United States Environmental Protection Agency

Office of Solid Waste and Emergency Response
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Superfund

EPA

Guidance for Data Useability in Risk Assessment

Office of Emergency and Remedial Response
Hazardous Site Evaluation Division, OS-230

Quick Reference Fact Sheet

EPA is establishing national guidance for minimum data quality requirements to optimize the useability of data collected under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA). Data useability is the process of assuring or determining that the quality of data generated meets the intended use. This guidance is designed 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 decisions, regardless of which parties conduct the investigation. EPA workgroups are defining the current uses and associated quality requirements of Superfund data, and developing minimum requirements for each data use category. Data use categories include site assessments, risk assessments, and removal and remedy selection for remedial and enforcement actions. Detailed data useability guidance is being prepared for each data use category; risk assessment is the prototype.

This fact sheet provides an overview of Guidance for Data Useability in Risk Assessment (EPA/540/G-90/008), highlights key points of the manual, and details where additional guidance is found. Copies of the manual can be obtained by calling EPA's Center for Environmental Research at 513-569-7652 (FTS 684-7562).

What Is This Manual?

The guidance manual 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.

The manual provides guidance on the following:

- How to design RI sampling and analytical activities that meet the data quality and data quantity needs of risk assessors.
- Procedures for assessing the useability of the data obtained in the RI.
- Options for combining data of varying levels of quality from different sources and incorporating them into the risk assessment.
- Procedures for determining the degree of confidence in the risk assessment based on the uncertainty in the environmental analytical data.
- Guidelines for timing the execution of the various activities.
- Appendices requested by risk assessors and RPMs that assist in selecting analytical methods to meet required detection limits.

The manual complements guidance provided in Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A) (RAGS), Guidance for Conducting Remedial Investigations and Feasibility Studies under CERCLA, and Data Quality Objectives for Remedial Response Activities. RAGS provides the framework for making data quality assessments in baseline risk assessments. This manual supplements and strengthens important technical details of this framework by providing minimum requirements for the 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. The guidance does not address the use of environmental data for purposes other than baseline risk assessments for human health.

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Who Will Use This Manual?

The guidance manual is addressed primarily to RPMs who have the principal responsibility for leading the data collection and assessment activities that support the human health risk assessment. Assistance is also provided to risk assessors who must effectively communicate their data needs to RPMs and use the data provided to them. Chemists, quality assurance specialists, hydrogeologists, statisticians 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.

Data collected only with a view towards identifying the "nature and extent" of contamination at a Superfund site may result in rejection of the risk assessment or the need for an additional round of sampling to support the risk assessment. Accordingly, risk assessors must be an integral part of the RI planning process to ensure that the environmental analytical data collected during the RI meet their needs. They should work closely with the RPM to identify and recommend sampling designs and analytical methods that will maximize the quality of the data collected for the baseline risk assessment for human health within the site-related and budgetary constraints of the RI.

RPMs oversee the preparation of work plans and sampling and analysis plans (SAPs) 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 and analysis decisions have on the level of certainty of baseline risk assessment for human health. This manual provides guidance in these areas. Highlight 1 summarizes each chapter of the manual.

DATA QUALITY ISSUES IN RISK ASSESSMENT

Five basic environmental data quality issues are frequently encountered in risk assessment. These issues affect both the planning for and the assessment of analytical data for use in the RI risk assessment.

- Data sources

  Practical tradeoffs among detection limits, response time, documentation, analytical costs and level of confidence should be considered prior to selecting analytical methods and serv-

Highlight 1

ORGANIZATION OF THE MANUAL

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 manual.

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
Criteria for Evaluating Data Useability in Baseline Risk Assessments
- Defines six criteria for assessing data useability.
- 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 plan design 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 presence (absence) of contamination.
- Discusses how to characterize exposure pathways.

APPENDICES
- Provide technical reference tables for sampling and analysis.
- Describe data review packages and meanings of selected data qualifiers.

ice providers. Many analytical sources are able to serve the needs of the Superfund program. RPMs and risk assessors should seek the source of data that best meets the data quality needs of the risk assessment.

Advances in technology, accompanied by appropriate quality control measures, allow field data to be used more frequently and with more confidence in risk assessments. By using field data, RPMs can increase sample numbers to better characterize the site, provided acceptable data quality is maintained.

- Detection limits

  Selecting the analytical method for optimal 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 (MDL) or sample quantitation limit (SQL), used in making data quality decisions affects the confidence of the risk assessment.

- Qualified data

  Qualified data must be appropriately used in risk assessments. Data are almost always useable in the risk assessment process, as long as the level of uncertainty in the data and its impact on the level of confidence of the risk assessment are thoroughly explained.

- Background samples

  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 increases the confidence in decisions about the presence or absence of site contamination.

- Consistency in data collection

  Consistency must be maintained among all parties conducting Superfund baseline risk assessments for human health. The guidance provided in RAGS and this manual ensures that

Highlight 2

IMPACT OF ANALYTICAL ISSUES ON RISK ASSESSMENT

ANALYTICAL ISSUE	IMPORTANCE	SUGGESTED ACTION
Chemicals of Potential Concern (3.3.1)	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.
Library Search/ Tentatively Identified Compounds (3.3.2)	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 (3.3.3)	False negatives may occur when analytes are present near the method detection limit.	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 (3.3.4)	Risk levels may be at concentrations lower than measureable.	Review available methods for appropriate detection limit.
Media Variability (3.3.5)	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 (3.3.6)	Variability and bias may be introduced to analytical measurements.	Select analytical methods based on sample medium and strengths of the sample preparation technique.
Fixed Laboratory vs. Field Analyses (3.3.7)	Tradeoffs required with regard to speed, precision, accuracy, personnel, identification, quantitation and detection limits.	Consider options and set priorities.
Laboratory Performance Problems (3.3.8)	Quality of data may be compromised.	Select experienced laboratory and maintain communication.

baseline risk assessments for human health are conducted consistently while being protective of public health.

Guidance for Data Useability in Risk Assessment addresses these issues in detail. Procedures, minimum requirements, and corrective actions are provided to resolve the impact the issues have on the confidence in the risk assessment.

MAKING DECISIONS WITH ENVIRONMENTAL DATA

Four fundamental decisions for risk assessment are made with the data acquired during the Remedial Investigation.

- What contamination is present and at what levels?

  The selection of analytical methods, laboratory performance, and type and level of data review affect the probability of false negatives and false positives for both site and background samples.

- Are site concentrations sufficiently different from background?

  Site concentrations must be distinguished from background levels to support an evaluation of increased risk for human health on the basis of the site contamination. Both sampling and analytical designs are considered.

- Are all exposure pathways identified and examined?

  All exposure pathways must be identified and exposure routes examined. Decisions concerning exposure pathways primarily involve identifying and sampling media of concern. Sampling must be representative.

- Are all exposure pathways fully characterized?

  The final decision involves the characterization of exposure pathways. Sampling must be representative and satisfy performance objectives determined during the planning process. A broad spectrum analysis must be available in order to characterize the pathways and avoid false negatives.

Highlight 3a

AUTOMATED SYSTEMS [1] TO SUPPORT ENVIRONMENTAL SAMPLING

SYSTEM	EPA CONTACT	DESCRIPTION
Data Quality Objective (Training) - Expert System	Dean Neptune USEPA Quality Assurance Management Staff (202) 475-9464	Training system designed to assist in planning of environmental investigations based on data quality objective 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.)
GEO - EAS 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 variogramanalysis.
SCOUT Multivariate Statistical Analysis Package	Jeff Van Ee Exposure Assessment Div. USEPA, EMSL-LV (702) 798-2367	A collection of statistical programs that accept GEO-EAS files for multivariate analysis.
ASSESS Assessment of Errors in Sampling of Soils	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 quality control data and error plots to assist in determining the appropriate amount of quality control samples.

[1] All systems will run on any IBM compatible PC AT with 640K RAM (minimum). A fixed disk is recommended.

Uncertainty in chemical identification and quantitation is determined based on decisions made during planning. This analytical data uncertainty affects the level of confidence of the final risk assessment.

Using Criteria for Planning and Assessing Data Useability

Six criteria assure the useability of environmental data in risk assessments. The criteria are:

- Data sources
- Documentation
- Analytical methods and detection limits
- Data quality indicators
- Data review
- Reports to risk assessors.

The manual explains how to use these criteria to plan data collection efforts that maximize the useability

Highlight 3b

AUTOMATED SYSTEMS [1] TO SUPPORT METHOD SELECTION

SYSTEM	CONTACT	DESCRIPTION
List of Lists	W. A. Telliard USEPA Office of Water (202) 382-7120	An automated sorting and selection software package that currently contains 150 methods and 1,700 analytes. These are cross-referenced to facilitate selection based on required needs (e.g., analyte detection limit, instrument).
Smart Method Index	John Nocerino Quality Assurance Div. USEPA, EMSL-LV (202) 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 (202) 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 quality assurance considerations.

[1] All systems will run on any IBM compatible PC AT with 640K RAM (minimum). A fixed disk is recommended.

of environmental analytical data in baseline risk assessments. Highlight 2 details analytical issues which impact the risk assessment and describes actions needed to resolve them. Guidance tools include a Sample Design Selection Worksheet and a Method Selection Worksheet. Step-by-step instructions for using the worksheets assist the RPM or risk assessor in planning RI sample collection and analysis to produce data meeting risk assessment needs. Highlights 3a and 3b list automated systems which may help in this planning. Regional Environmental Services Divisions (ESD) can also provide assistance.

ASSESSING ENVIRONMENTAL DATA FOR USEABILITY

Conducting the Data Assessment

Examine the data, documentation, and reports to determine if performance is within the limits required by the planning objectives. If no performance objectives have been specified or the specification is incomplete, the minimum acceptable requirements for the data useability criterion should be used for the minimum performance objectives. The manual presents minimum requirements for each data useability criterion. In evaluating the criteria, perform the following activities:

- Identify or determine minimum data requirements and performance objectives.
- Determine actual performance compared to objectives.
- Determine and execute any corrective action required.

Take corrective action when actual performance fails to meet the objectives for data critical to the risk assessment. Highlight 4 gives several corrective action options for resolving problems with data not meeting performance requirements.

Highlight 4

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 project chemist.
- Request additional sample collection and analysis for site or background characterization.
- Model potential impact on risk assessment certainty 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.

Highlight 5

MINIMUM REQUIREMENTS, IMPACT, AND CORRECTIVE ACTIONS FOR DATA USEABILITY CRITERIA

DATA USEABILITY CRITERION	MINIMUM REQUIREMENT	IMPACT ON RISK ASSESSMENT	CORRECTIVE ACTION
5.1 Reports To Risk Assessor	• Site description • Sample design with sample locations • Analytical method and detection limit • Results on per-sample basis, qualified for analytical limitations • Sample-specific quantitation limits (SQLs) and detection limit for non-detects • Field conditions for media and environment • Preliminary 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 units	• 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 and positives • Increased variability in exposure modeling	• Resampling or reanalysis for critical samples
5.4 Analytical Method and Detection Limit	• Routine methods used for critical samples and chemicals of potential concern • Detection limit less than 20% of concentration of concern	• Unvalidated precision and accuracy • False negatives	• Reanalysis • Resampling and analysis for critical samples • Documented caveats for non-critical samples
5.5 Data Review	• Correctness of analytical results reviewed	• Potential for false negatives or false positives • Increased variability and bias due to analytical process, calculation or transcription errors	• Perform data review
5.6 Data Quality Indicators	• Sampling variability quantified for each analyte • QC samples required 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

Organizing the Data Assessment

For each performance measure within an assessment phase, determine whether the actual performance for the data involved is satisfactory, questionable, or unsatisfactory. The manual includes a worksheet to assist in applying the useability criteria to the data. For each criterion, the worksheet requires a decision to be made: accept, accept with qualification, or reject the information involved for use in the risk assessment. Record the justification for each decision on the worksheet. Highlight 5 summarizes minimum requirements for each data useability criterion, lists its potential impact on the risk assessment, and identifies corrective actions that may be taken.

APPLYING DATA TO RISK ASSESSMENT

The level of confidence associated with the actual data that are obtained affects the ability to answer the four basic questions being addressed in the risk assessment process, as shown in Highlight 6. The final sections of the manual provide procedures to be followed to determine the level of certainty for each decision, given the results of the assessment of performance measures.

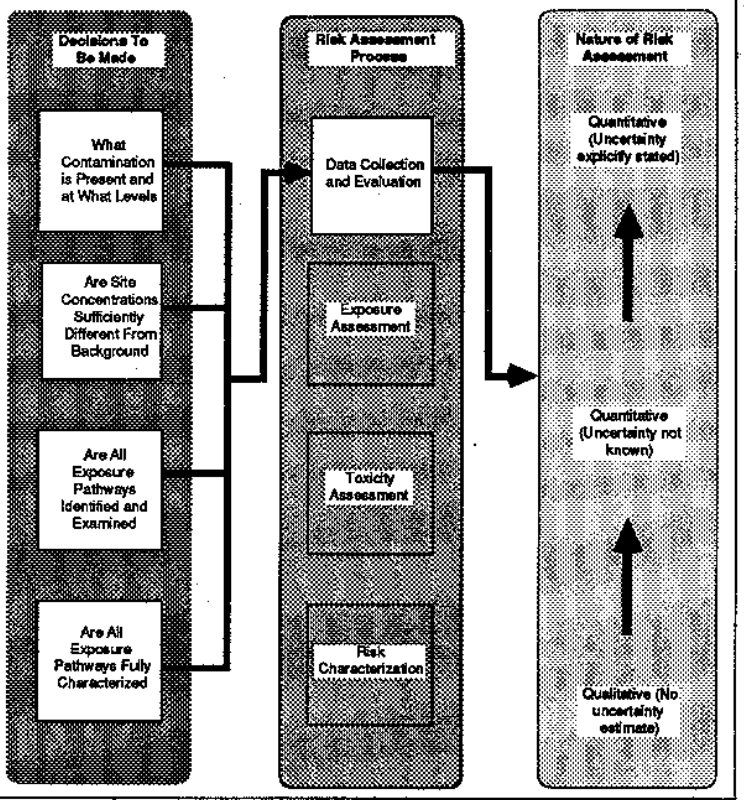
Uncertainty results from each of the components of risk assessment, and the results for each component should be presented with an explicit statement of the degree of confidence. These measures are the bases for the estimation of the degree of confidence in the risk assessment.

NEED MORE HELP?

Superfund Toxic Integration Coordinators are located in each region. Questions regarding site-specific Superfund risk assessment issues should be referred to the appropriate individuals listed in Highlight 7. The Toxics Integration Branch, Office of Energy and Remedial Response (OERR), may also be contacted at (202) 475-9486 or FTS 475-9486 for technical information sources and assistance with this guidance. Potential sources for technical assistance are Regional ESDs and Quality Assurance Officers. EMSL/LV may be a source for assistance on sampling or statistical issues.

Highlight 6

UNCERTAINTY IN DATA COLLECTION AND EVALUATION DECISIONS AFFECTS THE CERTAINTY OF THE RISK ASSESSMENT



Where to Obtain the Guidance Manual

To order a copy of the manual, call or write to EPA's Center for Environmental Research at 513-569-7652 or FTS 684-7562.

Additional copies of this fact sheet can be obtained by calling the Superfund Docket 202-382-6940 or FTS 382-6940.

Highlight 7

REGIONAL TOXICS INTEGRATION COORDINATORS

Region	Name and Address	Phone Number
I	Sarah Levinson Waste Management Division (HSS-CAN-7) EPA Region I John F. Kennedy Federal Building Boston, MA 02203	FTS 833-1504 617-573-9662
II	Peter Grevatt Program Support Branch ERR Division EPA Region II 26 Federal Plaza New York, NY 10278	FTS 264-8775 212-264-6323
III	Richard Brunker Hazardous Waste Management Division (3HW15) EPA Region III 841 Chestnut Street Philadelphia, PA 19107	FTS 597-0804 215-597-0804
IV	Elmer Akin Waste Management Division EPA Region IV 345 Courtland Street, NE Atlanta, GA 30365	FTS 257-1586 404-347-1586
V	Steve Ostrodka Technical Support Unit (5HSM-12) EPA Region V 230 South Dearborn Street Chicago, IL 60604	FTS 886-3011 312-886-3011
VI	Jon Rauscher EPA Region VI (6H-SR) First Interstate Bank Tower 1445 Ross Avenue Dallas, TX 75202-2733	FTS 255-2198 214-655-2198
VII	David Crawford EPA Region VII 726 Minnesota Avenue Kansas City, KS 66101	FTS 276-7052* 913-551-7052
VIII	Chris Weis EPA Region VIII (8HWM-SR) 999 18th Street, Suite 500 Denver, CO 80202-2405	FTS 330-7655 303-294-7655
IX	Gerald Hiatt Technical Support Section (H-8-4) Superfund Program EPA Region IX 1235 Mission Street San Francisco, CA 94103	FTS 484-1914 415-381-8917
X	Pat Cirone EPA Region X (ES-098) 1200 Sixth Avenue Seattle, WA 98101	FTS 399-2138 206-442-1597

* Caller must have FTS 2000. If not, use commercial number.