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Guidance for Data Useability in Risk Assessment (Part A)

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Notice: Guidance for Radioanalytical Data Useability in Risk Assessment is Given in Part B

Office of Emergency and Remedial Response
U.S. Environmental Protection Agency
Washington, DC 20460

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Tips*

- *The analytical data objective for baseline risk assessments is that uncertainty is known and acceptable, not that uncertainty be reduced to a particular level. (p. 3)*
- *To maximize data useability for the risk assessment, the risk assessor must be involved from the start of the RI. (p. 7)*
- *All data can be used in the baseline risk assessment as long as their uncertainties are clearly described. (p. 11)*
- *Uncertainty in the analytical data, compounded by uncertainty caused by the selection of the transport models, can yield results that are meaningless or that cannot be interpreted. (p. 14)*
- *Uncertainties in toxicological measures and exposure assessment are often assumed to be greater than uncertainties in environmental analytical data; thus, they are assumed to have a more significant effect on the uncertainty of the risk assessment. (p. 17)*
- *Analytical data collected solely for other purposes may not be of optimal use to the risk assessment. (p. 20)*
- *Effective planning improves the useability of environmental analytical data in the final risk assessment.*
  (p. 25)
- *Use historical analytical data and a broad spectrum analysis to initially identify the chemicals of potential concern or exposure areas. (p. 26)*
- *To expedite the risk assessment, preliminary data should be provided to the risk assessor as soon as they are available. (p. 35)*
- *To protect human health, place a higher priority on preventing false negatives in sampling and analysis than on preventing false positives. (p. 41)*
- *Use preliminary data to identify chemicals of potential concern and to determine any need to modify the sampling or analytical design. (p. 41)*
- *Specific analysis for compounds identified during library search can be requested. (p. 41)*
- *The closer the concentration of concern is to the detection limit, the greater the possibility of false negatives and false positives. (p. 47)*
- *The wide range of chemical concentrations in the environment may require multiple analyses or dilutions to obtain useable data. Request results from all analyses. (p. 47)*
- *Define the type of detection or quantitation limit for reporting purposes; request the sample quantitation limit for risk assessment. (p. 47)*
- *When contaminant levels in a medium vary widely, increase the number of samples or stratify the medium to reduce variability. (p. 50)*
- *Sampling variability typically contributes much more to total error than analytical variability. (p. 50)*
- *Field methods can produce legally defensible data if appropriate method QC is available and if documentation is adequate. (p. 57)*
- *To minimize the potential for false negatives, obtain data from a broad spectrum analysis from each medium and exposure pathway. (p. 58)*
- *The CLP or other fixed laboratory sources are most appropriate for broad spectrum analysis or for confirmatory analysis. (p. 58)*
- *Solicit the advice of the chemist to ensure proper laboratory selection and to minimize laboratory and/or methods performance problems that occur in sample analysis. (p. 58)*
- *Use of the Sampling Design Selection Worksheet will help the RPM or statistician determine an appropriate sampling design. (p. 65)*

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* For further information, refer to the text. Page numbers are provided.

Tips
(cont'd)

- *While other designs may be appropriate in many cases, stratified random or systematic sampling designs are always acceptable. (p. 65)*
- *If the natural variability of the chemicals of potential concern is large (e.g., greater than 30%), the major planning effort should be to collect more environmental samples. (p. 72)*
- *At least one broad spectrum analytical sample is required for risk assessment, and a minimum of two or three are recommended for each medium in an exposure pathway. (p. 73)*
- *Collect and analyze background samples prior to the final determination of the sampling design since the number of samples is significantly reduced if little background contamination is present. (p. 75)*
- *Systematic sampling supplemented by judgmental sampling is the best strategy for identifying hot spots. (p. 75)*
- *Focus planning efforts on maximizing the collection of useable data from critical samples. (p. 78)*
- *The ability to combine data from different sampling episodes or different sampling procedures is a very important consideration in selecting a sampling design but should be done with caution. (p. 78)*
- *Ensure that critical requirements and priorities are specified on the Method Selection Worksheet so that the most appropriate methods can be considered. (p. 83)*
- *Use routine methods wherever possible since method development is time-consuming and may result in problems with laboratory implementation. (p. 83)*
- *Analyte-specific methods that provide better quantitation can be considered for use once chemicals of potential concern have been identified by broad spectrum analysis. (p. 84)*
- *All results should be reported for samples analyzed at more than one dilution. (p. 85)*
- *Field analysis can be used to decrease cost and turnaround time providing data from a broad spectrum analysis are available. (p. 89)*
- *Focus corrective action on maximizing the useability of data from critical samples. (p. 97)*
- *Use preliminary data as a basis for identifying sampling or analysis deficiencies and taking corrective action. (p. 100)*
- *Problems in data useability due to sampling can affect all chemicals involved in the risk assessment; problems due to analysis may only affect specific chemicals. (p. 100)*
- *Qualified data can usually be used for quantitative risk assessments. (p. 105)*
- *Anticipate the need to combine data from different sampling events and/or different analytical methods. (p. 107)*
- *Determine the distribution of the data before applying statistical measures. (p. 109)*
- *Determine the statistical measures of performance most applicable to site conditions before assessing data useability. (p. 110)*
- *Use data qualified as U or J for risk assessment purposes. (p. 113)*
- *The major concern with false negatives is that the decision based on the risk assessment may not be protective of human health. (p. 117)*
- *False negatives can occur if sampling is not representative, if detection limits are above concentrations of concern, or if spike recoveries are very low. (p. 117)*
- *False positives can occur when blanks are contaminated or spike recoveries are very high. (p. 118)*
- *Statistical analysis may determine if site concentrations are significantly above background concentrations when the differences are not obvious. (p. 120)*
- *The primary planning objective is that uncertainty levels are acceptable, known and quantitatable, not that uncertainty be eliminated. (p. 121)*

PREFACE

The U.S. Environmental Protection Agency (EPA) has established a Data Useability Workgroup to develop national guidance for determining data useability requirements needed for environmental data collection on hazardous waste sites under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA) as amended by the Superfund Amendments and Reauthorization Act of 1986 (SARA). Data useability is the process of assuring or determining that the quality of data generated meets the intended use. This guidance has been designed by the Risk Assessment Subgroup of the Data Useability Workgroup to provide data users with a nationally consistent basis for making decisions about the minimum quality and quantity of environmental analytical data that are sufficient to support Superfund risk assessment decisions, regardless of which parties conduct the investigation. This document is the first part (Part A) of the two-part *Guidance for Data Useability in Risk Assessment*. Part B of this guidance addresses radioanalytical issues.

Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual, Part A (EPA 1989a) serves as a general guidance document for the risk assessment process. Building upon RAGS, an "interim final" version of *Guidance for Data Useability in Risk Assessment* was issued by the Risk Assessment Subgroup of the Data Useability Workgroup in October 1990. The guidance was issued as "interim final" in order to obtain and incorporate comments and criticisms from data users who tested it in real-world situations.

The authors acknowledge the significant help of all who have provided comments and criticisms. The results indicate that many people react favorably to the guidance and find it useful in planning a risk assessment or in evaluating assessments already underway. Issues were identified where guidance in the interim final needed to be supplemented or discussed in more detail. These issues include providing a more detailed discussion of sampling strategies, incorporating groundwater factors, addressing soil depth for exposure, and obtaining background data. Issues concerning data reporting formats, validation and use of non-CLP data, and tentatively identified compounds were also identified. The final version of the guidance provides greater detail in the discussion of these and other issues.

This guidance provides direction for planning and assessing analytical data collection activities for the baseline human health risk assessment, conducted as part of the remedial investigation (RI) process. **Although the guidance addresses the baseline risk assessment within the RI, it is appropriate for use in the new Superfund Accelerated Cleanup Model (SACM) where data needs for risk assessment are considered at the onset of site evaluation.** Site-specific conditions may often require sampling or analysis beyond the basic recommendations given in this guidance. The guidance does not directly address the use of ecological data for purposes other than baseline risk assessments for human health, although some considerations have been included when data may be used for both ecological and human health evaluation.

This guidance complements guidance provided in RAGS (EPA 1989a), *Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA* (EPA 1988a), and *Data Quality Objectives for Remedial Response Activities: Development Process* (EPA 1987a). RAGS provides the framework for making data quality assessments in baseline risk assessments, and this guidance supplements and strengthens important technical details of the framework by providing direction on minimum requirements for environmental analytical data used in baseline risk assessments. As such, it complements and builds upon Agency guidance for the development and use of data quality objectives in all data collection activities.

This guidance is addressed primarily to the remedial project managers (RPMs) who have the principal responsibility for leading the data collection and assessment activities that support the human health risk assessment and, secondarily, to risk assessors who must effectively communicate their data needs to the RPMs and use the data provided to them. Chemists, quality assurance specialists, statisticians, hydrogeologists and other technical experts involved in the RI process can use this guidance to optimize the useability of data collected in the RI for use in baseline risk assessments.

Comments on the guidance should be sent to:

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This guidance was developed by an EPA workgroup with membership from EPA Headquarters, EPA Regional offices and representatives of the contractor community. The EPA Risk Assessment Subgroup of the Data Useability Workgroup provided valuable input regarding the content, approach and organization of the guidance. Members of the Risk Assessment Subgroup, responsible for generating this guidance, have experience in human health risk assessment, remedial project management, chemistry, toxicology, hydrogeology, and quality assurance. Technical review was provided by toxicologists, chemists, quality assurance specialists, engineers, project managers, and statisticians from both EPA and contractor staff.

Leadership for development of the "interim final" version of this guidance was provided by Data Useability Workgroup Region III Co-chairpersons Chuck Sands [currently at the Analytical Operations Branch (AOB)] and Claudia Walters, and Ruth Bleyler of the Toxics Integration Branch (TIB).

Leadership for development of the "final" version of this guidance was provided by Ruth Bleyler and Lisa Matthews of TIB and Chuck Sands of AOB. We wish to acknowledge Region V and Region VI for their assistance with the implementation effort for the final version of the guidance.

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Chapter 1
Introduction and Background

This guidance was developed by the U.S. Environmental Protection Agency (EPA) for remedial project managers (RPMs), risk assessors, and contractors. It is published in two parts; this document is Part A. Part B solely addresses useability issues in radioanalytical sampling and analysis for risk assessment. Both parts of this guidance are designed to assist RPMs in maximizing the useability of environmental analytical data collected in the remedial investigation (RI) process for baseline human health risk assessments. Since RPMs, with assistance from technical experts, oversee the preparation of workplans and sampling and analysis plans for RI data collection, it is important for them to understand the types, quality and quantity of data needed by risk assessors, and the impact that their data collection decisions have on the level of certainty of baseline risk assessments for human health. This guidance provides detailed approaches and basic recommendations for both obtaining and interpreting data for risk assessment that specifically address:

- How to design RI sampling and analytical activities that meet the data quantity and data quality needs of risk assessors,
- Procedures for assessing the quality of the data obtained in the RI,
- Options for combining environmental analytical data of varying levels of quality from different sources and incorporating them into the risk assessment,
- Procedures for determining the level of certainty in the risk assessment based on the uncertainty in the environmental analytical data, and
- Guidelines on the timing and execution of the various activities in order to most efficiently produce deliverables.

Although the guidance addresses the baseline risk assessment within the RI, it is appropriate for use in the new Superfund Accelerated Cleanup Model (SACM) where data needs for risk assessment are considered at the onset of site evaluation.

Risk assessors should be an integral part of the RI planning process to ensure that adequate environmental analytical data of acceptable quality and quantity for the risk assessment are collected during the RI. This guidance assists risk assessors in communicating their environmental analytical data needs to the RPMs. Risk assessors should work closely with the RPMs to identify and recommend sampling designs and analytical methods that will maximize the quality of the baseline risk assessment for human health within the site-related and budgetary constraints of the RI, and will produce consistent risk assessments useful to risk managers.

This guidance provides a number of worksheets and exhibits that can be used as bases for the organization of sampling or analytical planning or assessment processes. However, implementation of guidance will be site-specific, and site personnel should develop and modify these guidance materials to best suit the conditions at their site.

Although ecological data useability is not addressed specifically in this guidance, the chemical data obtained from site characterization are useable for certain elements of the ecological assessment. In an ecological assessment, the chemicals of potential concern and their priorities may be different than those of the human health risk assessment. For example, iron is rarely of concern in human health risk assessments, but high levels of iron may pose a threat to aquatic species. Eco-guidance documents relevant to risk assessment include *Risk Assessment Guidance for Superfund, Volume II: Environmental Evaluation Manual* (EPA 1989b), *ECO Update* (EPA 1991a) *and Ecological Assessment of Hazardous Waste Sites: A Field and Laboratory Reference* (EPA 1989c).

1.1 CRITICAL DATA QUALITY ISSUES IN RISK ASSESSMENT

Five basic environmental data quality issues are frequently encountered in risk assessments. This guidance provides procedures, minimum requirements, and other information to resolve or minimize the effect of these issues on the assessment of uncertainty in the risk assessment. The issues affect both the planning for and the assessment of analytical data for use in RI risk assessments. The following sections describe these issues and their impact on data useability, and highlight the resolutions of these issues.

Acronyms

CLP	Contract Laboratory Program
EPA	U.S. Environmental Protection Agency
QAPjP	quality assurance project plan
RAGS	Risk Assessment Guidance for Superfund
RI	remedial investigation
RPM	remedial project manager
SACM	Superfund Accelerated Cleanup Model

1.1.1 Data Sources

Data users must select sampling and analytical procedures and providers appropriate to the data needs of each risk assessment. Practical tradeoffs among detection limits, response time, documentation, analytical costs, and level of uncertainty should be considered prior to selecting sampling designs, analytical methods, and service providers.

The Contract Laboratory Program (CLP) has been the principal source of analytical data for investigations at hazardous waste sites. The CLP requires adherence to specific data acceptance criteria which results in data of known analytical quality produced in a standardized package. Another principal source of analytical data is the EPA Regional laboratory, which often produces data similar in quality to that of the CLP. Other analytical sources, such as field analysis or fixed laboratories (EPA, state, or private), can also produce data of acceptable quality. Accordingly, RPMs and risk assessors should seek the source of data that best meets the data quality needs of the risk assessment. Section 4.2 provides guidance for selecting analytical sources.

Field analytical data have been used primarily to aid in making decisions during sampling. However, recent advances in technology, when accompanied by sufficient and appropriate quality control measures, allow field analytical data to be used in risk assessments with more frequency and more confidence than in the past. By using field analyses, RPMs can increase the number of samples to better characterize the site and significantly decrease sample turnaround time (to provide real-time decision-making in the field) as long as acceptable data quality is maintained. Guidance for assessing the useability and applicability of field analytical data in the risk assessment process is also provided in Section 4.2.

For any source of monitoring data, RPMs must ensure that data quality objectives, analytical methods, quality control requirements and criteria, level of documentation, and degree and assignment of responsibilities for quality assurance oversight are clearly documented in the quality assurance project plan (QAPjP). In addition, the RPM is responsible for the enforcement of these parameters. For non-Superfund-lead analyses, the potentially responsible party, state, or federal agency determines and documents these parameters. The QAPjP is then submitted to the RPM for review. In all cases involving risk assessment, the RPM should always seek the source of data that best meets the data quality needs of the risk assessor. The data source chosen must generate data of known quality.

1.1.2 Detection Limits

Selecting the analytical method to meet the required detection limits is fundamental to the useability of analytical data in risk assessments. In addition, the type of detection limit, such as method detection limit or sample quantitation limit, used in making data quality decisions affects the certainty of the risk assessment. Guidance for making these decisions is provided in Section 4.2. Preliminary remediation goals, as defined in *Risk Assessment Guidance for Superfund (RAGS) Volume I: Human Health Evaluation Manual, Part B* (EPA 1991b), provide criteria to be considered in evaluating the adequacy of detection limits.

1.1.3 Qualified Data

Laboratories, and individuals conducting independent data review, affix coded qualifiers to data when quality control requirements or other evaluation criteria are not met. Data reviewers assess these and many other criteria to determine the useability of data. Qualified data must be used appropriately in risk assessments. Data are almost always useable in the risk assessment process, as long as the uncertainty in the data and its impact on the risk assessment are thoroughly explained. Section 5.6 describes procedures for incorporating qualified data and data of varying analytical quality into the risk assessment.

1.1.4 Background Samples

In conducting a risk assessment, it is critical to distinguish site contamination from background levels due to anthropogenic or naturally occurring contamination in order to determine the presence or absence of contamination and to compare with background risk. Analytical data reported near method detection limits and sample results qualified during data review complicate the use of background sample data to determine site contamination. Planning for the collection of a sufficient number of background samples from representative locations increases the certainty in decisions about the significance of site contamination. Section 4.1 discusses how statistical analysis and professional judgment can be combined to design a sampling program for collecting adequate background data.

1.1.5 Consistency in Data Collection

Data collection activities may vary among parties conducting RIs. Consistency in all Superfund activities is increasingly crucial. All parties collecting

environmental analytical data for baseline risk assessments for human health should use guidance provided in *Risk Assessment Guidance for Superfund (RAGS) Volume I: Human Health Evaluation Manual, Part A* (EPA 1989a) and this guidance to ensure that baseline risk assessments for human health are conducted consistently and are protective of the public health.

1.2 FRAMEWORK AND ORGANIZATION OF THE GUIDANCE

This guidance is organized following the usual sequence used to determine the useability of environmental analytical data for baseline human health risk assessments. Exhibit 1 illustrates the conceptual framework for the guidance. Six criteria are used to evaluate data useability for baseline risk assessments for human health:

- Data sources,
- Documentation,
- Available analytical services in terms of analytical methods and detection limits,
- Data quality indicators,
- Data review, and
- Reports to risk assessor.

These criteria address the five major data quality issues described in Section 1.1 and other issues that impact data useability in the risk assessment. The data useability criteria are applied in RI planning to guide the design of sampling plans and select analytical methods for the data collection effort. The criteria are employed again to assess the useability of the analytical data collected during the RI, and of data from other studies and sources, such as site inspections. This guidance also describes how to determine the uncertainties in the risk assessment based on the level of uncertainty of the environmental analytical data, determined using the data useability criteria.

☛ *The analytical data objective for baseline risk assessments is that the uncertainty is known and acceptable, not that the uncertainty be reduced to a particular level.*

EXHIBIT 1. DATA USEABILITY CRITERIA TO PLAN SAMPLING, ANALYSIS AND ASSESSMENT EFFORTS IN BASELINE RISK ASSESSMENT

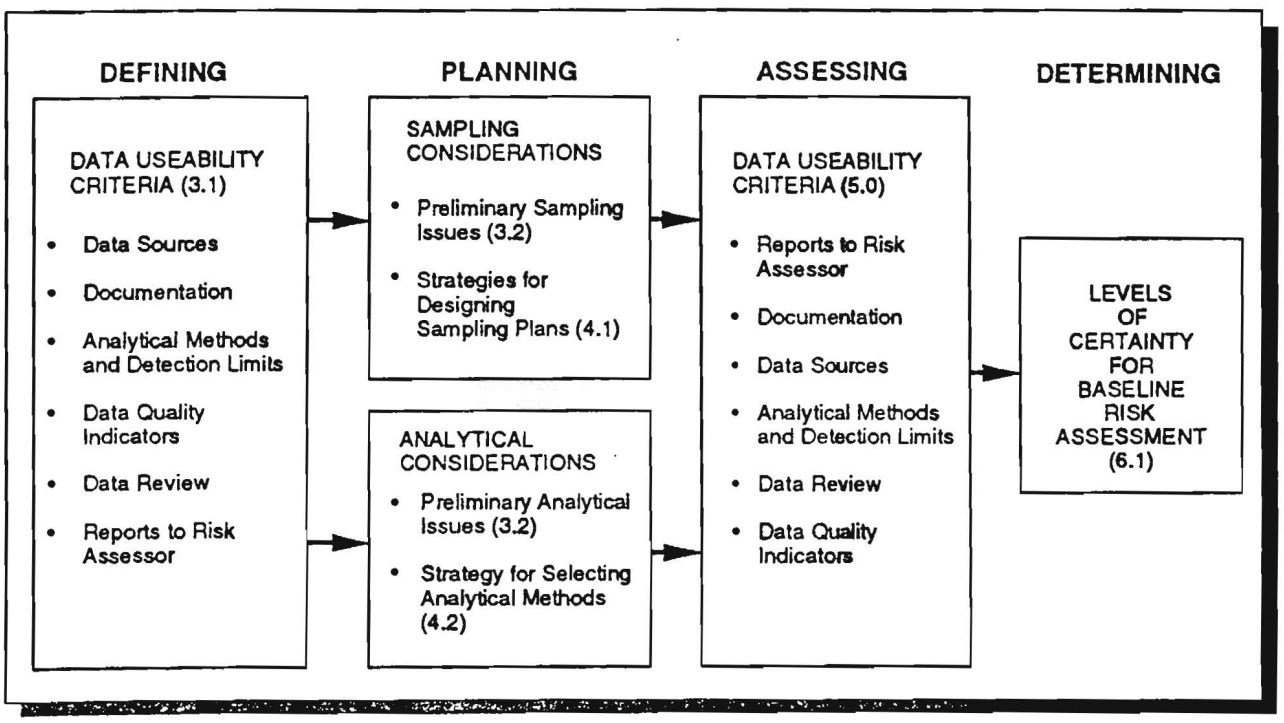

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Exhibit 2 summarizes the purpose of each chapter of this guidance and highlights how the chapters can best assist RPMs and risk assessors. Worksheets, assessment tables, and other aids are used extensively throughout the guidance. These are tools that can be used "as is," or they can be modified for use or used as the basis for site-specific worksheets or summaries. Chapter contents are summarized below.

- Chapter 2—The Risk Assessment Process: This chapter explains the purpose and objectives of a baseline human health risk assessment and describes the four basic elements of a risk assessment: data collection and evaluation, exposure assessment, toxicity assessment, and risk characterization. The chapter discusses the uncertainties associated with the risk assessment process and emphasizes the impact of analytical data quality on each element. The roles and responsibilities of the RPM, the risk assessor, and others involved in planning and conducting data collection activities to support the risk assessment are described.

- Chapter 3—Useability Criteria for Baseline Risk Assessments: Six criteria are defined in this chapter for interpreting the importance of sample collection, analytical techniques, and data review procedures to the useability of analytical data in risk assessments. The sampling and analytical issues that need to be addressed in using these criteria are discussed. The chapter stresses the need to consider and plan for risk assessment data requirements in the early design stages of the RI.

- Chapter 4—Steps for Planning for the Acquisition of Useable Environmental Data in Baseline Risk Assessments: This chapter provides explicit guidance for designing sampling plans and selecting analytical methods based on the data quality requirements of baseline risk assessments. Worksheets for sampling design selection, soil depth sampling, and method selection are provided as part of the step-by-step guidance for making data collection decisions for individual sites.

- Chapter 5—Assessment of Environmental Data for Useability in Baseline Risk Assessments: This chapter explains how to assess the useability of site-specific data for risk assessments after data collection according to the six criteria defined in Chapter 3. For each assessment criterion, the chapter defines minimum data requirements and explains how to determine actual performance compared to performance objectives and execute appropriate corrective actions for data critical to the risk assessment. The chapter also describes options available to risk assessors for incorporating analytical data from different sources and varying levels of quality into the baseline risk assessment.

- Chapter 6—Application of Data to Risk Assessments: This chapter details procedures for determining the overall level of uncertainty associated with the risk assessment. The discussion addresses characterization of contaminant concentrations within exposure areas, determining the presence or absence of chemicals of potential concern, and distinguishing site contamination from background levels.

- Appendices—The appendices provide analytical and sampling technical reference materials, including descriptions of generic organic and inorganic data review packages; listings of common industrial pollutants; analytical methods and detection or quantitation limits (see Section 3.2.4 for definitions); common laboratory contaminants; calculation formulas for statistical evaluation; information on analytical data qualifiers; a summary of Contract Laboratory Program methods with corresponding Target Compound List compounds and Target Analyte List anaytes; and an example of a conceptual site model.

- Index—The index provides cross-references throughout the guidance. This is important because Chapters 3, 4, and 5 present planning and assessment issues as complementary discussions that can be viewed independently.

- Tips—Tips, marked with a ☛, are incorporated into the text of the chapters. These tips draw attention to key issues in the text but are not intended to summarize the discussion in the chapter.

EXHIBIT 2. ORGANIZATION OF THE GUIDANCE

Chapter 1
Introduction and Background

- Presents critical data useability issues.
- Specifies audience to be primarily RPMs and risk assessors.
- Defines scope and specifies organization of the guidance.

Chapter 2
The Risk Assessment Process

- Explains the elements of a risk assessment and the impact of analytical data quality on each element.
- Defines the uncertainties in the risk assessment process.
- Describes the roles of the risk assessor, RPM and others involved with the risk assessment planning and assessment process.

Chapter 3
Useability Criteria for Baseline Risk Assessments

- Defines six criteria for assessing data useability: data sources, documentation, analytical methods/detection limits, data quality indicators, data review, and reports to the risk assessor.
- Applies criteria to sampling and analytical issues.

Chapter 4
Steps for Planning for the Acquisition of Useable Environmental Data in Baseline Risk Assessments

- Provides guidelines for designing sampling plans and selecting analytical methods.
- Provides worksheets to support sampling design selection, soil depth sampling, and analytical method selection.

Chapter 5
Assessment of Environmental Data for Useability in Baseline Risk Assessments

- Describes minimum requirements for useable data.
- Explains how to determine actual performance compared to objectives.
- Recommends corrective actions for critical data not meeting objectives.
- Describes options for combining data from different sources and of varying quality into the risk assessment.

Chapter 6
Application of Data to Risk Assessments

- Provides procedures to determine the uncertainty of the analytical data.
- Explains how to distinguish site from background levels of contamination and determine the presence (absence) of chemicals of potential concern.
- Discusses how to characterize contaminant concentrations within exposure areas.

Appendices

- Provide technical reference materials for sampling and analysis.
- Describe data review packages and meanings of selected data qualifers.

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Chapter 2
The Risk Assessment Process

This chapter is an overview of the data collection and evaluation issues that affect the quality and useability of baseline human health risk assessments. Ecological risk assessment is not discussed in this guidance. The discussion focuses on how the quality of environmental analytical data influences the level of certainty of the risk assessment and stresses the importance of understanding data limitations in characterizing risks to human health.

The chapter has two sections. Section 2.1 is an overview of baseline human health risk assessment and the significance of uncertainty in each stage of the risk assessment process. Section 2.2 summarizes the roles and responsibilities of key participants in the risk assessment process.

2.1 OVERVIEW OF BASELINE HUMAN HEALTH RISK ASSESSMENT AND THE EVALUATION OF UNCERTAINTY

The approach to the baseline human health risk assessment process used for exposure to chemicals of potential concern is well established. The National Research Council (NRC) prepared a comprehensive overview of this process (NRC 1983), which has become the foundation for subsequent EPA guidance (EPA 1986a, EPA 1989a, EPA 1989b). RAGS, Part A (EPA 1989a), discusses in detail the human health baseline risk assessment process which is used in the Superfund program.

The risk assessment process has four components:

- Data collection and evaluation,
- Exposure assessment,
- Toxicity assessment, and
- Risk characterization.

Exhibit 3 lists information sought in each component of the baseline risk assessment.

Uncertainty analysis is often viewed as the last step in the risk characterization process. However, as discussed in detail in RAGS, Part A, uncertainty analysis is a fundamental element of each component of risk assessment, and the results for each component require an explicit statement of the degree of uncertainty. These results are the bases for estimating the degree of uncertainty in the risk assessment as a whole. This chapter reviews the issues that determine the level of uncertainty in each component of risk assessment.

> ☛ *To maximize data useability for the risk assessment, the risk assessor must be involved from the start of the RI.*

The importance of obtaining analytical data that fulfill the needs of risk assessment cannot be overstated. The risk assessor must be involved from the start of the risk assessment process to help establish the scope of the investigation and the design of the sampling and analysis program.

All analytical data collected for baseline risk assessment must be evaluated for their useability. The procedures for evaluating the adequacy of the data are documented, along with the resulting estimates of the levels of certainty. Limitations in the analytical data are not the only source of uncertainty in risk assessment. Exhibit 4 identifies some typical sources of uncertainty, inherent in each component of the risk assessment, which restrict the depth and breadth of the evaluation. This guidance deals only with the uncertainty inherent in data collection and evaluation. Consult RAGS, Part A, for a more complete discussion of these and other uncertainties.

Acronyms

ATSDR	Agency for Toxic Substances and Disease Registry
DQO	data quality objective
EPA	U.S. Environmental Protection Agency
GIS	Geographical Information System
HEAST	Health Effects Assessment Summary Tables
IRIS	Integrated Risk Information System
LOAEL	lowest-observable-adverse-effect level
NOAEL	no-observable-adverse-effect level
NRC	National Research Council
PAH	polycyclic aromatic hydrocarbon
PCB	polychlorinated biphenyl
QA	quality assurance
QAPjP	quality assurance project plan
QC	quality control
RAGS	Risk Assessment Guidance for Superfund
RfC	reference concentration
RfD	reference dose
RI	remedial investigation
RME	reasonable maximum exposure
RPM	remedial project manager
SAP	sampling and analysis plan
SOP	standard operating procedure
UCL	upper confidence limit

EXHIBIT 3. DATA RELEVANT TO COMPONENTS OF THE RISK ASSESSMENT PROCESS

Risk Assessment Component	Data
Data Collection and Evaluation	• Background monitoring data for all affected media. • Environmental data for all relevant media. • List of chemicals of potential concern. • Distribution of sampling data. • Confidence limits surrounding estimates of representative values.
Exposure Assessment	• Release rates. • Physical, chemical and biological parameters, for evaluating transport and transformation of site-related chemicals. • Parameters to characterize receptors according to their activity, behavior and sensitivity. • Estimates of exposure concentrations for all chemicals, environmental media and receptors at risk. • Estimates of chemical intake or dose for all exposure pathways and exposure areas.
Toxicity Assessment	• Toxicity values for all chemicals, exposure pathways, and exposure areas of concern. • Uncertainty factors and confidence measures for RfDs; weight-of-evidence classifications for cancer slope factors.
Risk Characterization	• Hazard quotients and indices. • Estimates of excess lifetime cancer risk. • Uncertainty analysis.

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EXHIBIT 4. BASELINE RISK ASSESSMENT PROCESS AND TYPICAL SOURCES OF UNCERTAINTY

Data Collection and Evaluation

- Use of inappropriate method detection limits may result in underestimates of risk.
- Results may overestimate or underestimate risk when an insufficient number of samples are taken.
- Contaminant loss during sampling may result in underestimates of risk.
- Extraneous contamination introduced during sampling or analysis may result in overestimation of risk.

Exposure Assessment

- Assumptions regarding intake factors, population characteristics, and exposure patterns may not adequately characterize exposure and may result in underestimates or overestimates of risk.
- The degree to which release or transport models are representative of physical reality may overestimate or underestimate risk.
- Inappropriate selection of detection limit can result in overestimate or underestimate of risk.
- Assumption of 100% bioavailability of chemicals in environmental media (soil in particular) may result in overestimates of risk.
- Assumption that chemicals of potential concern do not degrade or transform in the environment may result in underestimates or overestimates of risk.
- Incremental risks associated with exposure to site-related chemicals of potential concern cannot be fully characterized and may result in underestimates of risk.
- Methods used to estimate inhalation exposure to volatiles, suspended particulates or dust may overestimate intake and risk.
- Very few percutaneous absorption factors are available for chemicals of potential concern. Exposure from dermal contact may be overestimated using conservative default values.

Toxicity Assessment

- Critical toxicity values are derived from animal studies using high dose levels. Exposures in humans occur at low dose levels. Assumption of linearity at low dose may result in overestimates or underestimates of risk.
- Inappropriate selection of detection limit can result in overestimates or underestimates of risk.
- Extrapolation of results of toxicity studies from animals to humans may introduce error and uncertainty, inadequate consideration of differences in absorption, pharmacokinetics, and target organ systems, and variability in population sensitivity.
- There is considerable uncertainty in estimates of toxicity values. Critical toxicity values are subject to change as new evidence becomes available. This may result in overestimates or underestimates of risk.
- Use of conservative high to low dose extrapolation models may result in overestimation of risk.

Risk Characterization

- Risk/dose estimates are assumed to be additive in the absence of information on synergism and antagonism. This may result in overestimates or underestimates of risk.
- Toxicity values are not available for all chemicals of potential concern. Risks cannot be quantitatively characterized for these compounds and may result in underestimates of risk.
- For some chemicals or classes (e.g., PCBs, PAHs), in the absence of toxicity values, the cancer slope factor or RfD of a highly toxic class member is commonly adopted. This approach may overestimate risks.

21-002-004

Source: Adapted from EPA 1989a.

Risk assessment can be a simple operation, using only screening-level data, or can be comprehensive, requiring a robust data set designed to support statistical analyses. Exhibit 5 discusses the range of uncertainty of baseline risk assessment. The first column in Exhibit 5 defines the range of the analysis from a low to a high degree of uncertainty. The second column describes the associated data useability and limitations in the risk analysis.

- The first level of analysis in Exhibit 5 is a quantitative risk assessment based on a sampling program that can be statistically analyzed. The assessment explicitly bounds and quantitates the uncertainty in all estimates. This analysis may strive to attain an ideal based upon the complexity of the site. The assessment is "quantitative" in that numeric estimates are derived for potentially adverse non-carcinogenic and carcinogenic effects, and in that the level of certainty is quantitated.

- The second level of analysis in Exhibit 5 is a quantitative assessment based on a limited number of samples or on data that cannot be fully quantitated. The risk characterization may include numeric estimates of excess lifetime cancer risks and the calculation of hazard indices. However, the level of analytical uncertainty for these measures may be significant but is either not quantitated or is estimated. Given the limitations of the analytical data, only a qualitative evaluation of the analytical uncertainty is feasible. Most baseline risk assessments fall within this category. Bias may need to be determined for its effect on predicted exposures and consequent risk.

- The third level of the continuum is a qualitative assessment of risk. The assessment is qualitative because no numeric measures can be derived to indicate the potential for adverse effects, and the level of certainty cannot be assessed. The risk to human health is considered only in general terms. Qualitative assessments are based upon limited sources of historical information, such as disposal records, circumstantial evidence of contamination, or preliminary site assessment data.

EXHIBIT 5. RANGE OF UNCERTAINTY OF RISK ASSESSMENT

Range of Analyses	Description/Limitations
Quantitative Assessment of Risk: Uncertainty minimized, quantified, and explicitly stated. Resulting or final uncertainty may be highly variable (either high or low).	Risk assessment conducted using well-designed, robust data sets and models directly applicable to site conditions. Sampling program, based on geostatistical or random design, will support statistical analysis of results. Statistical analysis used to characterize monitoring data. Confidence limits or probability distributions may be developed for all key input variables.
Quantitative Assessment of Risk: Magnitude of uncertainty unknown. No explicit quantitative estimates provided. Qualitative, tabular summary of factors influencing risk estimates may be provided for determination of possible bias in error.	Risk assessment conducted using data set of limited quality and size. No meaningful statistical analysis can be conducted. Results of risk assessment may be quantified but uncertainty surrounding these measures cannot be quantified. Only a qualitative statement is possible. The majority of baseline risk assessments typically fall within this category.
Qualitative Assessment of Risk: Only qualitative statement of uncertainty is possible. Uncertainty is high.	Risks cannot be quantified due to insufficient monitoring or modeling data. Qualitative statement of risks based on historical information or circumstantial evidence of contaminantion is provided. This evaluation must be considered a preliminary, screening level assessment.

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☛ *All data can be used in the baseline risk assessment as long as their uncertainties are clearly described.*

Risk assessments must sometimes be conducted using data of limited quantity and of differing quality. When RPMs and other technical experts involved in the RI understand the quantity and quality of data required in risk assessments, they are better able to design data collection programs to meet these requirements.

2.1.1 Data Collection and Evaluation

Overview of methods for data collection and evaluation. Data collection begins with a statement of the risk assessment purpose and a conceptual model of the current understanding of the problems to be addressed for the site under investigation. The model draws from all available historical data (EPA 1989a). It is first created with a best estimate of the types and concentrations of chemicals, or of key chemicals that are likely to be present, given the history of the site. Site records, site maps, the layout of existing structures, topography, and readily observable soil, water and air characteristics on and off the site help to estimate chemicals of potential concern, likely important exposure pathways, potentially exposed populations, and likely temporal and spatial variation. All of these elements comprise the conceptual model (Exhibit 6 and Appendix IX). Once the conceptual model has been developed and information has been disseminated to project staff, the site is scoped to identify data gaps and requirements for the baseline risk assessment.

Several key issues that are part of the development of data quality objectives (DQOs) should be addressed at scoping (Neptune, *et. al.* 1990):

- The types of data needed (e.g., environmental, toxicological),
- How the data will be used (e.g., site characterization, extent of plume, etc., what chemicals of concern will drive the risk-based decision), and
- The desired level of certainty for the conclusions derived from the analytical data (e.g., what are the probabilities of false positive and false negative results as a function of risk and concentration).

Carefully designed sampling and analysis programs minimize the subsequent need to qualify the environmental data during the data assessment phase. The objective of the data collection effort is to produce data that can be used to assess risks to human health with a known degree of certainty.

A complete list of chemicals of potential concern is produced when the analytical data have been collected and evaluated. This list of analytes is the focus of the risk assessment. EPA no longer advocates the selection of "indicator compounds," because this practice may not accurately reflect the total risk from exposure to multiple site chemicals of potential concern, nor does it improve the quality or accuracy of the risk assessment (EPA 1989a).

Uncertainty in data collection and evaluation. Four principal decisions must be made during data collection and evaluation in the risk assessment:

- The presence and levels of contaminants at the site at a predefined level of detail,
- If the levels of site-related chemicals differ significantly from their background levels,
- Whether the analytical data are adequate to identify and examine exposure pathways and exposure areas, and
- Whether the analytical data are adequate to fully characterize exposure areas.

These decisions are examined in detail in subsequent chapters. The discussion in this section introduces basic concepts.

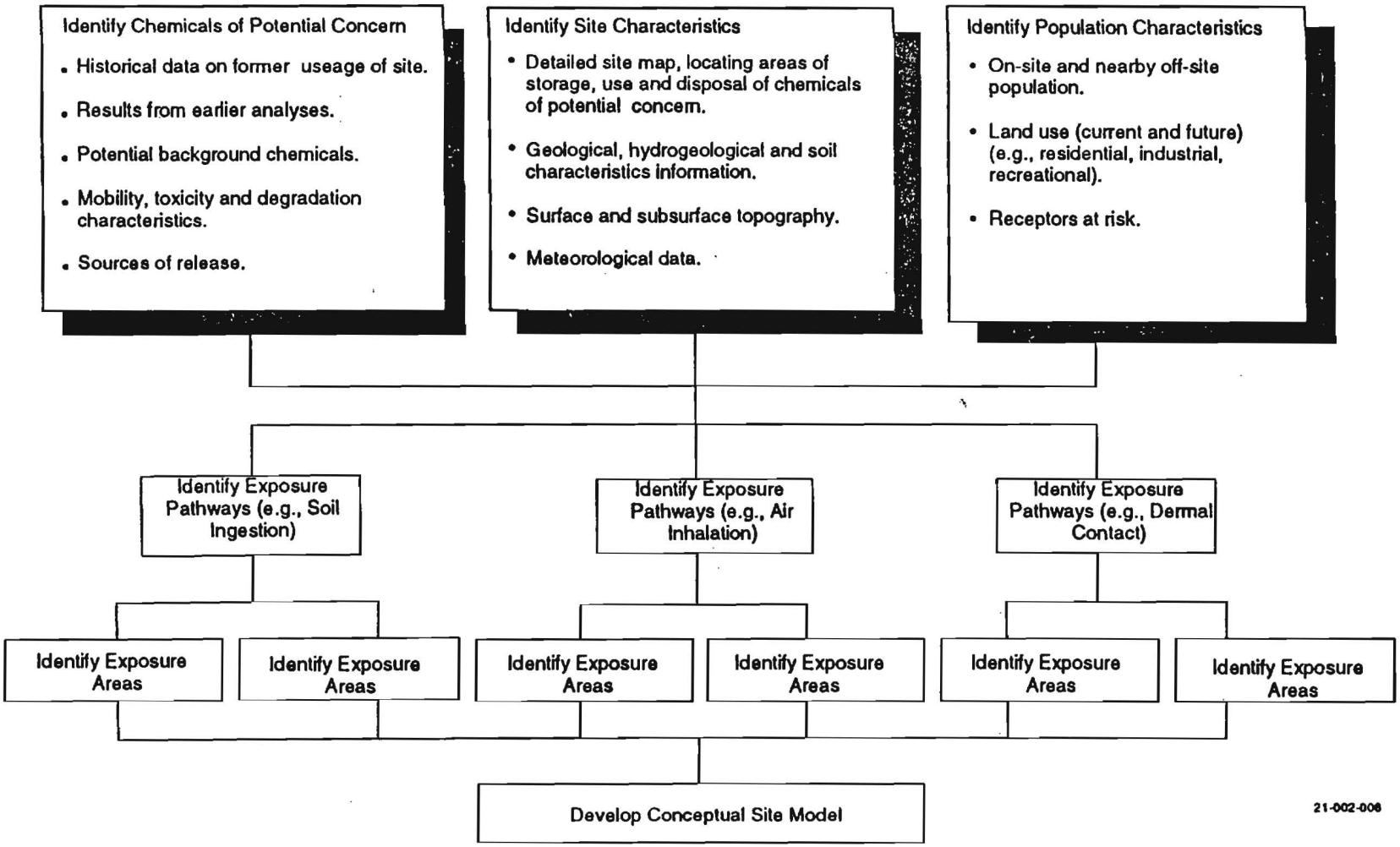
Determining what contamination is present and at what level. Once a site is suspected to be contaminated and chemicals of potential concern have been identified, the levels of chemical contamination in the affected environmental media must be quantitated to derive exposure and intake estimates. Estimates of the site contamination must be produced, with explicit descriptions of the degree of certainty associated with the concentration values.

Variability in observed concentration levels arises from a combination of variance in sampling characteristics of the site, in sampling techniques, and in laboratory analysis. The key issue in optimizing the useability of data for risk assessment is to understand, quantify, and minimize these variabilities.

EPA's objective is to protect human health and the environment. Therefore, the design of RI programs is intended to minimize two potential errors:

- Not detecting site contamination that is actually present (i.e., false negative values), and
- Deriving site concentrations that do not accurately characterize the magnitude of contamination.

EXHIBIT 6. DEVELOPMENT OF CONCEPTUAL SITE MODEL



Determining if site concentrations differ significantly from background concentrations. A fundamental decision in baseline risk assessments is whether the site poses an increased risk to human health and the environment. The decision depends on the degree of certainty that the background concentrations are significantly different from the concentrations of the chemicals of potential concern at the site. Generally, this question can be confidently answered only if the design of the sampling program accommodates the collection of both site and background samples and if the selection of analytical methods is appropriate.

The differences between site and background concentrations is evaluated by comparing observed levels of chemicals of potential concern at the site with measured background concentrations of the same chemicals in the same environmental media. Statistically, this is a test of the null hypothesis, that the mean concentration of a chemical at the study area is not significantly different from the mean concentration of the chemical at the background location. (Historical on-site levels or nearby off-site levels may be used to supplement background data. An example of an off-site area is the 4-mile radius used for the air exposure pathway in the Hazard Ranking System.) If data from background samples are clearly different from the results of site monitoring (e.g., mean chemical concentrations differ consistently by two orders of magnitude), statistical analysis of the data may not be necessary. Under such circumstances, RAGS indicates that the primary issue is establishing a reliable representation of the extent of the contaminated area. Determining extent of contamination is not discussed in this guidance and involves different decisions, DQOs, and sampling designs. If the results of site monitoring are less than two orders of magnitude above background, the procedures used for sampling and analysis for risk assessment should follow the recommendations of Chapter 4.

The null hypothesis is always evaluated and accepted or rejected with a specified level of certainty. This level of certainty is defined by the significance, or confidence, level. A type I error is the probability that the null hypothesis is rejected when in fact it is true (which contributes to false positive conclusions). A type II error is the probability that the null hypothesis is accepted when it is false (a false negative conclusion). How sampling and analysis design affects the likelihood of these two types of errors is described in Chapter 4.

Evaluating whether analytical data are adequate to identify and examine exposure pathways and their exposure areas. Identifying and delineating exposure pathways and their exposure areas are important in identifying potentially exposed populations and for developing intake estimates. In the baseline risk assessment, the risk assessor combines data on contamination with information on human activity patterns to identify exposure pathways and to determine the exposure area. The ability to accomplish this depends on the adequacy of analytical data.

Sampling should be designed to provide representative data for exposure areas at a site, to address hot spots, to evaluate the transport of site-related chemicals of potential concern, and to facilitate the identification of all exposure pathways. A well-designed sampling and analysis program results in data of known quality and quantification of spatial and temporal variability; it specifies how to interpret the magnitude of observed values (such as by comparison with background levels or some other benchmark). Analytical data should characterize the extent of contamination at the site in three dimensions.

Evaluating whether analytical data are adequate to fully characterize exposure areas. Heterogeneity should be considered in the environmental medium under evaluation. Hot spots need to be identified and characterized. Neptune, *et. al.* 1990, have proposed the concept of an "exposure unit" as the area over which receptors integrate exposure. This concept establishes a basis for summarizing the results of monitoring and transport modeling. The sampling and analysis program must be designed to enable the risk assessor to refine the initial characterization of exposure pathways and to spatially and temporally identify the critical areas of exposure.

2.1.2 Exposure Assessment

Overview of methods for exposure assessment. The objectives of the exposure assessment are:

- To identify or define the source of exposure,
- To define exposure pathways along with each of their components (e.g., source, mechanism of release, mechanism of transport, medium of transport, etc.),
- To identify potentially exposed populations (receptors), and
- To measure or estimate the magnitude, duration, and frequency of exposure to site contaminants for each receptor (or receptor group).

Actions at hazardous waste sites are based on an estimate of the reasonable maximum exposure (RME) expected to occur under both current and future conditions of land use (EPA 1989a). EPA defines the RME as the highest exposure that is reasonably expected to occur at a site

over time. RMEs are estimated for individual pathways and combined across exposure pathways if appropriate. Once potentially exposed populations are identified, environmental concentrations at points of exposure must be determined or projected. Intake estimates (in mg/kg-day) are then developed for each chemical of potential concern using a conservative estimate of the average concentration to which receptors are exposed over the exposure period. (RAGS recommends a 95% upper confidence limit (UCL) on the arithmetic mean.) The concentration estimate is then combined with other exposure parameters (e.g., frequency, duration, and body weight) to calculate intake.

In the risk assessment report, estimates of intake are accompanied by a full description (including sources) of the assumptions made in their development. This information may be used subsequently in sensitivity and uncertainty analyses in the risk characterization.

Uncertainty analysis in exposure assessment. Exposure assessments can introduce a great deal of uncertainty into the baseline risk assessment process. Small measures of uncertainty in each of the input parameters which comprise an exposure scenario may result in substantial uncertainty in the final assessment. The largest measure of uncertainty is associated with characterizing transport and transformation of chemicals in the environment, establishing exposure settings, and deriving estimates of chronic intake. The ultimate effect of uncertainty in the exposure assessment is an uncertain estimate of intake.

The following sections discuss the significance of the uncertainty in the analytical data set on selected aspects of exposure assessment. For a more complete discussion of the exposure assessment process, the reader is referred to RAGS, Part A.

Characterizing environmental fate, identifying exposure pathways, and identifying receptors at risk. An evaluation of the transport and transformation of chemicals in the environment is conducted for several reasons:

- To understand the behavior of site-related chemicals of potential concern,
- To project the ultimate disposition of these chemicals,
- To identify exposure pathways and receptors potentially at risk, and
- To characterize environmental concentrations at the point of exposure.

These evaluations cannot be accomplished with any degree of certainty if the analytical data are inadequate. Monitoring data are most appropriately used to estimate current or existing exposure when direct contact with contaminated environmental media is the primary concern. Modeling may be required, however, in order to evaluate the potential for future exposure, or exposure at a distance from the source of release, or to predict present concentrations where measurement is too costly. In each case, success in estimating potential exposures depends heavily on the adequacy of the analytical data.

Environmental fate and transport assessment often uses models to estimate concentrations in environmental media at points distant from the source of release. Models, of necessity, are simplifications of a real, physical system. Consequently, it is critical that the limitations of the model (the way that the model differs from reality) be understood and considered when applying the model to a particular site. The degree to which the model differs from reality (in critical areas of the analysis) contributes to the uncertainty of the analysis. Transport models are commonly selected for their utility in describing or interpreting a set of monitoring data. Chemical transport models must be carefully selected for their ability to meaningfully characterize the behavior of chemicals in the environmental medium for the specific site under investigation. Models that are inappropriate for the geophysical conditions at the site will result in errors in the exposure assessment. For example, the model may be designed to predict contaminant movement through sand, while soils at the site are primarily made up of clay. Additionally, if the analytical data set is severely limited in size or does not accurately characterize the nature of contamination at the site, a transport model cannot be properly selected or accurately calibrated. This introduces additional uncertainty.

> ☛ *Uncertainty in the analytical data, compounded by uncertainty caused by the selection of the transport models, can yield results that are meaningless or that cannot be interpreted.*

Estimating chemical intake. Uncertainties in all elements of the exposure assessment come together, and are compounded, in the estimate of intake. It is here that the professional judgment of the risk assessor is particularly important. The risk assessor must examine and interpret a diversity of information:

- The nature, extent and magnitude of contamination,
- Results of environmental transport modeling,
- Identification of exposure pathways and areas,

- Identification of receptor groups currently exposed and potentially exposed in the future, and
- Activity patterns and sensitivities of receptors and receptor groups.

Based on this information, the risk assessor characterizes the exposure setting and quantifies all parameters needed in the equations to estimate intake (EPA 1989a). Chemical intake is a function of the concentration of the chemical at the point of contact, the amount of contaminated medium contacted per unit time or event, the exposure frequency and duration, body weight, the ability of the chemical to penetrate the exchange boundary, and the average time period during which exposure occurs. Exhibit 7 is the generic form of the intake equation used in exposure assessment.

The specific form of the intake equation varies depending upon the exposure pathway under consideration (e.g., ingestion, inhalation, dermal contact) (EPA 1989a). Each of the variables in these equations, including chemical concentration, is commonly characterized as a point estimate. However, each intake variable in the equation has a range of possible values. Site-specific characteristics determine the selection of the most appropriate values. In an effort to increase consistency among Superfund risk assessments, EPA has established standardized exposure parameters to be used when site-specific data are unavailable (EPA 1991b). Note that the combination of all factors selected should result in an estimate of reasonable maximum exposure for each chemical in each pathway (EPA 1989a).

For most risk assessments, it may not be possible, nor necessarily advantageous, to develop a quantitative uncertainty analysis. In these cases, a summary of major assumptions and their anticipated effects on final exposure estimates should be included to provide a qualitative characterization of the level of certainty in the intake estimates.

2.1.3 Toxicity Assessment

Overview of methods for toxicity assessment. The objectives of toxicity assessment are to evaluate the inherent toxicity of the compounds at the site, and to identify and select toxicity values to evaluate the significance of receptor exposure to these compounds. Toxicity assessments rely on scientific data available in the literature on adverse effects on humans and nonhuman species.

Several values of toxicity are important in human health risk assessments. Reference doses (RfDs) and reference concentrations (RfCs) are used for oral and inhalation exposure, respectively, to evaluate non-carcinogenic and developmental effects; cancer slope factors and unit risk estimates are used for the oral and inhalation pathways for carcinogens.

RfDs and RfCs are values developed by EPA to evaluate the potential for non-carcinogenic effects in humans. The RfD is defined as an estimate (with uncertainty spanning an order of magnitude or more) of a daily exposure level for human populations, including sensitive sub-populations, that is likely to be without an appreciable risk of adverse health effects over the period of exposure (EPA 1989a). Subchronic or chronic RfDs may be derived for a chemical for intermediate or long-term exposure scenarios. These values are typically derived from the no-observable-adverse-effect level (NOAEL) or the lowest-observable-adverse-effect level (LOAEL) and the application of uncertainty and modifying factors (EPA 1989a). Uncertainty factors are used to account for the variation in sensitivity of human sub-populations and the uncertainty inherent in extrapolating the results of animal studies to humans. Modifying factors account for additional uncertainties in the studies used to derive the NOAEL or LOAEL.

Cancer slope factors and unit risk values are defined as plausible, upper-bound estimates of the probability of cancer response in an exposed individual, per unit intake over a lifetime exposure period (EPA 1989a). EPA commonly develops slope factors for carcinogens with weight-of-evidence classifications that reflect the likelihood that the toxicant is a human carcinogen (EPA 1989a).

To reduce variability in toxicological values used for risk assessment, a standardized hierarchy of available toxicological data is specified for Superfund. The primary source of information for these data is the Integrated Risk Information System (IRIS) database (EPA 1989d). IRIS consists of verified RfDs, RfCs, cancer slope factors, unit risks, and other health risk and EPA regulatory information. Data in IRIS are regularly reviewed and updated by an EPA workgroup. If toxicity values are not available in IRIS, the EPA *Health Effects Assessment Summary Tables* (HEAST) (EPA 1990a) are used as a secondary current source of information. Additional sources of toxicity information are provided in RAGS.

The toxicity assessment is conducted parallel with the exposure assessment, but may begin as early as the data collection and evaluation phase. As chemicals of potential concern are identified at the site, the toxicologist begins to identify the appropriate toxicity values. A well-designed sampling and analysis program facilitates timely identification of the chemicals that will be the focus of the risk assessment.

EXHIBIT 7. GENERIC EQUATION FOR CALCULATING CHEMICAL INTAKES

$$I = C \times \left(\frac{CR \times EFD}{BW}\right) \times \frac{1}{AT}$$

Where:

I = intake; the amount of chemical at the exchange boundary (mg/kg body weight-day)

Chemical-related variable

C = chemical concentration; the average concentration contacted over the exposure period (e.g., mg/liter water)

Variables that describe the exposed population

CR = contact rate; the amount of contaminated medium contacted per unit time or event (e.g., liters/day)

EFD = exposure frequency and duration; describes how long and how often exposure occurs. Often calculated using two terms (EF and ED):

EF = exposure frequency (days/year)

ED = exposure duration (years)

BW = body weight; the average body weight over the exposure period (kg)

Assessment-determined variable

AT = averaging time; period over which exposure is averaged (days)

Source: RAGS (EPA 1989a).

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Uncertainty analysis and toxicity assessment. The toxicity assessment is another contributor to uncertainty in risk assessment. Limitations in the analytical data from environmental samples affect the results of the toxicity assessment, but not to the extent that they affect other components of the risk assessment process. Data on physical and chemical parameters that may influence bioavailability can influence route-to-route and vehicle-related adjustments to toxicity values. The selection of appropriate toxicity values is influenced by monitoring data from environmental samples to the extent that this information assists in identifying chemicals of potential concern, exposure pathways, and the time periods over which exposure may occur. Based on this information, the toxicologist identifies sub-chronic or chronic RfDs, RfCs, and cancer slope factors for oral, dermal, and inhalation exposure pathways.

A list of toxicity values for risk assessment should include an indication of the degree of certainty associated with these values. Weight-of-evidence classifications provide a qualitative estimate of certainty and should be included in the discussion of cancer slope factors. Uncertainty and modifying factors used in deriving RfDs and RfCs should also be included in the discussion of non-carcinogenic effects.

2.1.4 Risk Characterization

Overview of methods for risk characterization. The last step in the baseline risk assessment is risk characterization. This is the process of integrating the results of the exposure and toxicity assessments, by comparing estimates of intake with appropriate toxicological values to determine the likelihood of adverse effects in potentially exposed populations. Risk characterization is considered separately for carcinogenic and non-carcinogenic effects, because organisms typically respond differently following exposure to carcinogenic and non-carcinogenic agents. For non-carcinogenic effects, toxicologists recognize the existence of a threshold of exposure below which there is likely to be no appreciable risk of adverse health impacts in an exposed individual. It is the current EPA position that exposure to any level of carcinogenic compounds is considered to carry a risk of adverse effect, and that exposure is not characterized by the existence of a threshold.

EPA's procedure for calculating risk from exposure to carcinogenic compounds (EPA 1986a, EPA 1989a, EPA 1989b) uses a non-threshold, dose-response model. The model is used to calculate a cancer slope factor (mathematically, the slope of the dose-response curve) for each chemical. Generally, the cancer slope factor is used in conjunction with the chronic daily intake to derive a probabilistic upperbound estimate of excess lifetime cancer risk to the individual.

The dose-response model most commonly used by EPA in deriving the cancer slope estimates is linearized and multistage. The mathematical relationship of the model assumes that the dose-response relationship is linear in the low-dose portion of the curve (EPA 1989a). Given this assumption, the slope factor is a constant, and risk is directly proportional to intake.

The recommended practice for evaluating the potential for non-carcinogenic effects is to compare the RfD of a given chemical to the estimated intake of the potentially exposed population from a given exposure pathway (EPA 1989a). This ratio (intake/RfD) is termed the "hazard quotient." It is not a probabilistic estimate of risk, but simply a measure of concern, or an indicator of the potential for adverse effects. A more detailed discussion of risk characterization is presented in RAGS. Further discussion of methods for risk characterization, and of specific factors such as metabolic rate factors, gender differences, and variable effects due to multiple chemicals of potential concern, is available from many sources (EPA 1988a, EPA 1989b, EPA 1989c).

Uncertainty analysis in risk characterization. No risk assessment is certain. Risk assessment is a process that provides an estimate of potential (present and future) individual risk, along with the limitations or uncertainties associated with the estimates. The most obvious effect of limitations in the analytical data on risk characterization is the ability to accurately estimate the potential for adverse effects in potentially exposed individuals. Clearly, if the available monitoring data do not facilitate a meaningful determination of RME values, the risk estimates will directly reflect this uncertainty.

> ☛ *Uncertainties in toxicological measures and exposure assessment are often assumed to be greater than uncertainties in environmental analytical data; thus, they are assumed to have a more significant effect on the uncertainty of the risk assessment.*

Resource and time constraints often limit the opportunity to develop a well-designed and comprehensive data set. Risk assessments must be conducted using the available information, even when there is no opportunity to improve the data set. However, the results should be presented with an explicit statement regarding limitations and uncertainty.

If possible, a sensitivity analysis should be conducted to bound the results of risk assessments. A simple approach might consist of establishing the range of potential values (e.g., minimum, most likely, and maximum) for key input variables and discussing the influence on the resulting risk estimates. The key variables can then be ranked with respect to the magnitude of potential effect on the risk estimates. In certain instances, more

quantitative approaches to uncertainty analysis may be useful if they can be supported by the available information. Combining probability distributions using Monte Carlo techniques is one commonly cited example (EPA 1988b, EPA 1989a, Finkel 1990). An overview of recommended methods for assessment of uncertainty in risk characterization is presented in RAGS. Risk*Assistant, a software tool developed for EPA, provides an uncertainty analysis that determines the effect on the final risk estimate of using alternative parameter values, indicates the relative contribution of each pathway to risks from the contaminated media, and (for carcinogenic risks) determines the percentage of total risk from a contaminant in each medium (Thistle Publishing 1991). A more detailed consideration of uncertainty analysis in risk assessment may be found in *Methodology for Characterization of Uncertainty in Exposure Assessment* (EPA 1985) and *Confronting Uncertainty in Risk Management: A Guide for Decision-Makers* (Finkel 1990).

2.2 ROLES AND RESPONSIBILITIES OF KEY RISK ASSESSMENT PERSONNEL

The risk assessor generally enlists the participation of individuals with specific skills and technical expertise. The quality and utility of the baseline risk assessment will ultimately depend on the planning and interaction of these technical professionals. Key participants include the RPM and the risk assessor, who are primarily responsible for ensuring that data collected during the RI are useable for risk assessment activities. Other participants include hydrogeologists, chemists, statisticians, quality assurance staff, and other technical support personnel involved in planning and conducting the RI. Exhibit 8 summarizes the roles and responsibilities of the risk assessment participants.

2.2.1 Project Coordination

All data collection activities that support the risk assessment are coordinated by the RPM. The RPM's responsibilities begin upon site listing and continue through deletion of the site from the National Priorities List. A network of technical experts, including representatives of other agencies involved in human health or environmental/ecological assessments or related issues, is established at the start of the RI. This ensures that the potential for adverse effects to human health and the environment is adequately assessed during the RI. To successfully plan and direct the sampling and analysis effort, the RPM must facilitate interaction among key participants.

2.2.2 Gathering Existing Site Data and Developing the Conceptual Model

The RPM is responsible for gathering and evaluating all historical and existing site data. This is an important element in planning the scope of the risk assessment and data collection, and in determining additional data needs. Sources of information especially pertinent for risk assessment include data from potentially responsible parties, industrial records identifying chemicals used in processes, preliminary natural resource studies, Agency for Toxic Substances and Disease Registry (ATSDR) health studies, environmental impact statements, transport manifests, site records, site inspection documents, and site visits. Aerial photographs and site maps showing past and present locations of structures and transportation corridors should also be collected. The RPM should also consider the application of a computer-based Geographical Information System (GIS) as a major tool.

The RPM should ensure that a broad spectrum analysis was conducted at the site for all media and should review industry-specific records to minimize the potential for false negatives. From the inspection of historical data and broad spectrum analyses, a preliminary list of the chemicals of potential concern is prepared to assist in scoping and in developing the conceptual model of the site. Once all the existing historical site data have been collected, the RPM works with the risk assessor to develop a conceptual model. The conceptual model is a depiction and discussion of the current understanding of the contamination, the sources of release to the environment, transport pathways, exposure pathways, exposure areas and receptors at risk. Preliminary identification of potential exposure pathways at the site under investigation is particularly important for the design of a thorough data collection effort. The conceptual site model should be provided to all key participants in the RI during the project scoping and should be included in the workplan. As work progresses and the site is better characterized, the RPM and the risk assessor should update the conceptual model.

2.2.3 Project Scoping

The adequacy of the sampling and analysis effort determines the quality of the risk assessment. Therefore, it is imperative that the risk assessor be an active member of RI planning and continue to be involved during the entire course of the project.

EXHIBIT 8. ROLES AND RESPONSIBILITIES OF RISK ASSESSMENT TEAM MEMBERS

Remedial project manager

- Directs, coordinates and monitors all activities.
- Establishes network with other data users including federal, state and local agencies.
- Creates conceptual model.
- Gathers existing site data.
- Organizes scoping meetings.
- Controls budget and schedule.
- Guides preparation of QA documents.
- Ensures that the risk assessor receives preliminary analytical data.
- Contributes to data assessment.
- Develops preliminary list of chemicals of potential concern.
- Resolves problems affecting RI objectives, including risk assessment issues (e.g., resampling, reanalysis).

Risk assessor

- Reviews all relevant existing site data.
- Assists the RPM in developing the conceptual model and the preliminary list of chemicals of potential concern.
- Contributes to recommendations on sampling design, analytical requirements, including chemicals of potential concern, detection limits and quality control needs during project scoping.
- Helps to refine the conceptual model.
- Communicates frequently with the RPM, hydrogeologist and chemist to ensure that data collection meets needs.
- Reviews and contributes to SAP and QA documents.
- Assesses preliminary data as soon as available to verify conceptual site model.
- Specifies additional needs.
- Assesses reviewed data for useability in risk assessment.
- Communicates all site activities with specific groups, such as chemists.
- Prepares risk assessment.

Hydrogeologist, chemist and other technical support

- Provides technical input to scoping.
- Prepares/provides input to SAP and QA documents in support of risk assessment data needs.
- Communicates frequently with the RPM and/or risk assessor on status of data collection and issues affecting data.
- Provides preliminary data to the RPM and/or risk assessor for review.
- Supports fate and transport modeling for the exposure assessment.
- Implements corrective actions to improve data useability.

Quality assurance specialist

- Responsible for data quality review and technical assistance in preparing QA documents.
- Provides historical performance QA data or recommendations for appropriate QC.
- Ensures adequate QA procedures are in place, including field and analytical audits.

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☛ *Analytical data collected solely for other purposes may not be of optimal use to the risk assessment.*

Data obtained solely with the aim of characterizing the nature and extent of contamination at a site may not fully support the needs of the risk assessor in quantitating exposure, and therefore the potential for adverse effects in human and nonhuman receptors. Data on the nature and extent of contamination may therefore be rejected by the risk assessor, requiring an additional round of sampling. For example, data identifying the boundaries of the site may not be representative of the level of contamination within an exposure area. Therefore, it is important to maintain the risk assessment data requirements as a high priority throughout remedial investigations.

Sampling and analysis methods discussed during scoping should ultimately be based on site-specific data needs. The RPM, risk assessor, hydrogeologist, statistician, and project chemist must maintain open communication during scoping and throughout the RI to ensure that this occurs. Data review and deliverable requirements should be determined during the scoping meetings so that these specifications can be included in the sampling and analysis plan (SAP) for the RI. The RPM should prepare a checklist of considerations for the scoping meetings and provide it to all individuals involved. Exhibit 9 presents an example checklist of items useful for risk assessment to be considered by the RPM during scoping. Chapters 3 and 4 give specific guidance for planning the data collection efforts to support risk assessments.

2.2.4 Quality Assurance Document Preparation and Review

After scoping, the RPM guides the preparation of the workplan and quality assurance documents. The workplan, the SAP, and the quality assurance project plan (QAPjP) should document the combined decisions of the RPM, risk assessor, and other project staff.

EXHIBIT 9. EXAMPLE RISK ASSESSMENT CHECKLIST FOR USE IN SCOPING

- Has all historical information been gathered and characterized and is it appropriate and available for use?
- What sample matrices should be investigated?
- What analytical methods should be used?
- Are the methods appropriate for risk assessment, given specific contaminants present and their toxicity?
- Will any special quality control requirements be necessary?
- Who will conduct the analysis (e.g., which type of laboratory)?
- What analytical data sources should be used (fixed laboratory and/or field analysis)?
- What sampling designs are appropriate?
- How many samples will be needed?
- How will the data review be accomplished?
- What types of deliverables will be required? Specify the types of deliverables required from both laboratory and data validation.
- What budget or other limitations constrain data collection (e.g., due date, contractor availability)?

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Particular emphasis is placed on establishing confidence limits, acceptable error, and level of quality control (discussed in Chapter 3). This facilitates cost-effective design of the sampling and analytical program and minimizes the collection of data of limited use for risk assessment.

The risk assessor reviews the workplan and SAP to ensure that the relevant data quality issues, sampling design, analytical needs, and data assessment procedures are adequately addressed for risk assessment. Exhibits 10 and 11 provide checklists to aid the review of the workplan and SAP.

2.2.5 Budgeting and Scheduling

As the overall site manager, the RPM must address and balance risk assessment data needs with other data use needs, such as health and safety, treatability studies, transport, and the nature and extent of contamination. The risk assessor is responsible for identifying specific data requirements for risk assessment and communicating these needs to the RPM. The RPM is responsible for developing and implementing the schedule for acquiring the data. Balancing costs and services while adhering to the schedule is a major responsibility of the RPM.

The RPM must coordinate the use of analytical services. Data from different analytical sources provide the flexibility needed to balance cost with sampling needs and time constraints. The advantages and disadvantages of field analyses and fixed laboratory analyses should be considered, as described in Chapters 3 and 4. The risk assessment participants can assist in the development of field sampling plans and the selection of appropriate analytical methods that will provide the risk assessor with a set of useable data, within the budgeting and scheduling constraints of the RPM.

2.2.6 Iterative Communication

Continuing, open, and frequent communication among the participants is critical to the success of the RI and baseline risk assessment. A single meeting or discussion is rarely adequate to ensure that all relevant issues have been addressed. Development of the risk assessment within the RI report is an iterative process of action, feedback, and correction or adjustment.

After review of the workplan, the SAP, and the QAPjP, the RPM monitors the flow of information. The risk assessor assists the RPM to ensure that the data produced are in compliance with the requirements of the workplan and SAP. Key questions they consider once the data become available are:

- Have correct sampling protocols been followed?
- Have all critical samples been collected?

EXHIBIT 10. CHECKLIST FOR REVIEWING THE WORKPLAN

- Does the workplan address the objectives of baseline risk assessment?
- Does the workplan document the current understanding of site history and the physical setting?
- Have historical data been gathered and assessed?
- Has information on probable background concentrations been obtained?
- Does the workplan provide a conceptual site model for the baseline risk assessment, including a summary of the nature and extent of contamination, exposure pathways of potential concern, and a preliminary assessment of potential risks to human health and the environment?
- Does the workplan document the decisions and evaluations made during project scoping, including specific sampling and analysis requirements for risk assessment?
- Does the workplan address all data requirements for the baseline risk assessment and explicitly describe the sampling, analysis and data review tasks?

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EXHIBIT 11. CHECKLIST FOR REVIEWING THE SAMPLING AND ANALYSIS PLAN

- Do the objectives of the QAPjP and the field sampling plan meet risk assessment needs established in the scoping meeting?
- Are QA/QC procedures provided for in the SAP adequate for the purposes of the baseline risk assessment?
- Have the data gaps for risk assessment that were identified in the RI workplan been adequately addressed in the SAP?
- Are there sufficient QC samples to measure the likelihood of false negatives and false positives, and to determine the precision and accuracy of resulting data?
- Have analytical methods been selected that have detection limits adequate to quantitate contaminants at the concentration of concern?
- Have SOPs been prepared for sampling, analysis and data review?
- Will the sampling and analysis program result in the data needed for the baseline risk assessment:
  - -- to address each medium, exposure pathway and chemical of potential concern,
  - -- to evaluate background concentrations,
  - -- to provide detail on sample locations, sampling frequency, statistical design and analysis,
  - -- to evaluate temporal as well as spatial variation, and
  - -- to support evaluation of current as well as future resource uses?

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- Have the samples been analyzed as requested?
- Are data arriving in a timely fashion?
- Have appropriate sample quantitation limits/detection limits been achieved?
- Has quality assurance been addressed as stated in the SAP and QAPjP?
- Have the data been reviewed as stated in the SAP?
- Is the quality of the analytical data acceptable for their intended use?

Based upon these considerations, the RPM, risk assessor and other technical team members must jointly determine if any corrective actions are needed, such as requesting additional sampling, using alternative analytical methods, or reanalyzing samples.

2.2.7 Data Assessment

The RPM and risk assessor work with other participants to identify a list of chemicals of potential concern and decide on data review procedures. This information is developed during project scoping and incorporated into the workplan and SAP. The RPM, risk assessor, and project chemist should agree on the type and level of data review required for both positive and "non-detect" results. Typically, the RPM assesses the overall data reviewed by the chemist, and the risk assessor reviews data relevant to risk assessment, unless other arrangements have been established and explicitly stated in the SAP.

The risk assessor may request preliminary data, or results that have received only a partial review, in order to expedite the risk assessment to save time and resources. Preliminary data can be used to validate the conceptual model or to begin the toxicity assessment. The data may also indicate a need for modifying sampling or analytical procedures. However, preliminary data should **not** be used in calculating risk. Once the full analytical data set is obtained, the RPM and risk assessor should consult with the project chemist and statistician to assess the utility of all available information.

2.2.8 Assessment and Presentation of Environmental Analytical Data

Once environmental data are evaluated in the data review process, the risk assessor develops a final data set for use in the baseline risk assessment. All chemicals of potential concern should now be identified. The risk assessor prepares summary tables containing the following information:

- Site name and sample locations,
- Number of samples per defined, representative area of each medium (e.g., do not count background samples together with other samples),
- Sample-specific results,
- Analyte-specific sample quantitation limits,
- Number of values above the quantitation limit,
- Measures of central tendency (e.g., 95% UCL on the arithmetic mean of the environmental concentration),
- Specifications for the treatment of detection or quantitation limits and treatment of qualified data, and
- Ranges of concentrations.

All assumptions, qualifications, and limitations should be explicitly stated in the tables. The risk assessor provides the final data summary tables to the RPM, project hydrogeologist, project chemist, and other appropriate project staff for review. These are the data that will be used in the baseline risk assessment to determine the potential risk to human health. It is essential, therefore, that this information consists of the best data available and reflects the collective review of the key participants in the risk assessment. An example of such a set of data is given in Appendix I.

Chapter 3
Useability Criteria for Baseline Risk Assessments

This chapter applies data useability criteria to data collection planning efforts to maximize the useability of environmental analytical data in baseline risk assessments. It also addresses preliminary issues in planning sampling and analysis programs.

The chapter has two sections. Section 3.1 discusses data useability criteria involved in risk assessment and suggests ways they can be applied to ensure data are useable. Section 3.2 presents preliminary sampling and analysis issues including identification of chemicals of potential concern, available sampling and analytical strategies or methods, and probable sources of uncertainty.

Before scoping the RI, it is critical for successful planning that the RPM develop a conceptual site model (Exhibit 6) in consultation with the risk assessor and all appropriate personnel. This chapter provides the background information necessary to plan for the acquisition of environmental data for baseline risk assessments. The quality of a risk assessment is intimately tied to the adequacy of the sampling and analysis plan (SAP) developed during the RI.

> ☛ *Effective planning improves the useability of environmental analytical data in the final risk assessment.*

Data needs for baseline risk assessments are not necessarily met by data the RPM acquires to identify the nature and extent of contamination at a Superfund site. For example, a sampling strategy designed to determine the boundaries of a contaminated area may not provide data to quantitate concentrations within an exposure area. The risk assessment may also require more precision and accuracy, and lower detection limits. Accordingly, the risk assessor should be an active member of the team planning the RI and must be consulted from the start of the planning process.

Four fundamental decisions for risk assessment are to be made with the data acquired during the RI, as discussed in Chapter 2.

- If the sampling design is representative, the question of what contamination is present and at what concentration is an analytical problem. Key concerns are the probability of false negatives and false positives. The selection of analytical methods, laboratory performance, and type and amount of data review affects these issues for both site and background samples.
- Assuming that chemicals of potential concern have been identified, the second question involves background levels of contamination. Are site concentrations sufficiently elevated from true background levels to indicate an increased risk for human health due to site contamination?
- All exposure pathways and exposure areas must be identified and examined. The two decisions concerning exposure pathways and areas primarily involve identifying and sampling the media of concern.
- The final decision involves characterizing exposure areas. Sampling and analysis must be representative and satisfy performance objectives determined during the planning process.

RI planning and implementation of RI plans affect the certainty of chemical identification and quantitation. Therefore, the RI needs to collect useable environmental analytical data to enable the risk assessor to make these decisions.

Acronyms

AA	atomic absorption
CLP	Contract Laboratory Program
CRDL	contract required detection limit
CRQL	contract required quantitation limit
DQI	data quality indicator
DQO	data quality objective
GC	gas chromatography
HRS	Hazard Ranking System
ICP	inductively coupled plasma
IDL	instrument detection limit
LOL	limit of linearity
LOQ	limit of quantitation
MDL	method detection limit
MS	mass spectrometry
OVA	organic vapor analyzer
PA/SI	primary assessment/site inspection
PAH	polycyclic aromatic hydrocarbon
PCB	polychlorinated biphenyl
PQL	practical quantitation limit
QA	quality assurance
QC	quality control
QAPjP	quality assurance project plan
QTM	Quick Turnaround Method
RI	remedial investigation
RI/FS	remedial investigation/feasibility study
RPM	remedial project manager
RRF	relative response factor
RRT	relative retention time
SAP	sampling and analysis plan
SOP	standard operating procedure
SQL	sample quantitation limit
TIC	tentatively identified compound
TRIS	Toxic Release Inventory System
XRF	X-ray fluorescence

3.1 DATA USEABILITY CRITERIA

Exhibit 12 lists the six data useability criteria involved in planning for the risk assessment, summarizes the importance of each criterion to risk assessment, and suggests actions to take during the planning process to improve the useability of data. The following sections define each criterion and describe its effect on risk assessment.

3.1.1 Data Sources

The data sources selected during the RI planning process depend on the type of data required and their intended use. Data collected prior to the RI are considered historical; data collected during the RI are considered current and are usually specified in the RI planning process. Data may be analytical or non-analytical. The same analytical data requirements apply, whether the data are current or historical. Field screening methods can be used, and sufficient documentation produced, to act as an initial source of data. The minimum criteria for analytical data are discussed in Chapter 5.

Exhibit 13 identifies available data sources and their primary uses in the risk assessment process. Historical and current analytical data sources are briefly discussed below.

Data sources prior to remedial investigation. Historical data sources are useful for determining sampling locations and analytical approaches in the RI. Early site inspections may locate industrial process information that suggests chemicals of potential concern. Historical data indicate industry-specific analytes and general levels of contamination and trends that are useful for identifying exposure pathways, for developing the sampling design, and for selecting analytical methods. Historical analytical data are often available from the preliminary assessment/site inspection (PA/SI), including reports on the physical testing, screening, and analysis of samples. Other sources of analytical data for baseline risk assessment include the Hazard Ranking System (HRS) documentation, site records on removal and disposal, and industry-specific systems for chemical discharge permits. Results from analyses by state or local governments may also indicate chemicals of potential concern. Exact locational data for historical samples should be obtained whenever possible.

> ☛ *Use historical analytical data and a broad spectrum analysis to initially identify the chemicals of potential concern or exposure areas.*

The quality of historical data must be determined prior to their use in the RI. For historical analytical data to be

EXHIBIT 12. IMPORTANCE OF DATA USEABILITY CRITERIA IN PLANNING FOR BASELINE RISK ASSESSMENT

Data Useability Criterion	Importance	Suggested Action
Data Sources (3.1.1)	Data sources must be comparable if data are combined for quantitative use in risk assessment. Plans can be made in the RI for use of appropriate data sources so that data compatibility does not become an issue.	Use data from different data sources together to balance turnaround time, quality of data, and cost. Consult with a chemist or statistician to assess compatibility of data sets.
Documentation (3.1.2)	Deviations from the SAP and SOPs must be documented so that the risk assessor will be aware of potential limitations in the data. The risk assessor may need additional documentation, such as field records on weather conditions, physical parameters and site-specific geology. Data useable for risk assessment must be linked to a specific location.	Review the workplan and SAP and, if appropriate, SOPs. As the data arrive, check for adherence to the SAP so that corrective action such as resampling may be taken and still adhere to the project timetable. Stress importance of chain-of-custody for sample point identification in RI planning meetings.
Analytical Methods and Detection Limits (3.1.3)	The method chosen must test for the chemical of potential concern at a detection limit that will meet the concentration levels of concern in applicable matrices. Samples may have to be reanalyzed at a lower detection limit if the detection limit is not low enough to confirm the presence and amount of contamination.	Participate with chemist in selecting methods with appropriate detection limits during RI planning. Consultation with a chemist is required when a method's detection limit is at or above the concentration level of concern.

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EXHIBIT 12. IMPORTANCE OF DATA USEABILITY CRITERIA IN PLANNING FOR BASELINE RISK ASSESSMENT (Cont'd)

Data Useability Criterion	Importance	Suggested Action
Data Quality Indicators (3.1.4)		
Completeness	Completeness for critical samples must be 100%. Unforeseen problems during sample collection (as defined in Chapter 4) and analysis can affect data completeness. If a sample data set for risk assessment is not complete, more samples may have to be analyzed, affecting RI time and resource constraints.	Define completeness in the SAP for both the number of samples and quantity of useable data needed to meet performance objectives. Identify critical samples during scoping. The SAP should be reviewed by the RPM before initiation of sampling.
Comparability	The risk levels generated in quantitative risk assessment may be questionable if incompatible data sets are used together.	Plan to use comparable methods, sufficient quality control, and common units of measure for different data sets that will be used together, to facilitate data compatability. Consult with a chemist to ensure comparibility of data sets.
Representa-tiveness	Sample data must accurately reflect the site characteristics to effectively represent the site's risk to human health and the environment. Hot spots and exposure area media must have representative data.	Discuss plans for collection of sufficient number of samples, a sample design that accounts for exposure area media, and an adequate number of samples for risk assessment during scoping and document plans in the SAP. This guidance may be modified by Region-specific guidelines.
Precision	If the reported result is near the concentration of concern, it is necessary to be as precise as possible in order to quantify the likelihood of false negatives and false positives.	Plan for the use of QC samples (duplicates, replicates and/or collocated samples) applicable to risk assessment before sampling activities begin. Assess confidence limits from the QC data on the basis of the sampling design or analytical method used.
Accuracy	Quantitative accuracy information is critical when results are reported near the level of concern. Contamination in the field, during shipping, or in the laboratory may bias the analytical results. Instruments that are not calibrated or tuned according to Statement of Work requirements may also bias results. The use of data that is biased may affect the interpretation of risk levels.	Plan and assess QC data (blanks, spikes, performance evaluation samples) to measure bias in sampling and analysis. Consult a chemist to interpret data qualified as "estimated" that are near a concentration of concern.
Data Review (3.1.5)	Use of preliminary data or partially reviewed data can conserve time and resources by allowing modification of the sampling plan while the RI is in process. Critical analytes and samples used for quantitative risk assessment require a full data review.	Decisions regarding level and depth of review will conserve time and project resources and should be made in conjunction with the RPM and analytical chemist. "Non-detect" results require a full review.
Reports to Risk Assessor (3.1.6)	Data reviewers should report data in a format that provides readability as well as clarifying information. SQLs, a narrative, and qualifiers that are fully explained reduce the time and effort required in interpreting and using the analytical results. Limitations can be readily identified and documented in the risk assessment report.	Prescribe a report format during scoping, and include it in the SAP. Communicate with the potential data reviewer to aid the definition of a specific report format. Region-specific guidelines may apply.

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EXHIBIT 13. DATA SOURCES AND THEIR USE IN RISK ASSESSMENT

Available Data Sources	Data Type	Primary Use(s)
PA/SI data	Analytical	• Scoping and planning • Identifying data trends • Determining historical background levels
HRS documentation	Site records, manifests, PA/SI, analytical	• Quantitating the risk assessment • Identifying trends • Planning (by identifying the chemicals present)
Site records on removal and disposal	Administrative	• Planning (by identifying the chemicals present)
Toxic Release Inventory System (TRIS) (Industry-Specific)	Chemical discharge	• Planning (by identifying the chemicals present)
Site, source and media characteristics as found in PA/SI data and reference materials	Physical parameters (e.g., meteorological, geological)	• Determining fate and transport • Defining exposure pathways
Field screening	Analytical	• Performing a preliminary assessment • Characterizing the site
Field analytical	Analytical	• Quantitating the risk assessment • Characterizing the site
Fixed laboratory,* both CLP and non-CLP (EPA, state, PRP, commercial)	Analytical	• Quantitating the risk assessment • Providing a reference • Broad screen • Confirming screening data • Characterizing a site

* Mobile laboratories often have the same instrumentation available as fixed laboratories, with the exception of ICP or MS.

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useful in the quantitative risk assessment, sampling design, sampling and analytical techniques, and detection limits must be documented, and the data must have been reviewed.

Historical analytical data of unknown quality may be used in developing the conceptual model or as a basis for scoping, but not in determining representative exposure concentrations. Analytical data from the PA/SI that meet minimum data useability requirements (see Section 5.1.1) can be combined with data from the RI to estimate exposure concentrations. Similarly, historical data of lower quality may be used if the concentrations are confirmed by subsequent RI analyses.

Data sources for the remedial investigation. It may be efficient to use a variety of data sources during an RI. For example, analytical services providing a rapid turnaround of estimated data can be used to estimate the three-dimensional extent of contamination or to "chase" a groundwater pollutant plume. Rapid turnaround analytical services include field analysis or Quick

Turnaround Method (QTM) analyses under the Contract Laboratory Program (CLP). On the other hand, if an unexpected situation arises, such as the discovery of buried drums on the site, it may be appropriate to procure the analytical services of a local commercial laboratory. Data requiring a rapid turnaround are typically produced from streamlined analytical methods, and a certain percentage should be analyzed using a confirmatory method, such as CLP analytical services.

The planning process for the RI identifies gaps in the available analytical data and determines additional data collection requirements. Three types of analytical data sources can be used during the RI to acquire analytical data for a risk assessment. These include field screening, field analyses, and fixed laboratory analyses.

- Field screens are performed using chemical field test kits, ion-specific probes, and other monitoring equipment, but should be confirmed by other techniques. Field screening is usually performed to provide a preliminary assessment of the type and level of concentration of the chemicals of potential concern.
- Field analyses are performed using instruments and procedures equivalent to fixed laboratory analyses; they produce legally defensible data if QC procedures are implemented. Field analyses are usually performed as part of an integrated sampling and analysis plan to quantitate risk assessment and site characterization.
- Fixed laboratory analyses are particularly useful for broad spectrum and confirmation analyses. They often provide more detailed information over a wider range of analytes than field analyses. Fixed laboratory analyses are critical to quantitative risk assessment and site characterization.

A discussion of issues related to field and fixed laboratory analyses is presented in Section 3.2.9.

Analytical services constitute a significant portion of the Superfund budget and should be conserved when possible. CLP costs do not appear on the remedial investigation/feasibility study (RI/FS) project budget. Analyte-specific methods may be used for chemicals identified after a broad spectrum analysis by CLP or other fixed laboratory analysis, and may provide more accurate results. Site samples analyzed by CLP routine analytical services take an average of 35 days to produce results and data review will add to the overall turnaround time. Other data sources, such as a mobile laboratory or CLP QTM or special analytical services, can quickly produce good "first look" results which can be followed up immediately while on site. Mobile laboratory services can replace some CLP services if analytical capabilities are adequately demonstrated by method validation data and if minimum QC requirements are met (see p. 59). At least 10% of sample analyses should be confirmed by fixed laboratory analysis in all situations.

3.1.2 Documentation

Data collection and analysis procedures must be accurately documented to substantiate the analysis of the sample, conclusions derived from the data, and the reliability of the reported analytical data. Plans should be prepared during the RI scoping to document data collection activities. This RI documentation can be used later to evaluate completeness, comparability, representativeness, precision, and accuracy of the analytical data sets. Four major types of documentation are produced during an RI:

- The sampling and analysis plan, including a quality assurance project plan (QAPjP),
- Standard operating procedures (SOPs),
- Field and analytical records, and
- Chain-of-custody records.

Sampling and analysis plan. The scoping meetings and the SAP must clearly establish the end use requirements for data. The data quality indicators for assessing results against stated performance objectives should also be documented in the SAP (see Section 3.1.4). The SAP includes the QAPjP and information required in the SOPs, field and analytical records, and chain-of-custody records (EPA 1989a).

Standard operating procedures and field and analytical records. SOPs for field and analytical methods must be written for all field and laboratory processes. Adherence to SOPs provides consistency in sampling and analysis and reduces the level of systematic error associated with data collection and analysis. Exhibit 14 lists the types of SOPs, field records, and analytical records that are usually associated with RI data collection and analyses, and relates the importance of each to the risk assessment.

All deviations from the referenced SOPs should be pre-approved by the RPM and documented. Samples that are not collected or analyzed in accordance with established SOPs may be of limited use because their quality cannot be determined.

Chain-of-custody. The technical team must decide during scoping what data may be used for cost recovery actions, and plan accordingly for the use of full-scale chain-of-custody or less formal chain-of-custody procedures. Full-scale chain-of-custody is required for

EXHIBIT 14. RELATIVE IMPORTANCE OF DOCUMENTATION IN PLANNING AND ASSESSMENT

Documentation	Importance
Sampling and Analysis Plan	
• Selection and identification of sampling points	Critical
• Sample collection SOP	High
• Analytical procedures or protocols	High
• SOP for data reporting and review	High
• QA project plan	High
• Method-specific QC procedures	Medium
• QA/QC procedures	Medium
• Documented procedures for corrective action	Medium
• SOP for corrective action and maintenance	Medium
• Sample preservation and shipping SOP	Medium
• SOPs for sample receipt, custody, tracking and storage	Low
• SOP for installation and monitoring of equipment	Low
Chain-of-Custody	
• Documentation records linking data to sample location	Critical
• Sampling date	Critical
• Sample tags	High
• Custody seals	Low
• Laboratory receipt and tracking	Low
Field and Analytical Records	
• Field log records	High
• Field information describing weather conditions, physical parameters or site-specific geology	High
• Documentation for deviations from SAP and SOPs	High
• Data from analysis -- raw data such as instrument output, spectra, chromatograms and laboratory narrative	High
• Internal laboratory records	Low

KEY
- Critical = Essential to the useability of data for risk assessment.
- High = Should be addressed in planning for risk assessment.
- Medium = Primarily impacts how data are qualified in risk assessment.
- Low = Usually has little effect on useability of data for risk assessment.

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cost recovery and enforcement actions, but does not affect a quantitative determination of risk. Full-scale chain-of-custody includes sample labels and formal documentation that prove the sample was not tampered with or lost in the data collection and analysis process. Sample identity must be verifiable from the collector's notebook and laboratory data sheets, as well as from a formal chain-of-custody.

3.1.3 Analytical Methods and Detection Limits

The choice of analytical methods is important in RI planning. Appropriate analytical methods have detection limits that meet risk assessment requirements for chemicals of potential concern and have sufficient QC measures to quantitate target compound identification and measurement. The detection limit of the method directly affects the useability of data because chemicals reported near the detection limit have a greater possibility of false negatives and false positives. The risk assessor or RPM must consult a chemist for assistance in choosing an analytical method when those available have detection limits near the required action level. Whenever possible, methods should not be used if the detection limits are above the relevant concentrations of concern.

3.1.4 Data Quality Indicators

Data quality indicators (DQIs) are identified during the development of data quality objectives (DQOs), to provide quantitative measures of the achievement of quality objectives. This section discusses each of five DQIs as they relate to the assessment of sampling and analysis.

- Completeness
- Comparability
- Representativeness
- Precision
- Accuracy

These indicators are evaluated through the review of sampling and analytical data and accompanying documentation. The risk assessor may need to communicate with a chemist or statistician after the data collection process has been completed to evaluate DQIs. Therefore, the SAP, field and analytical records, and SOPs should be accessible. Exhibits 15 and 16 summarize the importance of DQIs to sampling and analysis in risk assessment and suggest planning actions.

Each DQI is defined in this section. Note that the specific use of the indicators to measure data useability is different for sampling and analysis. For example, completeness as applied to sampling refers to the number of samples to be collected. Completeness as applied to analytical performance primarily refers to the number of data points that indicate an analytical result for each chemical of interest (e.g., 10 samples analyzed for 25 chemicals will produce a total of 250 data points, 10 data points for each chemical).

EXHIBIT 15. RELEVANCE OF SAMPLING DATA QUALITY INDICATORS

Data Quality Indicators	Importance	Suggested Planning Action
Completeness	Complete materials enable assessment of sample representativeness for identification of false negatives and estimation of average concentration.	Stipulate SOPs for sample collection and handling in the SAP to specify requirements for completeness.
Comparability	Comparable data give the ability to combine analytical results across sampling episodes and time periods.	Use the same sample design across sampling episodes and similar time periods.
Representativeness	Representative data avoid false negatives and false positives (field sampling contamination). Non-representative data may result in bias of concentration estimates.	Use an unbiased sample design. Collect additional samples as required. Prepare detailed SOPs for handling field equipment.
Precision	Variability in concentration estimates may increase uncertainty.	Increase number of samples. Use appropriate sample designs. Use QC results for monitoring.
Accuracy	Contamination during sampling process, loss of sample from improper collection or handling (loss of volatiles) may result in bias, false negatives, or false positives and inaccurate estimates of concentration.	Use SOPs for sample collection, handling, and decontamination. Use QC results for monitoring.

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EXHIBIT 16. RELEVANCE OF ANALYTICAL DATA QUALITY INDICATORS

Data Quality Indicators	Importance	Suggested Planning Action
Completeness	Poor data quality or lost samples reduces the size of the data set and decreases confidence in supporting information.	Prepare SOPs to support sample tracking and analytical procedures, review, and reporting aspects of laboratory operations.
Comparability	Comparable data allow the ability to combine analytical results acquired from various sources using different methods for samples taken over the period of investigation.	Reference analyte-specific method performance characteristics. Reference applicable fate and transport documentation. Anticipate field and laboratory variability.
Representativeness	Non-representative data or non-homogeneity of sample increases the potential for false negatives or false positives. Potential for change in sample before analysis may decrease representativeness.	Include requirement for broad spectrum analyses across site area. Ensure sample is mixed and adequately represents the environment (not applicable to volatiles). Include provision for blank (transport, storage and analytical) QC monitoring. Use field methods when applicable, since they have an advantage in minimizing variability from transport and storage.
Precision	Monitoring can indicate the level of precision. Precision provides the level of confidence to distinguish between site and background levels of contamination. It is of primary importance when the concentration of concern approaches the detection limit.	Method QC component and site-specific QC samples that use external reference are the best monitoring techniques. Consider in method selection whether anticipated site levels are near the MDL and above action limits.
Accuracy	Accuracy also provides the level of confidence to distinguish between site and background levels of contamination. As concentration of concern approaches the detection limit, the differentiation includes confidence in determining presence or absence of chemical of potential concern.	Broad spectrum screening methods may have significant negative bias for chemicals of potential concern. Consider method accuracy and detection limits if site levels approach concentrations of concern.

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Completeness. Completeness is a measure of the amount of useable data resulting from a data collection activity. The required level of completeness should be defined in the QAPjP for the number of samples required in the sampling design and for the quantity of useable data for chemical-specific data points needed to meet performance objectives. All required data items must be obtained for critical samples and chemicals, which are identified in the QAPjP. Incompleteness in any data item may bias results as well as reduce the amount of useable data.

Problems that occur during data collection and analysis affect the completeness of a data set. Fewer samples may be collected and analyzed than originally planned because of site access problems. Laboratory performance may be affected if capacity is exceeded, causing data to be rejected. Some samples may not be analyzed due to matrix problems. Samples that are invalid due to holding time violations may have to be re-collected or the data set may be determined as useable only to a limited extent. Therefore, both advance planning in identifying critical samples and the use of alternative sampling procedures are necessary to ensure completeness of a data set for the baseline risk assessment.

Comparability. Comparability expresses the confidence with which data are considered to be equivalent. Combined data sets are used regularly to develop quantitative estimates of risk. The ability to compare data sets is particularly critical when a set of data for a specific parameter is applied to a particular concentration of concern.

Comparability for sampling primarily involves sampling designs and time periods. Typical questions to consider in determining sampling comparability include:

- Was the same approach to sampling taken in two sampling designs?
- Was the sampling performed at the same time of year and under similar physical conditions in the individual events?
- Were samples filtered or unfiltered?
- Were samples preserved?

Typical questions to consider in determining analytical comparability include:

- Were different analytical methodologies used?
- Were detection limits the same or at least similar?
- Were different laboratories used?
- Were the units of measure the same?
- Were sample preparation procedures the same?

Use routine available methods and consistent units of measure when data collection will span several different sampling events and laboratories, to increase the likelihood that analytical results will be comparable. For field analyses confirmed by laboratory analyses, careful attention must be taken to ensure that the data from field and fixed laboratories are comparable or equivalent (see Section 3.2.9). When precision and accuracy are known, the data sets can be compared with confidence. Planning ahead for comparable sampling designs, methods, quality control, and documentation will aid the risk assessor in combining data sets for each exposure pathway.

Representativeness. For risk assessment, representativeness is the extent to which data define the true risk to human health and the environment. Samples must be collected to reflect the site's characteristics and sample analyses must represent the properties of the field sample. The homogeneity of the sample, use of appropriate handling, storage, preservation procedures, and the detection of any artifacts of laboratory analyses, such as blank contamination, are particularly important. For risk assessment, sampling and analyses must adequately represent each exposure area or the definition of an exposure boundary.

Representativeness can be maximized by ensuring that sampling locations are selected properly, potential hot spots are addressed, and a sufficient number of samples are collected over a specified time span. The SAP should describe sampling techniques and the rationale used to select sampling locations.

Precision. Precision is a quantitative measure of variability, comparing results for site samples to the mean, and is usually reported as a coefficient of variation or a standard deviation of the arithmetic mean. Results of QC samples are used to calculate the precision of the analytical or sampling process. Measurement error is a combination of sample collection and analytical factors. Field duplicate samples help to clarify the distinction between uncertainty from sampling techniques and uncertainty from analytical variability. Analytical variability can be measured through the analysis of laboratory duplicates or through multiple analyses of performance evaluation samples. If analytical results are reported near a concentration of concern, the standard deviation or coefficient of variation can be incorporated in standard statistical evaluations to determine the confidence level of the reported data. A statistician or

a chemist should be consulted to make this determination. Total variability must be evaluated to assess the precision of data used to define parameters in risk assessment.

Accuracy. Accuracy is a measure of the closeness of a reported concentration to the true value. This measure is usually expressed as bias (high or low) and determined by calculating percent recovery from spiked samples. The risk assessor should know the required level of certainty for the end use of the data, expressed as DQOs, when reviewing accuracy information. When results are reported at or near a concentration of concern, accuracy information is critical.

Accuracy of identification may be affected by sample contamination introduced in the field, during shipping, or at the laboratory. Field and trip blanks should be used during the RI to identify contamination and the associated bias related to sample collection or shipment. Method blanks, audit samples, and calibration check standards should be used to monitor laboratory contamination. Accuracy information may be of less importance if the precision (bias) is known.

3.1.5 Data Review

This section discusses the importance of alternative levels of data review to the risk assessment. The two major effects of data review on data useability are:

- The timeliness of the data review and
- The level and depth of review (e.g., entire site, specific sample focus, specific analyte focus, amount of QC data assessed).

A tiered approach involving combinations of data review alternatives is recommended so that the risk assessor can use preliminary data before extensive review. The RPM, in conjunction with the risk assessor and the project chemist, must reach a consensus on the level and depth of data review to be performed for each data source, to balance useability of data and resource constraints. Exhibit 17 summarizes the characteristics and uses of different levels of data review.

Timing of review. Plans for the timing of the data review should be made prior to data collection and analysis. The risk assessor uses preliminary data in a qualitative manner to identify compounds for toxicity studies and, initially, to ascertain trends in concentrations and distributions of the analytes of concern, to plan for additional sampling, and to request additional analyses. Using data as they become available will usually reduce the time needed to complete the risk assessment. However, all data must receive a minimum level of review before use in the quantitative aspects of risk assessment. Iterations on data review is resource intensive; if they are used, they should be planned carefully as part of a structured process.

EXHIBIT 17. ALTERNATIVE LEVELS OF REVIEW OF ANALYTICAL DATA

Level of Review	Samples	Analytes	Parameters	Potential Uses
None	Initial	All	Analytical results	Qualitatively identify risk assessment analytes. Modify SAP.
Full	Initial samples analyzed for broad spectrum components	All	All analytical results, QC, and raw data	Quantitatively perform risk assessment. Modify SAP. Modify review process.
Partial	Critical samples for all analytes or All samples for critical analytes		Selected analytical results, QC, or raw data	Improve timeliness, overall efficiency, save resources. Focus on chemicals of potential concern.
Automated	All	All	Parameters available to the automated system. No raw data are evaluated.	Improve timeliness, consistency, cost effectiveness. If data are electronically transferred to a database, eliminates transcription errors.

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☛ *To expedite the risk assessment, preliminary data should be provided to the risk assessor as soon as they are available.*

Level and depth of review. The RPM may select different levels of data review, in consultation with the risk assessor or other data users and the project chemist. All data must have a minimum level of review. Data review levels can range from all site samples with all reported data to specific key analytes and samples and may be specified in EPA Regional policies. Careful consideration is required in selecting a level of review that is consistent with data quality requirements.

A full data review minimizes false positives, false negatives, calculation errors, and transcription errors. "Non-detect" results must be reviewed to avoid "false negative" conclusions. Partial review should be utilized only after broad spectrum analysis results have undergone full review; it may be useful after chemicals of potential concern have been identified. A flexible approach to data review alternatives allows the RPM to balance time and resource constraints.

Depth of data review refers to which evaluation criteria are selected, ranging from generalized criteria that may affect an entire data set (e.g., holding time) to analyte-specific criteria that may affect only a portion of results from one sample (e.g., recovery of a surrogate spike for organics or analyte spike recovery for inorganics). The RPM decides the depth of review for each data source, to provide a balance between useability of data and resource constraints. Chemicals of potential concern in the quantitative risk assessment should not be eliminated from concern without a full data review.

Automated data review systems. Automated data review systems can be used to assess all samples and analytes for which there are computer-readable data in the format required by the automated system. The depth of review depends on both the data and the assessment system. The primary advantages of automated data review systems for the risk assessor are timeliness, the elimination of transcription errors that can be introduced during manual review processes, and computer-readable output which usually includes results and qualifiers. This information can be transferred to computer-assisted risk assessment and exposure modeling systems. Exhibit 18 provides a list of software that aid data review and evaluation.

EXHIBIT 18. AUTOMATED SYSTEMS* TO SUPPORT DATA REVIEW

System	EPA Contact	Description
CADRE Computer Assisted Data Review and Evaluation	Gary Robertson Quality Assurance Div. USEPA, EMSL-LV (702) 798-2215	An automated evaluation system that accepts files from CLP format disk delivery or mainframe transfer and assesses data based on *National Functional Guidelines for Organic (or Inorganic) Data Review* (EPA 1991e, EPA 1988e) (default criteria). System accepts manual entry of other data sets, and rules for evaluation can be user-defined to reflect specific information needs. (Inorganic system is in development.)
eDATA Electronic Data Transfer and Validation System	William Coakley USEPA, Emergency Response Team (908) 906-6921	An automated review system developed to assist in rapid evaluation of data in emergency response. May be applicable for both CLP and non-CLP data. System combines DQOs, pre-established site specifications, QC criteria, and sample collection data with laboratory results to determine useability.

* Both systems operate on an IBM-compatible PC AT with a minimum of 640K RAM. A fixed disk is recommended.

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3.1.6 Reports from Sampling and Analysis to the Risk Assessor

Preliminary data reports assist the risk assessor in identifying sampling or analytical problems early enough so that corrective actions can be taken during data collection, before sampling or analysis resources are exhausted. The risk assessor should request preliminary data during RI planning and formalize the request in the SAP. The use of such information may reduce the overall time required for the risk assessment and increase the quality of a quantitative risk assessment.

Exhibit 19 lists the final data and documentation needed to support risk assessment, and rates the importance of each item. Data are most useable when reported in a readable format and accompanied by additional, clarifying information. Regional policy usually defines report structures which specify the format for manual summaries, for machine-readable data (where required), and for summary tables from data review. The RPM can request the data reviewers to provide a data summary table listing sample results, sample quantitation limits, and qualifiers on diskette for downloading into Risk* Assistant (an automated tool to support risk assessment), spreadsheets, or other software programs that the risk

EXHIBIT 19. DATA AND DOCUMENTATION NEEDED FOR RISK ASSESSMENT

Data and Documentation	Importance
• Site description with a detailed map indicating site location, showing the site relative to surrounding structures, terrain features, population or receptors, indicating air and water flow, and describing the operative industrial process if appropriate.	Critical
• Site map with sample locations (including soil depths) identified.	Critical
• Description of sampling design and procedures including rationale.	Critical
• Description of analytical method used and detection limits including SQLs and detection limits for non-detect data.	Critical
• Results given on a per-sample basis, qualified for analytical limitations and error, and accompanied by SQLs. Estimated quantities of compounds/tentatively identified compounds.	Critical
• Field conditions and physical parameter data as appropriate for the media involved in the exposure assessment.	Critical
• Narrative explanation of qualified data on an analyte and sample basis, indicating direction of bias.	High
• QC data results for audits, blanks, replicates and spikes from the field and laboratory.	High
• Definitions and descriptions of flagged data.	High
• Hardcopy or diskette results.	Medium
• Raw data (instrument output, chromatograms, spectra).	High
• Definitions of technical jargon used in narratives.	Low

KEY
Critical = Essential to the useability of data for risk assessment.
High = Should be addressed in planning for risk assessment.
Medium = Primarily impacts how data are qualified in risk assessment.
Low = Has little effect on useability of data for risk assessment.

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assessor may use. An example of a recommended report format for tabular results appears in Appendix I.

The data reviewer should provide a narrative summary, which is comprehensible to a nonchemist, describing specific sampling or analytical problems, data qualification flags, detection limit definitions, and interpretation of QC data. This summary must always be followed and supported by a detailed commentary that explicitly addresses each item from the narrative on a technical basis. The explanation for data qualification in the commentary facilitates data use. If a nontechnical narrative is unavailable, the risk assessor must (at a minimum) be provided with explanations of qualification flags, detection limits, and interpretation of QC data (see Appendices I, V and VI for examples). A chemist familiar with the site can be requested to interpret the analytical review with site-specific information, such as physical site conditions that affect sample results.

3.2 PRELIMINARY SAMPLING AND ANALYTICAL ISSUES

This guidance cannot encompass sampling design in the assessment of environmental sampling and analysis procedures; however, this section does sketch a framework for these activities. It discusses key issues for determining the potential impact of sampling and analysis procedures on data useability for risk assessment and for identifying situations that require statistical or methodological support. The sampling discussion primarily focuses on soil issues, but some generalizations can be made to other media such as sediment or groundwater. Rules of thumb, reference tables, statistical formats and checklists support the statistical understanding and sophistication of RPMs and risk assessors. A Sampling Design Selection Worksheet, a Soil Depth Sampling Worksheet, and a Method Selection Worksheet are tools, presented with step-by-step instructions in Chapter 4, to focus planning efforts.

Sampling issues. Resolving statistical and non-statistical sampling issues provides the risk assessor, project chemist, and QA personnel with a basis for identifying sampling design and data collection problems, interpreting the significance of analytical error, and selecting methods based on the expected contribution of sampling and analytical components to total measurement error. Comprehensive discussions of environmental sampling procedures are given in *Principles of Environmental Sampling* (Keith 1987), *Environmental Sampling and Analysis* (Keith 1990a), *Methods for Evaluating the Attainment of Cleanup Standards* (EPA 1989e), *and the Soil Sampling Quality Assurance User's Guide* (EPA 1989f).

Several assumptions concerning sampling and associated statistical procedures have been made to simplify the discussion in this section:

- The RPM and risk assessor are familiar with basic environmental sampling and statistical terms and logic and have access to a statistician.
- Sampling designs are mainly based on stratified random or systematic random sampling (grid), or variations thereof. Systematic sampling requires special variance calculations for estimating statistical performance parameters such as power and confidence level; these calculations are not provided in this guidance.
- Statisticians are consulted for any significant problems or issues not covered in this guidance.
- Superfund contaminant concentrations for a site generally fit a log-normal distribution. Measurements of variability are generally given in log-transformed units. Overviews of statistical methodology include Gilbert (1987) and Koch and Link (1971). Parametric tests in transformed units (Aitchison and Brown 1957) have logarithmic forms (Seichel 1956). Graphical methods of determining re-transformed means and their 95% confidence levels are available (Krige 1978).
- Quality assurance procedures for sampling and analysis are not separate, even though the discussion addresses them separately.

Exhibit 20 summarizes the importance of each of the preliminary sampling planning issues to the risk assessment, proposes planning actions to reduce or eliminate their effect on data useability, and refers the reader to further discussion in the text. Information relevant to preliminary sampling planning can be obtained by collecting site maps, photographs and other historical and current documents which depict production, buildings, sewage and storm drains, transport corridors, dump sites, loading zones, and storage areas. A reliable and current base map is particularly important.

Data adequacy. All data users should clearly state the level of data adequacy they desire. These statements, and the resources that will be committed, should be incorporated into the sampling plan objectives. If an appropriate level of uncertainty cannot be determined at this stage, an initial goal should be agreed on for the final level of reliability, which may be revised during the iterative sampling process. Since each site is unique, it may be extremely difficult to attain a given level of data adequacy. An iterative sampling program may

EXHIBIT 20. IMPORTANCE OF SAMPLING ISSUES IN RISK ASSESSMENT

Issue	Importance	Suggested Action
Chemicals of Potential Concern (3.2.1)	Chemicals have different rates of occurrence and coefficients of variation. This impacts the probability of false negatives and reduces confidence limits for estimates of concentration.	Increase the number of samples for chemicals with low occurrence and/or high coefficients of variation.
Sampling and Analytical Variability versus Measurement Error (3.2.5)	Sampling variability can exceed measurement error by a factor of three to four (EPA 1989c). Sampling variability increases uncertainty or variability; measurement error increases bias.	Reduce sampling variability by taking more samples (using less expensive methods). This allows more samples to be analyzed. Use QC samples to estimate and control bias. Prepare SOPs for handling all field equipment.
Media Variability (3.2.5)	Sampling problems vary widely by media as do variability and bias.	Design media-specific sampling approaches.
Sample Preparation and Sample Preservation (3.2.6)	Contamination can be introduced during sample preparation, producing false positives. Filtering may remove contaminants sorbed on particles.	Use blanks at sources of potential contamination. Collect filtered and unfiltered samples.
Identification of Exposure Pathways (3.2.7)	Not all samples taken in a site characterization are useful for risk assessment. Often only a few samples have been taken in the area of interest.	Specifically address exposure pathways in sampling designs. Risk assessors should participate in scoping meeting.
Use of Judgmental or Purposive Sampling Design (3.2.8)	Statistical sampling designs may be costly and do not take advantage of known areas of contamination.	Use judgmental sampling to examine known contaminated areas, then use an unbiased method to characterize exposure.

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allow a realistic appraisal of the variability present at the site; a phased investigation may be warranted, with an increase in data adequacy at each phase.

Natural variation. It is important to realize that natural variation (environmental heterogeneity) in both soil and water systems may be so great that variation due to field sampling is significantly greater than that due to laboratory analysis. For example, laboratory sample-sample precision is commonly of the order of less than 1%, whereas soil sample-sample precision is commonly between 30% to 40%. Sampling variation is influenced by the homogeneity of material being sampled, the number of samples, collection procedures, and the size of individual samples.

Uncertainty in sampling measurements is additive. Exhibit 21 lists the components of sampling variability and measurement error. The final error associated with an estimate is the sum of the errors associated with natural variation (intrinsic randomness, microstructure, macrostructure), plus sampling error, plus laboratory measurement error. Poor sampling techniques can swamp the natural phenomenon that is being evaluated. Therefore, sampling options must be fully reviewed and the probable uncertainty from sampling must be acceptable.

Initial survey sampling plan. A preliminary sampling plan should be chosen that provides a basis for evaluation of overall sampling goals, sampling techniques, feasibility, and statistical analysis techniques. General categories of sampling plans include simple random, stratified random, systematic, judgmental/purposive, and spatial systematic. The features of these different plans are discussed in more detail in Chapter 4.

Statistical analysis of the survey data allows evaluation of how well the sampling program is doing. Depending on the contaminant, current technology may allow on-site "laboratory" analysis of the samples using portable microcomputers and telecommunications. On-site statistical analysis is also possible. On-site analysis reduces project completion time and costs. In a truly

EXHIBIT 21. SAMPLING VARIABILITY AND MEASUREMENT ERROR

Sampling variability: The variation between true sample values that is a function of the spatial variation in the pollutant concentrations.

Measurement error: The variation resulting from differences between true sample values and reported values. Measurement error is a function of uncertainty due to the following:

- Sample collection variation
- Sample preparation/handling/ preservation/storage variation
- Analytical variation
- Data processing variation

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iterative sampling campaign, on-site statistical analysis can guide the sampling teams, maximizing information capture and minimizing time-related costs.

Analytical issues. The following assumptions concerning analytical procedures have been made in this section:

- The RPM and the risk assessor are familiar with standard analytical chemical procedures. Reference books on environmental issues in analytical chemistry are available and can be consulted (ASTM 1979, Manahan 1975, Dragun 1988, Baudo, *et. al.*, eds. 1990, Taylor 1987).
- Chemists are available and will be consulted for any significant problems or situations not covered in this guidance.
- Analytical QA procedures are used in conjunction with and affect sampling QA procedures, even though the discussion treats these procedures separately.

Exhibit 22 summarizes the importance of each analytical issue to risk assessment, lists suggested actions during the planning process, and refers the reader to further discussion in the text. Each issue is discussed in terms of its effect on data quality for risk assessment, and how to anticipate and plan for potential problems. The RPM should also consult the project chemist to determine the appropriate sample volumes or weights required for different types of analysis.

Biota sampling and analytical issues. The type of assessment (e.g., human health or ecological) determines the type of samples to be collected. An ecological assessment may require analysis of the whole body or of a specific organ system of a target species (because organic, and some inorganic, chemicals of concern are often concentrated in tissues with high lipid contents). Human health risk assessment usually concentrates on edible portions.

Typical sampling considerations for biota include specifying the species to be sampled, sampling locations, tissue to be analyzed, number of individuals to be sampled, and the method of analysis of the chemical of concern. Biota analyses should include a method validation that incorporates tissues or plant analyte spikes, and any available performance evaluation materials. The purpose of spiking is to determine whether the analytes are recoverable from the matrix or clean-up steps hinder detection of the analyte.

Spiking and duplicate information can be used to assess method precision and accuracy. The primary source of performance evaluation materials is the National Bureau of Standards repository. Samples and performance evaluation materials should be matched by matrix (species and whole/edible portions).

Volatile analytes are very difficult to measure in biota. Samples should be stored on dry ice immediately after collection. Fat and cholesterol can also block columns and impede chromatography for base/neutral/acid extractable tissue analysis. Gel permeation chromatography procedures may only be marginally effective in clean up, and the lipids present may retain analytes of concern, thereby reducing recoveries. Plant matrices are often difficult to digest, and a variety of digestion procedures using hydrogen peroxide or phosphoric acid may be warranted. Tissues for organic analysis should be wrapped in aluminum foil for shipment to the laboratory, and tissues for metals analysis should be wrapped in plastic film. All tissues should be sent frozen on dry ice.

Air sampling and analysis issues. Air sampling procedures should account for wind speed and direction as well as seasonal and daily fluctuations; they should also account for the influence of these factors on the exposed population (e.g., the largest population may be potentially exposed in the evening when the wind speed may be least). The definition of detection limits is very important for air analyses. For example, the same concentration will appear very different if expressed on a weight/volume basis than on a volume/volume basis.

Sampling strategies may need to distinguish between particulate and gaseous forms of chemicals of concern. It is important to collect media blanks to determine the type and amount of contamination that may be found. Blanks should also be provided to the laboratory for spiking to determine analytical precision and accuracy.

EXHIBIT 22. IMPORTANCE OF ANALYTICAL ISSUES IN RISK ASSESSMENT

Analytical Issue	Importance	Suggested Action
Chemicals of Potential Concern (3.2.1)	Chemicals of potential toxicological significance may be omitted.	Examine existing data and site history for industry-specific wastes to determine analytes for measurement. Perform broad spectrum analysis.
Tentatively Identified Compounds (3.2.2)	Identification and quantitation do not have high confidence.	Be prepared to request further analyses if potentially toxic compounds are discovered during screening. Compare results from multiple samplings or historical data.
Identification and Quantitation (3.2.3)	False negatives may occur when analytes are present near the MDL.	Use technique with definitive identification (e.g., GC-MS). Alternatively, use technique with definitive identification first, followed by another technique (e.g., GC) to achieve lower quantitation limits.
Detection Limits (3.2.4)	Significant risk may result at concentrations lower than measurable.	Review available methods for appropriate detection limit.
Media Variability (3.2.5)	Variability and bias may be introduced to analytical measurements.	Use environmental samples as QC samples to determine recovery and reproducibility in the sample media.
Sample Preparation (3.2.6)	Variability and bias may be introduced to analytical measurements.	Select analytical methods based on sample medium and strengths of the sample preparation technique.
Field Analyses versus Fixed Laboratory Analyses (3.2.9)	Tradeoffs required with regard to speed, precision, accuracy, personnel requirements, identification, quantitation and detection limits.	Consider options and set priorities.
Laboratory Performance Problems (3.2.10)	Quality of data may be compromised.	Select experienced laboratory and maintain communication.

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The sample medium should be checked to ensure that recovery rates are documented.

3.2.1 Chemicals of Potential Concern

Chemicals of potential concern are chemicals that may be hazardous to human health or the environment and are identified at the site, initially from historical sources. Chemicals identified at Superfund sites have varying rates of occurrence, average concentrations, and coefficients of variation. These differences are a function of fate and transport properties, occurrence in different media, and interactions with other chemicals, in addition to use and disposal practices. Information on frequency of occurrence and coefficient of variation determines the number of samples required to adequately characterize exposure pathways and is essential in designing sampling plans. Low frequencies of occurrence and high coefficients of variation mean that more samples will be required to characterize the exposure pathways of interest. Potential false negatives

occur as variability increases and occurrence rates decrease. From an ecological standpoint, chemicals of potential concern may be different from those for human health concerns. For example, copper is an analyte of high concern from an ecological perspective, but of low concern from a human health perspective. In addition, if water quality criteria are used as toxicological thresholds, it should be determined whether the criteria are based on ecological or human health effects.

> ☛ *To protect human health, place a higher priority on preventing false negatives in sampling and analysis than on preventing false positives.*

Data are available for volatiles, extractable organics, pesticides/PCBs, tentatively identified organic compounds, and metals (see Appendix II), for aqueous and soil/sediment matrices, and releases from industries known to produce waste commonly found at Superfund sites. Data from CLP Superfund sites are also available for calculating site-specific coefficients of variation. Exhibit 23 indicates the occurrence rates and coefficients of variation for selected chemicals of potential concern to risk assessors. Many other chemicals (which are not of concern) may be present without affecting the level of risk to the exposed population.

> ☛ *Use preliminary data to identify chemicals of potential concern and to determine any need to modify the sampling or analytical design.*

The need for risk assessment indicates that there is already some knowledge of contamination at the site. Based on available toxicological and site data, the risk assessor can recommend target chemicals (or chemical classes) for analysis and desired detection limits. For example, explosive chemicals are likely to be present at a former munitions site. Exhibit 24 presents data on munitions compounds, such as feasible detection limits and health advisory limits.

Information on industry-specific analytes is summarized in Exhibit 25 and detailed in Appendix II. If historical data are incomplete, a broad spectrum analysis should be performed on selected samples from each sampling location to provide necessary scoping information.

The RPM or risk assessor should inform the planning team about chemicals of potential concern at the site, exposure pathways, if known, concentrations of concern, and other pertinent information, particularly any requirement to distinguish specific states of the chemicals of potential concern. Some oxidation states of metals (e.g., chromium) are more easily absorbed or are more toxic than others, and organically substituted metals such as mercury are more toxic than their elemental states. If these concerns are important, analyses that determine metal specification rather than elemental analyses should be performed, if available. Similarly, for organic compounds, such as tetrachloroethane, degradation products or metabolites may be more toxic than the parent compounds. In this case, sampling procedures and analytical methods should include the parent compound, degradation products, and metabolites of chemicals of potential concern.

3.2.2 Tentatively Identified Compounds

Gas chromatography-mass spectrometry (GC-MS) analyses categorize organic compounds in two ways. Target compounds are those compounds for which the GC-MS instrument has been specifically calibrated using authentic chemical standards. A target compound in an environmental sample is identified by matching its mass spectrum and relative retention time (RRT) to those obtained for the authentic standard during calibration. Quantitation of a target compound is achieved by comparison of its chromatographic peak area to that of an internal standard compound, normalized to the relative response factor (RRF) which is the ratio of the peak areas of the authentic chemical standard and the internal standard measured during calibration.

> ☛ *Specific analysis for compounds identified during library search can be requested.*

Tentatively Identified Compounds (TICs) are any other compounds which are reported in the sample analysis, but for which the GC-MS instrument was not specifically calibrated. A TIC is identified by taking its mass spectrum from the environmental sample, and comparing it to a computerized library of mass spectra. Computerized comparison routines score the various library spectra for their similarity to the TIC and rank the spectra most similar to the TIC's spectrum. If the TIC is reported as a specific compound, it is usually reported to be one of the compounds whose spectra were retrieved in the library search. Quantitation of a TIC is less accurate than for target compounds, because the true RRF is not known (since no calibration for this specific compound was performed). The RRF is assumed to be 1.0; whereas, measured RRFs below 0.05 and above 10.0 are known.

Confidence in the identification of a TIC can be increased in several ways. The main steps in identifying and quantitating TIC data are summarized in Exhibit 26. An analytical chemist trained in the interpretation of mass spectra and chromatograms can review TIC data

EXHIBIT 23. MEDIAN COEFFICIENT OF VARIATION FOR CHEMICALS OF POTENTIAL CONCERN [1]

Chemical of Potential Concern	Soil/Sediment Median %CV[2]	Number of Sites at Which Chemical was detected[3]	Water Median %CV[2]	Number of Sites at Which Chemical was detected[3]
Chloromethane	16.7	61	50.0	134
Trichloromethane/Chloroform	53.9	392	45.2	519
Tetrachloromethane/Carbon tetrachloride	15.4	38	9.3	90
1,2-Dichloroethane	17.6	64	24.7	158
Tetrachloroethane	17.0	56	17.4	101
Vinyl chloride	11.0	55	15.7	197
Tetrachloroethene	24.5	392	33.3	367
Dichloropropane	19.0	29	13.3	79
Isophorone	0.7	74	18.4	72
Bis (2-chloroethyl) ether	0.5	10	20.1	34
1,4-Dichlorobenzene	0.9	120	17.3	119
Bis (2-ethylhexyl) phthalate	0.7	1197	29.5	782
Benzo(a) pyrene	0.5	1058	10.8	76
Styrene	16.9	117	33.3	69
N-nitrosodiphenylamine	0.5	142	30.5	96
DDE	4.5	329	813.0	40
DDT	2.9	521	588.2	125
Dieldrin	4.4	274	3.3	101
Heptachlor	4.8	249	351.9	151
Gamma-BHC (lindane)	6.3	142	454.1	134
PCB1260	0.21	251	41.7	23
Arsenic	40.3	1098	58.0	940
Beryllium	271.3	1091	100.0	931
Cadmium	134.6	1096	33.7	945
Chromium	11.9	1098	23.0	948
Mercury	1032.3	1098	500.0	948
Lead (Pb)	10.9	1098	97.3	939

1 List of chemicals of potential concern is derived from health-based levels and frequency of occurence at Superfund sites listed in the CLP Statistical Database. (Number of sites for which data exist totals 8,900.)

2 Median percent coefficient of variation of analyte concentrations.

3 November 1988 to present.

21-002-023

EXHIBIT 24. MUNITIONS COMPOUNDS AND THEIR DETECTION LIMITS

Health Advisory	Acronym	Compound Name[1]	Detection Limit[2] (ppb)
*	HMX	Octahydro-1,3,5,7-tetranitro-1,3,5,7-tetrazocine	5.1
*	RDX	Hexahydro-1,3,5-trinitro-1,3,5-triazine	4.2
	---	Nitrobenzene	6.4
	TNB	1,3,5-Trinitrobenzene	5.9
**	DNB	1,3-Dinitrobenzene	9.1
	Tetryl	Methyl-2,4,6-trinitrophenylnitramine	4.4
*	TNT	2,4,6-Trinitrotoluene	6.3
**	2,4 DNT	2,4-Dinitrotoluene	2.3
	TAX	Hexahydro-1-(N)-acetyl-3,5-dinitro-1,3,5-triazine	
	SEX	Octahydro-1-(N)-acetyl-3,5,7-trinitro-1,3,5,7-tetrazocine	
**	2,6 DNT	2,6-Dinitrotoluene	5.1
*	2,4,5 TNT	2,4,5-Trinitrotoluene	
	2 Am DNT	2-Amino-4,6-dinitrotoluene	
	4 Am DNT	4-Amino-2,6-dinitrotoluene	
	2,4 DAmNT	2,4-Diamino-6-nitrotoluene	
	2,6 DAmNT	2,6-Diamino-4-nitrotoluene	
*	DIMP	Disopropyl-methylphosphonate	
*	TNG	Gylcerol trinitrate (Nitroglycerin)	
*	---	Nitrocellulose	
**	DMMP	Dimethyl methylphosphonate	
**	NG	Nitroguanadine	

* Health advisory complete.
** Health advisory in preparation (1990).

1 Depending upon matrix and instrument conditions, these compounds may be chromatographable and may be tentatively identified as indicators of the presence of munitions during GC-MS library search procedures.

2 Detection limits are provided where available. Specific compounds with complete health advisories are designated as target analytes with defined detection limits specified in a high performance liquid chromatographic method developed and provided by the U.S. Army Toxic and Hazardous Materials Agency.

21-002-024

EXHIBIT 25. SUMMARY OF MOST FREQUENTLY OCCURRING CHEMICALS OF POTENTIAL CONCERN BY INDUSTRY*

Compound	Industry						
	1	2	3	4	5	6	7
Acetone		X					
Aluminum							X
Ammonia		X	X		X	X	X
Ammonium Nitrate		X					
Ammonium Sulfate	X					X	
Anthracene					X		
Arsenic					X		
Benzene							X
Biphenyl					X		
Chlorine		X					
Chlorobenzene			X				
Chromium				X	X	X	
Copper					X		
Cyclohexane		X					
Dibenzofuran					X		
Dichloromethane			X	X			
Formaldehyde					X		
Freon	X						
Glycol Ethers						X	
Hydrochloric Acid			X	X			
Lead	X						
Manganese	X						
Methanol	X		X				
Methyl Ethyl Ketone		X				X	X
Naphthalene					X		
Nickel				X			
Nitric Acid		X		X			
Pentachlorophenol		X			X		
Propylene							X
Sodium Sulfate	X	X	X	X		X	X
Sodium Hydroxide	X		X	X		X	X
Sulfuric Acid	X	X		X		X	X
Trichloroethene	X			X			
Toluene			X			X	X
Titanium Tetrachloride			X				
Xylene			X			X	X
1,1,1-trichloroethane	X			X			

KEY
1 = Battery Recycling
2 = Munitions/Explosives
3 = Pesticide Manufacturing
4 = Electroplating
5 = Wood Preservatives
6 = Leather Tanning
7 = Petroleum Refining

*Summarized from Appendix II.

21-002-025

EXHIBIT 26. STEPS IN THE ASSESSMENT OF TENTATIVELY IDENTIFIED COMPOUNDS

Identification	• GC-MS analysis indicates the presence of a tentatively identified compound.
	• Incorporate retention time/retention index matching and use physical characteristics (boiling point or vapor pressure) to determine if identification is reasonable.
	• Examine historical data and industry-specific compound lists.
	• Reanalyze sample with an authentic standard.
Quantitation	• Assess known analytical response characteristics for similar compounds or similar compound classes.
	• Determine response characteristics by analysis of an authentic standard.

21-002-026

mass spectra and chromatograms can review TIC data and eliminate many false positive identifications. The use of retention indices or relative retention times can confirm TICs identified by the GC-MS computer (Eckel, *et. al.* 1989). Examination of historical data, industry-specific compound lists, compound identifications from iterative sampling episodes, and analyses performed by different laboratories may also increase confidence in the identification of a TIC. The final identification step is to reanalyze the sample after calibrating the GC-MS instrument with an authentic standard of the compound that the TIC is believed to be.

If toxic compounds are identified as TICs by this type of broad spectrum analysis, the RPM or risk assessor should request further analyses to positively identify the compound and to accurately quantitate it. The risk assessor or RPM should discuss data requirements with an analytical chemist to determine the appropriate analytical method.

Many compounds that appear as TICs during broad spectrum analyses belong to compound classes. Examples of compound classes are saturated aliphatic hydrocarbons and polycyclic aromatic hydrocarbons (PAHs). The risk assessor may be able to make a preliminary judgment of toxicity at the compound class level without a definitive identification of each compound present. For example, in a sample contaminated by gasoline, organics analysis would indicate a series of TICs as aliphatic hydrocarbons of increasing size. These may not be carcinogenic, and more precise identification may not be required. If a similar sample were contaminated with coal tar, larger hydrocarbons and a series of PAHs would be found during the analysis. The aliphatic hydrocarbons are not especially toxic, but the PAH compound class contains carcinogens and are of greater concern.

3.2.3 Identification and Quantitation

A risk assessor first confirms chemical identification, and then determines the level of contamination. This section summarizes the effects of detection limits and sample contamination considerations on the confidence in analyte identification and quantitation. Requirements for confidence are specified in Exhibit 27. When analytes have concentrations of concern approaching method detection limits, the confidence in both identification and quantitation is low. This case is illustrated in Exhibit 28. In addition, confidence in identifying and quantitating as representative of site

EXHIBIT 27. REQUIREMENTS FOR CONFIDENT IDENTIFICATION AND QUANTITATION

Identification	• Analyte present above the IDL.
	• Organic – Retention time and/or mass spectra matches authentic standards.
	• Inorganic – Spectral absorptions compared to authentic standards.
	• Knowledge of blank contamination (if any).
Quantitation	• Instrument response known from analysis of an authentic standard.
	• Detected concentration above the limit of quantitation and within the limit of linearity (instrument response not saturated).

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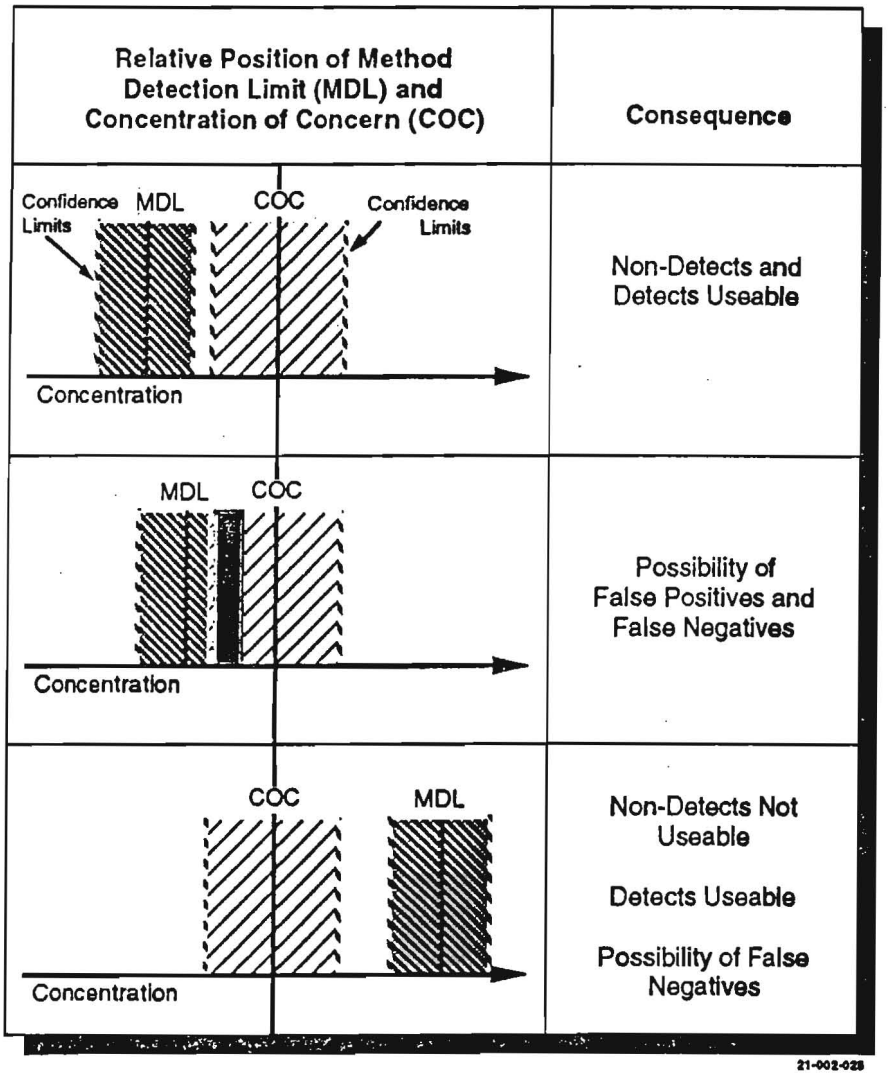
EXHIBIT 28. RELATIVE IMPACTS OF DETECTION LIMIT AND CONCENTRATION OF CONCERN: DATA PLANNING



conditions is potentially diminished if the chemicals of potential concern are present as contaminants from laboratory or field procedures. This section identifies analytes and cites situations in which this is most likely to occur.

The first requirement of analysis is confidence in the identification of chemicals of potential concern. Identification means that the chemical was present in the environmental sample above the detection limit. Chemicals can be correctly identified at lower concentrations than are suitable for accurate quantitation. If lower quantitation limits are required for risk assessment purposes, a larger initial sample size may be processed, or the sample extract may be concentrated to a smaller final volume. However, concentration of an extract to a smaller volume, or increasing the sample size, may saturate the instrument in the presence of matrix interferences. The RPM should discuss these issues with an analytical chemist to determine the best approach. A further discussion of limits of quantitation is presented in Section 3.2.4. and Appendix III.

To ensure maximum confidence in the identification of an organic chemical contaminant, an instrumental technique, such as mass spectrometry, that provides definitive results is necessary. Although alternative techniques are available, GC-MS determination is the best available procedure for confident identification or confirmation of volatile and extractable organic chemicals of potential concern. The application of this technique minimizes the risk of error in qualitative identification and measures chemicals of potential concern at environmental levels above the detection or quantitation limits listed in Appendix III. In cases where the target detection limit is too low to allow

but more definitive, instrumental techniques can be used.

The identification of inorganic chemicals is more certain. A reported concentration determined by atomic absorption (AA) spectroscopy or inductively coupled plasma (ICP) atomic emission spectroscopy is generally considered evidence of presence at the designated level reported, provided there is no interference. If interferences exist, the laboratory should try to characterize the type of interferences (background, spectral or chemical) and take the necessary steps to correct them.

3.2.4 Detection and Quantitation Limits and Range of Linearity

The following discussion is intended to provide the RPM and risk assessor with an understanding of the various ways that detection or quantitation limits can be reported. The term "detection limit" is frequently used without qualification. However, there are several methods for calculating detection limits. The RPM should consult with the project chemist and the risk assessor whenever analytical methods are to be selected, and specify the nature of the detection limits that must be reported; it is the laboratory's responsibility to adhere to this requirement. If no requirement has been specified, then the laboratory should be requested to explicitly describe the types of the detection limits it reports. Detection limits can be calculated for the instrument used for measurement, for the analytical method, or as a sample-specific quantitation limit. The risk assessor should request that the sample quantitation limit (SQL) be reported whenever possible. The term "detection limit" should be considered generic unless the specific type is defined. Exhibit 29 illustrates the relationship between instrument response and the quantity of analyte presented to the analytical system (i.e., a calibration curve).

> **Common Detection and Quantitation Limits**
>
> **Instrument detection limit.** The IDL includes only the instrument portion of detection, not sample preparation, concentration/dilution factors, or method-specific parameters.
>
> **Method detection limit.** The MDL is the minimum amount of an analyte that can be routinely identified using a specific method. The MDL can be calculated from the IDL by using sample size and concentration factors and assuming 100% analyte recovery.
>
> **Sample quantitation limit.** The SQL is the MDL adjusted to reflect sample-specific action such as dilution or use of a smaller sample aliquot for analysis due to matrix effects or the high concentration of some analytes.
>
> **Contract required quantitation (detection) limit.** The CRQL for organics and CRDL for inorganics are related to the SQL that has been shown through laboratory validation to be the lower limit for confident quantitation and to be routinely within the defined linear ranges of the required calibration procedures.
>
> **Practical quantitation limit.** The PQL, defined in SW846 methods, is the lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions.

☛ *The closer the concentration of concern is to the detection limit, the greater the possibility of false negatives and false positives.*

☛ *The wide range of chemical concentrations in the environment may require multiple analyses or dilutions to obtain useable data. Request results from all analyses.*

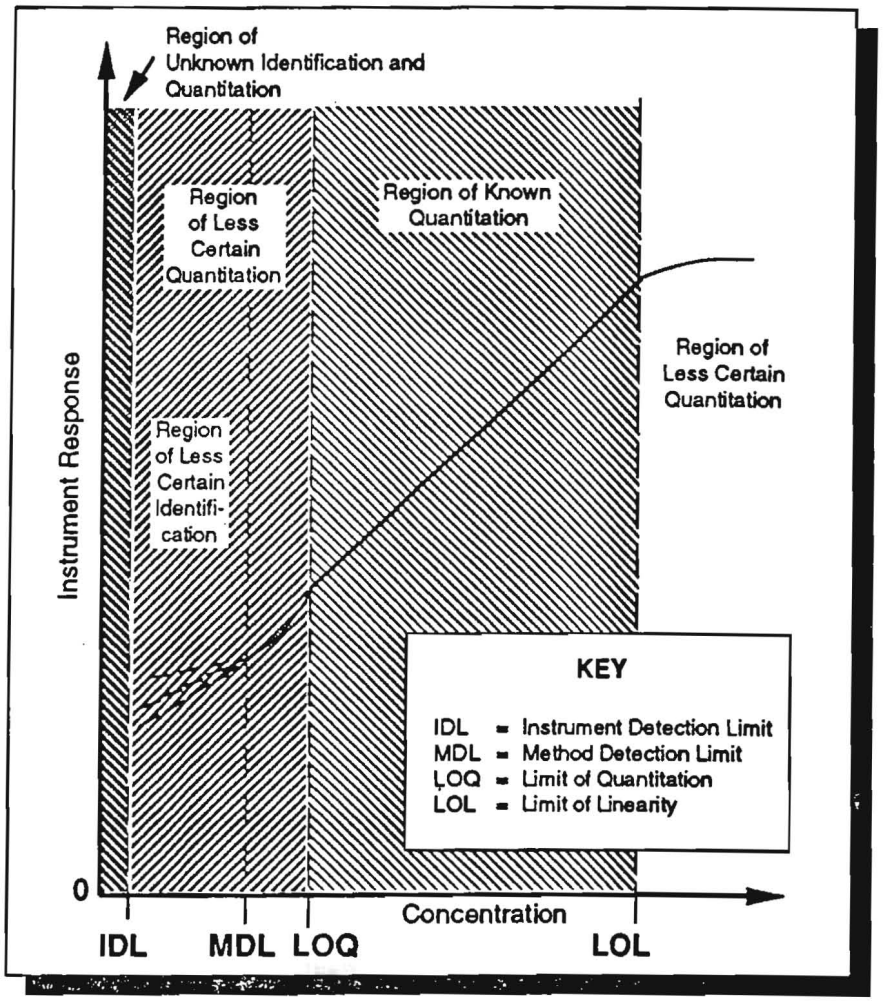
The definitions that follow are intended to provide the RPM and risk assessor with an understanding of the various methods for calculating detection limits, the terms used to describe specific detection limits, and the limitations associated with identification and quantitation of chemicals of potential concern at concentrations near specified detection limits. Understanding the different terms used to describe detection limits helps avoid reporting problems. Exhibit 30 provides examples of calculations of the three most commonly reported types of detection limits.

☛ *Define the type of detection or quantitation limit for reporting purposes; request the sample quantitation limit for risk assessment.*

Instrument detection limit. The instrument detection limit (IDL) includes only the instrument portion of detection, not sample preparation, concentration/dilution factors, or method-specific parameters. The IDL is operationally defined as three times the standard deviation of seven replicate analyses at the lowest concentration that is statistically different from a blank. This represents 99% confidence that the signal identified is the result of the presence of the analyte, not random noise. The IDL is not the same as the method detection limit. Use of the IDL should be avoided for risk assessment.

Method detection limit. The method detection limit

EXHIBIT 29. THE RELATIONSHIP OF INSTRUMENT CALIBRATION CURVE AND ANALYTE DETECTION



Method detection limit. The method detection limit (MDL) is the minimum amount of an analyte that can be routinely identified using a specific method. The MDL can be calculated from the IDL by using sample size and concentration factors and assuming 100% analyte recovery. This estimate of detection limit may be biased low because recovery is frequently less than 100%. MDLs are operationally determined as three times the standard deviation of seven replicate spiked samples run according to the complete method. Since this estimate includes sample preparation effects, the procedure is more accurate than reported IDLs. However, the evaluation is routinely completed on reagent water. As a result, potentially significant matrix interferences that decrease analyte recoveries are not addressed.

The impact of an MDL on risk assessment is illustrated in Exhibit 28. When planning to obtain analytical data, the risk assessor knows the concentration of concern or preliminary remediation goal. When the concentration of concern of an analyte is greater than the MDL, to the extent that the confidence limits of both the MDL and concentration of concern do not overlap, then both "non-detect" and "detect" results can be used with confidence. There will be a possibility of false positives and false negatives if the confidence limits of the MDL and concentration of concern overlap. When the concentration of concern is sufficiently less than the MDL that the confidence limits do not overlap, then there is a strong possibility of false negatives and only "detect" results are useable.

EXHIBIT 30. EXAMPLE OF DETECTION LIMIT CALCULATION

IDL = 3 x SD* of replicate injections

Example: 100 ppb pentachlorophenol standard

If: SD = 5 ppb

Then: IDL = 3 x 5 ppb = 15 ppb

MDL = 3 x SD of replicate analyses (extraction and injection)

Example: 100 ppb pentachlorophenol spiked in sample producing average measured concentration of 50 ppb (not all analyte is recovered or measured)

If: SD = 18 ppb

Then: MDL = 3 x 18 ppb = 54 ppb

Incorporate calculation of MDL from IDL

SQL = MDL corrected for sample parameters

Example: 100 ppb pentachlorophenol with MDL of 57 ppb

If: Dilution factor = 10 (sample is diluted due to matrix interference or high concentrations of other analytes)

Then: SQL = 10 x 57 ppb = 570 ppb

* SD = Standard Deviation

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Sample quantitation limit. The SQL is the MDL adjusted to reflect sample-specific action such as dilution or use of smaller aliquot sizes than prescribed in the method. These adjustments may be due to matrix effects or the high concentration of some analytes. The SQL is the most useful limit for the risk assessor and should always be requested.

For the same chemical, the SQL in one sample may be higher than, lower than, or equal to SQL values for other samples. In addition, preparation or analytical adjustments, such as dilution of the sample for quantitation of an extremely high level of one chemical, could result in non-detects for other chemicals included in the analysis, even though these chemicals may have been present at trace quantities in the undiluted sample. The risk assessor should request results of both original and dilution analyses in this case. Since the reported SQLs take into account sample characteristics, sample preparation, and analytical adjustments, they are the most relevant quantitation limits for evaluating non-detected chemicals.

Contract required quantitation (detection) limit. The CLP specifies a contract required quantitation limit (CRQL) for organics and a contract required detection limit (CRDL) for inorganics. Each of these quantities is related to the SQL that has been shown through laboratory validation to be the lower limit for confident quantitation and to be routinely within the defined linear ranges of the required calibration procedures.

The use of CRQLs and CRDLs attempts to maintain the analytical requirements within performance limits (which are based upon laboratory variability using a variety of instruments). CRQLs are typically two to five times the reported MDLs and they generally correspond to the limit of quantitation.

Practical quantitation limit. The practical quantitation limit (PQL), defined in SW846 methods, is the lowest level that can be reliably achieved within specified limits of precision and accuracy during routine laboratory operating conditions. It is important to note that the SQL and PQL are not equivalent. Use of PQL values as measures of quantitation limits should be avoided wherever possible in risk assessment.

Other quantitation measurements. The limit of quantitation (LOQ) is the level above which quantitative

results may be obtained with a specified degree of confidence. At analyte concentrations close to, but above the MDL, the uncertainty in quantitation is relatively high. Although the presence of the analyte is accepted at 99% confidence, the reported quantity may be in the range of ±30%. Ten times the standard deviation measured for instrument detection is recommended to demonstrate a level at which confidence is maximized (Borgman 1988).

The limit of linearity (LOL) is the point at or above the upper end of the calibration curve at which the relationship between the quantity present and the instrument response ceases to be linear (Taylor 1987). Instrument response usually decreases at the LOL, and the concentration reported is less than the amount actually present in the sample because of instrument saturation. Dilution is necessary to analyze samples in which analyte concentrations are above the LOQ. However, dilutions correspondingly increase SQLs. Data should be requested from both diluted and undiluted analyses.

3.2.5 Sampling and Analytical Variability Versus Measurement Error

Sampling and analytical variability and measurement error are two key concepts in data collection. Each is discussed in the context of evaluating strategies for the collection and analysis of both site and background samples.

Exhibit 21 defines sampling variability and measurement error. Most SAPs are a necessary compromise between cost and confidence level. Basically, two types of decisions must be made in planning:

- What statistical performance is necessary to produce the quality of data appropriate to meet the risk assessor's sampling variability performance objectives and
- What types and numbers of QC samples are required to detect and estimate measurement error.

☛ *When contaminant levels in a medium vary widely, increase the number of samples or stratify the medium to reduce variability.*

Sampling plans attempt to estimate and minimize both sampling variability and measurement error. Sampling variability affects the degree of confidence and power the risk assessor can expect from the results. Confidence is the ability to detect a false positive hypothesis, and power is the ability to detect a false negative. Power is more important for risk assessment. An estimate of the sampling variability that is a function of the spatial variation in the concentrations of chemicals of potential concern is obtained by calculating the coefficient of variation for each chemical. When the coefficient of variation is less than 20% and a substantial quantity of data are available, the effect of spatial and temporal variation on concentrations of chemicals of potential concern is minimal, and the power and certainty of statistical tests is high (EPA 1989c).

Spatial variability can be analyzed after an initial sampling effort through simple statistical summation or through the use of variogram analysis, a part of the geostatistics. EPA has developed software to assist a risk assessor in this analysis: Geostatistical Environmental Assessment Software (GEOEAS) (EPA 1988c) and Geostatistics for Waste Management (GEOPACK) (EPA 1990b).

Measurement error is estimated using the results of QC samples and represents the difference between the true sample value and the reported value. This difference has five basic sources: the contaminant being measured, sample collection procedures, sample handling procedures, analytical procedures, and data production procedures. Measurement error due to analytical procedures is discussed in Section 3.2 under analytical issues. Measurement error due to sampling is estimated by examining the precision of results from field duplicates. The minimum recommended number of field duplicates is 1 for every 20 environmental samples (5%). A minimum of one set of duplicates should be taken per medium sampled unless many strata are involved; five sets are recommended. Exhibit 31 summarizes the types and uses of QC samples in defining variation and bias in measurement.

☛ *Sampling variability typically contributes much more to total error than analytical variability.*

In summarizing the discussion of sampling variability and measurement error, one finding puts the concepts in perspective: "An analysis of the components of total error from soils data from an NPL site sampled for PCBs indicated that 92% of the total variation came from the location of the sample and 8% from the measurement process" (EPA 1989f). Of the 8%, less than 1% could be attributed to the analytical process. The rest of the 8% is attributable to sample collection, sample handling, data processing and pollutant characteristics. Sampling variability is often three to four times that introduced by measurement error. Exceptions to this observation on the components of variation or sources of error occur in instances of poor method performance for specific analytes.

EXHIBIT 31. MEASUREMENT OF VARIATION AND BIAS USING FIELD QUALITY CONTROL SAMPLES

Quality Control Sample Types	Variation or Bias Measured
Field duplicate	Provides data required to estimate the sum of subsampling and analytical variances.
Field blank	Provides data required to estimate the bias due to contamination introduced during field sampling or cleaning procedures. Also measures contamination at laboratory. Compare with laboratory method blank to determine source of contamination.
Field rinsate	Provides data required to estimate the sum of the bias caused by contamination at the time of sampling from sampling equipment and by analysis and data handling. Indicates cross-contamination and potential contamination due to sampling devices.
Trip blank	Provides data required to estimate the bias due to contamination from migration of volatile organics into the sample during sample shipping from the field and sample storage at the laboratory.

Source: EPA 1990c.

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Media or matrix variability. Appropriate samples must be collected from each medium of concern and, for heterogeneous media, from designated strata. Stratification reduces variability in results from individual strata, which can be different layers or surface areas. Media to be sampled should include those currently uncontaminated but of concern, as well as those currently contaminated. For media of a heterogeneous nature (e.g., soil, surface water, or hazardous waste), strata should be established and samples specified by stratum to reduce variability, the coefficient of variation and the required number of samples.

Sampling considerations vary according to media. The sampling concern may involve contaminant occurrence, temporal variation, spatial variation, sample collection, or sample preservation. Exhibit 32 indicates potential sampling problem areas for each medium. Problem areas are classified relative to other media. RPMs can use this exhibit to plan for possible sampling problems in the data collection design. Sampling designs must be structured to identify and characterize hot spots. Information needed for fate and transport modeling should be obtained during a site sampling investigation. This information also differs by the medium of concern (EPA 1989a).

The type of medium in which a chemical is present affects the potential sensitivity, precision, and accuracy of the measurement. Sharp distinctions occur in applying a single method to media such as water, oil, sludge, soil, or tissue. Medium or matrix problems are indicated by the presence of analytical interferences, poor recovery of analytes from the matrix, physical problems such as viscosity (flow parameters), and particulate content that affect sample processing. Exhibit 33 shows the sources of uncertainty across media. Spiked environmental samples monitor the effect of these sources of uncertainty on the accuracy of recovery of target compounds from the matrix. Duplicates quantify the effect of these parameters on precision. The method must be chosen carefully if a difficult medium such as oily waste or soil is to be analyzed. Routine methods usually specify the medium or media for which they are applicable.

Method detection and general confidence in analytical determinations are also often affected by specific media types and by analytical interference. The impact of matrix interference on detection limits, identification,

EXHIBIT 32. SAMPLING ISSUES AFFECTING CONFIDENCE IN ANALYTICAL RESULTS

Major Sampling Issues	Problem Likelihood by Medium					
	Soil	Ground Water	Surface Water	Air	Biota	Hazardous Waste
Contaminant Migration	√√		√	√		√√
Temporal Variation			√√	√		
Spatial Variation	√√	√√	√√	√	√	√√
Topographic/ Geological Properties	√√			√		
Hot Spots	√√	√√				√√
Sample Collection	√		√√	√√		√
Sample Preparation/ Handling	√√	√	√√	√√	√	√
Sample Storage		√√	√√	√√	√√	
Sample Preservation		√√	√√		√√	

Key: √√ = Likely source of significant sampling problem.
√ = Potential source of sampling problem.

Source: Modified from Keith 1990b.

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and quantitation is illustrated by the following discussions (which are not meant to be comprehensive).

- Oil and hydrocarbons affecting GC-MS analyses,
- Phthalates and non-pesticide chlorinated compounds that can interfere with pesticide analyses, and
- Iron spectral interference affecting ICP sample results.

Oil and hydrocarbons. The presence of appreciable concentrations of oil and other hydrocarbons may interfere with the extraction or concentration process. Also, even at low concentrations, oil in a sample usually produces a large series of chromatographic peaks that interfere with the detection of other chemicals of potential concern during gas chromatography. Any chemicals of potential concern that may elute concurrently from the GC column are obscured by the hydrocarbon response and may not present a distinct spectrum. Also, hydrocarbons that are present in significant quantity are often identified as TICs, potentially adding a large number of compounds for consideration by the risk assessor.

During RI planning, the risk assessor should determine if there is a potential for hydrocarbon contamination, through knowledge of historical site use and examination of historical data. The laboratory can be instructed to add cleanup protocols to the analysis, or to use a supplemental analysis for which the hydrocarbons are not interferences (e.g., electron capture detection for halogenated compounds).

Phthalates and non-pesticide chlorinated compounds. Phthalates interfere with pesticide analyses by providing a detector response similar to that for chlorinated compounds. Phthalates and non-pesticide

EXHIBIT 33. SOURCES OF UNCERTAINTY THAT FREQUENTLY AFFECT CONFIDENCE IN ANALYTICAL RESULTS

Source of Uncertainty	Degree of Significance by Medium: Soil	Water	Air	Biota	Hazardous Waste
SAMPLING					
Design	√√	√	√√		√
Contamination	√√	√	√		
Collection	√	√√	√√		√
Preparation	√√				
Storage		√√	√√		
Preservation		√√			
LABORATORY					
Storage	√√	√√	√√		
Preparation	√√/√	√√/√		√√	√√
Analysis	√√		√	√	√√
Reporting			√	√√	√√
ANALYTE-SPECIFIC					
Volatility	√√	√	√		
Photodegradation		√	√		
Chemical Degradation	√	√√			
Microbial Degradation	√√	√√			
Contamination	√√		√√		

KEY:
√√ = Likely source of significant error or uncertainty.
√ = Potentially source of significant error or uncertainty.
√√/√ = Magnitude of effect determined by examination of data.

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chlorinated compounds are often present in greater concentrations than the pesticides of concern. Pesticide data are often required at low detection limits and, therefore, GC-MS analyses are not used for quantitation. In these cases, a gas chromatographic analysis using electron capture detection is more sensitive, providing a wider useful range of detection. The phthalates and chlorinated compounds can coelute with chemicals of potential concern, thereby obscuring the detection of target analytes and raising the analyte-specific quantitation limit. Phthalates and chlorinated compounds also produce additional peaks on the chromatogram that can be interpreted as false positive responses to pesticides. A second analysis using a different column provides an extra measure of confidence in identification. Alternatively, sample extracts from positive analyses can be further concentrated for confirmation by GC-MS if concentrations of analytes are sufficient.

Iron. Large quantities of iron in a sample affect the detection and quantitation of other metallic elements analyzed by ICP atomic emission spectroscopy at wavelengths near the iron signals. The strong iron response overlaps nearby signals, thereby obscuring the results of potentially toxic elements present at much lower concentrations. An interference check sample for ICP analyses monitors the effect of such elements. High concentrations of iron are analyzed with low concentrations of other metals in these samples to indicate whether iron interfered with metal detection at lower concentrations. If spectral interferences are observed, data may be qualified as overestimated. The risk assessor or RPM should consult the project chemist to determine if a particular method requires a performance check.

3.2.6 Sample Preparation and Sample Preservation

Some samples require preparation in the field to ensure that the results of analyses reflect the true characteristics of the sample. Sample filtration and compositing procedures are discussed in this section. Exhibit 34 summarizes the issues which the various sample preparation methods address. Exhibit 35 outlines the primary information gained with the various sampling techniques.

EXHIBIT 34. SAMPLE PREPARATION ISSUES

Issue	Action
Sample Integrity	Preservation --- acids, biocides (may be applicable to volatiles or metals).
Source of Analyte Media	Unfiltered samples -- measure total analytes Filtered samples -- discriminate sorbed and unsorbed analytes
Analyte Speciation	Choice of sample preparation protocols affects analyte speciation
Large Number of Samples to be Analyzed	Composite samples (However, this raises the effective detection limit in proportion to the number of samples composited.)

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Filtration. If the risk assessor needs to discriminate between the amount of analyte present in true solution in a sample and that amount sorbed to solid particles, then the sample must be filtered and analyses should be performed for both filtered and unfiltered compounds. Some samples, such as tap water, are never filtered because there is no particulate content. Filtration should be performed in the field as soon as possible after the sample has been taken and before any preservative has been added to the sample. Filtration often does not proceed smoothly. It is common practice only to filter a small proportion of all samples taken, and to perform analyses for the total content of the analyte in the majority of samples. Filtered samples generally provide a good indication of the fraction of contaminant likely to be transported over large distances horizontally in a plume. However, in the immediate vicinity of a source or point of exposure, unfiltered samples may be valuable in providing an indication of suspended material that

EXHIBIT 35. INFORMATION AVAILABLE FROM DIFFERENT SAMPLING TECHNIQUES

Sample Type	Information
Filtered	Can differentiate sorbed and unsorbed analytes.
Unfiltered	Total amount of analyte in sample is measured.
Grab	Can be used to locate hot spots.
Composite	Can provide average concentrations over an area at reduced cost.

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may act as a source or sink of dissolved contaminants and may therefore modify overall transport.

Compositing. Reducing the number of samples by compositing is also a form of sample preparation. Compositing may be performed to reduce analytical costs, or in situations where the risk assessor has determined that an average value will best characterize an exposure pathway. Compositing cannot be used to identify hot spots, but can be effective when averaging across the exposure area. Caution should be exercised when compositing since low level detects can be averaged out and become non-detects.

Preservation. Sample characteristics can be disturbed by post-sampling biological activity or by irreversible sorption of analytes of concern onto the walls of the sample container. A variety of acids and biocides used for preservation are discussed in standard works such as *Standard Methods for the Examination of Water and Wastewater* (Clesceri, *et. al.*, eds. 1989). Samples are also usually shipped with ice to reduce biological activity.

Preparation. Several factors in sample preparation affect analytical data. These factors include sample matrix, desired detection limit, extraction solvent, extraction efficiency, sample preparation technique, and whether the analysis is performed in the field or in a fixed laboratory. In addition, parameters such as turnaround time may preclude the use of some sample preparation alternatives.

An extraction method must be able to release the chemicals of concern from the sample matrix. For example, organic solvents will extract non-polar organic compounds from water. Polar and ionic compounds

(such as unsymmetrically halogen-substituted compounds, phenols, and carboxylic acids) may require additional techniques for extraction from water. The choice of solvent is also critical to the extraction efficiency. Methanol would be expected to extract a larger quantity of volatile organic material from soils or sediments than from water. For inorganic analyses, the matrix may require additional acidification to dissolve metal salts that have precipitated from the solution.

Sample preparation procedures for organic analytes are applied based on volatility. Volatile organics are analyzed using head-space or purge and trap techniques. Extraction alternatives for the analysis of less volatile (extractable) organic chemicals include separatory funnels, Soxhlet extraction apparatus, continuous liquid-liquid extractors, and solid phase cartridges. Details of these extraction options can be obtained from the project chemist. Strengths and weaknesses of each of these preparation procedures are described in Exhibit 36.

For inorganic analyses, the sample matrix is usually digested in concentrated acid. The released metals are introduced into the instrument, then analyzed by flame AA or ICP atomic emission spectrophotometry. The selection of the acid for digestion influences the detection limit because different acids have different digestion abilities.

- If digestion is not used, the sample measurement corresponds to a determination of soluble metals rather than total metals. If soluble metals have a greater toxicological significance, this difference may be important to the risk assessment.
- If the sample is filtered in the field or the laboratory before digestion, any metals associated with particulates are removed before analysis. If particulates are an exposure pathway in the risk assessment, sample filteration would underestimate risk.

The analytical request must specify if the sample is to be filtered and whether or not it is to be digested (to measure soluble metals). Unless otherwise specified, samples are usually digested but not filtered.

3.2.7 Identification of Exposure Pathways

Exposure pathways and their components, such as source, mechanism of release, etc., should be designated prior to the design of the sampling procedures. For the risk assessment, at least one broad spectrum analytical sample is required and two or three are recommended for each medium and potential source in an exposure pathway. If the site sampling design fails to consider all exposure pathways and media, additional samples will be required.

Current and future exposure pathways may be limited to particular areas of a site. If sampling activity can be concentrated in these areas, the precision and accuracy of the data supporting risk assessments can be improved.

Risk assessment requires characterization of each exposure area for the site. Samples not falling within the areas of potential concern are not used in the identification of chemicals of potential concern nor in the calculation of reasonable maximum exposure concentration. Depending on exposure pathways, the risk assessor may utilize only a small number of samples that were collected at a site. Exhibit 37 shows why the identification of exposure pathways is critical to the sampling design in order to maximize the number of samples that are useable in the risk assessment.

3.2.8 Use of Judgmental or Purposive Sampling Design

Judgmental or purposive designs that specify sampling points based on existing site knowledge may be appropriate for the initial phase of site sampling or when the risk assessment is performed using few samples. In such instances, non-statistical approaches may be more effective in accomplishing the purpose of the risk assessment for human health, than statistical designs with unacceptably large sampling variability.

Judgmental samples can be incorporated into a statistical design if the samples designate the area of suspected contamination as an exposure area or stratum. The judgmental samples are then selected randomly or within a grid in the area of known contamination. Under the procedures described, the initial judgmental samples are not considered biased for the exposure area. Exhibit 38 summarizes some strengths and weaknesses of biased and unbiased sampling designs.

Resource constraints sometimes restrict the number of samples for the risk assessment and therefore potentially increase the variability associated with the results. When the number of samples that can be taken is restricted, judgmental sampling may identify the chemicals of potential concern, but cannot estimate the uncertainty of chemical quantities. The reasonable maximum exposure or upper confidence limit cannot be calculated from results of a judgmental design. Bias can be avoided with the procedures described in the previous paragraph.

EXHIBIT 36. COMPARISON OF SAMPLE PREPARATION OPTIONS

Fraction & Matrix	Preparation	Strengths	Weaknesses
Volatile Soil/Water	Head-space	Rapid, simple, potentially automated and minimal interferences if standards are prepared using sample media to minimize the effects of ionic strength variability between samples and standards.	Qualitative identification; comparison of concentration possible but quantitative standardization is difficult, especially true for complex matrix (e.g., particulates and clay in soil); no mechanism for concentration; application and sensitivity are very analyte-specific.
	Purge and Trap	Generally recommended for this analysis (comparabilities); can be automated; broadly applicable and allows concentration factor; good recoveries across analyte list.	Sacrifice of either highly volatile analytes or inadequate purge of low volatility analytes; dependent on purge and trap parameters.
		High precision and recoveries for waters.	Soils have variable response dependent on soil characteristics. Efficiency of soil purge is not monitored.
Extractable Organics in Water	Separatory Funnel	Relatively rapid processing and low set-up costs; relatively high PAH recovery.	Generally low recovery of target analytes; high potential for matrix problems; poor method precision.
	Continuous Extraction	Minimal matrix problems; generally higher analytical precision and high phenol recoveries; overall high extraction efficiency (accuracy).	Lower recovery of PAH and phthalates (especially higher molecular weight); time-consuming procedure and high initial set-up costs; more potential for contamination.
	Solid Phase Extraction	Very rapid, simple technique; samples can be extracted in the field for laboratory analysis; potentially low MDL in a clean matrix.	Procedure has limited available performance data. Presence of interference and matrix problems can affect extraction efficiency and data quality. Each batch of extraction medium must be tested for efficiency by recovery of standards, preferably in the same matrix. Breakthrough (loss) occurs at high sample concentrations.
Extractable Organics in Soil	Sonication	Rapid sample preparation; relatively low solvent requirement; good efficiency of analyte recovery/matrix exposure to solvent.	Labor intensive; constant attention to procedure; relatively high initial cost. Methylene chloride/acetone solvent mixture results in many condensation products and often in method blank contamination.
	Soxhlet Extraction	Relatively routine requirement for direct analytical support; relatively good exposure of sample to solvent if sample texture appropriate; relatively low initial cost.	Relatively high operating cost-replacement apparatus; solvent; for some matrices may not provide efficient sample/solvent contact (e.g., channeling, very slow sample output).
Inorganics	Acid Digestion	Dissolves particulates; provides results for total metals.	Some compounds are acid insoluble; digestion may promote interference effects.
	0.45 um Membrane Filtration	Isolates dissolved metals species.	Filtration problems in field; does not provide a total metals assay; is an extra step in sample collection.
	Direct Aspiration	No preparation required; provides results for dissolved metals.	Particulates affect sample introduction.

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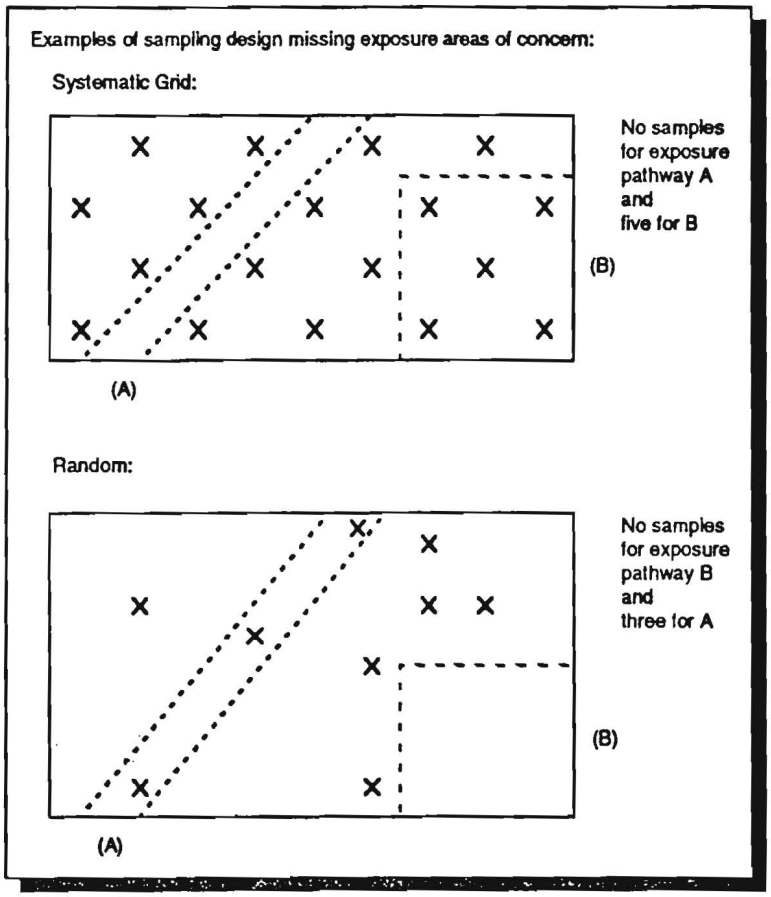
EXHIBIT 37. IDENTIFICATION OF EXPOSURE PATHWAYS PRIOR TO SAMPLING DESIGN IS CRITICAL TO RISK ASSESSMENT



3.2.9 Field Analyses Versus Fixed Laboratory Analyses

Field analyses are typically used to gather preliminary information to reduce errors associated with spatial heterogeneity, or to prepare preliminary maps to guide further sampling. Field analyses are often conducted during the RI to provide data to determine worker protection levels, the extent of contamination, well screen casing depths, and the presence of underground contamination, and to locate hot spots. For many sites, field analyses can often provide useful data for risk assessment. The analyses provide semi-quantitative results, often free of significant matrix interference, that can be used quantitatively if confirmed by a quantitative analysis from fixed laboratories.

Field instruments are usually divided into three classes: field portable instruments that can be carried by a single person, field transportable instruments that can be moved and used in the field or in a mobile laboratory, and mobile laboratory instruments that are installed in a trailer for transport to a site. Instrumentation used may be GC, X-ray fluorescence (XRF), or organic vapor analyzer (OVA). Examples and applications of these instruments might include on-site GC analysis of soil gas to indicate the presence of underground contamination, XRF for soil lead analyses, and the OVA to detect volatile organics, reported in benzene equivalents rather than in standard units of concentration.

Analytical methods that have traditionally been restricted to off-site laboratories can now be employed in the field. In addition, the quality of field instrumentation has improved steadily, allowing for better measurements at the site. Rugged versions of fixed laboratory instrumentation, such as XRF and GCs, can often be performed in trailers if adequate ventilation and power supplies are available. With field analyses, greater numbers of samples can be analyzed with immediate, or very short, holding times with no shipping and storage requirements. At least 10% of field analyses should be confirmed by fixed laboratory analyses to ensure comparability.

☛ *Field methods can produce legally defensible data if appropriate method QC is available and if documentation is adequate.*

EXHIBIT 38. STRENGTHS AND WEAKNESSES OF BIASED AND UNBIASED SAMPLING DESIGNS

Sampling Design	Strengths	Weaknesses
Biased (judgmental, purposive)	• Uses knowledge of location • Fewer resources • Timeliness • Focuses sampling effort	• Inability to calculate uncertainty • Inability to determine upper confidence limit • Decreases representativeness • Increases probability of false negatives
Unbiased (random, systematic grid, geostatistical)	• Ability to calculate uncertainty • Ability to determine upper confidence limit • Representativeness • Reduces probability of false negative	• Resource intensive • May require statistician • Timeliness • More samples required

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Significant QA oversight of field analyses is recommended to enable the data to be widely used. Field analysis performance data are often not available—in part because of the variety of equipment and operating environments, variety of sample matrices, and relative "newness" of certain technologies. Therefore, an in-field method validation program is recommended. Spikes and performance evaluation materials should be incorporated, if available in addition to other standard QC measures such as blanks, calibration standards, and duplicates.

The precision and accuracy of individual measurements may be lower in the field than at fixed laboratories, but the quicker turnaround and the possibility of analyzing a larger number of samples may compensate for this factor. A final consideration is the qualifications of operators in the field. The RPM, in consultation with chemists and quality assurance personnel, should set proficiency levels required for each instrument class and decide whether proposed instrument operators comply with these specifications.

Fixed laboratory analyses are particularly useful for conducting broad spectrum analyses for target compounds, to avoid the possibility of false negatives. They generally provide more information for a wider range of analytes than field analyses, and are generally more reliable than field screening or field analytical techniques.

> ☛ *To minimize the potential for false negatives, obtain data from a broad spectrum analysis from each medium and exposure pathway.*

Fixed laboratory analysis commonly uses mass spectrometry for organic analyses, which provides greatly enhanced abilities for compound identification. For inorganics, AA spectroscopy or ICP atomic emission spectroscopy should be used for reliable identification of target analytes. Once the broad spectrum analysis and contaminant identification has occurred, other methods may be employed that offer lower detection limits, better quantitate specific analytes of concern, and that may be less expensive.

> ☛ *The CLP or other fixed laboratory sources are most appropriate for broad spectrum analysis or for confirmatory analysis.*

Characteristics such as turnaround time, detection and identification ability of the instruments, precision and accuracy requirements of the measurements, and operator qualifications should be considered when selecting field or fixed laboratory instrumentation. Exhibit 39 compares the characteristics of field and fixed laboratory analyses. The risk assessor and RPM should consult the project chemist to consider the available options and make a choice of analysis based on method parameters, turnaround time, and cost, as well as other data requirements pertinent to risk assessment needs (e.g., legal defensibility). Exhibit 40 compares the strengths and weaknesses of field and fixed laboratory analyses.

3.2.10 Laboratory Performance Problems

The RPM should be aware of problems that occur during laboratory analyses, even though the resolution of such problems are usually handled by the project chemist. This section discusses common performance problems and explains how to differentiate laboratory performance problems from method performance problems.

> ☛ *Solicit the advice of the chemist to ensure proper laboratory selection and to minimize laboratory and/or methods performance problems that occur in sample analysis.*

EXHIBIT 39. CHARACTERISTICS OF FIELD AND FIXED LABORATORY ANALYSES

Characteristic	Field Analysis	Fixed Laboratory Analysis
Prevention of false negatives	Immediate analysis means volatiles not lost due to shipment and storage.	More extensive sample preparation available to increase recovery of analytes.
Prevention of false positives	No sample to sample contamination during shipment and storage.	Contamination by laboratory solvents minimized by storage away from analytical system.
Analytical Turnaround Time	Data available immediately or in up to 24 to 48 hours (additional time necessary for data review).	Data available in 7 to 35 days unless quick turnaround time requested (at increased cost).
Sample Preparation	Limited ability to prepare samples prior to analysis.	Samples can be extracted or digested, thereby increasing the range of analyses available.

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Laboratory performance problems may occur for routine or non-routine analytical services and can happen with the most technically experienced and responsive laboratories. Laboratory problems include instrument problems and down-time, personnel inexperience or insufficient training, and overload of samples. Issues that may appear to be laboratory problems, although they are actually planning problems, include inadequate access to standards, unclear requirements in the analytical specifications, difficulty in implementing non-routine methods, and some sample-related problems. Another problem for the RPM may be a lack of laboratories with appropriate experience or available capacity to meet analytical needs. These problems can usually be averted by "up-front" planning and by a detailed description of required analytical specifications.

- Instrument problems can be revealed with a unique identifier for each instrument in the laboratory that is reported with the analyses. Calibration and performance standards, such as calibration check standards, internal standards, or system monitoring compounds, should be specified in the analytical method to monitor performance of each instrument. In addition, the use of instrument blanks should be specified (to avoid the possibility of carry-over during the analysis).
- Some degradation in data quality may appear when new personnel are operating or when the sample load for a laboratory is high. The contributing personnel for each analysis should be identified clearly in laboratory records and reports, and qualifications of personnel required in contracts should be documented.
- Sample and method problems can often be distinguished from laboratory problems if they are not associated with a specific instrument or analyst. A review of method QC data should distinguish between laboratory and sample problems.

EXHIBIT 40. STRENGTHS AND WEAKNESSES OF FIELD AND FIXED LABORATORY ANALYSES

Analysis*	Strengths	Weaknesses
Field -Portable XRF (Metals)	Extremely high volume sampling and analysis; compatible with sophisticated sampling and data handling software. Detection limit may be above laboratory instrument values but applicable to specific site levels of interest.	Confirmation technique recommended. Comparability may require external standardization of calibration because quantitation is based on soil surface area versus a soil volume. Results often lower than from AA analyses.
Field GC	Rapid analysis supporting high volume sampling for variety of volatile and extractable organic target compounds (includes pesticides/PCBs). Minimization of sample handling variability and data quality indicators comparable to fixed laboratory methods.	Requires prior site knowledge to ensure applicability to specific conditions (e.g., soil-gas may not be appropriate for investigation in sandy area). Confidence in identification is matrix- and site-specific and highly variable depending on sample complexity. Confirmation technique recommended.
Mobile Laboratory XRF, AA (Metals)	Combines the high volume sample capacity of field analyses with the detection limits, data quality and confidence associated with laboratory analyses.	Requires significant resources, time, and personnel to transport, maintain and operate; generally most appropriate at high volume sites, especially remote.
Mobile Laboratory Luminescence	Rapid survey of analytes that routinely require sample preparation (e.g., PAHs and PCBs). Detection limits can be adjusted within limits to site-specific concentrations of concern.	Technique has had minimal use in EPA site investigation. Comparability may be an issue and require extensive confirmatory analyses.
Mobile Laboratory GC, GC-MS	Combines high volume capacity of field analyses with increased confidence in identification (GC-MS) or improved data quality (GC). GC methods may be identical to laboratory procedures but quality is intermediate due to site conditions (e.g., temperature, humidity and power requirements).	Same weaknesses as for mobile laboratory inorganics. An additional weakness is the increased training requirements and decreased availability of experienced GC-MS operators for totally independent system operation. Possibiity of site contamination and cross-contamination.
Fixed Laboratory XRF, AA, ICP (Metals - Available Routine Methods)	Highest comparability and representativeness. Data quality, including detection limits, generally predictable. Efficient match of analyses required to instrument (e.g., multiple analyses run simultaneously by ICP).	Slow delivery of data; increased documentation requirement due to the number of participants--relatively high sample cost.
Fixed Laboratory GC & GC-MS (Organics - Available Routine Methods)	Highest comparability and representativeness. Necessary confirmation of qualitative identification. Data quality and detection limits generally predictable. In depth analysis and sample archives for follow-up testing.	Same weaknesses as for fixed laboratory metals; analyte-specific performance.

* ICP = Inductively Coupled Plasma Spectroscopy. Graphite AA = Graphite Furnace (electrothermal) Atomic Absorption Spectroscopy. Flame AA = Flame Atomic Absorption Spectroscopy. ICP-MS = Inductively Coupled Plasma-Mass Spectroscopy. XRF = X-Ray Fluorescence. GC = Gas Chromatography. GC-MS = Gas Chromatography-Mass Spectrometry. AA = Atomic Absorption Spectroscopy.

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EXHIBIT 40. STRENGTHS AND WEAKNESSES OF FIELD AND FIXED LABORATORY ANALYSES (Cont'd)

Analysis*	Strengths	Weaknesses
ICP	Simple, automated, extremely rapid; can assay metals simultaneously; can detect ppb levels.	Subject to salt or iron interferences; lacks detection capability at low levels; not suitable for less than 20 ppb Arsenic, Lead, Selenium, Thallium, Cadmium, Antimony; requires background and interelement correction.
Graphite AA	Simple, automated; can assay most metals; can assay low level metals; can detect ppb levels.	Lower precision and accuracy result unless methods of standard additions used. Method is time-consuming; requires background correction; requires matrix modifiers; subject to spectral interferences. Graphite tube requires replacement frequently.
Flame AA	Simple, rapid, very suitable for high concentration sodium and potassium assays; commonly used and rugged.	Not as sensitive as graphite AA; salts can interfere; limited by lamp capabilities; detects ppm levels.
ICP-MS	Rapid; can detect low levels; accurate.	Method is subject to isobaric molecular and ion interferences. Nebulization, transport process, and memory physical interferences occur. Method is relatively new and is expensive. Specialized training is required.
ICP-Hydride	Rapid; can detect low levels of Antimony, Arsenic, Selenium; Hydride formation eliminates spectral interferences.	Dependent on analyte oxidation state; especially sensitive to copper interference. Method is relatively new. Specialized training is required.

* ICP = Inductively Coupled Plasma Spectroscopy. Graphite AA = Graphite Furnace (electrothermal) Atomic Absorption Spectroscopy. Flame AA = Flame Atomic Absorption Spectroscopy. ICP-MS = Inductively Coupled Plasma-Mass Spectroscopy. XRF = X-Ray Fluorescence. GC = Gas Chromatography. GC-MS = Gas Chromatography-Mass Spectrometry. AA = Atomic Absorption Spectroscopy.

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Chapter 4
Steps for Planning for the Acquisition of Useable Environmental Data in Baseline Risk Assessments

This chapter provides planning guidance to the RPM and risk assessor for designing an effective sampling plan and selecting suitable analytical methods to collect environmental analytical data for use in baseline risk assessments. It is important to understand that the variances inherent in both sampling and analytical designs combine to contribute to the overall level of uncertainty. The chapter also provides a number of charts and worksheets that should be useful in planning. It is important to remember that these are provided for guidance only. Each Region, or the staff at an individual site, may modify these for their use or develop their own materials.

The chapter has two sections. The first section of the chapter describes the process of selecting a sampling design strategy and developing a sampling plan to resolve the four fundamental risk assessment decisions presented in Chapter 2:

- What contamination is present and at what levels?
- Are site concentrations sufficiently different from background?
- Are all exposure pathways and exposure areas identified and examined?
- Are all exposure areas fully characterized?

A Sampling Design Selection Worksheet and a Soil Depth Sampling Worksheet are used as data collection and decision-making tools in this process. Guidance for evaluating alternative sampling strategies and designing statistical sampling plans is included.

The second section of the chapter provides guidance on selecting the methods for analyzing samples collected during the RI. A Method Selection Worksheet is used to compile the list of chemicals of potential concern and to determine analytical priorities so that the most suitable combination of methods is selected.

The risk assessor or RPM, in consultation with other technical experts, will probably complete several worksheets, representing different media, exposure pathways, potential sampling strategies, chemicals of potential concern, and analytical priorities. This is done to compile sufficient information to communicate basic risk assessment requirements to the RPM, and to ensure that these requirements are addressed in the sampling and analysis plan (SAP).

The selection of sampling plans and analytical methods should be based on the performance measures discussed in this chapter. These measures are assessed by data quality indicators that quantify attainment of the data quality objectives (DQOs) developed by the RPM for the total data collection and evaluation effort.

4.1 STRATEGIES FOR DESIGNING SAMPLING PLANS

This section provides guidance for evaluating alternative sampling strategies. Risk assessment may involve sampling many media at a site: groundwater, surface water, soil, sediment, industrial sludge, mine tailings, or air. The strategies for sampling different media often vary. For example, random stratified sampling may be the appropriate method for examination of soils at a site, but the positioning of groundwater monitoring wells is seldom done on a random basis. Sampling designs for soils and sediments are usually created to examine spatial distribution and heterogeneity of chemicals of concern. Groundwater sampling plans examine the

Acronyms

AA	atomic absorption
BNA	base/neutral/acid
CAS	Chemical Abstracts Service
CLP	Contract Laboratory Program
CV	coefficient of variation
CVAA	cold vapor atomic absorption
DQO	data quality objective
EMMI	Environmental Monitoring Methods Index
EMSL-LV	Environmental Monitoring Systems Laboratory - Las Vegas
EPA	U.S. Environmental Protection Agency
GC	gas chromatography
GFAA	graphite furnace atomic absorption
GIS	Geographic Information System
GPC	gel permeation chromatography
ICP	inductively coupled plasma
MDL	method detection limit
MDRD	minimum detectable relative difference
MS	mass spectrometry
PA/SI	primary assessment/site inspection
PCB	polychlorinated biphenyl
QA	quality assurance
QC	quality control
RAS	routine analytical services
RI	remedial investigation
RME	reasonable maximum exposure
RPM	remedial project manager
SAP	sampling and analysis plan
VOA	volatile organics
XRF	X-ray fluorescence

extent of a plume containing the chemical of concern, and also often examine seasonal or temporal variability in chemical concentrations. Exhibit 41 summarizes the relative variation in spatial and temporal properties for different types of measurement.

The terms stratum and strata are used frequently in this section. A stratum is usually a physically defined layer or area; it can also be a conceptual grouping of data or site characteristics that is used in statistical analysis.

Sampling guidance in this section is focused on determining the spatial extent and variability of the concentration of chemicals of potential concern. Therefore, it applies most directly to soils and sediments. Some EPA Regions have developed sampling guidances for groundwater, and the RPM and risk assessor should consult these whenever available.

Examples of common sampling designs are given in Exhibit 42, and their overall applicability is shown in Exhibit 43. Schematic examples of some of the designs are illustrated in Exhibit 44.

The objective of the sampling plan is to determine a strategy that collects data representative of site conditions. The data must have acceptable levels of precision and accuracy, obtain minimum required levels of detection for chemicals of potential concern, and have acceptable probabilities of false positives and false negatives. Meeting these objectives involves optimizing the confidence in concentration estimates and the ability to detect differences between site and background levels. To accomplish these objectives, the RPM can optimize the number of samples, the sampling design, or the efficiency of statistical estimators (e.g., mean, standard deviation, and standard error).

Increasing the number of samples may increase initial costs, depending on whether fixed or field analytical methods are used for analysis, but it is necessary in

EXHIBIT 41. EXAMPLES OF SPATIALLY AND TEMPORALLY DEPENDENT VARIABLES

Measurement	Relative Variation in Measurements Attributable to:	
	Spatial	Temporal
Geophysical Measurements	Large	Small
Soil-Gas Measurements	Large	Large
Weather/Air Quality	Large	Large
Surface Water Quality	Usually Small	Usually Large
Physical Soil Properties	Large	Small
Soil Moisture	Large	Large
Soil Quality	Large	Small
Aquifer Properties	Large	Small
Groundwater Flow	Usually Large	Usually Small
Concentration of Groundwater Contaminants	Large	Large

21-002-041

EXHIBIT 42. EXAMPLES OF SAMPLING DESIGNS

Design	Examples of Application
Judgmental/ Purposive	Monitoring Wells Hot Spots
Classical Random	Background Soil
Classical Stratified:	
Random	Drums at Surface
Systematic	Waste Piles
Cluster	Soil from Boreholes
Composite	Soil from Test Pits
Systematic:	
Random	Determine Concentrations of Chemicals of Potential Concern in Soil
Grid	Concentrations of Chemicals of Potential Concern. Surface Soil Characteristics
Search	Contaminant Hot Spots
Surrogate	Gas Detector Measurements
Phased	Extent of Contamination
Geostatistical	Distribution of Contamination

21-002-042

certain situations (see Section 4.1.2). The sampling design can often be improved by stratifying within a medium to reduce variability, or by selecting a different sampling approach, such as a geostatistical procedure termed "kriging." Improving the efficiency of the statistical estimators involves specifying the type of data distribution if parametric procedures are being used, or switching from nonparametric to parametric procedures if distributional assumptions can be made.

Exhibit 45 is a Sampling Design Selection Worksheet, structured to assist design selection for the most complex environmental situation, which is usually soil sampling. The worksheet contains the elements needed to support the decisions for RI sampling design to meet data requirements for risk assessment. The RPM and risk assessor may use this worksheet or use it as a model to create one specifically suited to their needs. The final site sampling plan must meet the data useability requirements of risk assessment. The final procedure for sampling design should be selected based on the specific reason for sampling (e.g., defining a boundary or obtaining an average over some surface or volume). The worksheet should be completed for each medium and exposure pathway at the site. Once completed, this initial set of worksheets can be modified to assess alternative sampling strategies. Completion of a set of worksheets (i.e., a worksheet for each medium and exposure pathway at a site, based on a single sampling strategy) specifies the total number of samples to be taken for an exposure pathway, and sample breakdown according to type (i.e., field samples, quality control samples, and background samples).

The remainder of this section is a step-by-step guide to completing the Sampling Design Selection Worksheet. Chemicals of potential concern listed on the Sampling Design Selection Worksheet should be the same as those used for the Method Selection Worksheet (Exhibit 52).

4.1.1 Completing the Sampling Design Selection Worksheet

☛ *Use of the Sampling Design Selection Worksheet will help the RPM or statistician determine an appropriate sampling design.*

Pathway, medium and design alternatives. Sampling procedures used in environmental sampling are either unbiased or biased. Classical and geostatistical models are unbiased in terms of sample evaluation and hypothesis testing. The classical model is based on random, or stratified random procedures, and the geostatistical model on optimizing co-variance. Systematic grid sampling can be utilized by either the classical or geostatistical model. Biased, or judgmental/ purposive, design requires the use of different approaches to planning and evaluation.

☛ *While other designs may be appropriate in many cases, stratified random or systematic sampling designs are always acceptable.*

- Classical model: The classical model uses either a random or stratified random sampling design. It is appropriate for use in sampling any medium to define the representative concentration value over the exposure area. It is not subject to judgmental biases, and produces known estimates and recognized statistical measures and guidelines. A stratified random design provides the RPM and risk assessor with great flexibility. If the nature and extent of the exposure areas are not yet well defined, a pilot random study can be conducted and the results included in the final design. The data can be averaged for any exposure area. The classical model is the basis for calculating

EXHIBIT 43. APPLICABILITY OF SAMPLING DESIGNS

Design	Objective of Sampling		
	Estimate Chemical Concentration Distribution	Evaluate Trends	Identify Hot Spots
Judgmental/ Purposive	No	Maybe	Maybe
Classical Random	Yes	Yes	No
Classical Stratified:			
Random	Yes	Yes	Maybe
Systematic	Maybe	Yes	Maybe
Cluster	Yes	No	No
Composite	Maybe	No	Maybe
Systematic:			
Random	Maybe	Yes	Maybe
Grid	No	Yes	Yes
Search	No	No	Yes
Surrogate	No	Yes	Maybe
Phased	No	Maybe	Yes
Geostatistical	Yes	Yes	Yes

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confidence levels, power, and minimum detectable relative differences (MDRDs).

- Geostatistical model: Geostatistical techniques are good for identifying hot spots and can be used for calculating reasonable maximum exposure (RME). These techniques require complex judgmental or purposive calculation procedures. Even with the use of available computer programs, a statistician should be consulted because different approaches to estimating key parameters can produce different estimates.

- Systematic grid sampling: Systematic grid sampling procedures are good for identifying unknown hot spots and also provide unbiased estimates of chemical occurrence and concentration (Gilbert 1987) useful in calculating the RME. Systematic sampling can be used in geostatistical or classical estimation models. Variance

EXHIBIT 44. COMMON SAMPLING DESIGNS

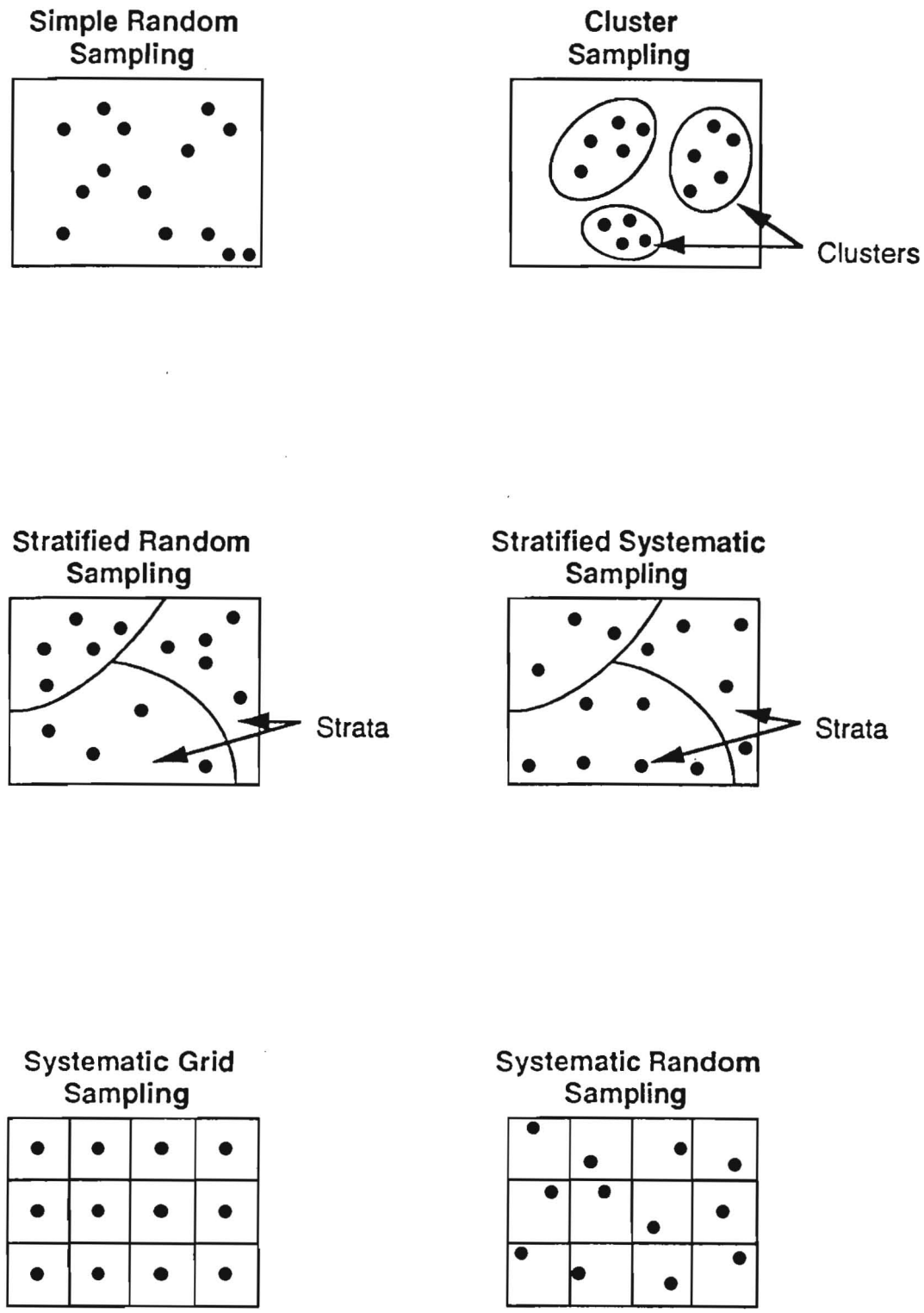

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EXHIBIT 45. HIERARCHICAL STRUCTURE OF SAMPLING DESIGN SELECTION WORKSHEET

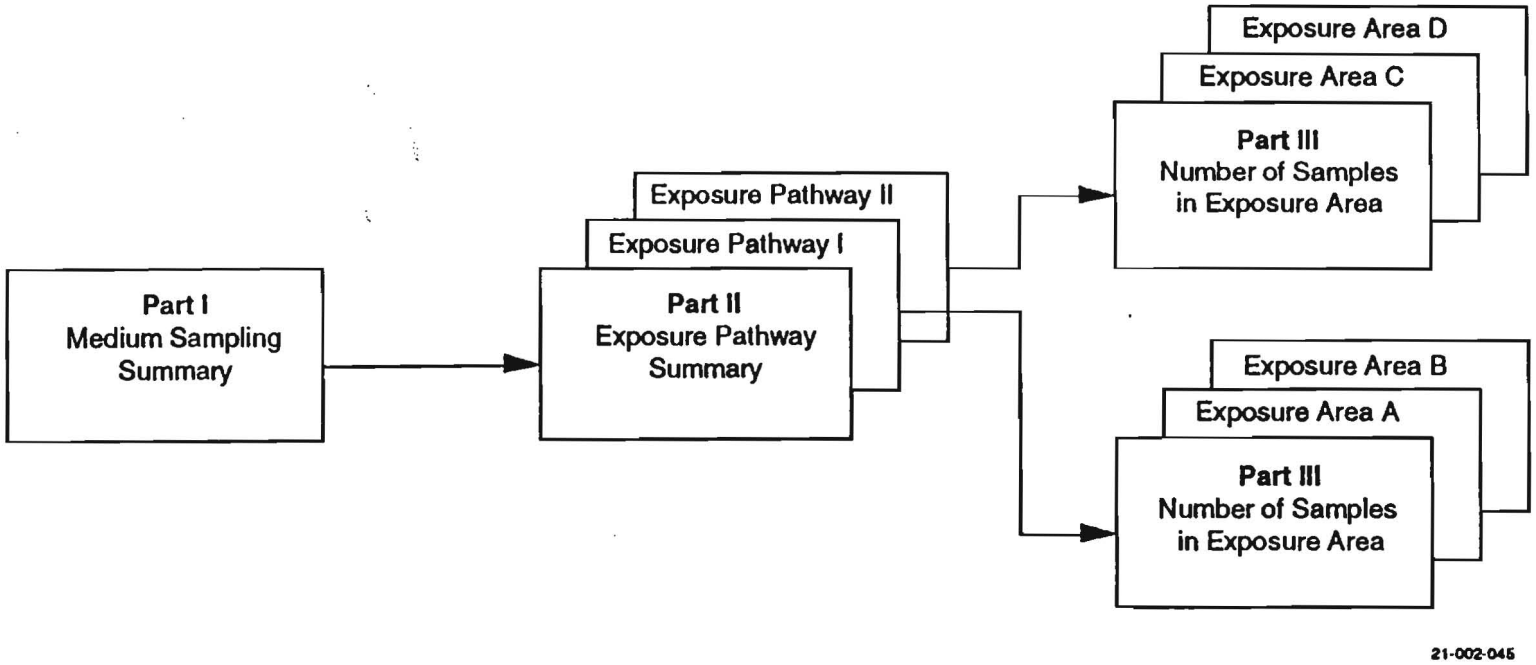

EXHIBIT 45. PART I: MEDIUM SAMPLING SUMMARY SAMPLING DESIGN SELECTION WORKSHEET (Cont'd)

A. Site Name _____ B. Base Map Code _____

C. Medium: Groundwater, Soil, Sediment, Surface Water, Air

Other (Specify) _____

D. Comments: _____

E. Medium/ Pathway Code	Exposure Pathway/ Exposure Area Name	F. Number of Samples from Part II					
		Judgmental/ Purposive	Back-ground	Statistical Design	Geo-metrical or Geo-statistical Design	QC	Row Total
	Column Totals:						
						G: Grand Total:	

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EXHIBIT 45. PART II: EXPOSURE PATHWAY SUMMARY SAMPLING DESIGN SELECTION WORKSHEET (Cont'd)

H. Chemical of Potential Concern and CAS Number	I. Frequency of Occurrence	J. Estimation		K. CV	L. Background
		Arithmetic Mean	Maximum		

M. Code (CAS Number) of Chemical of Potential Concern Selected as Proxy _____

N. Reason for Defining New Stratum or Domain (Circle one)

1. Heterogeneous Chemical Distribution
2. Geological Stratum Controls
3. Historical Information Indicates Difference
4. Field Screening Indicates Difference
5. Exposure Variations
6. Other (specify) _____

O. Stratum or Exposure Area	P. Reason	Q. Number of Samples from Part III					
Name and Code		Judgmental/ Purposive	Back-ground	Statistical Design	Geo-metrical or Geo-statistical Design	QC	Row Total
	R. Total (Part I, Step F):						

21-002-045-02

EXHIBIT 45. PART III: EXPOSURE AREA SUMMARY SAMPLING DESIGN SELECTION WORKSHEET (Cont'd)

O. Stratum or Exposure Area _____ Domain Code _____
E. Medium/Pathway Code _____ Pathway Code _____

S. Judgmental or Purposive Sampling
Comments: _____
_____

Use prior site information to place samples, or determine location and extent of contamination. Judgmental or purposive samples generally cannot be used to replace statistically located samples.

An exposure area and stratum MUST be sampled by at least TWO samples.

Number of Samples

T. Background Samples
Background samples must be taken for each medium relevant to each stratum/area. Zero background samples are not acceptable. See the discussion on page pp. 74-75.

Number of Background Samples

U. Statistical Samples
CV of proxy or chemical of potential concern _____
Minimum Detectable Relative Difference (MDRD) _____ (<40% if no other information exists)
Confidence Level _____ (>80%) Power of Test _____ (>90%)

Number of Samples
(See formula in Appendix IV)

V. Geometrical Samples
Hot spot radius _____ (Enter distance units) _____
Probability of hot spot prior to investigation _____ (0 to 100%)
Probability that NO hot spot exists after investigation _____ (enter only if >75%)
(see formula in Appendix IV)

W. Geostatistical Samples

Required number of samples to complete grid +
Number of short range samples

X. Quality Control Samples
Number of Duplicates (Minimum 1:20 environmental samples) _____
Number of Blanks (Minimum 1 per medium per day or 1 per sampling process, whichever is greater) _____

Y. Sample Total for Stratum
(Part II, Step U)

Judgmental/ Purposive	Back-ground	Statis-tical Design	Geo-metrical or Geo-statistical	QC	Row Total

21-002-045-03

calculations required to estimate confidence limits on the average concentration are available (Caulcutt 1983). Systematic sampling is powerful for complete site or exposure area characterization when the exposure area is known to be heterogeneous.

Determining number of samples. Four factors need to be considered in determining the total number of samples required (see Exhibit 46):

- Exposure areas,
- Statistical performance objectives (based on site environmental samples),
- Quality assurance objectives (based on QC samples), and
- Background samples (based on MDRD).

EXHIBIT 46. FACTORS IN DETERMINING TOTAL NUMBER OF SAMPLES COLLECTED

Number of Exposure Areas That will be Sampled (p. 74)

- Media within exposure area
- Strata within exposure area medium

Number of Samples for Each Exposure Area Grouping Given Required Statistical Performance (p. 75)

- Confidence (1- α), where α is the probability of a type I error
- Power (1- β), where β is the probability of a type II error
- Minimum detectable relative difference

Number of Quality Control Samples (p. 76)

- Field duplicate (collocated)
- Field duplicate (split)
- Blank (trip, field, and equipment (rinsate))
- Field evaluation

Number of Background Samples (p. 74)

- Number of site samples collected
- Minimum detectable relative difference

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The number of environmental site samples is ultimately controlled by performance requirements, given the statistical sampling design. The relationship between number of samples and measures of performance depends upon the variability of the chemicals of potential concern, which is measured by the coefficient of variation. In other words, the relationship between the coefficient of variation for a chemical of potential concern and measures of performance is the basis for determining the number of samples necessary to provide useable data for risk assessment.

> ☛ *If the natural variability of the chemicals of potential concern is large (e.g., greater than 30%), the major planning effort should be to collect more environmental samples.*

The number of samples can be calculated given a coefficient of variation, a required confidence level or certainty, a required statistical power, and an MDRD. Exhibit 47 illustrates the relationships between the number of samples required given typical values for the coefficient of variation and statistical performance objectives. Calculation formulas in Appendix IV facilitate the examination of effects beyond the examples cited.

4.1.2 Guidance for Completing the Sampling Design Selection Worksheet

This section provides step-by-step instructions for completing the Sampling Design Selection Worksheet shown in Exhibit 45.

Part I: Medium Sampling Summary

A. Enter the Superfund site name.

B. Enter a code that uniquely identifies a base map of the site or the exposure unit.

   All sampling events should be identified on a map or in a database such as a Geographical Information System (GIS).

C. Identify the medium to be sampled (e.g., soil, groundwater, industrial sludge, mine tailings, smelter slag, etc.).

D. Enter any comments required to describe the exposure area, and other information such as the RPM's name.

E. Enter a medium/pathway code that has been assigned for the risk investigation.

F. Specify the exposure pathway (e.g., ingestion of soil).

   Leave this entry blank for now, then enter the number of samples for each category that have been selected from Part II (Step R) of the worksheet when completed.

EXHIBIT 47. RELATIONSHIPS BETWEEN MEASURES OF STATISTICAL PERFORMANCE AND NUMBER OF SAMPLES REQUIRED

Coefficient of Variation (%)	Power (%)	Confidence Level (%)	Samples Required to Meet Minimum Detectable Relative Difference 5%	10%	20%
10	95	90	36	10	3
15	95	90	78	21	6
20	95	90	138	36	10
25	95	90	216	55	15
30	95	90	310	78	21
35	95	90	421	106	28

Note: Number of samples required in a one-sided one-sample t-test to achieve a minimum detectable relative difference at confidence level and power. CV based on geometric mean for transformed data.

Source: EPA 1989c.

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Sample types are broken out by sample type:

- Judgmental/Purposive,
- Background,
- Statistical design (e.g., stratified random sampling),
- Geometrical or geostatistical design (including hot spot sampling), and
- Quality control samples.

☛ *At least one broad spectrum analytical sample is required for risk assessment, and a minimum of two or three are recommended for each medium in an exposure pathway.*

G. Enter the grand total of all samples within a specific medium.

Part II: Exposure Pathway Summary

H. List the chemicals of potential concern and their CAS numbers.

List the known or suspected chemicals of potential concern based on historical data. This will generally be from the PA/SI.

I. List the frequency of occurrence (%).

The frequency of occurrence is the percent of samples in which the chemical of potential concern has been identified. This may be obtained from site-specific data or calculated from historial (PA/SI) data or fate and transport modeling.

J. Enter an estimate of the average (arithmetic mean) and maximum concentration of the chemical of potential concern.

Historical data or data from similar sites can be used to derive these values. More sampling will usually be necessary to determine statistically

significant differences if these values are close to background levels or to the levels of detection.

K. Estimate the coefficient of variation.

The coefficient of variation (CV) can be estimated from site-specific data or from data from similar sites. The number of samples necessary to produce useable data will generally increase as the CV increases. The definition of separate strata or domains should be investigated if a CV is above 50%. Exhibit 23 contains a listing of historical values for CVs that may be used as an estimate in the absence of site-specific data.

L. Estimate background concentration.

Background concentration estimates should be for each medium relevant to each strata/area. Site-specific data are preferred, but data from similar sites can be utilized.

M. Select a proxy chemical of potential concern.

Choose a proxy from the list of chemicals of potential concern to develop sampling plans. Note that a proxy that has the highest CV, lowest frequency of occurrence, or whose concentration at the site is closest to background levels will require the most samples.

N. Develop the reason for defining new strata or areas.

- Heterogeneous Chemical Distribution: If a chemical can be shown to have dissimilar distributions of concentration in different areas, then the areas should be subdivided. For example, hot spots may be considered separately.
- Geological Stratum Controls: Knowledge of local geologic conditions can be used to produce separate areas where similar statistical distributions are likely to exist. In particular, different "stratigraphic" layers may produce distinct strata.
- Historical Information: Historical information on production, discharge or storage of chemicals of potential concern can be used to identify separate areas.
- Field Screening: Field analytical results can be used to locate sub-populations that are mapped into exposure areas.
- Exposure Variations: Information or variations in behavior patterns, land use or receptor groups can be used to identify separate areas.
- Other reasons can be used to produce separate sampling areas, such as observed stress on vegetation, oily appearance of soils, or the existence of refuse, etc.

O. List the stratum or area name and code.

The stratum or area identifies sub-areas on the site base-map.

P. Annotate reason from Step N.

Q. List the number of samples estimated after completing Part III of this worksheet.

R. List the number of samples estimated after completing Part II and Part III of this worksheet.

Part III: Exposure Area Summary

S. Enter judgmental/purposive sampling comments.

A minimum of three to five judgmental or purposive samples must be used to sample a stratum or exposure area. Historical or prior site information can be used to locate sampling positions to determine the extent and magnitude of contamination. Chemical field screening, geophysics, vegetation stress, remote sensing, geology, etc. can also be used to guide judgmental sampling. Judgmental or purposive samples are not recommended for estimating average and maximum values within a stratum or domain area, but they can be used in geostatistical kriging estimations and can be included in calculating risk.

T. Identify background samples.

For statistical purposes, a sufficient number of background samples must be taken to determine the validity of the null hypothesis that there is no difference between mean values of concentration in the site and the background samples at the desired level of confidence. Early sampling and analysis of background samples will indicate the ease with which background levels can be discriminated, and allow modifications to be made to the SAP if necessary.

Background samples must be taken for each exposure pathway. As with QC samples, results from the background sample should be assessed early to see if background levels will severely impact the sampling design. The number of necessary background samples increases as the variability of the background values increases. Background samples should not be used in the estimation of average or maximum values within a stratum or exposure area, but they can be used in

kriging estimations. In those instances where background levels are close to on-site contamination levels, it may be necessary to collect as many background samples as site samples. Small numbers of background samples increase the probability of a type II, false negative error (i.e., that no difference exists between site and background when a difference does, in fact, exist). However, rigorous statistical analyses involving background samples may be unnecessary if site and non-site related contamination clearly differ.

☛ *Collect and analyze background samples prior to the final determination of the sampling design since the number of samples is significantly reduced if little background contamination is present.*

Background levels of contaminants vary by medium and the type of contamination. If a detectable background level of a contaminant occurs infrequently, the number of background samples analyzed might be kept small. Metals often have high rates of detection in background samples. Some pesticides, such as DDT, are anthropogenic and also have high rates of detection in particular matrices. Anthropogenic background levels are also found in sites near industries and urban areas. It is important to distinguish detection, or lack of detection, in a single sample from a false positive or false negative result. Results from single samples are different estimators than those from statistical parameters from pooled samples. Background sampling must be increased in the following situations:

- Contamination exists in more than one medium,
- Expected coefficients of variation in chemicals of concern are high and confirmed by actual data,
- Relative differences between site and background levels are small, and
- Site concentrations and concentrations of concern are low.

U. Identify statistical samples.

Samples should be systematically or randomly located. The number of samples can be calculated using the CV of the proxy variable, the required MDRD, the required confidence level and power of the test, and the appropriate statistical formula and appropriate charts.

For example, using the equation in Appendix IV:

> Where Z_α and Z_β are obtained from the normal distribution tables for significance levels α and β respectively; α is the probability of the false positive error rate, and β is the probability of the false negative error rate.
>
> Then, if α is 0.2 (20%) and the confidence level is 80% then Z_α is 0.842. If β is 0.05 (5%) then the power is 95% and Z_β is 1.648.
>
> If the MDRD is 20% and the CV is 30%, then $D = \frac{MDRD}{CV}$ which equals 0.666
> and n>15 samples are required.

V. Identify samples from geometrical design.

☛ *Systematic sampling supplemented by judgmental sampling is the best strategy for identifying hot spots.*

For example, using the equation in Appendix IV:

> Where R = 20 m
>
> and A = 37,160 m^2
>
> and X = 0.3 Probability that a hot spot is in the exposure area from "historical records" or from field screening or geophysical tests.
>
> and C = 0.2 The acceptable "walk away" probability that a hot spot exists after a sampling grid has been done.
>
> then:
>
> D = 2.7, R = 54.8 m, and
> n = 27,160/54.82 = 12.37
>
> Therefore 12 samples are required.

Note that the requirements for 15 samples from a statistical sampling approach can be met in this example if the hot spot search is augmented by randomly locating two additional samples. The results for number of samples from U and V are not additive.

W. Identify samples from geostatistical design.

A geostatistical sampling pattern should be designed at the early stage of planning. A statistician should be consulted to develop the design.

X. Quality Control Samples

Generally, duplicates should be taken at a minimum of 1 duplicate for every 20 environmental samples (EPA 1989f). However, this frequency may be modified based on site conditions. For example, the number of duplicates and other QC samples may be set high for the beginning of site sampling, evaluated after several duplicates to determine routine measurement error, and subsequently adjusted according to observed performance. The information in Exhibit 48 shows that confidence in measurement error increases sharply when four or more pairs of duplicate samples are taken per medium. Critical samples are recommended for designation as duplicates in the QA sampling design.

EXHIBIT 48. NUMBER OF SAMPLES REQUIRED TO ACHIEVE GIVEN LEVELS OF CONFIDENCE, POWER, AND MDRD [1]

Confidence (1-α)	Power (1-β)	MDRD	No. of Samples
90%	90%	10%	42
90%	90%	20%	12
80%[2]	90%[2]	20%	8
80%	80%	10%	19
80%	80%	20%	5
80%[2]	90%[2]	40%	3

[1] Values for number of samples are based on a CV of 25%.

[2] The minimum recommended performance measures for risk assessment are: confidence (80%) and power (90%).

Source: EPA 1989c.

Blanks provide an estimate of bias due to contamination introduced by sampling, transportation, carryover during field filtration, preservation, or storage. At least one field blank per medium should be collected each day, and at least one blank must be collected for each sampling process (EPA 1989f).

Examine results from duplicate and blank samples as early as possible in the sampling operation to ascertain if presumed sampling characteristics are accurate and discover areas where the sampling strategy requires modification. For a more detailed discussion of the types and use of QC samples see *A Rationale for the Assessment of Errors in the Sampling of Soils* (EPA 1990c).

Y. Calculate the sample total for stratum or exposure area (enter in Part II, Step U).

4.1.3 Specific Sampling Issues

Selection of performance measures. Quantitative data quality indicators based on performance objectives should be proposed for completeness, comparability, representativeness, precision, and accuracy during planning. Performance measures are specified as minimum limits for each stratum. Based on the coefficients of variation of the analyte concentrations, these limits will determine the numbers of samples required. The actual values or objectives are determined by the level of acceptable uncertainty, which includes that associated with hot spot identification. Recommended minimum criteria are specified in Exhibit 48 for statistical performance measures associated with the uncertainty in risk assessment: confidence level, power, and MDRD. Recommended minimum criteria for measurement error and completeness for critical samples are discussed in the following sections.

Setting minimum acceptable limits for confidence level, power, and minimum detectable relative difference. Confidence level, power, and MDRD are three measures of sampling design precision. These measures are ultimately determined by the coefficient of variation of chemical concentration and the number of samples. Each measure is briefly defined as follows:

- Confidence level: The confidence level is 100 minus α, where α is the percent probability of taking action when no action is required (false positive).
- Power: Power is 100 minus β, where β is the percent probability of not taking action when action is required (false negative).
- Minimum detectable relative difference: MDRD is the percent difference required between site and background concentration levels before the difference can be detected statistically.

The power and ability to detect differences between site concentration levels compared to background levels are critical for risk assessment. Given a CV, the required levels of confidence, power, and MDRD significantly affect the number of samples. Exhibit 48 illustrates the effect when the CV is equal to 25%.

It is important to note that the number of samples required to meet confidence and power requirements will be low if the acceptable MDRD is large; that is, if site contamination is easily discriminated from background levels.

Determining required precision of measurement error. Field duplicates and blanks are the major field QC samples of importance to the precision of measurement error. Duplicates provide an estimate of

total measurement error variance, including variance due to sample collection, preparation, analysis, and data processing. They do not discriminate between-batch error variance. If the duplicate is collocated, contaminant sample variation caused by a heterogeneous medium is also included in the measure. The precision of the measurement error estimate is subject to the number of duplicates on which the estimate is based. Exhibit 49 gives the estimated precision of the measurement error based on the number of duplicate pairs. With three duplicates, the true measurement error variance could be as much as 13.89 times the observed variance, if a 95% level of confidence is required. The resources needed for the collection and analysis of duplicates depend on the magnitude and variability of the concentration of concern for the chemicals of potential concern.

- Little room for measurement error exists if the level of concentration of concern is near the method detection limit, and the precision of the estimate of measurement error is critical.
- If the natural variability of the chemicals of potential concern is relatively large, the major planning effort will be to collect more samples from the exposure areas, rather than collecting more QC samples. More detailed discussions of the use of QC measures and selection of the appropriate number of QC samples may be found in *A Rationale for the Assessment of Errors in the Sampling of Soils* (EPA 1990c).

Planning for 100% completeness for critical samples. Certain samples in a sampling plan may be designated by the RPM or risk assessor as critical in determining the potential risk for an exposure area. For example, if only one background sample is taken for a given medium and exposure area, then that sample would be considered

EXHIBIT 49. CONFIDENCE LEVELS FOR THE ASSESSMENT OF MEASUREMENT VARIABILITY

Number of Duplicate Pair Samples	Interval for 95% Confidence that Measurement Error is Within Limits				
	Observed Variance (s^2)		True Variance		Observed Variance (s^2)
2	.27	≤	σ^2	≤	39.21
3	.32	≤	σ^2	≤	13.89
4	.36	≤	σ^2	≤	8.26
5	.39	≤	σ^2	≤	6.02
6	.42	≤	σ^2	≤	4.84
7	.44	≤	σ^2	≤	4.14
8	.46	≤	σ^2	≤	3.67
9	.47	≤	σ^2	≤	3.33
10	.49	≤	σ^2	≤	3.08
15	.54	≤	σ^2	≤	2.40
20	.58	≤	σ^2	≤	2.08
25	.62	≤	σ^2	≤	1.91
50	.70	≤	σ^2	≤	1.61
100	.77	≤	σ^2	≤	1.35

s^2 = Observed variance (precision of an estimate).

σ^2 = True variance (population variance).

Note: Assumes data are or have been transformed to normal distribution.
Source: EPA 1990c.

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"critical." All data associated with such a sample must be complete. The only acceptable level of completeness for critical samples is 100%.

> ☛ *Focus planning efforts on maximizing the collection of useable data from critical samples.*

Hot spots and the probability of missing a hot spot. Hot spots are primarily an issue in soil sampling. The RPM and risk assessor must determine whether hot spots exist in the exposure area and the probable size of the hot spot. This information can often be deduced from historical data and assisted by judgmental sampling, although judgmental sampling alone cannot produce estimates of the probability that a hot spot has been missed. Procedures for determining the probability of missing a hot spot are not as effective in random designs as in systematic and geostatistical designs. However, a search strategy which stratifies the area based on grids and then randomly samples within each grid can be used within the classical technique. Systematic and geostatistical design approaches provide the best approach to unknown hot spot identification.

Appendix IV describes numerical procedures and assumptions to determine the probability that a given systematic design will detect a hot spot and provides a calculation formula based on a geometrical approach. To employ this formula, the distance between grid points and the estimated size of the hot spot as a radius must be specified.

Historical data comparability. The RPM may wish to assess historical data along with current results or may anticipate that the current data will need to be compared with results from future sampling activities. Consult a statistician in either of these cases to determine if the current sampling design will allow the production of data of known comparability. Factors other than statistics may need to be considered when attempting to combine data from different sampling episodes. Physical properties of the site such as weather patterns, rainfall and geologic characteristics of different exposure areas may need to be considered. Temporal effects, such as the seasonality or time period of sampling, or seasonal height of a water table, may also be important. Analytical methods have been modified over time and many required detection limits have been revised.

> ☛ *The ability to combine data from different sampling episodes or different sampling procedures is a very important consideration in selecting a sampling design but should be done with caution.*

4.1.4 Soil Depth Issues

The appropriate depth or depths to take soil samples can be a major issue in determining a sampling design. Exhibit 50 is a worksheet designed to help the RPM and risk assessor to determine an appropriate soil sampling depth. The conceptual site model (Exhibit 6) provides the basis for completing this worksheet. The nature and depth of soil horizons at the site should be established wherever possible. Features such as porosity, humic content, clay content, pH, and aerobic status often affect the movement or fate of chemicals of potential concern through a soil. As with other worksheets provided in this guidance, this worksheet is intended as a guide or basis for development. RPMs, in consultation with the risk assessor and other staff, can revise or modify this worksheet as appropriate to the site. Consider both current and future land use scenarios in soil exposure areas because of the sorptive and retentive properties of soils.

Completing the Soil Depth Sampling Worksheet

1. **Land Use Alternatives**

   A. Identify current or future land use.

   B. Identify exposure scenario.

   The exposure scenario should be identified for current or future land use. Identify the scenario according to *Role of Baseline Risk Assessment in Superfund Remedy Selection Decision* (EPA 1991c) and *Human Health Evaluation Manual Supplemental Guidance: Standard Default Exposure Factors* (EPA 1991d). A residential exposure scenario should be used whenever there are, or may be, occupied residences on or adjacent to the site. Unoccupied sites should be assumed to be residential in the future unless residential land use is unreasonable. Sites that are surrounded by operating industrial facilities can be assumed to remain as industrial areas unless there is an indication that this assumption is not appropriate. Other potential land uses, such as recreation and agricultural, may be used if appropriate.

2. **Chemicals of Potential Concern**

   A. Specify class of chemical.

   Circle the classes of chemicals of potential concern (e.g., volatile organics (VOAs), semivolatile organics (semi-VOAs), inorganics or metals, or special class) that apply.

EXHIBIT 50. SOIL DEPTH SAMPLING WORKSHEET

Step 1 - Land Use Specifications*	
1A (check one) _ Current _ Future _ Current & Future, Same	1B (check one) _ Residential _ Commercial/Industrial _ Other (Specify) _ Recreational _ Agricultural

Sampling Depth Considerations	Step 6. Expected Depth of Contamination by Chemicals of Potential Concern		Step 7. Exposure Pathways			Step 8. Representative Sample Depths (units _____)
	Surface Units	Subsurface	Ingestion	Dermal	Inhalation	
Step 2: Chemicals of Concern **A** Class: VOAs, Metals, semi-VOAs, Special (e.g., PCBs, dioxin) **B** Physical Properties: Mobile, Soluble, or Leachable **Step 3:** Soil Characteristics **A** Taxonomy _____ **B** Organic Content _____ **C** Particle Size _____ **D** Concern for Migration to Other Media, (Air, SW, sediments, GW)_____ _____ **Step 4:** Vegetative Cover Heavy/Sparse/Intermittent **Step 5:** Other Factors _____ _____						

* The complexity of a site determines if multiple worksheets are necessary to distinguish between current and future land use scenarios (e.g., mix of residential and commercial use for different areas of a site, possible future residential use, etc.).

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B. Record physical properties.

Circle the physical properties of the chemicals of potential concern that apply. These properties can be estimated from factors such as the octanol/water partition coefficient, Henry's law constant, and water solubility appropriate to each chemical.

3. **Soil Characteristics**

A. Record the taxonomic designation of the soil, if known.

B. Record the organic matter content of the soil.

C. Record the most common particle size of the soil.

D. Identify any concern for migration of the chemicals of potential concern to other media (e.g., air, sediment, surface water, and groundwater).

4. **Vegetative Cover**

Circle whether the vegetative cover of the site is heavy, sparse or intermittent.

5. **Other Factors**

List other factors or considerations that influence the desired depth of soil sampling. For example, geological factors (e.g., depth to groundwater or bedrock) could influence soil sampling.

6. **Expected Depth of Contamination by Chemicals of Potential Concern**

Enter expected depth (and units) of contamination by chemicals of potential concern, given the chemicals, soil characteristics and vegetative cover. Depth can be influenced by disposal practices or deposition patterns, soil characteristics, vegetative cover, and physical and chemical properties of the chemicals of potential concern.

7. **Exposure Pathways**

Enter exposure pathways by chemicals of potential concern, soil characteristics and vegetative cover. Physical and chemical properties of the chemicals of potential concern will influence their activity in the exposure pathway (e.g., VOAs and the inhalation pathway). Soil characteristics and vegetative cover will also influence the exposure pathway (e.g., groundwater and water ingestion pathway).

8. **Representative Sample Depths**

Record representative sample depths (including units) indicated by the data completed in Steps 2 through 7.

Basic Soil Depth Definitions

Surface dust is the top 0 to 2 inches of soil that can be carried by the wind and tracked into houses.

Surface soil is the top 0 to 6 inches of soil. If the surface is grass covered, surface soil is considered the 2 inches below the grass layer.

Subsurface soil can typically range from 6 inches to 6 or more feet in soil depth. For example, at sites with potential soil moving activity, soil depths greater than 6 feet could be of concern in risk assessment.

Other Performance Measures. Other performance measures may be designated to facilitate the monitoring and assessment of sampling. For example, field spikes and field evaluation or audit samples can be used to assess the accuracy and comparability of results. Field matrix spikes are routine samples spiked with the contaminant of interest in the field and do not increase the number of field samples. Field evaluation samples are of known concentration, which are introduced in the field at the earliest stage possible and subject to the same manipulation as routine samples. Field evaluation samples will increase the total number of samples collected. Performance measures for field spikes and evaluation samples are expressed in terms of percent recovery. Difficulties associated with field spiking, especially in soil, have resulted in limited use of this practice (EPA 1989f).

4.1.5 Balancing Issues for Decision-Making

Completing a number of Sampling Design Selection Worksheets (Exhibit 45) for different exposure areas, media, and sampling design alternatives will enable the RPM and risk assessor to compare and evaluate sampling design options and consequences and select the appropriate sampling design for each medium and exposure pathway. Practical tradeoffs between response time, analytical costs, number of samples, sampling costs, and level of uncertainty can then be weighed. For example, perhaps more samples can be collected if less expensive analyses are used. Or, if the risk assessment is based on a point source, collection of additional samples to estimate chemical concentrations and distribution can be avoided.

Computer programs are useful tools in developing and evaluating sampling strategies, especially in trading off costs against uncertainty, and identifying situations when additional samples will not significantly affect the useability of the data (i.e., the point of diminishing returns). Each automated system has specific data requirements and is based on specific site assumptions. The major systems that support environmental sampling decisions are listed, contacts for information given, and brief descriptions provided in Exhibit 51.

4.1.6 Documenting Sampling Design Decisions

It is important to document the primary issues considered in balancing tradeoff to accommodate resource concerns and their impact on data useability. Fully document all final sampling design decisions, including the rationale for each decision. During the course of the RI, continue to document pertinent issues that arise and any sampling plan modifications which are implemented.

4.2 STRATEGY FOR SELECTING ANALYTICAL METHODS

This section describes how to use the Method Selection Worksheet shown in Exhibit 52 as a data collection and decision-making tool to guide the selection of analytical methods that meet the needs of the risk assessment and to select the most appropriate method for each analyte. The RPM and risk assessor should consult the project chemist and use this worksheet in method selection. Alternatively, it can be a model to create a worksheet specifically suited to their needs. Methods selected in this process may be routine or non-routine.

EXHIBIT 51. AUTOMATED SYSTEMS* TO SUPPORT ENVIRONMENTAL SAMPLING

System	EPA Contact	Description
Data Quality Objective (Training) - Expert System	Dean Neptune USEPA Quality Assurance Management Staff (202) 260-9464	Training system designed to assist in planning of environmental investigations based on DQO process.
ESES Environmental Sampling (Plan Design) - Expert System	Jeff Van Ee Exposure Assessment Div. USEPA, EMSL-LV (702) 798-2367	Expert system designed to assist in planning sample collection. Includes models that address statistical design, QC, sampling procedures, sample handling, budget, and documentation. Current system addresses metal contaminants in a soil matrix. (Expanded application under development, contact EMSL-LV.)
GEOEAS Geostatistical Environmental Assessment Software	Evan Englund Exposure Assessment Div. USEPA, EMSL-LV (702) 798-2248	Collection of software tools for two-dimensional geostatistical analysis of spatially distributed data points. Programs include file management, contour mapping, kriging, and variogram analysis.
SCOUT Multivariate Statistical Analysis Package	Jeff Van Ee Exposure Assessment Div. USEPA, EMSL-LV (702) 798-2367	A collection of statistical programs that accept GEOEAS files for multivariate analysis.
ASSESS	Jeff Van Ee Exposure Assessment Div. USEPA, EMSL-LV (702) 798-2367	System designed to assist in assessment of error in sampling of soils. Estimates measurement error variance components. Presents scatter plots of QC data and error plots to assist in determining the appropriate amount of QC samples.

* All systems will run on any IBM-compatible PC AT with a minimum of 640K RAM. A fixed disk is recommended.

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EXHIBIT 52. METHOD SELECTION WORKSHEET

I. Analytes		II. Medium	III. Critical Parameters				IV. Routine Available Methods[4]
A. Chemical or Class of Chemicals of Potential Concern	B. Reporting Requirement[1] (Y or N)		A. Turnaround Time (enter hours or days)	B. ID Only or ID Plus Quant (ID or ID+Q)	C. Concen-tration of Concern (or PRG)[2]	D. Required Method Detection Limit[3]	

[1] Y= Total reported for compound class.
N = Each analyte reported separately.
[2] Preliminary remediation goal.
[3] Method detection limit should be no greater than 20% of concentration of concern.
[4] Refer to Appendix III for specific methods. Recommend consultation with chemist and/or automated methods search to determine all methods available. (Exhibit 53 lists computer systems that support method selection.)

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☛ *Ensure that critical requirements and priorities are specified on the Method Selection Worksheet so that the most appropriate methods can be considered.*

- Routine methods are issued by an organization with appropriate responsibility (e.g., state or federal agency with regulatory responsibility, professional organization), are validated, documented, and published, and contain information on minimum performance characteristics such as detection limit, precision and accuracy, and useful range.
- Non-routine methods address situations with unusual or problematic matrices, low detection limits or new parameters, procedures or techniques; they often contain adjustments to routine methods.

☛ *Use routine methods wherever possible since method development is time-consuming and may result in problems with laboratory implementation.*

4.2.1 Completing the Method Selection Worksheet

1. **Identify analytes.**

   List the chemicals of potential concern to risk assessment for the site on the Method Selection Worksheet. Use the same list of chemicals that appears on the Sampling Design Selection Worksheets. Under Column 1B, indicate whether the concentration for each analyte should be reported separately, or the total for the compound class reported.

2. **Identify medium for analysis.**

   Specify the analysis medium (e.g., soil, sediment, groundwater, surface water, air, biota).

3. **Decide on critical parameters.**

   Specify the required data turnaround time (IIIA) as the number of hours or days from the time of sample collection. Indicate whether chemical identification alone is desired or identification plus quantitation (IIIB). Specify the concentration of concern (IIIC) and required detection or quantitation limit (IIID).

4. **Identify routine available methods.**

   Use the final worksheet column, in consultation with the project chemist, to list the methods available that satisfy the requirements in the preceding steps. Reference sources and software are available to assist in identifying routine analytical methods applicable for environmental samples (Exhibit 53). The most common routine methods for organics and inorganics analyses for risk assessment are listed in Appendix III. The methods in the appendix are from the following sources:

   - Contract Laboratory Program (CLP) Statements of Work for Routine Analytical Services (EPA 1990d, EPA 1990e),
   - *Test Methods for Evaluating Solid Waste (SW846): Physical/Chemical Methods* (EPA 1986b),
   - *Standard Methods for the Examination of Water and Wastewater* (Clesceri, *et. al.*, eds. 1989), and
   - EPA Series 200, 300, 500, 600 and 1600 Methods (EPA 1983, EPA 1984, EPA 1988d, and EPA 1989g).

   Other sources of methods are:

   - Field Analytical Support Project (FASP) (EPA 1989h),
   - *Field Screening Methods Catalog* (EPA 1987b),
   - *Field Analytical Methods Catalog*,
   - *ERT Standard Operating Guidelines*,
   - *Close Support Analytical Methods*,
   - *A Compendium of Superfund Field Operations Methods* (EPA 1987c),
   - Association of Official Analytical Chemists (AOAC), and
   - American Society for Testing and Materials (ASTM).

   Several computer-assisted search and artificial intelligence-based tools are available, including the Environmental Monitoring Methods Index (EMMI), the Smart Methods Index, and a computerized reference book on analytical methods. Some of these systems are designed as teaching tools, as well as informational compendia. All offer the ability to rapidly search and compare lists of chemicals and method characteristics from accepted reference sources. Exhibit 53 lists software products that aid method selection, identifies contacts for information, and gives a short description of the product.

EXHIBIT 53. AUTOMATED SYSTEMS* TO SUPPORT METHOD SELECTION

System	Contact	Description
Environmental Monitoring Methods Index (EMMI)	W. A. Telliard USEPA Office of Water (202) 260-7120	An automated sorting and selection software package that currently contains over 900 methods and over 2600 analytes from more than 80 regulating and non-regulating lists. These are cross-referenced to facilitate selection based on required needs (e.g., analyte detection limit, instrument).
Smart Methods Index	John Nocerino Quality Assurance Div. USEPA, EMSL-LV (702) 798-2110	Natural language expert system prototype that provides interactive queries of databases cross-referenced by method, analyte, and performance features.
Geophysical Techniques Expert System	Aldo Maggella Advanced Monitoring Div. USEPA, EMSL-LV (702) 798-2254	An expert system that suggests and ranks geophysical techniques, including soil-gas, for applicability of use based on site-specific characteristics.
EPA Sampling and Analysis Data Base	Lewis Publishers 1-800-272-7737	A three-volume set of diskettes and a printed manual provides a search of sampling and analytical method summaries from a menu-driven program of 150 EPA-approved methods. The database can be searched by method, analyte, matrix, and various QA considerations.

*All systems will run on any IBM-compatible PC AT with a minimum of 640K RAM. A fixed disk is recommended.

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4.2.2 Evaluating the Appropriateness of Routine Methods

☛ *Analyte-specific methods that provide better quantitation can be considered for use once chemicals of potential concern have been identified by a broad spectrum analysis.*

Choice of the proper method is critical to the acquisition of useable data. See Section 3.2 for a more detailed discussion. Routine methods provide data of known quality for the analysis of chemicals and sample types described in the method. Data quality issues (precision, accuracy, and interferences) are usually described in the method. Consult the project chemist and examine available methods with respect to the criteria defined on the Method Selection Worksheet. It may be helpful to divide the analyte list into categories based on the types of analysis. For example, a requirement for chromium, cadmium, and arsenic data could not be generated by the same analysis as data for chlorinated hydrocarbons because of sample extraction and treatment procedures. It may be possible to use several methods independently and combine the data sets for risk assessment purposes. This is done routinely by the CLP, where inorganics (elemental analysis), volatiles, extractable organics, and pesticides are analyzed by different methods. In some cases, no routine method or series of methods will be able to satisfy all criteria and compromises must be considered. The RPM, with the advice of the risk assessor, must then determine which criteria are of highest priority and which can be modified. For example, if a low detection limit is of high priority, turnaround time and cost of analysis will likely increase. Alternatively, low detection limit and precision requirements may need to be modified if an initial broad spectrum analysis is of high priority to quickly determine the largest number of chemicals present at the site.

Turnaround time. Turnaround time is determined by the available instrumentation, sample capacity, and methods requirements. Turnaround times for field analyses can be as short as a few hours, while those for fixed laboratory analyses include transport time and range from several days to several weeks. Field instruments can provide the quickest results, especially if the data do not go through a formal review process. However, the confidence in chemical identification, and particularly quantitation, may not be as high. In general, methods with quick turnaround times may be less precise and have higher detection limits. If data are needed quickly, a field method can be used for initial results and a fixed laboratory method used to produce more detailed results (or confirm the earlier results), thereby increasing the confidence in field analyses.

Sample quantitation limits. Risk assessment often requires a sample quantitation limit at or below the detection limit for routine methods for many chemicals of toxicological concern (see Section 3.2.4). The sample quantitation limits vary according to the size, treatment, and analysis of each individual sample. The quantitation limits for chemicals in water samples are often far lower than for the same chemicals in soils because of co-extractable components in the soil. Interferences known for the method may hinder acquisition of data of acceptable quality and are more pronounced near the method detection limit. Compare documented method interferences with site conditions to identify potential method problems. Some common sources of interference in organic and inorganic analyses are summarized in Exhibits 54 and 55. If needed sample quantitation limits cannot be met by available methods, consult the project chemist for the feasibility of detection at the desired level in the required sample type. The chemist can help determine if method adaptation can resolve the problem, or if a non-routine method of analysis can be used.

Useful range. The useful range of a method is the range of concentration of chemicals for which precise and accurate results can be generated. This range is analyte-specific. The lower end of the useful range is the method detection limit, often generically referred to as

EXHIBIT 54. COMMON LABORATORY CONTAMINANTS AND INTERFERENCES BY ORGANIC ANALYTE

Contamination or Interference	Fraction	Matrix	Effects on Analysis	Removal* / Action
Fat/Oil	Extractable organics, pesticides, and PCBs	Tissue, waste, soils	Increased detection limit, decreased precision/ accuracy	GPC (all groups), florisil (pesticides), acid digestion (PCBs only)
Sulfur	Extractable organics, chlorinated and phosphorus-containing pesticides	Sediment, waste, soils	Presence/ absence, detection limits, precision/ accuracy	GPC, copper, mercury, tetrabutyl ammonium sulfate
Phthalate Esters	Chlorinated pesticides, PCBs, and extractable organics	All	False positive identification (pesticides and extractable organics) or positive bias (pesticides and extractable organics)	Florisil, GC-MS confirmation of identity (pesticides, PCBs), evaluation of reagents and method blanks for contamination
Laboratory Solvents	Volatile organics (methylene chloride, acetone, and 2-butanone)	All	False positive identification or positive bias	Confidence in data use based on interpretation of blank data

*Source: EPA 1986a.

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the "detection limit." If a lower detection limit is required, use of a larger sample or smaller final extract volume can sometimes compensate. However, any interfering chemicals are also concentrated, thereby producing greater interference effects. Above the useful range, the response may not be linear and may affect quantitation. This causes inaccurate and/or imprecise measurements. Reducing the sample size for analysis or diluting the extracted material may bring the concentration within the useful range. With individual environmental samples, some chemicals are sometimes present at the low end of the useful range of the method, while others are above the useful range. In this situation, two analyses, at different effective dilutions, are necessary to produce accurate and precise data on all chemicals. If detailed criteria for performing and reporting such actions are not already part of the analytical Statement of Work, then the laboratory should be instructed to notify the RPM if this situation occurs, to allow for sufficient time for reanalysis within the specified holding time. All relevant analyses should be reported to maximize the useability of both detected and non-detected analytes.

☛ *All results should be reported for samples analyzed at more than one dilution.*

Precision and accuracy. Routine methods often specify precision and accuracy with respect to specific analytes (chemicals) and matrices (sample media). However, be aware that environmental samples are often difficult to analyze because of the complexity of the matrix or the

EXHIBIT 55. COMMON LABORATORY CONTAMINANTS AND INTERFERENCES BY INORGANIC ANALYTE

Analyte	Technique	Interference	Removal/ Action
Arsenic	GFAA	Iron, Aluminum	Background correction (not deuterium) (Zeeman).
	ICP	Aluminum	If above 100 ppm, correction factor utilized.
Beryllium	ICP	Titanium, Vanadium	If above 100 ppm, correction factor utilized.
Cadmium	GFAA	None except possible sample matrix effects	Background correction for matrix effects.
	ICP	Iron	If above 100 ppm, correction factor utilized.
Chromium	GFAA	Calcium	Add calcium, standardize suppression, background correction.
	ICP	Iron, Manganese	If above 100 ppm, correction factor utilized.
Lead	GFAA	Sulfate	Lanthanum nitrate addition as matrix modifier, background correction.
	ICP	Aluminum	If above 100 ppm, correction factor utilized.
Mercury	CVAA	Sulfide, High Chloride	Remove interferences with cadmium carbonate (removes sulfide), potassium permanganate (removes chloride), excess hydroxylamine sulfate (removes free chlorine).
Selenium	GFAA	Iron, Aluminum	Alternate wavelength for analysis, background correction (not deuterium) (Zeeman).
	ICP	Aluminum	Above 100 ppm, correction factor utilized.
Cyanide	Colorimetric/ spectrophotometric	Acids, Sulfide, Chlorine oxidizing agents	Increase pH to > 12 in field to remove acids, cadmium carbonate (removes sulfide), ascorbic acid (removes free chlorine).

Key: ICP = Inductively coupled plasma.
GFAA = Graphite furnace atomic absorption.
CVAA = Cold vapor atomic absorption.

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presence of a large number of contaminants; this usually results in lower levels of precision and accuracy than those cited in the method.

4.2.3 Developing Alternatives When Routine Methods are not Available

If routine methods are not available to suit the parameters of interest, it is often due to one or more of the following factors:

- The detection limit of commonly available instrumentation has been reached, and a lower detection limit is required for the risk assessment,
- An unusual combination of chemicals are of potential concern,
- The sample matrix is complex, and
- The chemicals of potential concern or other analytical parameters are unique to a particular site.

Consult an analytical chemist for specific guidance on the potential limitations of alternative approaches. These may include adaptation of a routine method or use of a non-routine method. Be aware that certain conditions, such as extremely low detection limits for some chemicals, may be beyond the capability of current analytical technology. Turnaround times and costs may also be increased.

Adaptation of routine methods. Adapting routine methods may be a solution when routine methods will not provide the desired data even after compromises have been made with respect to parameters such as turnaround time and cost. Using the completed Method Selection Worksheet as the starting point, work closely with an analytical chemist to formulate suitable modifications to the routine method. Evaluate and document any effects on data quality that will result from the modifications.

Within the CLP, such analyses can be obtained by special analytical requests. Before analysis of site samples, it is advisable to confirm a laboratory's ability to perform the adapted method with preliminary data.

Use of non-routine methods. Existing non-routine methods that meet criteria can be used if a routine method cannot be adapted to provide the necessary data. Such analyses can be found in the research literature, usually catalogued by analyte or instrument. On-line computerized search services can be of considerable help in identifying such methods. Work interactively with an analytical chemist in reviewing selected methods. Recognize that non-routine analyses require a greater level of capability and experience from the analytical laboratory, and that turnaround time can be longer because the method may need alteration during analysis if problems develop.

Development of new methods. Developing new methods should be the option of last resort. The RPM, risk assessor, and project chemist should consider recommending the development of new methods only for chemicals of substantial potential concern that cannot currently be analyzed at appropriate limits of detection.

Although designing a method based on data available for a given instrument and analytes may seem straightforward, the process is time-consuming and expensive. Unforeseen problems can often arise when the method is implemented in the laboratory. Problems can occur even when laboratory personnel have superior training and experience. Consider the following points when requesting the development of a new method:

- If possible, select a laboratory with a recognized reputation for performance and flexibility in a related area. Treat laboratory personnel as partners in the development process. This is true whether a commercial or a government laboratory is used.
- Identify sources for authentic standards of the chemicals in question to support method development. Computerized databases such as the EPA EMMI (see Exhibit 53) may be useful for such a determination.
- Be aware that turnaround time for useable data may be long (potentially several months) because of the likelihood of trying different approaches before discovering an acceptable procedure.

4.2.4 Selecting Analytical Laboratories

In selecting a laboratory to produce analytical data for risk assessment purposes, identify and evaluate the following laboratory qualifications:

- Possession of appropriate instrumentation and trained personnel to perform the required analyses, as defined in the analytical specifications,
- Experience in performing the same or similar analyses,
- Performance evaluation results from formal monitoring or accreditation programs,
- Adequate laboratory capacity to perform all analyses in the desired timeframe,

- Intra-laboratory QC review of all generated data, independent of the data generators, and
- Adequate laboratory protocols for method performance documentation and sample security.

For non-routine analyses, the laboratory should have highly trained personnel and instrumentation not dedicated to production work, especially if new methods or untested modifications are requested.

Accreditation programs monitor the level of quality of laboratory performance within the scope of their charters. Many of these programs periodically provide performance evaluation samples that the laboratories must analyze within certain limits in order to maintain their status. Prior to laboratory selection, request that laboratories provide information about their performance in accreditation programs. This information can be used for evaluation of laboratory quality, in the case of similar matrices and analytes. Laboratory adherence to standards of performance such as the Good Laboratory Practices Standards (*Annual Book of ASTM Standards*) also provides a measure of laboratory quality.

4.2.5 Writing the Analysis Request

Include the following items in the analysis request:

- A clear, complete description of the sample preparation, extraction, and analysis procedures including detailed performance specifications. For adaptation of routine methods, specify the routine method and explicitly state alterations with applicable references.
- Documented reporting requirements.
- Laboratory access to required authentic chemical standards.
- A mechanism for the laboratory to obtain EPA technical assistance in implementing method modifications or performing non-routine methods.

If the analysis request is for a non-routine method, reference the published material with a detailed specification of procedures and requirements prepared by the analytical chemist who has been working with the RPM and risk assessor. The specification must include the frequency, acceptance criteria, and corrective action requirements for each of the following:

- Instrument standardization, including tuning and initial and continuing calibration,
- QC check samples such as surrogate compound and internal standard recoveries,
- Method blank performance (permissible level of contamination),
- Spike sample recovery requirements,
- Duplicate analysis requirements, and
- Performance evaluation or QC sample results.

Allow time for the laboratory to review the analysis request and question any part of the description that seems unclear or unworkable according to its experience with the analytes or sample matrix. Preliminary data, such as precision and accuracy data on a subset of the analytes, can be requested to determine if the laboratory can implement the proposed method. Should the criteria not be met in the preliminary analyses, the analytical chemist should advise the laboratory on additional method modifications to produce the required data. In some cases, even qualitative data can be used to note the presence of chemicals of potential concern.

In all cases, require the laboratory performing the analyses to contact the project chemist at the first sign of a problem that may affect data quality. The RPM and the site technical team can then judge the magnitude of the problem and determine appropriate corrective action.

4.3 BALANCING ISSUES FOR DECISION-MAKING

Resource issues. Resource limitations are a major reason for sampling design modification. The number of samples required to achieve desired performance measures may exceed resource availability. Modifying the sampling design and the efficiency of statistical estimators can reduce sample size and costs, and improve overall timeliness for the risk assessment. Analytical methods such as field analyses may also reduce cost. Systematic and geostatistical sampling designs can often achieve the required performance measures with fewer samples than classical random sampling (Gilbert 1987). Pilot sampling can be used to verify initial assumptions of the SAP, increase knowledge of contaminant distribution, and support SAP modifications to reduce the number of samples. Explain resource issues and record potential design modifications in documentation developed during planning.

Completing a number of Sampling Design Selection Worksheets (Exhibit 45) for different exposure areas,

media, and sampling design alternatives will enable the RPM and risk assessor to compare and evaluate sampling design options and consequences and select the appropriate sampling design for each medium and exposure pathway.

Computer programs are useful tools in developing and evaluating sampling strategies, especially in trading off costs against uncertainty, and identifying situations when additional samples will not significantly affect the useability of the data (i.e., the point of diminishing returns). Each automated system has specific data requirements and is based on specific site assumptions. The major systems that support environmental sampling decisions are listed, contacts for information given, and brief descriptions provided in Exhibit 51.

Documenting design decisions. It is important to document the primary issues considered in balancing tradeoffs to accommodate resource concerns and their impact on data useability. Several compromises among options are discussed in this section. Features of analytical options available for organic and inorganic analytes are summarized in Exhibits 56 through 59. Fully document all final sampling and analytical design decisions, including the rationale for each decision. During the course of the RI, continue to document pertinent issues that arise and any plan modifications which are implemented.

The goal of balancing issues in the selection of analytical methods is to obtain the best analytical performance without sacrificing risk assessment requirements. The selection of analytical methods often involves tradeoffs among the required detection limit, number of analytes involved, precision and accuracy, turnaround time, and cost. Some choices may conflict with others.

Cost should be considered only after the most appropriate methods have been determined. Methods requiring specialized instrumentation, such as high resolution mass spectrometry, will be more expensive. Methods for use on matrices such as soil, can be more expensive than similar methods for a simpler matrix such as water. Less expensive methods often have higher detection limits and less specific confirmation of identification. However, the turnaround times are often quicker and a larger number of samples can be analyzed. This often significantly increases sampling precision and reduces the probability of missing hot spots. Less expensive methods are often chosen if the site has already been characterized by broad spectrum analyses. In evaluating routine methods, consider whether analysis of more samples through use of less expensive methods can provide a similar level of data quality to that achieved through the use of more expensive methods on fewer samples. By remaining aware of the effect of individual issues on the data quality, the RPM can determine the optimum choices.

> ☛ *Field analysis can be used to decrease cost and turnaround time, providing data from a broad spectrum analysis are available.*

In addition to turnaround time for analysis, time must also be scheduled for data review. This will not hinder the availability of laboratory and field data for preliminary use if a tiered data review sequence is incorporated.

When using the tiered approach, consider the use of split samples (i.e., sending sample splits for analysis by field and fixed laboratories). Quantitative comparison can then be made between the precision and accuracy of the field analyses and those of the fixed laboratory. Confirmation of identification by both field and fixed laboratories also increases data confidence and useability. It is recommended that field methods should be used with at least a 10% rate of confirmation or comparison by fixed laboratory analyses.

EXHIBIT 56. COMPARISON OF ANALYTICAL OPTIONS FOR ORGANIC ANALYTES IN WATER

Method	MDL	Quantitative Confidence	Timeliness	Precision & Accuracy	Comparability
FIELD SCREEN/FIELD ANALYSIS (Assumes preparation step)					
GC(PCB)	√	√	√		√
GC (Pesticides)	√		√		√
GC (VOA)	√		√		√
G C (Soil Gas)	√		√		
GC (BNA)	√		√		√
PHOTO VAC Detector			√		
FIXED LABORATORY					
CLP RAS					
VOA		√			√
BNA		√			√
Pesticides					√
Dioxin		√		√	√
CLP LOW CONC					
GC	√			√	√
VOA	√	√		√	√
BNA	√	√		√	√
500 SERIES					
GC	√				√
VOA	√	√			√
BNA	√	√			√
600 SERIES					
GC	√				√
VOA	√	√			√
BNA	√	√			√
SW846					
GC	√				√
VOA		√			√
BNA		√			√
1600 SERIES					
GC	√			√	√
VOA		√		√	√
BNA		√		√	√
Dioxin		√		√	√
PCDDs, PCDFs		√		√	√

Key: √ = Method strength

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EXHIBIT 57. COMPARISON OF ANALYTICAL OPTIONS FOR ORGANIC ANALYTES IN SOIL

Method	MDL	Quantitative Confidence	Timeliness	Precision & Accuracy	Comparability
FIXED LABORATORY					
CLP RAS					
VOA		√			√
BNA		√			√
Pesticides					√
Dioxin (2,3,7,8 TCDD)		√		√	√
SW846					
GC	√				√
VOA		√			√
BNA		√			√
1600 SERIES					
GC	√			√	√
VOA		√		√	√
BNA		√		√	√
Dioxin		√		√	√
FIELD SCREEN					
GC(PCB)	√	√	√		√
GC(Pesticides)			√		√
GC(VOA)	√		√		√
GC(Soil Gas)	√		√		
GC(BNA)	√		√		√
PHOTO VAC Detector			√		

Key: √ = Method strength

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EXHIBIT 58. COMPARISON OF ANALYTICAL OPTIONS FOR INORGANIC ANALYTES IN WATER AND SOIL

Method	MDL	Quantitative Confidence	Timeliness	Precision & Accuracy [1]	Comparability [2]
FIXED LABORATORY					
CLP RAS					
ICP		√		√	√
GFAA	√	√		√	√
Flame AA					
200 Series					
GFAA	√	√		√	√
AA					
ICP-MS[3]	√	√			√
ICP-Hydride[3]	√				
FIELD SCREEN					
XRF			√		
AA			√		

Key: √ = Method strength

[1] CLP inorganic water assays are more accurate and precise than soil assays.

[2] ICP and GFAA are comparable at medium to high ppb levels. For As, Pb, Se, Tl and Sb at less than 20 ppb, GFAA is the method of choice.

[3] ICP-MS and ICP-Hydride methods are relatively new; therefore, precision, accuracy, and comparability estimates based on large statistical sampling are not available.

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EXHIBIT 59. COMPARISON OF ANALYTICAL OPTIONS* FOR ORGANIC AND INORGANIC ANALYTES IN AIR

Method	MDL	Quantitative Confidence	Timeliness	Precision & Accuracy	Comparability
FIXED LABORATORY					
CLP VOA					
Cannister	2-5 ppb	√		√	
Tenax	2-30 ppb (for most)	√		√	
CLP BNA	0.00001-0.001 ug/m3	√		√	
CLP Metals	3-10 ng/m3	√		√	

Key: √ = Method strength

* The methods described are new Statements of Work.

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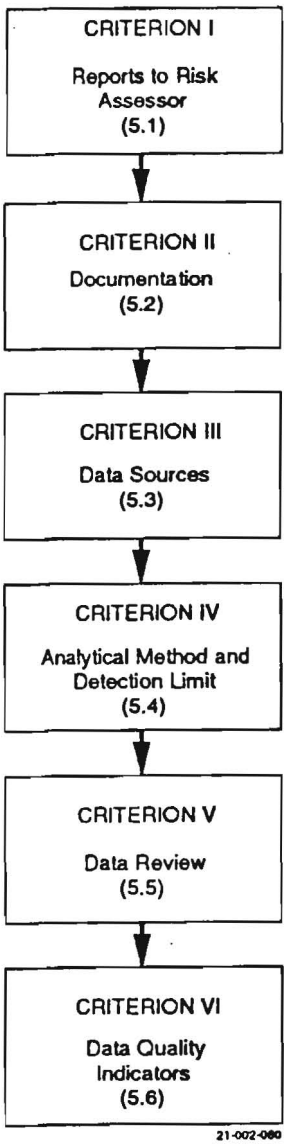
Chapter 5
Assessment of Environmental Data for Useability in Baseline Risk Assessments

This chapter provides guidance for the assessment and interpretation of environmental data for use in baseline human health risk assessments. Ecological risk assessments follow a similar logic but may differ in some details of sampling and analytical methodologies and minimum data requirements. The discussion of data assessment is presented as six steps that define the assessment process for each data useability criterion. Exhibit 60 lists the six criteria in the order that a risk assessor would evaluate them. It also gives references to the sections in this chapter where they are further discussed.

EXHIBIT 60. DATA USEABILITY ASSESSMENT OF CRITERIA



The four basic decisions to be made from data collected in the RI are:

- What contamination is present and at what levels?
- Are site concentrations sufficiently different from background?
- Are all exposure pathways and exposure areas identified and examined?
- Are all exposure areas fully characterized?

The uncertainty associated with each data useability criterion affects the level of confidence associated with each of these decisions.

How to conduct the data assessment. The risk assessor or RPM examines the data, documentation, and reports for each assessment criterion (I - VI) to determine if performance is within the limits specified in the planning objectives. The data assessment process for each criterion should be conducted according to the step-by-step procedures discussed in this chapter. Minimum requirements are listed for each criterion. Potential effects of not meeting the minimum requirements are also discussed and corrective action options are presented. Exhibit 61 summarizes the major impact on assessment if the minimum requirements associated with each data useability criterion have not been met.

Acronyms

CLP	Contract Laboratory Program
CV	coefficient of variation
CRDL	contract required detection limit
CRQL	contract required quantitation limit
DQO	data quality objective
GC	gas chromatography
ICP	inductively coupled plasma
MDL	method detection limit
MS	mass spectrometry
QA	quality assurance
QC	quality control
RAGS	Risk Assessment Guidance for Superfund
RI	remedial investigation
RME	reasonable maximum exposure
RPD	relative percent difference
RPM	remedial project manager
SAP	sampling and analysis plan
SOP	standard operating procedure
SQL	sample quantitation limit

EXHIBIT 61. MINIMUM REQUIREMENTS, IMPACT IF NOT MET, AND CORRECTIVE ACTIONS FOR DATA USEABILITY CRITERIA

Data Useability Criterion	Minimum Requirement	Impact on Risk Assessment If Criterion Not Met	Corrective Action
5.1 Reports to Risk Assessor	• Site description • Sampling design with sample locations • Analytical method and detection limit • Results on per-sample basis, qualified for analytical limitations • Sample quantitation limits and detection limits for non-detects • Field conditions for media and environment • Preliminary reports • Meteorological data • Field reports	• Unable to perform quantitative risk assessment	• Request missing information • Perform qualitative risk assessment
5.2 Documentation	• Sample results related to geographic location (chain-of-custody records, SOPs, field and analytical records)	• Unable to assess exposure pathways • Unable to identify appropriate concentration for exposure areas	• Request locations identified • Resampling
5.3 Data Sources	• Analytical data results for one sample per medium per exposure pathway • Broad spectrum analysis for one sample per medium per exposure pathway • Field measurements data for media and environment	• Potential for false negatives or false positives • Increased variability in exposure modeling	• Resampling or reanalysis for critical samples
5.4 Analytical Method and Detection Limit	• Routine (federally documented) methods used to analyze chemicals of potential concern in critical samples	• Unquantified precision and accuracy • False negatives	• Reanalysis • Resampling or reanalysis for critical samples • Documented statements of limitation for non-critical samples
5.5 Data Review	• Defined level of data review for all data	• Potential for false negatives or false positives • Increased variability and bias due to analytical process, calculation errors or transcription errors	• Perform data review
5.6 Data Quality Indicators	• Sampling variability quantified for each analyte • QC samples to identify and quantify precision and accuracy • Sampling and analytical precision and accuracy quantified	• Unable to quantify confidence levels for uncertainty • Potential for false negatives or false positives	• Resampling for critical samples • Perform qualitative risk assessment • Perform quantitative risk assessment for non-critical samples with documented discussion of potential limitations

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The following activities should be performed for each assessment criterion:

- Identify or determine performance objectives and minimum data requirements.

  Quantitative or qualitative performance objectives should be specified in the sampling and analysis plan for all components of the acquisition of environmental data (as discussed in Chapter 4). The first step in assessing each criterion is to assemble these performance objectives and note any changes. Performance objectives should also be compared with the minimum acceptable requirements for data useability presented in this chapter. These minimum requirements can be adopted as performance objectives if objectives were not specified. For example, the requirement that there must be a broad spectrum analysis for at least one sample in each medium for each exposure area would be a performance objective, if performance were not specified during planning.

- Determine actual performance compared to performance objectives.

  The next step in the assessment of each criterion is to examine results to determine the performance that was achieved for each data useability criterion. This performance should then be compared with the objectives established during planning. Take particular note of performance for samples or analyses that are critical to the baseline risk assessment. All deviations from the objectives should be noted. In those cases where performance was better than that required in the objective, it may be useful for assessment of future activities to determine if this is due to unanticipated characteristics of the site or to superior performance in some stage of the data acquisition. Corrective action is the next step where performance does not meet performance objectives for data critical to the risk assessment.

- Determine and execute any corrective action required.

  ☛ *Focus corrective action on maximizing the useability of data from critical samples.*

Corrective action should be taken to improve data useability when performance fails to meet objectives for data critical to the risk assessment. Corrective action options are described in Exhibit 62. These options require communication among the risk assessor, the RPM, and the technical team. Sensitivity analysis may be performed by the risk assessor to estimate the effects of not meeting performance requirements given the certainty of the risk assessment. Corrective actions may improve data quality and reduce uncertainty, and may eliminate the need to qualify or reject data.

EXHIBIT 62. CORRECTIVE ACTION OPTIONS WHEN DATA DO NOT MEET PERFORMANCE OBJECTIVES

- Retrieve missing information.
- Resolve technical or procedural problems by requesting additional explanation or clarification from the technical team.
- Request reanalysis of sample(s) from extract.
- Request construction and re-interpretation of analytical results from the laboratory or the project chemist.
- Request additional sample collection and analysis for site or background characterization.
- Model potential impact on risk assessment uncertainty using sensitivity analysis to determine range of effect.
- Adjust or impute data based on approved default options and imputation routines.
- Qualify or reject data for use in risk assessment.

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Using a worksheet to organize the data assessment. The level of certainty associated with the data component of risk assessment depends on the amount of data that meet performance objectives. The risk assessor determines whether the data for each performance measure are satisfactory (data accepted), questionable (data qualified) or unsatisfactory (data rejected). The worksheet provided in this chapter may be used as a guide or organizational tool.

Use the Data Useability Worksheet, Exhibit 63, to document data assessment decisions. Record the decision as accepted, accepted with qualification, or rejected for use in the risk assessment for each data

EXHIBIT 63. DATA USEABILITY WORKSHEET

Data Useability Criterion		Decision*	Comments
I	Reports to Risk Assessor		
II	Documentation A. Work Plan/SAP/QAPjP		
	B. SOPs		
	C. Field and Analytical Records		
III	Data Sources A. Analytical		
	B. Non-analytical		
IV	Analytical Methods		
V	Data Review		

* Decision: Accept, Qualified Accept, Reject

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