United States Environmental Protection Agency

Office of Solid Waste and Emergency Response

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Guidance For Data Useability In Risk Assessment

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

Quick Reference Fact Sheet

The U.S. Environmental Protection Agency (EPA) is establishing national guidance for data quality requirements to optimize the useability of data collected under the Comprehensive Environmental Response, Compensation, and Liability Act of 1980 (CERCLA). "Useable" data are data of sufficient quality to meet their intended use. The *Guidance for Data Useability in Risk Assessment (Part A)* (9285.7-09A) provides risk assessors and RPMs with nationally-consistent procedures to plan and assess sampling and analysis of useable environmental data for baseline human health risk assessments. Although the guidance addresses the baseline risk assessment within the remedial investigation (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. The guidance is useful to all parties involved in a site evaluation. This final version supersedes the "interim final" *Guidance for Data Useability in Risk Assessment* (EPA/540/G-90/008).

This fact sheet provides an overview of Part A and Part B of the *Guidance for Data Useability in Risk Assessment*. It highlights key points of the documents and states where additional information can be found. Copies of the guidances can be obtained from the National Technical Information Service at 703-487-4650. Part B of the guidance specifically addresses the useability of radioanalytical data for baseline human health risk assessment.

Who is This Guidance for?

Remedial project managers (RPMs), who have the principal responsibility for leading data collection and assessment activities, and risk assessors, who support human health risk assessments, will benefit the most from the guidance. RPMs oversee the preparation of work plans 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 and analysis decisions have on the level of certainty of baseline risk assessment for human health.

The guidance will help risk assessors to be an integral part of the RI planning process, to ensure that the environmental data collected during the RI meet their needs. Data collected only to identify the "nature and extent" of contamination at a site may not necessarily satisfy the data needs for baseline risk assessments. For example, a sampling strategy designed to determine the spatial boundaries of a contaminated area may not provide adequate data to quantitate concentrations within an exposure area. The risk assessor should work closely with the RPM to identify and recommend sampling designs and analytical methods that will optimize the quality of the data collected for a baseline human health risk assessment within the site-related and budgetary constraints of the RI. Chemists, quality assurance specialists, hydrogeologists, statisticians and other technical personnel involved in the RI process will also find this guidance useful.

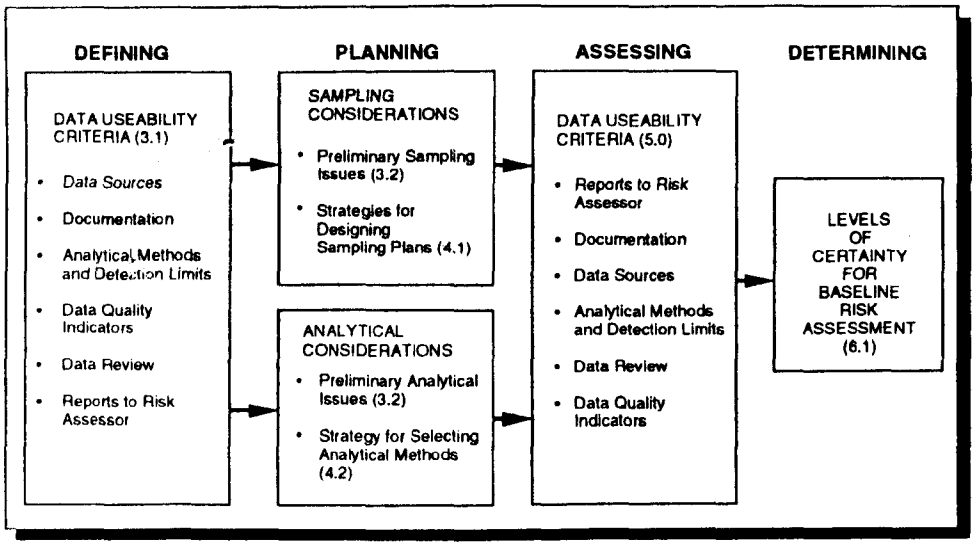
Part B of the *Guidance for Data Useability in Risk Assessment* is addressed primarily to RPMs and risk assessors who share the responsibility of ensuring that the data collected during the RI for a radiation site are of sufficient quality and quantity to be useable in developing a baseline human health risk assessment. It is also directed to radiation protection specialists, health physicists and radiochemists who are called upon by RPMs and risk assessors to assist in the identification and evaluation of radiation hazards, to recommend specific radionuclide sampling and analysis procedures, and to interpret and comment on the useability of resultant radioanalytical data.

What is the Guidance?

The guidance is a tool for obtaining and assessing analytical data for baseline human health risk assessments that are conducted as part of an RI. The guidance:

- Defines six criteria which determine data useability and describes how they are applied through the planning and assessment phases of baseline risk assessment (see Highlight 1),
- Discusses the issues involved in planning and assessing sampling and analysis activities for risk assessment,
- Describes how to design RI sampling and analytical activities that meet the data quality and data quantity needs of risk assessors,
- Describes how to assess the useability of data obtained in the RI for risk assessment,
- Describes how to combine data of various levels of quality from different sources and incorporate them into risk assessments, and
- Describes how to determine the degree of confidence in the risk assessment based on the uncertainty in the environmental data.

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



An "interim final" version of this guidance was issued in October 1990, to obtain and incorporate comments and criticisms following a period of use at Superfund sites. Based on input from users of the "interim final," the "final" guidance provides a more detailed discussion of sampling and background sampling strategies and addresses soil depth sampling issues. The use and validation of fixed laboratory analyses, field analyses, tentatively identified compound data, and non-CLP analyses are also discussed in greater detail.

Attention to ecological data needs is included. The guidance does not directly address the use of ecological data for purposes other than baseline risk assessments for human health. However, the chemical data obtained from site characterization are useable in the ecological assessment. Biota sampling and analytical issues are discussed, as well as ways to differentiate chemicals of potential concern to ecological risk assessments from those of concern to human health risk assessments.

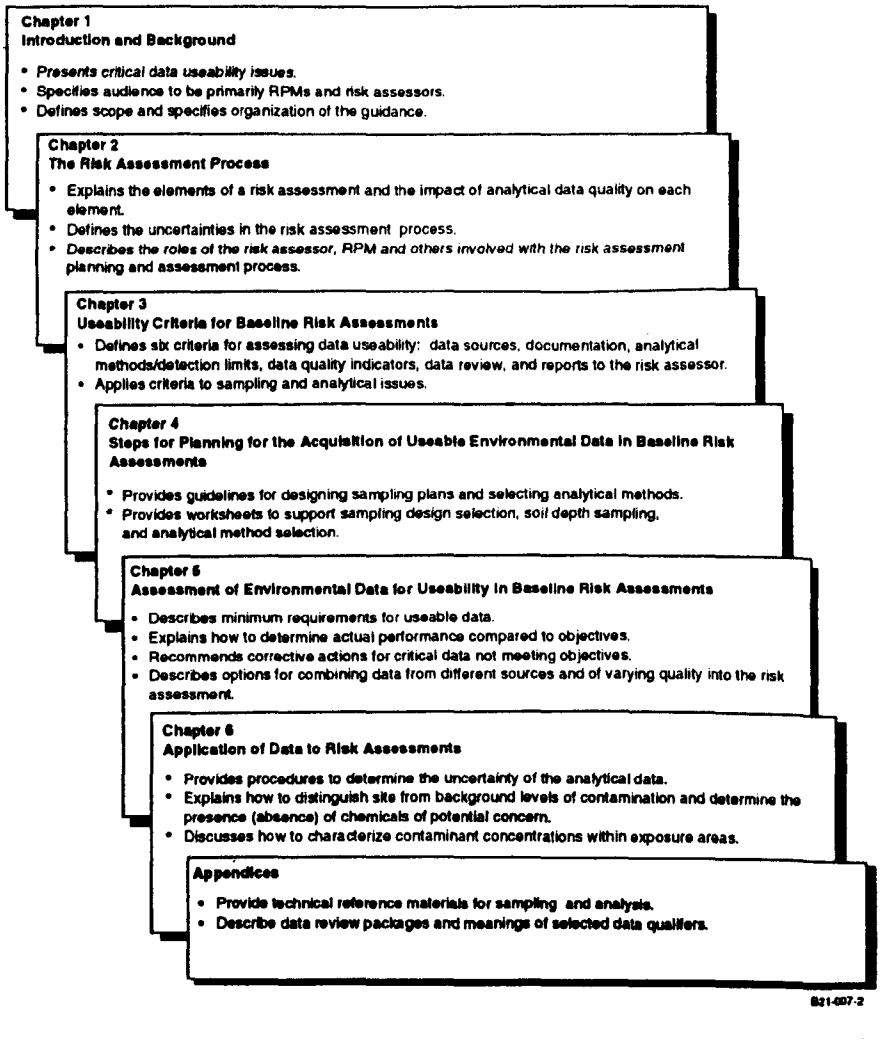
Highlight 2 outlines the content of each chapter of Part A of the guidance. Various tools to assist RPMs and risk assessors to plan and assess sampling and analysis complement the text of the chapter.

- Worksheets to organize sampling or analytical planning strategies, and to clarify depth of sampling requirements in soil investigations.
- Checklists for workplans and sampling and analysis plans.
- Available software to assist in planning and assessment.
- Tips that draw attention to key issues in the text. For example:

  All data can be used in baseline risk assessment as long as their uncertainties are clearly described.
- Appendices requested by risk assessors and RPMs, including a model for data review packages, a list of common pollutants generated by seven industries, a list of laboratory contaminants, and statistical calculations.

Part B provides supplemental guidance on data collection and evaluation issues that affect the quality and useability of radioanalytical data required for performing baseline risk assessments at sites contaminated with radioactive substances. The guidance:

HIGHLIGHT 2 . ORGANIZATION OF PART A OF THE GUIDANCE



- Provides an overview of the similarities and key differences between chemical and radionuclide risk assessments with respect to data collection and evaluation, exposure assessment, and risk characterization,
- Discusses data useability criteria and preliminary sampling and analysis issues for baseline radiation risk assessments,
- Outlines steps involved in planning for the acquisition of useable environmental radiation data, including strategies for designing sampling plans and considerations for selecting radioanalytical methods and laboratories,
- Describes how to assess and interpret environmental radioanalytical data, and
- Discusses how to apply the radioanalytical data to the baseline human health risk assessment.
- Includes a glossary of radiation terminology and concepts, a discussion of potential sources, properties, and migration pathways for naturally occurring and manmade radionuclides in the environment, and a listing of the names and addresses of EPA's regional, laboratory and headquarters radiation programs staff.

Chemical and radiation risk assessments share many of the same data useability issues, criteria and objectives. To avoid redundancy in these cases, Part B refers back to specific detailed discussions, exhibits and guidance provided in Part A of *Guidance for Data Useability in Risk Assessment*. Consequently, **Part B is not a stand-alone document; it must be used in conjunction with Part A at all times.**

The guidance provided in Part A and Part B complements the *Risk Assessment Guidance for Superfund (RAGS) Volume I: Human Health Evaluation Manual, Part A*. RAGS provides the framework for making data quality assessments in baseline risk assessments. The *Guidance for Data Useability in Risk Assessment (Part A)* supplements the RAGS framework by providing minimum requirements for the sampling strategies and the resulting environmental analytical data used in baseline risk assessments. As such, it also complements and builds upon Agency guidance for the development and use of data quality objectives in all data collection activities, as found in the *Guidance for Conducting Remedial Investigations and Feasibility Studies under CERCLA* and the *Data Quality Objectives for Remedial Response Activities: Development Process.*

Why Use This Guidance?

Optimizing data useability in baseline human health risk assessments reduces uncertainty in environmental data used in risk assessment and also saves time and money. With this guidance risk assessors and RPMs can more efficiently identify and communicate risk assessment needs during RI planning for both sampling and analysis. They can also determine the useability of previously obtained data, thus minimizing requirements for more data.

Data Useability Issues in Risk Assessment

Risk assessors and RPMs identified five basic issues that are frequently encountered in obtaining useable data for risk assessment:

Data sources. Practical tradeoffs among available sampling strategies typically include weighing the available resources against the needs to locate "hot spots," to provide representative site sampling, to provide representative background samples, and to quantitate sampling error. Variable sampling results are often the major determinant in the overall level of certainty in risk assessment. RPMs and risk assessors should determine the sampling strategy or combination of strategies that best serve the data quality needs of risk assessment. A combination of statistically based and purposive sampling can often provide samples representative of a site and of the background. Highlight 3 summarizes the importance of sampling issues in risk assessment.

HIGHLIGHT 3. 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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Detection limits. Risk assessors and RPMs choose the analytical methods to optimize detection limits; this is fundamental to the useability of analytical data in risk assessments. The type of detection limit used in making data quality decisions, such as method detection limit or sample quantitation limit, also affects the certainty of the risk assessment. Advances in analytical

technology have lowered detection limits in field analyses. With the appropriate quality control measures, field data can be used more frequently in risk assessments. A combination of field analyses and fixed laboratory analyses optimizes the amount of available data to characterize a site.

Qualified data. Data assessment often results in qualification of environmental data. Qualified data are almost always useable as long as the uncertainty in the data and its impact on the certainty of the risk assessment are documented and explained. Procedures are provided for incorporating qualified data and data of various analytical quality into the risk assessment.

Background samples. Distinguishing site contamination from background levels in risk assessment is critical. Analytical data reported near method detection limits and sample results qualified during data review often complicate data use in risk assessment. Planning for collection of a sufficient number of background samples increases the certainty 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, and among different sampling and analytical events at a given site. The guidance provided in this document and in RAGS helps RPMs and risk assessors to ensure that baseline risk assessments for human health are conducted consistently and each are equally protective of the public health.

The *Guidance for Data Useability in Risk Assessment* addresses these five issues in detail and provides procedures, minimum requirements, and corrective actions to resolve the impact the issues have on the confidence in the risk assessment.

Making Decisions with Environmental Data

The following questions guide risk assessment planning:

What contamination is present and at what level? When the sampling design is representative of the site and exposure area, then appropriate analytical methods can determine the presence or absence of contamination at the site. The RPM's selection of sampling strategies, analytical methods, and the type and level of data review can affect the probability of false negatives and false positives for both site and background samples. Selecting the appropriate sampling design is critical and is discussed at length in the guidance.

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. The guidance discusses both sampling and analytical designs.

Are all exposure pathways and exposure areas identified and examined? All exposure pathways and exposure areas must be identified. Identifying and sampling the media of concern and the importance of representative sampling are discussed in the guidance.

Are all exposure areas fully characterized? For all exposure areas to be fully characterized, sampling must be representative and must satisfy performance objectives determined during the planning process. A broad spectrum analysis must be available in order to characterize the areas and avoid false negatives.

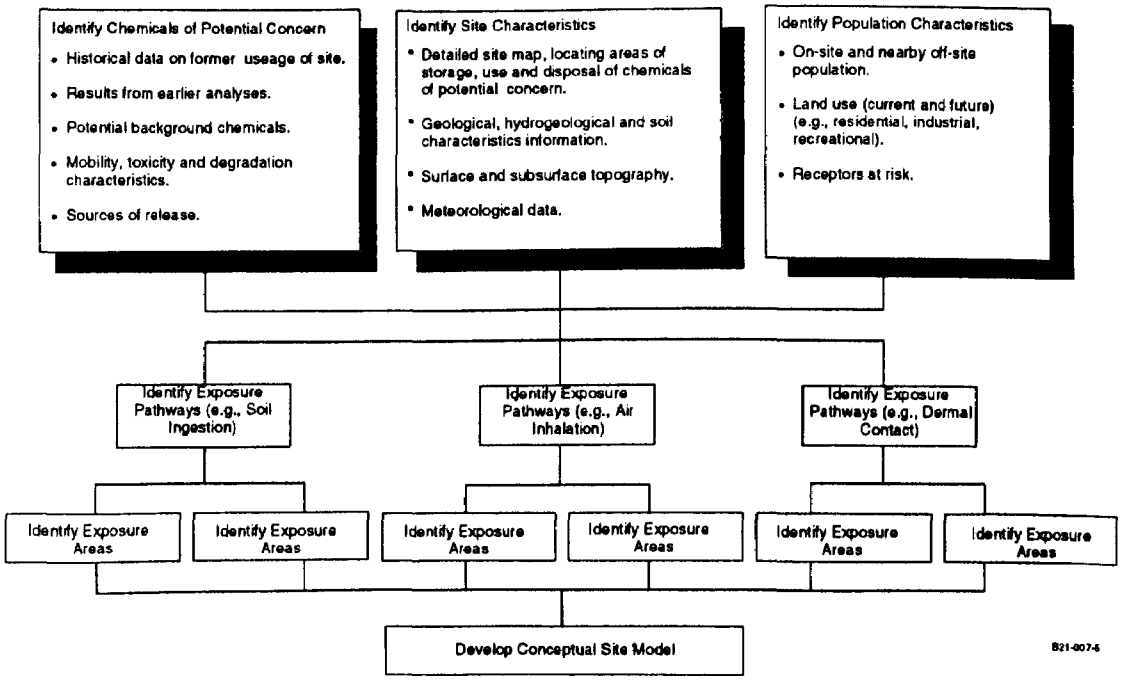
Uncertainty in chemical identification and quantitation is determined based on how these questions are decided. This analytical data uncertainty affects the level of confidence of the final risk assessment.

Planning for Risk Assessment

RPMs and risk assessors should develop a conceptual model of the site before planning data collection activities for risk assessment. The model acts as a sketch which the sampling effort completes. Highlight 4 illustrates how a conceptual site model is developed. The guidance describes the six planning and assessment criteria that follow from such a model to ensure data useability.

- *Data sources* must be comparable if data are combined for quantitative use in risk assessment.
- *Documentation*, such as sampling and analysis plans and standard operating procedures, must be followed or deviations must be documented.

HIGHLIGHT 4. DEVELOPMENT OF CONCEPTUAL SITE MODEL



- *Analytical methods and detection limits* must test for the chemicals of potential concern at the concentration levels of concern.
- *Data quality indicators* (such as representativeness and completeness) must be met.
- *Data review* must be apropriate to the use of the data.
- *Reports to risk assessors* must be clear.

The guidance explains how to use these criteria with the conceptual model to plan data collection efforts that maximize the useability of environmental analytical data in baseline risk assessments. Worksheets are provided to help select the most appropriate sampling and analytical procedures and the appropriate depth for soil sampling. Checklists and tips are also included. Automated systems are referenced that are useful in selecting sampling and analytical procedures. Regional Environmental Services Divisions (ESDs) can also provide assistance.

Assessing Environmental Data for Useability

Conducting the Data Assessment. The risk assessor and data reviewer examine the data, documentation, and reports to determine if they meet the performance objectives required in the RI planning. If no performance objectives have been specified or the specification is incomplete, the minimum acceptable requirements for the data useability criterion should be used. The guidance presents minimum requirements for each data useability criterion.

The guidance describes how to evaluate each criterion. The process is briefly outlined below:

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

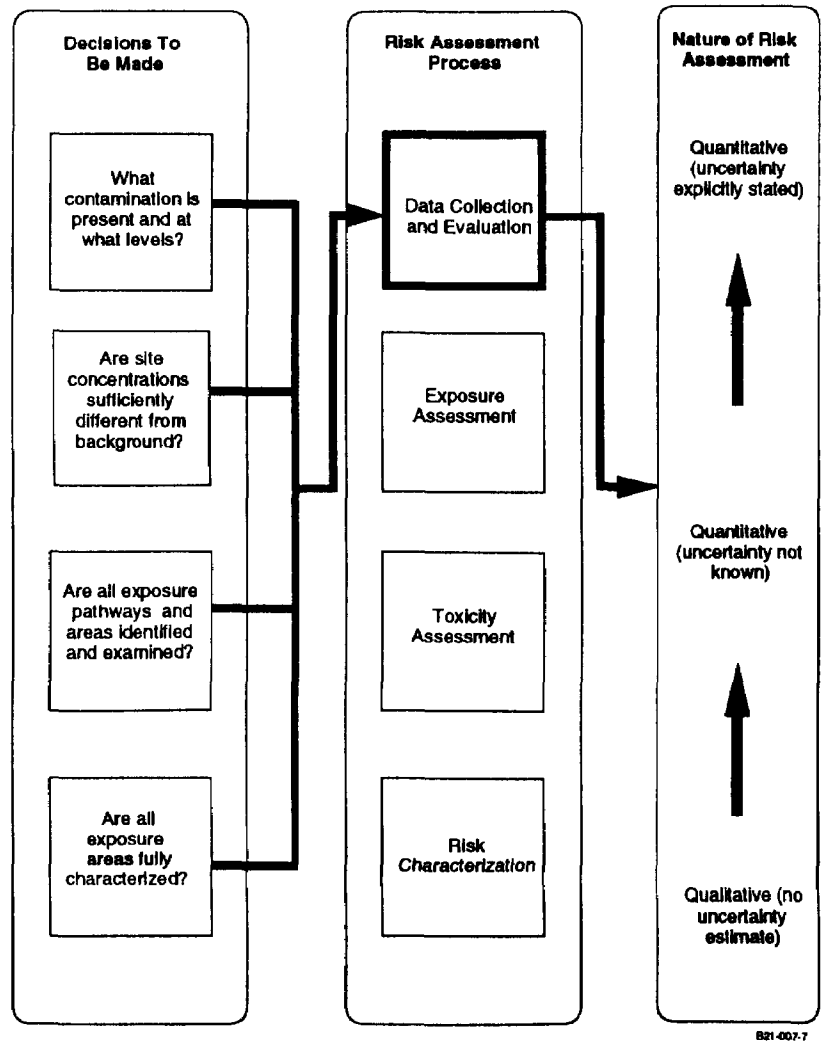
The guidance also provides the appropriate corrective actions when actual performance fails to meet the objectives for data critical to risk assessment.

Organizing the Data Assessment. The guidance helps risk assessors to determine whether the level of certainty for the data involved is satisfactory, questionable, or unsatisfactory for each performance measure within an assessment phase. Guidance tools include a worksheet to apply useability criteria to the data. For each criterion, the worksheet requires a decision to be made: whether to accept, accept with qualification, or reject the data for use in the risk assessment. The justification for each decision is also recorded on the worksheet.

Applying Data to Risk Assessment

As shown in Highlight 5, the level of certainty associated with data determines the certainty in the answers to the four fundamental decisions that risk assessors must make. The final sections of the guidance provide procedures for determining the level of certainty for each decision, given the results of the assessment of performance measures. These measures are the bases for the estimation of the degree of confidence in the risk assessment.

HIGHLIGHT 5. UNCERTAINTY IN DATA COLLECTION AND EVALUATION DECISIONS AFFECTS THE CERTAINTY OF THE RISK ASSESSMENT



Need More Help?

Questions regarding site-specific Superfund risk assessment issues should be referred to the Superfund Toxics Integration Coordinators listed in Highlight 6. Questions regarding Superfund radiation risk assessment issues should be directed to the EPA Regional Radiation Program Managers or to the Office of Radiation Programs (ORP) Laboratory Directors listed in Highlight 7. The ORP Radiation Assessment Branch (RAB) can be contacted at 202-260-9630. The Toxics Integration Branch (TIB), Office of Emergency and Remedial Response (OERR), may also be contacted at 202-260-9486 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. The mailing address for EMSL/LV is:

U.S. EPA Environmental Monitoring Systems Laboratory (EMSL)
944 E. Harmon Avenue
Box 93478
Las Vegas, NV 89119

How to Obtain the Guidance

To order a copy of the guidance, call or write:

National Technical Information Service
5285 Port Royal Road
Springfield, VA 22161
Phone: 703-487-4650

HIGHLIGHT 6. REGIONAL TOXICS INTEGRATION COORDINATORS

Region	Name, Address and Phone Number
I	Ann-Marie Burke Waste Management Division (HSS-CAN-7) EPA Region I 90 Canal Street Boston, MA 02110 FTS 833-1528 617-223-5528
II	Peter Grevatt Program Support Branch ERR Division EPA Region II 26 Federal Plaza New York, NY 10278 FTS 597-6323 212-597-6323
III	Debra Forman Hazardous Waste Management Division (3HW15) EPA Region III 841 Chestnut Street Philadelphia, PA 19107 FTS 597-6626 215-597-6626
IV	Elmer Akin Waste Management Division EPA Region IV 345 Courtland Street, NE Atlanta, GA 30365 FTS 257-1536 404-347-1586
V	Erin Moran Technical Support Unit (SHSM-TUB12) EPA Region V 77 West Jackson Boulevard Chicago, IL 60604 FTS 353-1420 312-353-1420
VI	Jon Rauscher EPA Region VI (6H-SR) 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 276-7702 913-551-7702
VIII	Chris Weis EPA Region VIII (8HWM-SRM) 999 18th Street, Suite 500 Denver, CO 80202-2405 FTS 330-7655 303-294-7655
IX	Daniel Stralka Technical Support Section (H-8-4) EPA Region IX 75 Hawthorne Street San Francisco, CA 94105 FTS 484-2310 415-744-2310
X	Pat Cirone EPA Region X (ES-098) 1200 Sixth Avenue Seattle, WA 98101 FTS 399-1597 206-553-1597

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HIGHLIGHT 7. EPA REGIONAL AND LABORATORY RADIATION PROGRAM STAFF

Region	Name, Address and Phone Number
I	Tom D'Avanzo Radiation Program Manager EPA Region I John F. Kennedy Federal Building, Rm. 2311 Boston, MA 02203 617-565-4502
II	Paul A. Giardina Radiation Program Manager EPA Region II Rm. 1005 (AWM-RAD) 26 Federal Plaza New York, NY 10278 212-264-4110
III	Lewis Felleisen Radiation Program Manager EPA Region III Special Program Section (3AM12) 841 Chestnut Street Philadelphia, PA 19107 215-597-8326
IV	Chuck Wakamo Radiation Program Manager EPA Region IV 345 Courtland Street, NE Atlanta, GA 30365 404-347-3907
V	Gary V. Gulezian Radiation Program Manager (AT18J) EPA Region V 77 West Jackson Boulevard Chicago, IL 60604 312-353-2206
VI	Donna Ascenzi Radiation Program Manager EPA Region VI Air Enforcement Branch (6TE) 1445 Ross Avenue Dallas, TX 75202-2733 214-655-7223
VII	Gale Wright Radiation Program Manager EPA Region VII 726 Minnesota Avenue Kansas City, KS 66101 913-551-7600
VIII	Milton W. Lammering Radiation Program Manager EPA Region VIII (8AT-RP) 999 18th Street Denver, CO 80202-2405 303-294-1709
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NAREL	Samuel T. Windham Director National Air and Radiation Environmental Laboratory (NAREL) 1504 Avenue A Montgomery, AL 36115-2601 205-270-3400
ORP-LV	Jed Harrison Acting Director Office of Radiation Programs - Las Vegas Facility (ORP-LV) P.O. Box 98517 Las Vegas, NV 89193-8517 206-798-2476