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

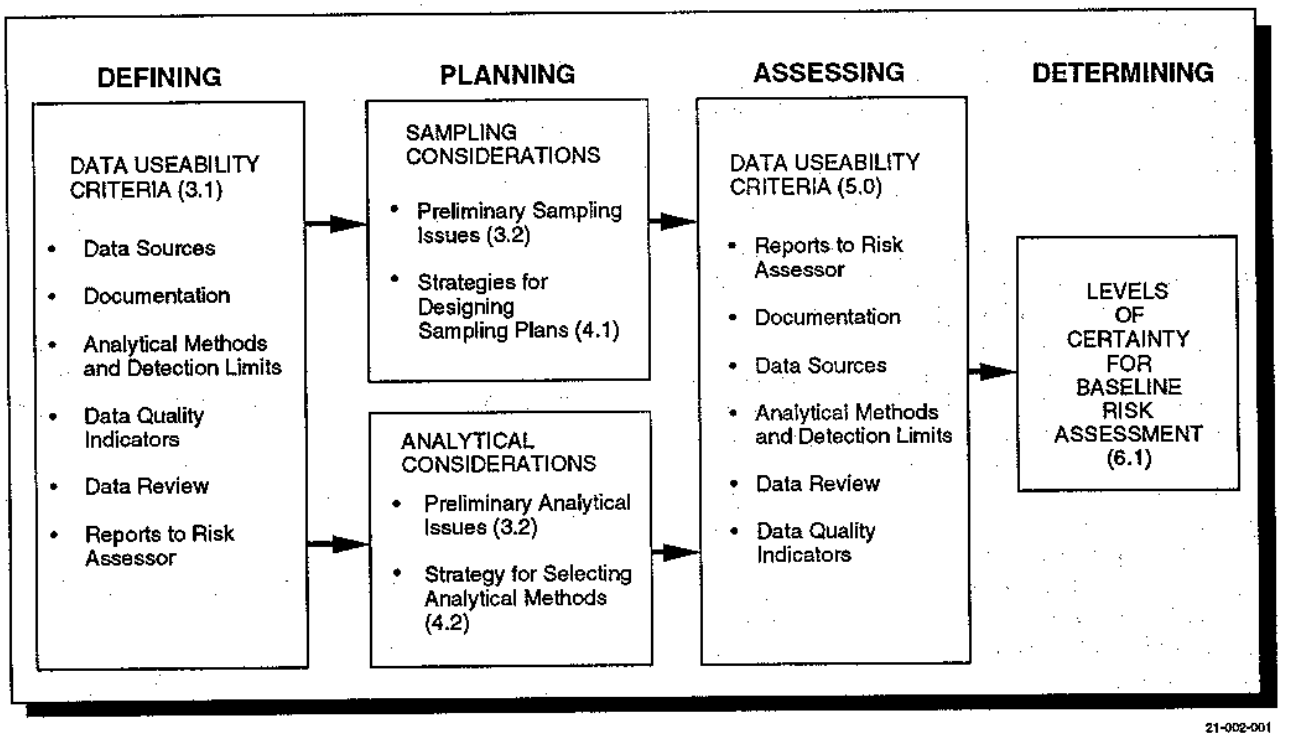

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Exhibit 2 summarizes the purpose of each chapter of this guidance and highlights how the chapters can best assist RPMs and risk assessors. Worksheets, assessment tables, and other aids are used extensively throughout the guidance. These are tools that 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 qualifiers.

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