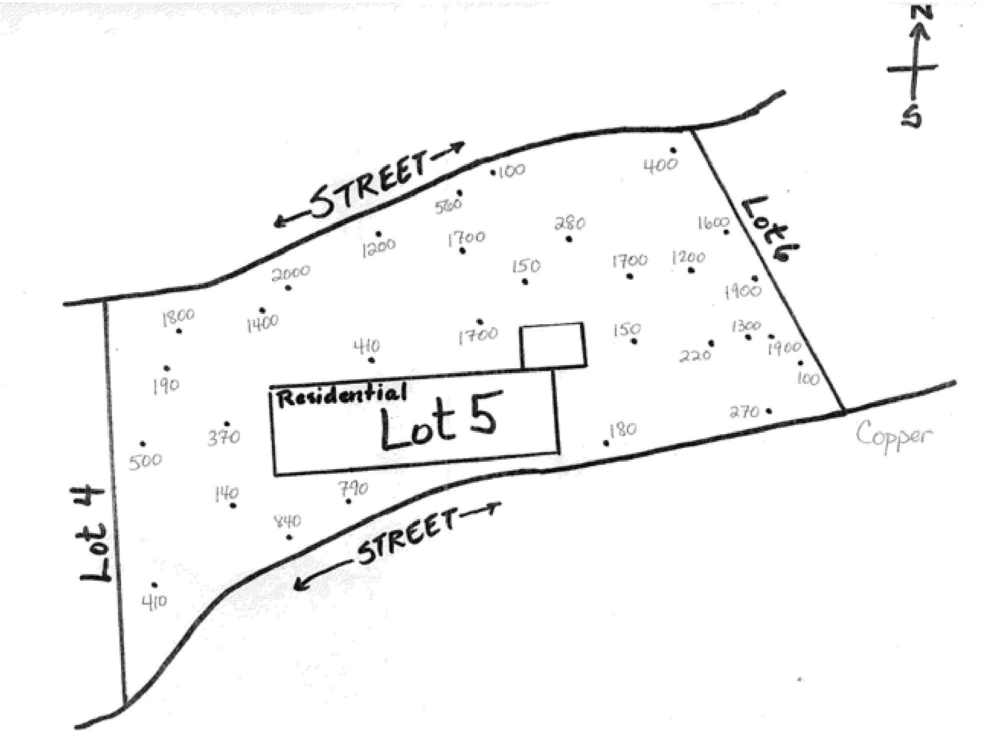
35


N
S
STREET
STREET
Lot 4
Lot 6
Residential
Lot 5
Copper
100
400
560
280
1600
1200
1700
1200
2000
150
1700
1900
1800
1400
410
1700
150
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220
1900
100
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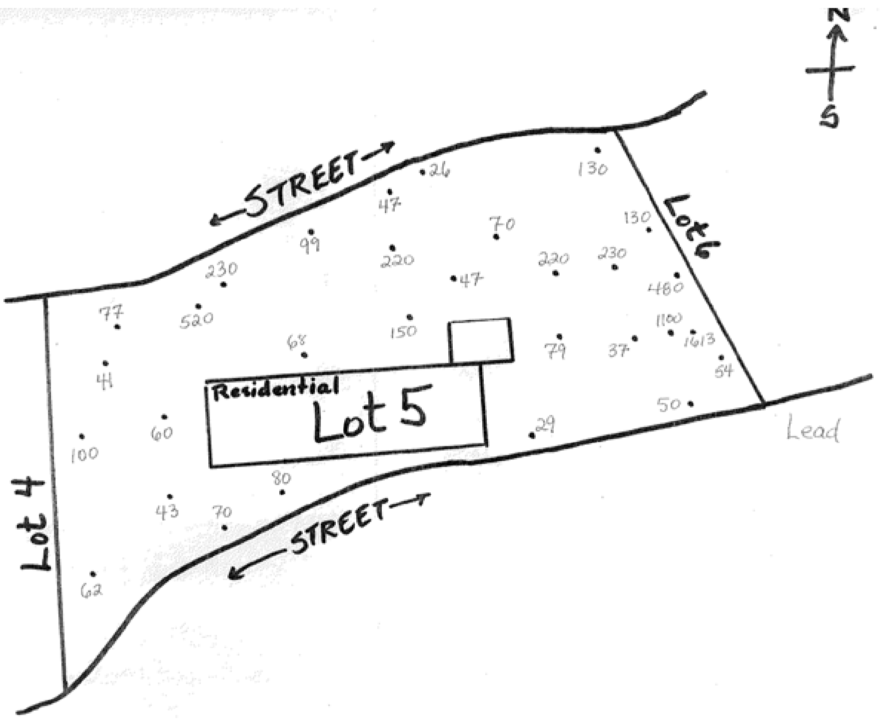
270
370
180
500
140
790
840
410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S
←STREET→
Lot 6
Lot 4
Residential
Lot 5
←STREET→
Lead
26
130
47
130
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99
230
220
220
230
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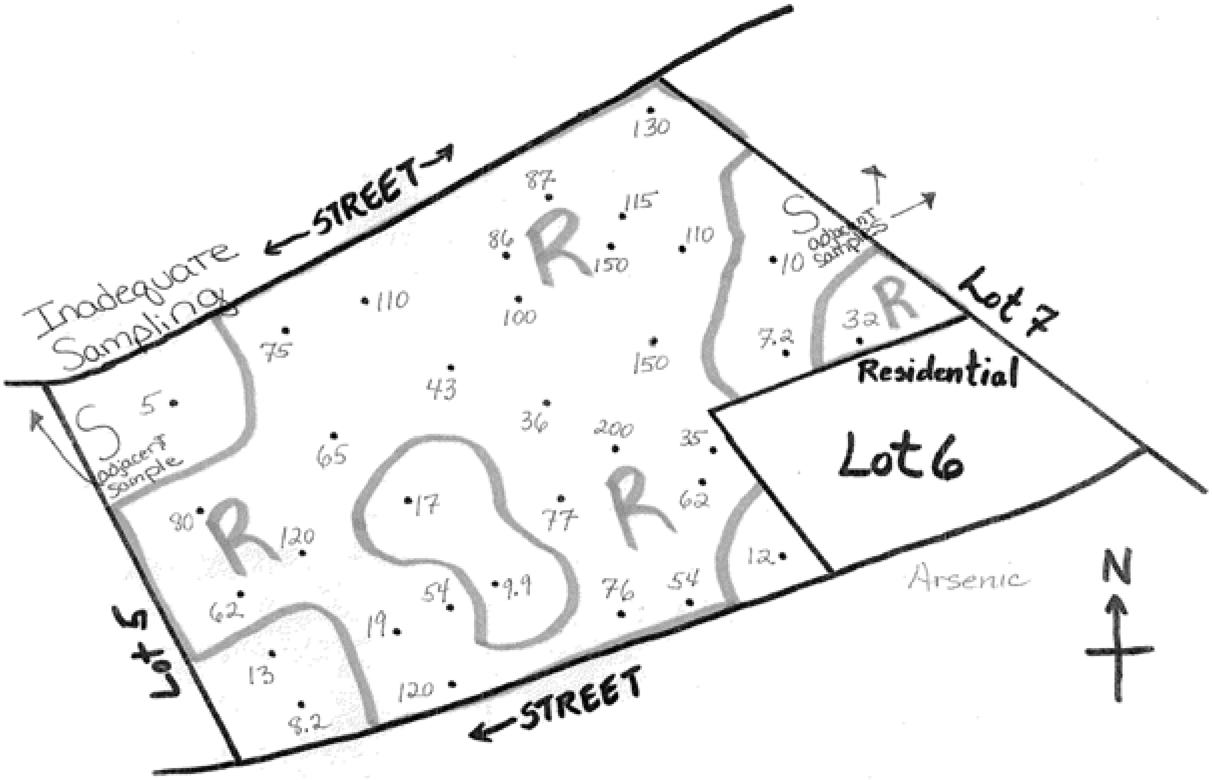
100
80
43
70
62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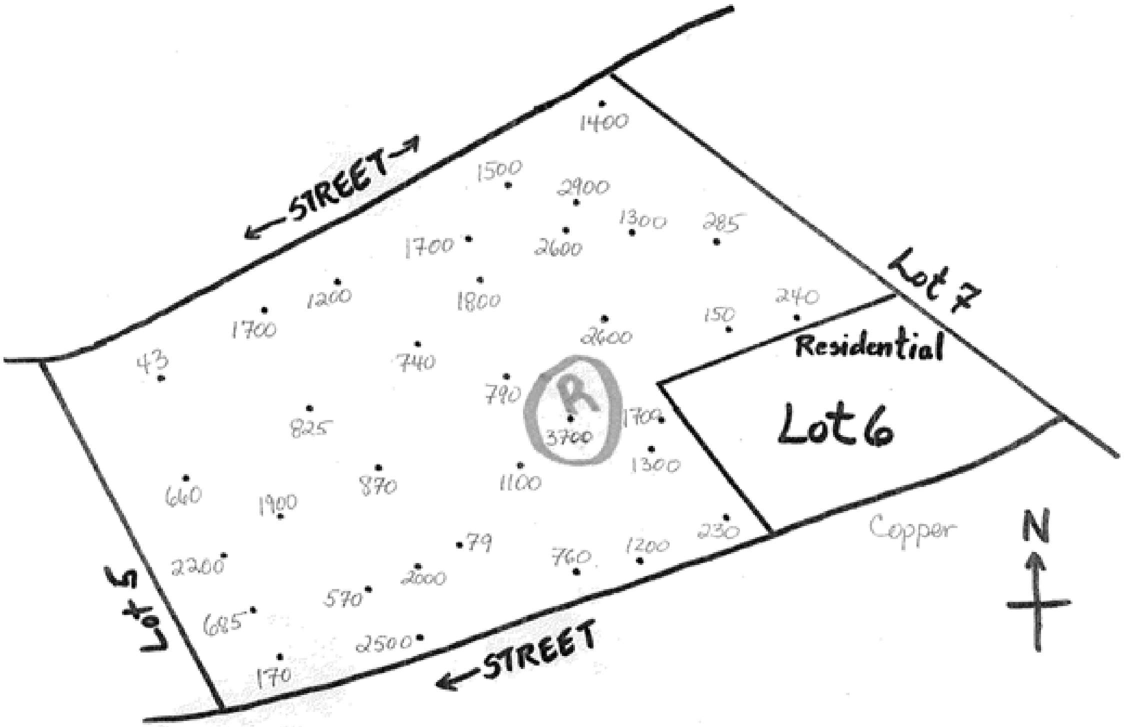
Inadequate Sampling
130
87
115
86
R
110
150
S
adjacent samples
10
110
100
R
Lot 7
75
7.2
32
Residential
150
5
S
adjacent sample
43
36
200
35
Lot 6
65
80
R
17
77
R
62
120
12
54
9.9
76
54
Arsenic
N
62
19
Lot 5
13
120
←STREET
8.2



←STREET→
1400
1500
2900
1300
285
1700
2600
Lot 7
1200
1800
240
1700
150
43
740
2600
Residential
790
R
1700
825
3700
Lot 6
1300
640
1900
870
1100
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Copper
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79
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1200
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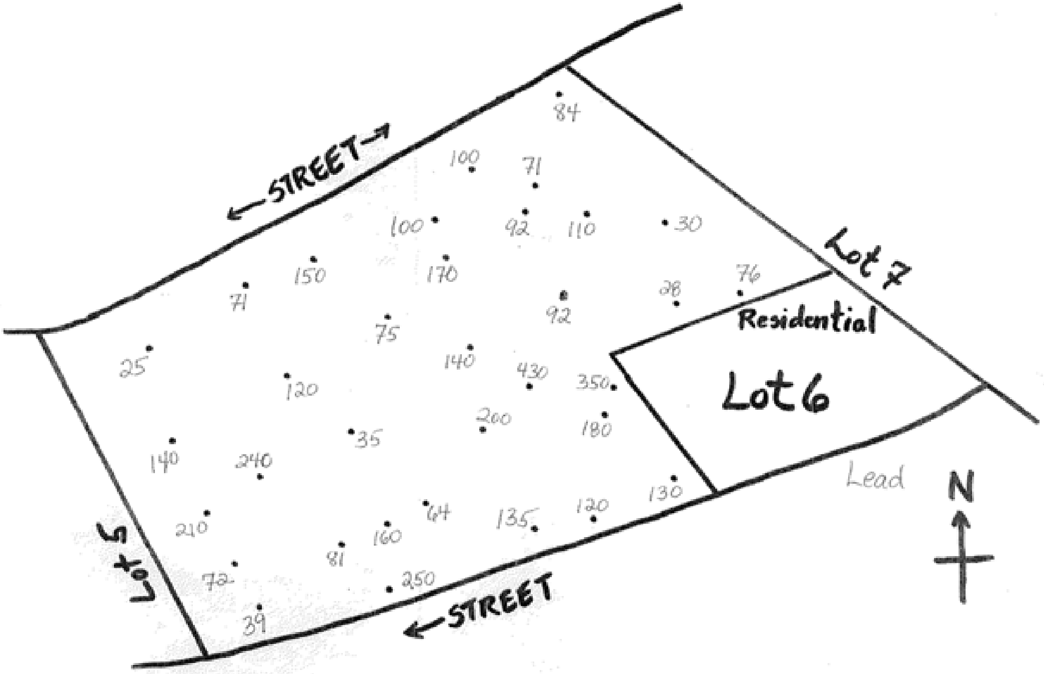
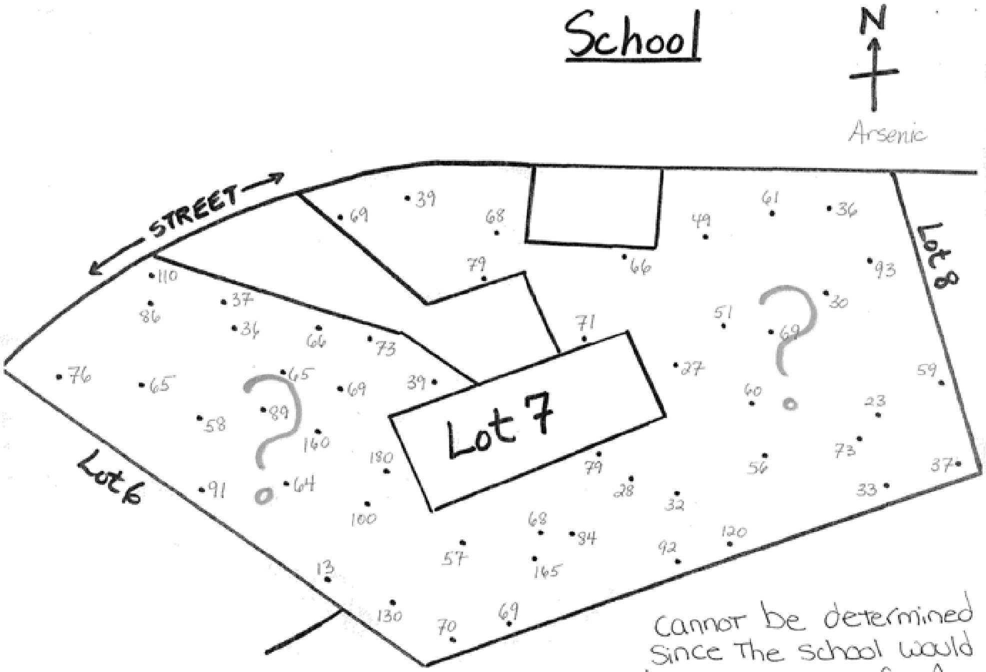
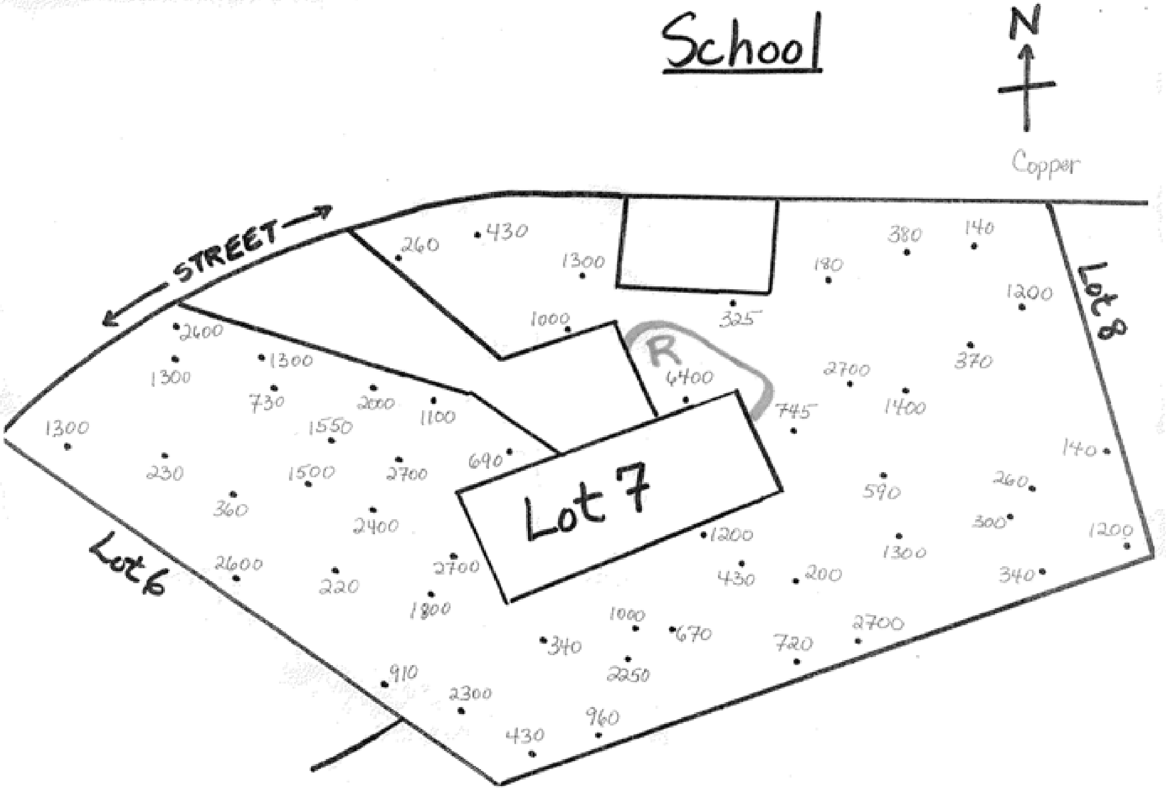
570
2000
Lot 5
2500
170
←STREET

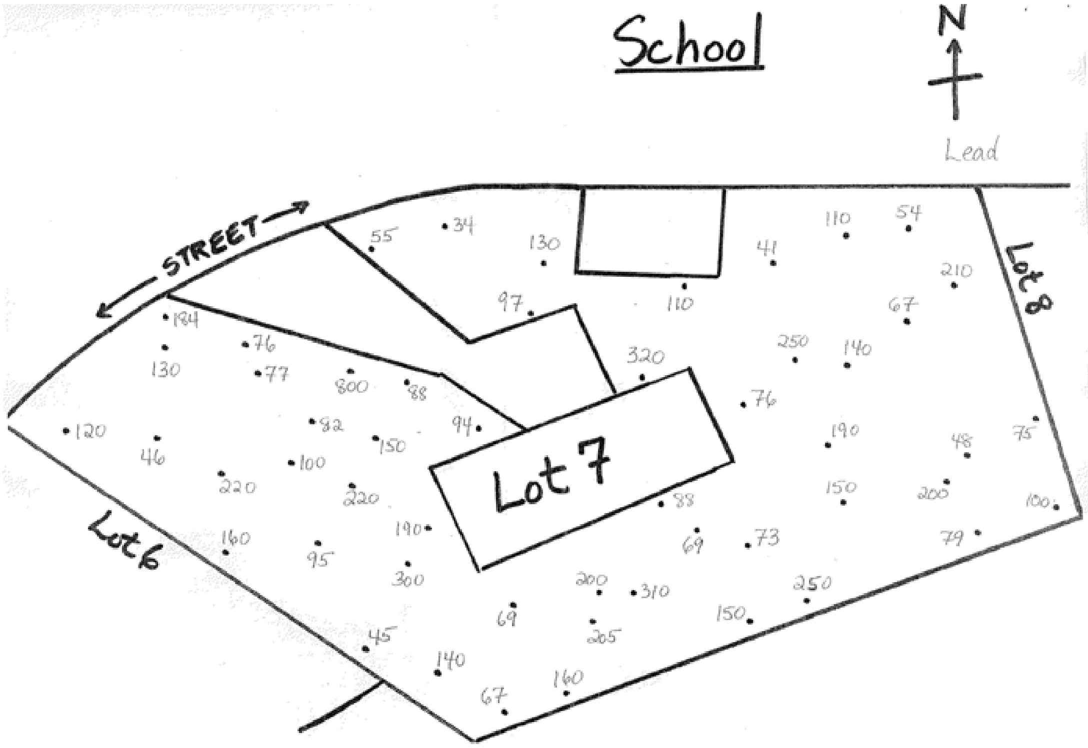


←STREET→
84
100
71
100
92
110
30
150
170
Lot 7
71
38
76
92
Residential
75
25
140
120
430
350
Lot 6
35
200
180
140
240
130
Lead
N
210
64
135
120
160
81
72
250
Lot 5
39
←STREET

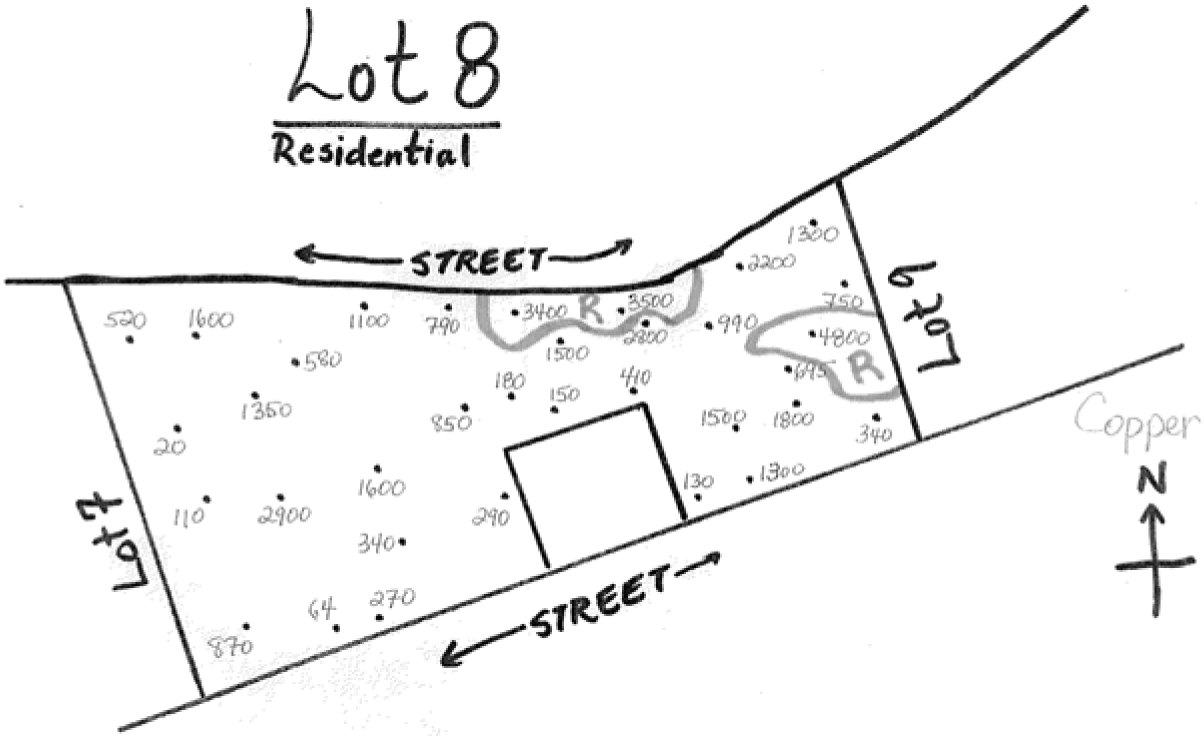


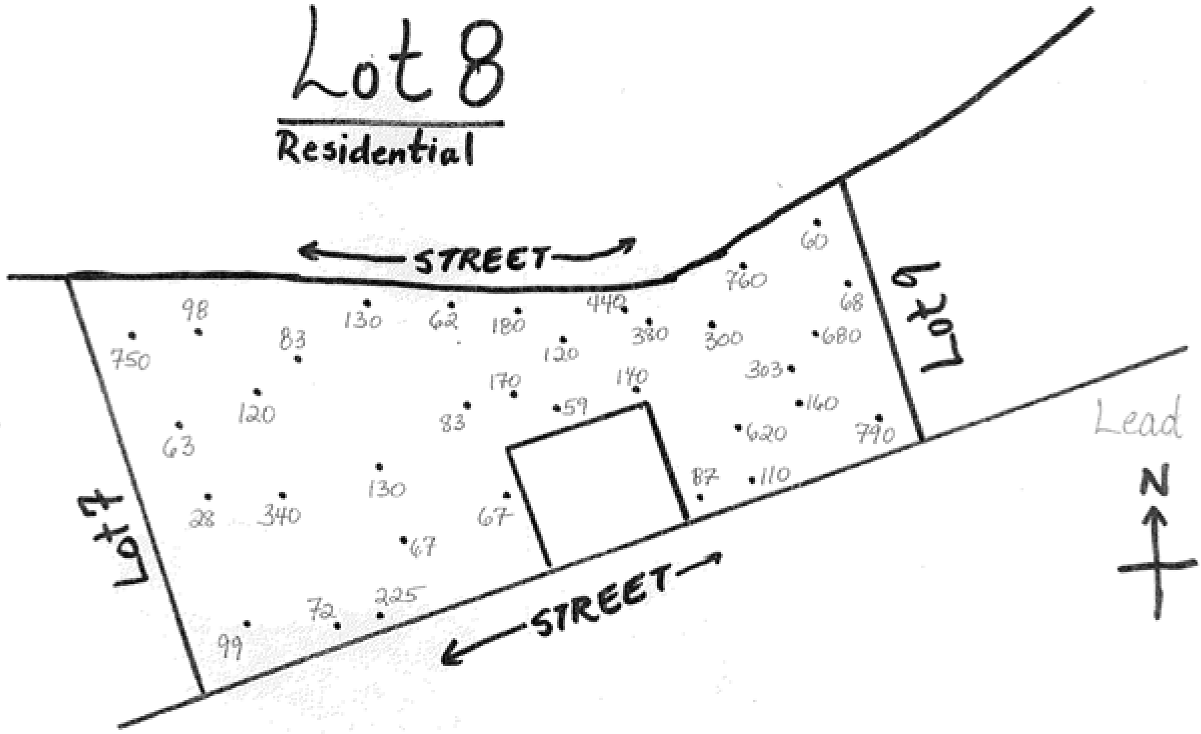
Cannot be determined Since The school would have a site-specific As number different from residential or commercial




School
N
Lead
STREET
Lot 7
Lot 6
Lot 8
55
34
130
110
54
41
210
97
110
67
184
76
130
77
800
88
250
140
320
76
120
46
82
150
94
190
48
75
100
220
220
150
200
100
88
160
95
190
300
69
73
79
200
310
250
69
205
150
45
140
160
67


Lot 8
Residential
Inadequate Sampling
STREET
Lot 9
Lot 7
Arsenic
N
79
130
58
51
90
33
160
250
94
370
55
38
R
37
130
130
R
41
65
18
60
23
28
280
59
66
100
38
120
210
74
S7.9
adjacent samples
32
R
9.1
38
43
STREET


Lot 8
Residential
STREET
STREET
Lot 7
Lot 9
Copper
N
R
R
520
1600
1100
790
3400
3500
2200
1300
750
990
4800
2800
1500
580
180
150
410
695
1350
850
1500
1800
340
20
1600
130
1300
110
2900
290
340
64
270
870


Lot 8
Residential
STREET
STREET
Lot 7
Lot 9
Lead
N
60
760
98
130
62
180
440
68
750
83
120
380
300
680
170
140
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83
59
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790
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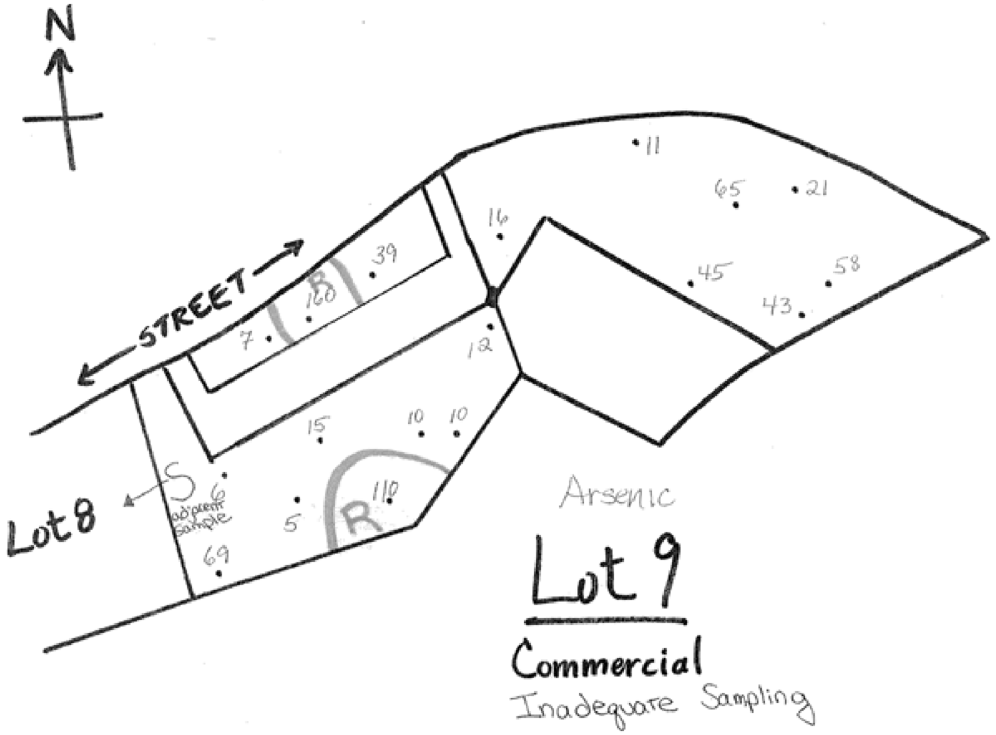
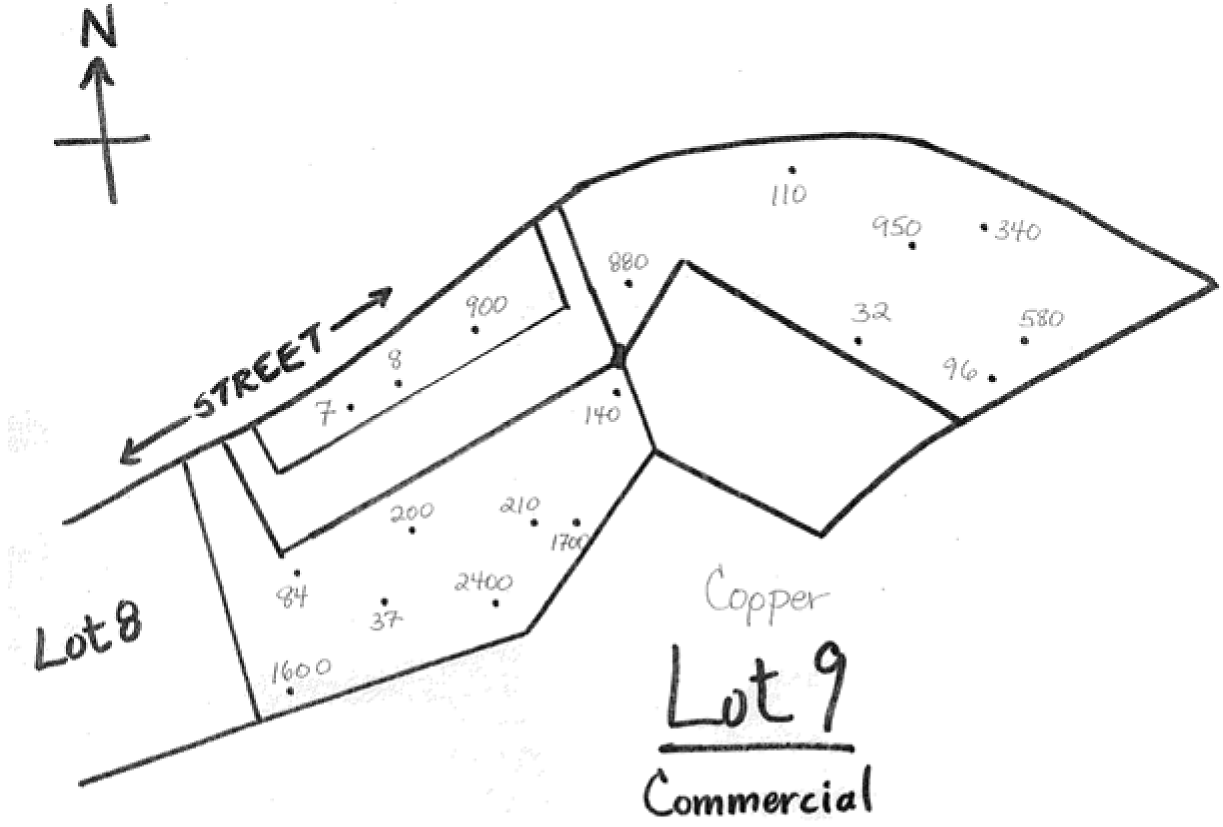
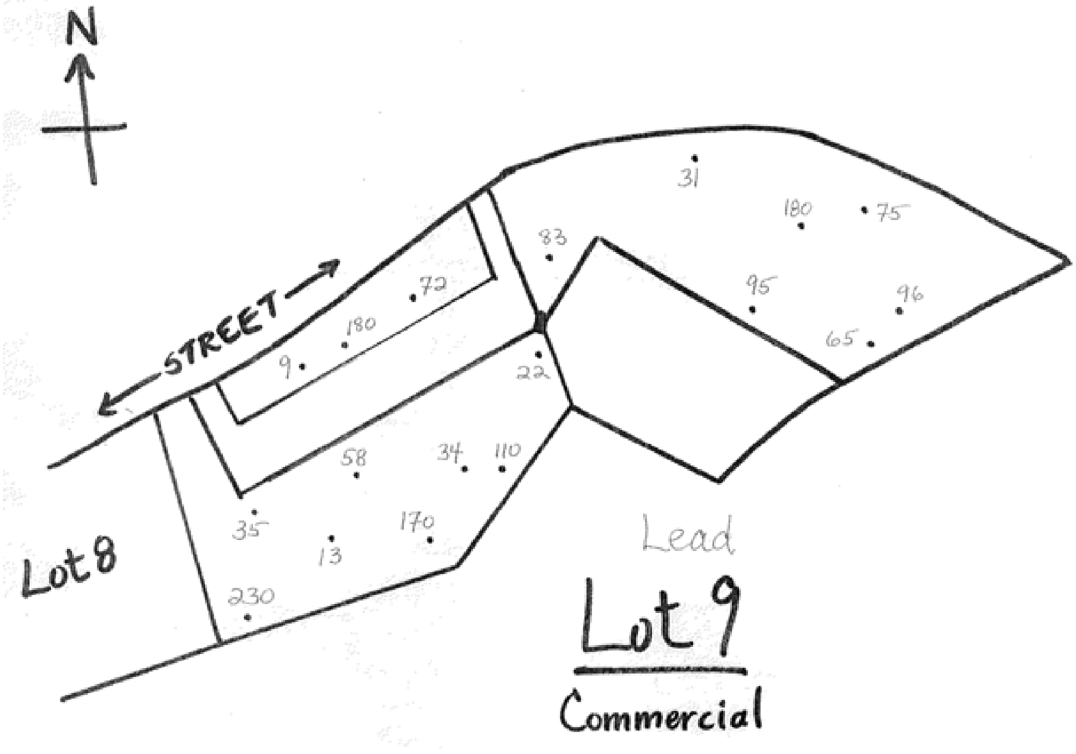
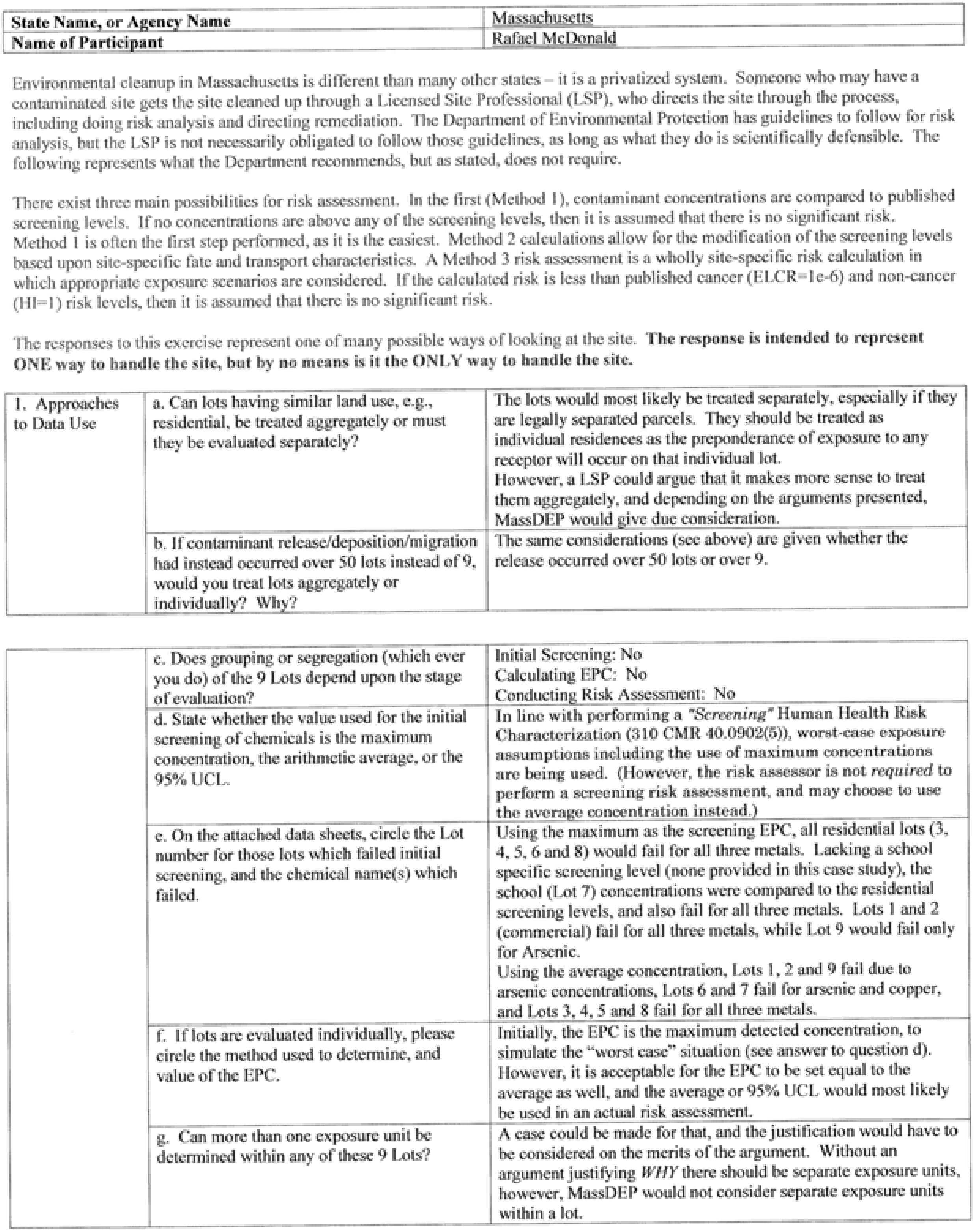
28
340
67
67
72
225
99


N
STREET
11
65
21
16
39
R
160
7
45
58
43
12
15
10
10
S
adjacent sample
6
5
110
R
69
Lot 8
Arsenic
Lot 9
Commercial
Inadequate Sampling


N
110
950
340
880
900
STREET
8
7
32
580
96
140
200
210
1700
84
2400
37
1600
Lot 8
Copper
Lot 9
Commercial


N
31
180
75
83
72
95
96
STREET
180
9
22
65
58
34
110
35
170
13
Lot 8
230
Lead
Lot 9
Commercial

C.2.6 Second Comparative Case Study—Massachusetts Respondent



State Name, or Agency Name	Massachusetts
Name of Participant	Rafael McDonald

Environmental cleanup in Massachusetts is different than many other states – it is a privatized system. Someone who may have a contaminated site gets the site cleaned up through a Licensed Site Professional (LSP), who directs the site through the process, including doing risk analysis and directing remediation. The Department of Environmental Protection has guidelines to follow for risk analysis, but the LSP is not necessarily obligated to follow those guidelines, as long as what they do is scientifically defensible. The following represents what the Department recommends, but as stated, does not require.

There exist three main possibilities for risk assessment. In the first (Method 1), contaminant concentrations are compared to published screening levels. If no concentrations are above any of the screening levels, then it is assumed that there is no significant risk. Method 1 is often the first step performed, as it is the easiest. Method 2 calculations allow for the modification of the screening levels based upon site-specific fate and transport characteristics. A Method 3 risk assessment is a wholly site-specific risk calculation in which appropriate exposure scenarios are considered. If the calculated risk is less than published cancer (ELCR=1e-6) and non-cancer (HI=1) risk levels, then it is assumed that there is no significant risk.

The responses to this exercise represent one of many possible ways of looking at the site. **The response is intended to represent ONE way to handle the site, but by no means is it the ONLY way to handle the site.**

1. Approaches to Data Use	a. Can lots having similar land use, e.g., residential, be treated aggregately or must they be evaluated separately?	The lots would most likely be treated separately, especially if they are legally separated parcels. They should be treated as individual residences as the preponderance of exposure to any receptor will occur on that individual lot. However, a LSP could argue that it makes more sense to treat them aggregately, and depending on the arguments presented, MassDEP would give due consideration.
	b. If contaminant release/deposition/migration had instead occurred over 50 lots instead of 9, would you treat lots aggregately or individually? Why?	The same considerations (see above) are given whether the release occurred over 50 lots or over 9.
	c. Does grouping or segregation (which ever you do) of the 9 Lots depend upon the stage of evaluation?	Initial Screening: No Calculating EPC: No Conducting Risk Assessment: No
	d. State whether the value used for the initial screening of chemicals is the maximum concentration, the arithmetic average, or the 95% UCL.	In line with performing a *"Screening"* Human Health Risk Characterization (310 CMR 40.0902(5)), worst-case exposure assumptions including the use of maximum concentrations are being used. (However, the risk assessor is not *required* to perform a screening risk assessment, and may choose to use the average concentration instead.)
	e. On the attached data sheets, circle the Lot number for those lots which failed initial screening, and the chemical name(s) which failed.	Using the maximum as the screening EPC, all residential lots (3, 4, 5, 6 and 8) would fail for all three metals. Lacking a school specific screening level (none provided in this case study), the school (Lot 7) concentrations were compared to the residential screening levels, and also fail for all three metals. Lots 1 and 2 (commercial) fail for all three metals, while Lot 9 would fail only for Arsenic. Using the average concentration, Lots 1, 2 and 9 fail due to arsenic concentrations, Lots 6 and 7 fail for arsenic and copper, and Lots 3, 4, 5 and 8 fail for all three metals.
	f. If lots are evaluated individually, please circle the method used to determine, and value of the EPC.	Initially, the EPC is the maximum detected concentration, to simulate the "worst case" situation (see answer to question d). However, it is acceptable for the EPC to be set equal to the average as well, and the average or 95% UCL would most likely be used in an actual risk assessment.
	g. Can more than one exposure unit be determined within any of these 9 Lots?	A case could be made for that, and the justification would have to be considered on the merits of the argument. Without an argument justifying *WHY* there should be separate exposure units, however, MassDEP would not consider separate exposure units within a lot.

	h. Had all the samples within a lot been composited in equal volume aliquots, would you use the average concentration shown for the EPC?	The concentration of a composite soil sample may be used to approximate the arithmetic average of the subsample concentrations. However, the concentration detected in a composite is representative of the average concentration of subsamples only if: (1) the subsamples are representative of the exposure area (2) the composite sample is well mixed and (3) the process of compositing does not result in analyte loss. These conditions can be verified by comparing the average concentration of a set of single location samples with the concentration of a composite of sample collected from the same area. If a composite sample from one area is checked in this manner and demonstrated to be accurate for each sampling event, it is not necessary to check all composites from all areas.
2. Data Needs	a. Indicate on the Lot Maps which lots have an inadequate sampling density to meet the data quality requirements for a risk assessment.	All sampling densities are adequate.
	b. State the density or frequency of sampling required, and mark the area on the map needing further sampling as "S".	Massachusetts does not proscribe a specific sampling density. However, as a rule of thumb, MassDEP believes that in order to assess both the central tendency and the variability of the concentrations at a location, a minimum of three (3) must be taken for each contaminated medium. This value is considered a ***bare minimum*** for a small, simple release at a small (< 3 acres) site.
	c. Indicate on the Lot Map whether additional sampling is dependent upon the concentration of an adjacent sample, land use, or other.	Additional samples may be necessary to identify the presence or absence of "Hot Spots."
3. Risk Assessment	a. Please write RA under each Lot No. on the Data Sheets for those lots eligible to conduct a site-specific risk assessment.	An LSP always has the option of performing a site-specific risk assessment. Seeing that all of the lots failed a comparison to screening concentrations (similar in some ways to a Method 1 Risk Assessment, but VERY different in other ways), all of the lots would be eligible.

<table>
<tr>
<td></td>
<td>A reverse risk assessment has been conducted which shows the following site-specific concentrations at the indicated ELCR or hazard index. Does any chemical on any lot now become eliminated from any further consideration? Please state which Lots based on which chemical.
<table>
<tr><td></td><td colspan="2">Residential</td><td colspan="2">Commercial</td></tr>
<tr><td>Chemical</td><td>10 ⁻⁶</td><td>HI = 1</td><td>10 ⁻⁶</td><td>HI = 1</td></tr>
<tr><td>Arsenic</td><td>12</td><td>33</td><td>48</td><td>390</td></tr>
<tr><td>Copper</td><td>▨</td><td>3,100</td><td>▨</td><td>5,800</td></tr>
<tr><td>Lead *</td><td colspan="2">400</td><td colspan="2">1,000</td></tr>
</table>
*Based on achieving target blood lead level by pharmacokinetic modeling.</td>
<td>No. The only way that a Chemical of Concern can be eliminated from a risk assessment is to be below background levels. All lots had both maxima and averages that were above the prescribed background concentrations. Risks, based on ELCRs and HI's for <i><u>individual</u></i> chemicals, are not considered.

IT IS ASSUMED THAT THESE CONCENTRATIONS ARE INDICATIVE OF RISK USING APPROPRIATE AGE EXPOSURE PARAMETERS AND TOXICITY INFORMATION.</td>
</tr>
<tr>
<td></td>
<td>b. Using the table above, please calculate the cumulative health risk and hazard for those lots which exceeded the applicable cleanup levels. Write in on Data Sheets under Lot No.</td>
<td>
<table>
<tr><td>LOT</td><td>ELCR (x10⁻⁵)</td><td>HI</td></tr>
<tr><td>1</td><td>0.3</td><td>0.6</td></tr>
<tr><td>2</td><td>0.3</td><td>0.5</td></tr>
<tr><td>3</td><td>2.8</td><td>4.2</td></tr>
<tr><td>4</td><td>0.9</td><td>2.1</td></tr>
<tr><td>5</td><td>1.0</td><td>2.5</td></tr>
<tr><td>6</td><td>0.9</td><td>3.8</td></tr>
<tr><td>7</td><td>0.9</td><td>2.9</td></tr>
<tr><td>8</td><td>1.3</td><td>3.6</td></tr>
<tr><td>9</td><td>0.2</td><td>0.3</td></tr>
<tr><td></td><td></td><td></td></tr>
</table>
Cells highlighted in red indicate a cumulative risk higher than allowed in a Method 3 Risk Assessment.</td>
</tr>
<tr>
<td></td>
<td>c. Were all chemicals included, even if eliminated in the initial screening or screening against the EPC?</td>
<td>If risk is being calculated (a Method 3 Risk Assessment), then a chemical can only be eliminated from the risk assessment if the exposure point concentration is consistent with background. As all of the average concentrations for each lot were above background, they were all included in the risk assessments for all lots.</td>
</tr>
</table>

ITRC HYPOTHETICAL CASE STUDY QUESTIONS

	d. Was the non-carcinogenic arsenic contribution to the hazard quotient included?	Yes. Since a concentration corresponding to an HQ of 1 could be back calculated, it has to be assumed that appropriate toxicity information was available.
	e. Was lead considered separately or combined by some method for contribution to the overall health hazard?	Lead was treated the same as the other chemicals. LSPs in Massachusetts have the option of using the IEUBK model or using Reference Doses and Cancer Slope factors as is done for any other chemical.
	f. Federal guidance suggests that arsenic and lead have greater than additive effects on neurological toxicity. How would you account for this:	(i) quantitatively in the risk characterization calculation; X (ii) qualitatively in the uncertainty section; X (iii) use this information in setting risk management decision and final cleanup goals; (iv) other:
	g. Do you account for the contribution of background levels in the risk characterization? Indicate if the level of risk due to background is:	X (i) quantitated and combined with the risk estimate due to the contaminant release; If the concentration is below background concentration (which none are in this case study) is can be eliminated from the risk assessment. Otherwise, it is included. (ii) is quantitated and not included with the overall risk estimate, but used in risk management decision-making; (iii) discussed qualitatively in the uncertainty section only; (iv) other:
3. Risk Management Decisions	a. For those lots having the EPC in exceedance of the site-specific cleanup level, do you remediate the whole lot for that chemical or just portions? If portions, circle the areas on Lot Maps as "R".	The LSP with the PRP makes the decision of how to bring the site into compliance.

ITRC HYPOTHETICAL CASE STUDY QUESTIONS

	b. Is the remediation different had the site-specific risk assessment not been conducted?	A site specific risk assessment is always required, even if that is comparing the site-specific EPCs to our Method 1 standards.
	c. What elements of this site would you require to be discussed in the uncertainty section of the risk assessment, and would any elements result in a determination of a more stringent cleanup level for 1 or more chemicals?	
	d. How was the school lot treated differently in this scenario?	Since Massachusetts does not have school specific Method 1 standards, the school concentrations were compared to residential numbers, which would be considered appropriately conservative. To calculate risk (Method 3), a case could be made for using different exposure parameters, and MassDEP's decision to accept those parameters and resulting risk calculations would be dependent upon the strength of the arguments made to do so.

C.2.7 Second Comparative Case Study—Joint Submittal from Representatives from Army, Navy And Air Force

Combined: All services agree that 95% UCL should be used as the EPC.

g. Can more than one exposure unit be determined within any of these 9 lots?

Combined: While none of the services have specific guidance on this issue, the majority concurred with the concept that only one exposure unit would be evaluated per lot. The site-specific determination would be made based on the CSM.

h. Had all the samples within a lot been composited in equal volume aliquots, would you use the average concentration shown for the EPC?

Combined: None of the services have specific guidance on this issue. Answers varied from an exclusive dependence on discrete samples to referring to the discretion of the specific project personnel. If the data is a composited sample(s), one would have no other choice but to use the mean.

2. Data Needs.

a. Indicate on the lot maps which lots have an inadequate sampling density to meet the data quality requirements for a risk assessment.

Combined: While none of the services have guidance specifically addressing this issue, it was agreed that the sampling depicted represents an adequate database to evaluate risk from exposure to the surface soils.

b. State the density or frequency of sampling required, and mark the area on the map needing further sampling as "S".

Combined: While none of the services have guidance specifically addressing this issue, it was agreed that the sampling depicted represents an adequate database to evaluate risk from exposure to the surface soils.

c. Indicate on the lot map whether additional sampling is dependent upon the concentration of an adjacent sample, land use, or other.

Combined: None of the services have guidance specifically addressing this issue. The services felt that the sampling of the area was adequate, and thus would most likely not request additional sampling. If additional sampling was desired, a scientific basis should be used to justify the sampling.

3. Risk Assessment.

a. Please write RA under each lot no. on the data sheets for those lots eligible to conduct a site-specific risk assessment.

Combined: All the services agreed that all of the lots would require further evaluation. The majority of the services would suggest screening the site again with site-specific RBCs prior to a site-specific risk assessment.

a+. A reverse risk assessment has been conducted which shows the following site-specific concentrations at the indicated ELCR or hazard index. Does any chemical on any lot now become eliminated from any further consideration? Please state which lots based on which chemical.

Combined: The majority of the services would use a reverse risk assessment value to screen out additional chemicals or sites. One of the services only uses reverse risk assessment to set cleanup goals after the baseline risk assessment.

b. Using the table above, please calculate the cumulative health risk and hazard for those lots which exceeded the applicable cleanup levels. Write in on data sheets under lot no.

Combined: While the actual risk values varied slightly between the services due to the differences in inclusion or elimination of certain chemical, threshold exceedances (or non-exceedances) were identical between the services. Carcinogenic risk exceeded the NCP point of departure but not the range deemed acceptable by the NCP. Non-carciogenic hazard indeces exceeded the threshold for lots 3 through 8, due mainly to arsenic.

c. Were all chemicals included, even if eliminated in the initial screening or screening against EPC?

Combined: All the services agreed that once a chemical was eliminated, it was not considered further in the evaluation.

d. Was the non-carcinogenic arsenic contribution to the hazard quotient included?

Combined: All services agreed that arsenic non-carcinogenic contribution was included.

e. Was lead considered separately or combined by some method for contribution to the overall health hazard?

Combined: All services agreed that lead should be evaluated separately.

f. Federal guidance suggests that arsenic and lead have greater than additive effects on neurological toxicity. How would you account for this?

Combined: While the services did not have specific guidance on this issue, all agreed that accounting for any synergistic effects other than additivity would be uncommon due to the lack of specific EPA guidance on issue and lack of information in IRIS to quantify synergism.

g. Do you account for contribution of background levels in the risk characterization? Indicate if the level of risk due to background is:

Combined: All the services use background in a similar manner. Site chemical concentrations that do not exceed their background values are eliminated from further evaluation. However, background concentrations are not used to adjust site concentrations that exceed background.

4. Risk Management Decisions

a. For those lots having the EPC in exceedance of the site-specific cleanup level, do you remediate the whole lot for that chemical or just a portion? If portions, circle the areas on lot maps as "R".

Combined: While one service had specific guidance, all the services agreed that remediation goals must be developed and applied in the context of exposure area and the exposure point concentration. It is not necessary to remediate all media to or below the remediation goal.

b. Is the remediation different had the site–specific risk assessment not been conducted?

Combined: While none of the services had specific guidance on this issue, site remediation could have differed significantly due to the performance or non-performance of a risk assessment. Initial screening exceedances may have triggered a cleanup action, whereas, the risk assessment results could have been interpreted to show that the risks were "acceptable". Such determinations would be at the discretion of the project personnel.

c. What elements of this site would you require to be discussed in the uncertainty section of the risk assessment, and would any elements result in a determination of a more stringent cleanup level for 1 or more chemicals?

Combined: While none of the services has specific guidance on requirements for the uncertainty section, all agreed that the elements of the risk assessment should be addressed in an uncertainty analysis.

d. How was the school lot treated differently in this scenario?

Combined: The services would treat this exposure as a residence or possibly create an exposure scenario consistent with a school. This determination would be made at the discretion of the project personnel.

The views expressed in this presentation are those of the author and do not reflect the official policy or position of the Department of Army, Department of the Navy, Department of the Air Force, Department of Defense, or the U.S. Government.

In hard copies, Appendices A–C are provided only on the accompanying CD

Appendix A. Detailed Information on State Approaches to the Use of Background
Appendix B. Detailed Case Studies
Appendix C. Comparative Case Studies

Appendix D

Risk Assessment Resources Team Contacts

RISK ASSESSMENT RESOURCES TEAM CONTACTS

Stephen DiZio, Team Co-Leader
CalEPA Dept. of Toxic Substances Control
916-255-6634
sdizio@dtsc.ca.gov

Brian C. Espy, Team Co-Leader
Alabama Dept. of Environmental Management
334-271-7749
bespy@adem.state.al.us

Smita Siddhanti, Program Advisor
EnDyna, Inc.
703-848-8840
Siddhanti@endyna.com

David Bell
Air Force Institute for Operational Health
210-536-5553
david.bell@brooks.af.mil

Marlena Brewer
Alaska Dept. of Environmental Conservation
907-269-3084
marlena.brewer@alaska.gov

Jim Brown
Georgia Environmental Protection Div.
404-656-7802
jim_brown@dnr.state.ga.us

Anna H. Butler
U.S. Army Corps of Engineers
912-652-5515
anna.h.butler@usace.army.mil

Frank Camera
New Jersey Dept. of Environmental Protection
609-633-7840
Frank.Camera@dep.state.nj.us

Fran Collier
CalEPA Dept. of Toxic Substances Control
916-255-6431
fcollier@dtsc.ca.gov

Jennifer Corack
Navy and Marine Corps Public Health Center
757-953-0950
jennifer.corack@med.navy.mil

Kurt Frantzen
Kleinfelder
860-683-4200
kfrantzen@kleinfelder.com

Dibakar (Dib) Goswami
Washington State Dept. of Ecology
509-372-7902
dgos461@ecy.wa.gov

Paul Hadley
CalEPA Dept. of Toxic Substances Control
916-324-3823
phadley@dtsc.ca.gov

Melissa Hamer-Bailey
Lee & Ryan
317-396-1543
mhamer@leeandryan.com

Jeanene Hanley
Arizona Dept. of Environmental Quality
602-771-4314
jph@azdeq.gov

Scott Hill
U.S. Army Environmental Center
410-436-6868
scott.hill1@us.army.mil

Keith Hoddinott
U.S. Army Center for Health Promotion & Preventative Medicine
410-436-5209
keith.hoddinott@us.army.mil

Bennett D. Kottler
Nevada Div. of Environmental Protection
775-687-9378
bkottler@ndep.nv.gov

Irwin Lourie
Pennsylvania Dept. of Environmental Protection
484-250-5784
ilourie@state.pa.us

Anita Meyer
U.S. Army Corps of Engineers
402-697-2585
anita.k.meyer@usace.army.mil

Ligia Mora-Applegate
Florida Dept. of Environmental Protection
850-245-8992
ligia.mora-applegate@dep.state.fl.us

Stephen D. Mueller
Wisconsin Dept. of Commerce
414-357-4704
Stephen.Mueller@Wisconsin.gov

Katherine Owens
Paragon Professional Associates
208-522-0513
paragon@ida.net

Ashley Whitlow
Arkansas Dept. of Health
501-280-4041
ashley.whitlow@arkansas.gov

Appendix E

Acronyms

ACRONYMS

ARAR	applicable or relevant and appropriate requirement
ASTM	American Society for Testing and Materials
ATSDR	Agency for Toxic Substances and Disease Registry
AUES	American University Experiment Station
bgs	below ground surface
BHHRA	Baseline Human Health Risk Assessment
BRA	baseline risk assessment
CA	cost analysis
CalEPA	California Environmental Protection Agency
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
CFR	Code of Federal Regulations
CMR	Code of Massachusetts Regulations
COC	chemical of concern
COPC	chemical of potential concern
CSF	cancer slope factor
CSM	conceptual site model
CTA	Central Testing Area
CWM	chemical warfare material
DDE	dichlorodiphenyldichloroethylene
DDT	dichlorodiphenyltrichloroethane
DQO	data quality objective
DTSC	Department of Toxic Substances Control
EE	engineering evaluation
EPA	(U.S.) Environmental Protection Agency
EPC	exposure point concentration
ESD	explanation of significant differences
EU	exposure unit
FS	feasibility study
GSMS	Grand Street Mercury Site
HBH	Hoboken Board of Health
HEAST	Health Effects Assessment Summary Table
HHMSSL	Human Health Medium-Specific Screening Level
HHRAP	Human Health Risk Assessment Protocol
HI	hazard index
HRHC	Hudson Regional Health Commission
HSRP	Hazardous Site Response Program
IELCR	individual excess lifetime cancer risk
IEUBK	integrated exposure uptake biokinetic (model for lead in children)
IH	imminent hazard
ILCR	incremental lifetime cancer risk
IRIS	Integrated Risk Information System
ITRC	Interstate Technology & Regulatory Council
LUST	leaking underground storage tank

MADEP	Massachusetts Department of Environmental Protection
NAS	National Academy of Sciences
NCP	National Contingency Plan
NFA	no further action
NJDEP	New Jersey Department of Environmental Protection
NJDHSS	New Jersey Department of Health and Senior Services
NPL	National Priorities List
NRC	National Research Council
OEHHA	Office of Environmental and Human Health Assessment
OSWER	Office of Solid Waste and Emergency Response
OU	operable unit
PAH	polynuclear aromatic hydrocarbon
PCB	polychlorinated biphenyl
PEA	preliminary endangerment assessment
POI	point of interest
PPRTV	Provisional Peer-Reviewed Toxicity Values
PRA	probabilistic risk assessment
PRG	preliminary remediation goal
PVOC	petroleum volatile organic compound
QA/QC	quality assurance/quality control
RA	remedial action
RAGS	Risk Assessment Guidance for Superfund
RAW	remedial action workplan
RBC	risk-based concentration
RBCA	risk-based corrective action
RBCL	risk-based cleanup level
RCRA	Resource Conservation and Recovery Act
RD	remedial design
RfD	reference dose
RI	remedial investigation
RME	reasonable maximum exposure
ROD	record of decision
RP	responsible party
SPS	soil performance standard
TDEC	Tennessee Department of Environment and Conservation
TRSR	Technical Requirements for Site Remediation
UCL	upper confidence limit
USACE	U.S. Army Corps of Engineers
UST	underground storage tank
VOC	volatile organic compound
WDNR	Wisconsin Department of Natural Resources
WWI	World War I
XRF	X-ray fluorescence