

US EPA ARCHIVE DOCUMENT



Managing Risks and Uncertainties

Project Managers are also Risk and Uncertainty Managers, and sometimes Risk Assessors, for RCRA Corrective Action Projects

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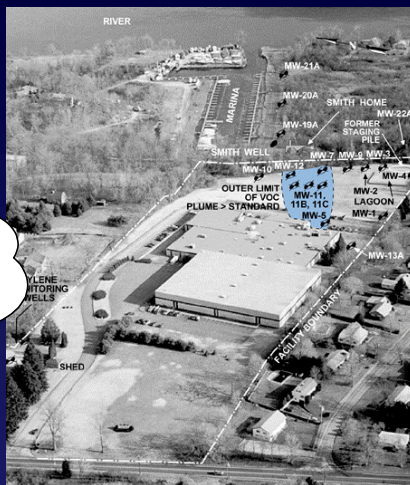
Managing Risks and Uncertainties

What uncertainties and risks must I understand?

What information must be communicated among key parties?



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Notes:

Data collection and risk management decisions are often the focus of many corrective action project meetings, discussions, and disagreements.

Data collection and risk management decisions are often best addressed by focusing on three sub-elements:

1. What results need to be achieved and what decisions need to be made to achieve these results?
2. What amount and type of information is needed to make the decision?
3. What tools are available to identify, assess, and manage actual or potential risks?

Objectives

Participants will be able to:

- Understand and use tools to address technical uncertainties that exist in Corrective Action projects
- Define risk-related terminology and describe typical roles and responsibilities of regulators
- Decide the level of risk expertise needed and apply proper tools to assist in risk assessment and risk management activities



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Notes:

Guidance on uncertainties is found in the reference materials provided for this module.

A list of Internet sites with risk assessment and risk management tools also is included on pages 27 and 28.

What are “Uncertainties”?

- Things you do not know and may need to know to make project decisions
- Found in all Corrective Action projects

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Notes:

Project managers should:

- Identify and understand uncertainties
- Understand whether uncertainties matter for decisions being made at the time
- If they do matter, decide what to do about them
- Communicate the answer

Why do uncertainties matter?

- Often the source of technical disagreements
- Failure to understand them leads to a conclusion that all uncertainties need to be eliminated before project decisions can be made

Uncertainties at the AMT Site

Have contaminants reached surface water?

What is extent of xylene plume?

Does TCA extend beyond facility boundary?

Is a NAPL present? Could it be mobile?

Is there another source of TCA?

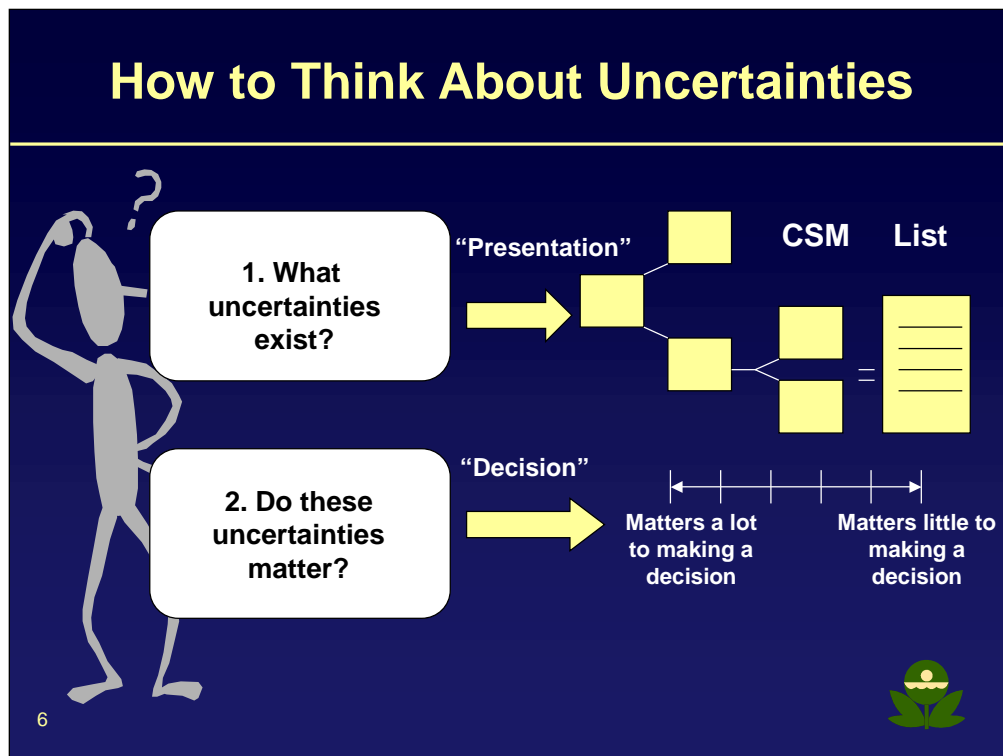
WHAT ARE SOME OTHERS?

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Notes:

The relevant case study information from the last module helps to understand the nature of these uncertainties:

- Contaminants are not currently detected in wells MW 19A-21A nor in the Smith well. Are these results sufficient to conclude that the plume has not reached surface water?
- The monitoring well and borings around the hit of xylene in MW-6A show no migration of xylene. Are these data sufficient to define the extent of the xylene contamination?
- The lateral extent of the TCA plume is inferred from the wells located along the eastern boundary of the property and no detection of TCA at the Smith well. Is this adequate to determine whether the TCA plume extends beyond the boundary?
- MW-13A and 1A may indicate another source of TCA outside of the known plume. Is this significant?
- Fugacity analysis shows TCA, DCA, and DCE can be present as a NAPL. Is it important to know whether a mobile NAPL is present?



Notes:

Identification of uncertainties is a central part of a good Conceptual Site Model. Documentation can be aided by other tools, such as an uncertainty matrix, an example of which is included in the reference fact sheet.

The first decision about how to manage uncertainties relates to their significance given the decision being addressed.

Uncertainty Outcomes Depend on the Decision Being Made

Uncertainties that matter right now

Uncertainties that may matter later in the project

Uncertainties that do not matter

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“Significance” of an uncertainty is simply an indicator of how important the uncertainty is to the decision and the management strategy to be considered.

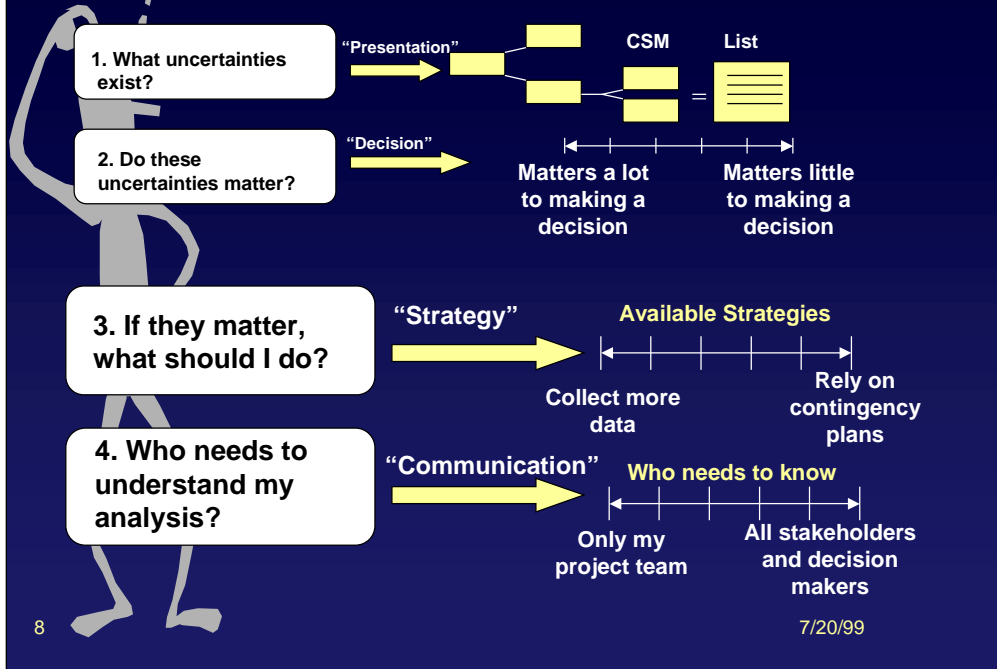
Uncertainties take on significance relative to the decision being made and the timing in the process of that decision. An uncertainty about the viability or long-term effectiveness of a long-term remedy, for example, is less significant (or insignificant) in the context of an environmental indicator determination.

“Significance” is also often an indication of whether additional data collection is needed to reduce or eliminate the uncertainty. It is much less likely that additional data collection is needed for an uncertainty that is insignificant, or for one that can be effectively managed through a contingency plan or additional monitoring.

At any time, uncertainties can be:

- insignificant (although potentially later they will be important)
- significant and need to be reduced or eliminated (e.g., through additional data collection)
- significant but chosen not to be reduced or eliminated, but rather managed in other ways (e.g., contingency planning, additional monitoring)

How to Think About Uncertainties

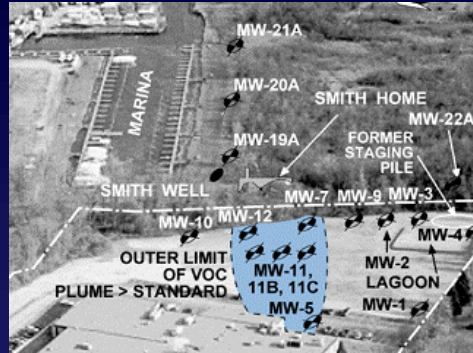


What to do if Uncertainties Matter

Example:

Are there exposures to residents at the Smith home?

- Options to address this uncertainty:
 - Collect additional data on possible vapors
 - Monitor routinely and develop contingency plan if future sampling shows vapors in home or detects in well
- Communicate decision to appropriate parties



Example #1: Are Contaminants Reaching Surface Water?

- Determination is important for making both the human exposure and groundwater controlled EI determinations
- Known conditions
 - data from MW-19A - 21A show no detection at entry to marina
 - sampling at Smith well shows no detection



Have
contaminants
reached the
surface water?



Example #1: Are Contaminants Reaching Surface Water? (cont.)



Have contaminants reached surface water?

- Uncertainty: are current data sufficient to make a decision?
- Available strategies:
 - additional sampling points
 - continue monitoring at current points and develop contingency response if detected



Example #2: Are Vapors from the TCA Release Affecting Workers in the Plant

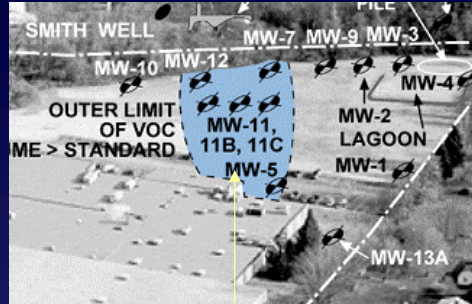


- Small Group Exercise: Use the uncertainty management matrix to analyze this uncertain condition.

Are vapors affecting workers?



Example # 3: Is a NAPL Present? Could it be Mobile?



Is there a NAPL?

- Is this a significant uncertainty for making an EI determination? For a final remedy?
- What are appropriate uncertainty management strategies?

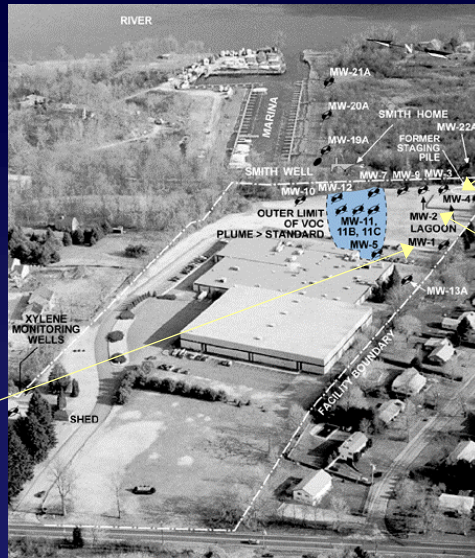


What is Risk?

“RISK” is the likelihood or probability that a given contaminant exposure or series of exposures may damage human health or the environment.



Uncertainty and Risk

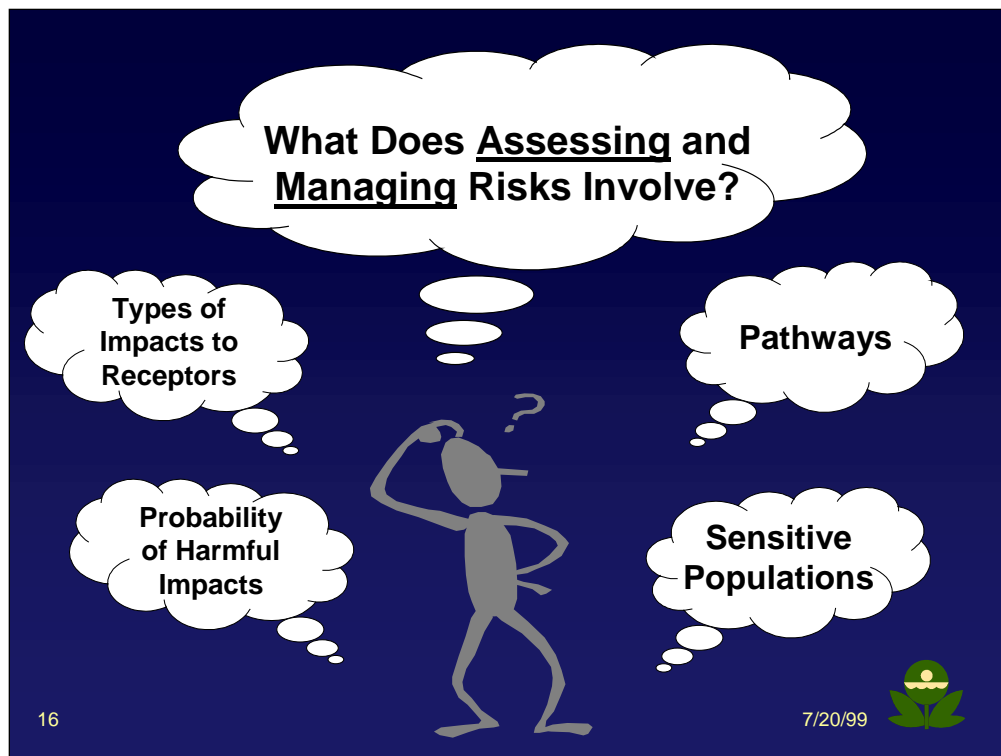


Is the current TCA management approach an adequate risk management strategy?

Does metals contamination in surface soils pose an unacceptable risk?

Does the TCA plume pose a risk to receptors?





Notes:

Here are some traditional definitions of risk.

Risk is “a measure of the probability that damage to life, health, property, and/or the environment will occur as a result of a given hazard.”

U.S. EPA Terms of Environment, May 1998

Risk is “the probability of injury, disease, or death under specific circumstances. In quantitative terms, risk is expressed in values ranging from zero (presenting the certainty that harm will not occur) to one (representing the certainty that harm will occur). The following are examples showing the manner in which risk can be expressed: E-4 = a risk of 1/10,000; E-5 = a risk of 1/100,000; E-6 = a risk of 1/1,000,000. Similarly, 1.3E-3 = a risk of 1.3/1,000 = 1/770; 8E-3 = a risk of 1/125; and 1.2E-5 = a risk of 1/83,000.”

U.S. EPA Glossary of Risk Assessment Related Terms, February 1994

Risk is “the probability of a specific outcome, generally adverse, given a particular set of conditions.”

*Risk Assessment and Risk Management in Regulatory Decision-Making,
The Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997*

Risk is “the likelihood that adverse ecological effects may occur or are occurring as a result of exposure to one or more stressors.”

EPA’s Proposed Guidelines for Ecological Risk Assessments, September 1996

What are Risk Roles of Regulators?

- Vary among Regions, States, and individuals
- Always risk managers
 - They make decisions (or review owner/operator proposed decisions) regarding risk activities

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Notes:

Regulators also have a role in risk assessment activities (even if it is to verify risk assessment assumptions) before they can make risk management decisions.

Project managers need to realize that many key aspects of Corrective Action are risk activities. For example, setting media cleanup objectives in many cases is a risk-based activity.

Practical examples of the range of activities where regulators may be involved in conducting risk assessment activities include the following:

- Selecting an action level at a site where conditions are consistent with use of those action levels, their assumptions, and the decisions they support.
- Reviewing and recommending modifications to an ecological risk assessment data collection workplan.
- Using a risk assessor's expertise to calculate a media cleanup standard for a given set of pathways affecting a single receptor as illustrated in a conceptual site model.

What are Risk Roles of Regulators? (cont.)

- May be risk assessors
 - May use available tools or rely on the expertise of risk assessors
 - Often review results of owner/operator risk assessments
 - May conduct a range of risk assessment activities

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Notes Continued:

What level of risk expertise is needed?

- Type of expertise varies with site conditions and decisions that need to be made
- Standardized tools can help project managers review or make risk assessment or risk management decisions

Some situations support a straightforward risk evaluation. For example, where:

- a single contaminant is the primary driver
- toxicity information is available
- fate and transport to receptors are well understood
- standard exposure pathways exist

Many situations will warrant more consultation or involvement of trained risk assessors. Examples include:

- Multiple contaminants could have synergistic effects
- Controversial chemicals pose issues (e.g., dioxins)
- No standardized toxicity information exists for human or environmental receptors

Other examples of situations that typically warrant more consultation or involvement of trained risk assessors may include:

- Unusual pathways (e.g. subsistence fishing) are present
- Level designed to be protective of humans does not address impacts to ecological receptors

Let's Make a Risk Decision!

1. What type of risk decision am I making?

2. Are exposure pathways/assumptions well defined and standard?

3. Is contaminant toxicity information accessible/easily used?

4. Is standard tool available/applicable?

Project Manager

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Notes:

No single set of rules will determine when or how much to involve risk assessors.

- Recognize that owners/operators often use formal techniques and risk assessors in their work

Use the tools that follow to help define general conditions or tasks where more or less regulator risk assessor involvement may be helpful

Let's Make a Risk Decision!, cont.

5. What ecological impacts may exist?

6. What is owner/operator's expertise and approach?

7. Are data available/usable to make risk decision?



Project
Manager



Let's Make a Risk Decision!, cont.

What door do I pick?

Door #1
Newer Project Manager Has the Risk Expertise
"It works often at many sites..."

Door #2
Experienced Project Manager With Some Risk Expertise
"I can help with risk too..."

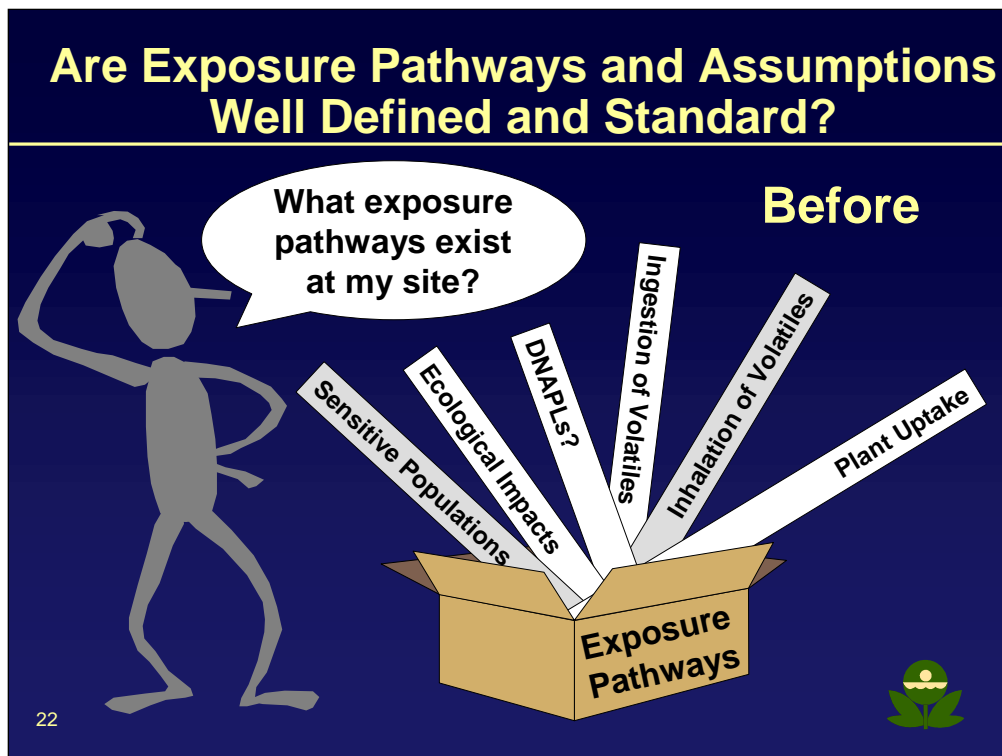
Door #3
Professional Risk Assessment
"Help's always available (if you can find me)..."

Project Manager

Are there unique site issues that require a risk professional?

What is my level of expertise?

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Notes:

- Guidance of defining pathways and assumptions can be found in *Soil Screening Guidance: Fact Sheet*, Publication 9355.4-14FSA, July 1996, and *Soil Screening Guidance: User's Guide*, Publication 9355.4-23, July 1996.
- Pathways addressed by SSLs for residential scenarios include:
 1. Direct ingestion;
 2. Inhalation of volatiles and fugitive dusts;
 3. Ingestion of contaminated groundwater caused by migration of chemicals through soil to an underlying potable aquifer;
 4. Dermal absorption;
 5. Ingestion of homegrown produce that has been contaminated via plant uptake; and
 6. Migration of volatiles into basements.

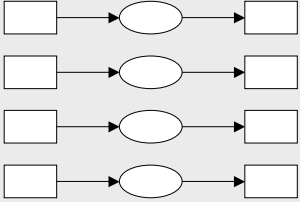
Are Exposure Pathways and Assumptions Well Defined and Standard?, cont.

After



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1. Conceptual Site Model




3. Review Standard Exposure Pathways (Action Levels)

- Ingestion from drinking
- Inhalation of volatiles
- Dermal absorption

2. My List of Exposure Pathways

- Ingestion from drinking
- Inhalation of volatiles
- Ingestion via plant, meat, and dairy



Notes:

- Pathways addressed by action levels may differ, as can the standard assumptions that underlie their use.
- Action levels such as SSLs still are based on the reasonable maximum exposure (RME) concept. Although they may correspond to a 1×10^{-6} risk for carcinogens and a hazard quotient of 1 for noncarcinogens, some uses of action levels may be based on other levels depending on assumptions and uses.
- Action levels for ecological impacts are also available under some circumstances (see tools on pages 27-28).

What Type of Risk-Related Decision Am I Making?

	Near-Term Priorities	
Risk decisions	Screening to Determine if Problem Exists	Evaluating if Environmental Indicators are Met
Some obvious starting points	EPA, Region, or State action levels (if applicable)	EPA Environmental Indicator Guidance
Do I need help from a risk professional?	May or may not involve risk professional depending on site circumstances	EI Module of this course evaluates this in detail



What Type of Risk-Related Decision Am I Making?, cont.

	Ultimate Long-Term Objectives	
Risk decisions	Setting Final Cleanup Standards for Human/Ecological Receptors	Evaluating if Final Cleanup has been Achieved
Some obvious starting points	EPA Program Expectations for Final Remedies	
Do I need help from a risk professional?	May or may not involve risk professional	Seldom needed if standards clearly defined

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Risk Assessment and Risk Assessment Tools:

Risk Assessment Guidance for Superfund, Volumes 1-3, EPA/540/1-89/001-004, March 1989 (www.epa.gov/cgi-bin/claritbw?op-Display&Document=clserv:epa-cinn:5561;&rank=4&template=epa)

Risk Assessment Guidance for Superfund (RAGS), Part D, (www.epa.gov/superfund/resources) - a standardized approach for assessing, documenting, and communicating risk assessment activities for hazardous waste sites

Soil Screening Guidance: Fact Sheet (www.epa.gov/superfund/resources) - an approach to using action levels for making risk decisions at hazardous waste sites

ECOTOX (www.epa.gov/superfund/resources) - software for evaluating ecological toxicity thresholds at hazardous waste sites

Risk Assessment and Risk Assessment Tools (cont.)

Center for Risk Excellence, compendium of risk assessment and risk management tools (<http://riskcenter.doe.gov/cre>) - links to software, databases, and other tools for risk professionals, including an on-line calculator for action levels

Regional and State Action Level Policies. For example, EPA Region IX Preliminary Remediation Goals (www.epa.gov/region09/waste/sfund/prg)

Risk Management Plan Data Elements, EPA/550/3-96/012, May 1996
(www.epa.gov/clhtml/pubalpha.html)

Integrated Risk Information System (IRIS), (www.epa.gov/iris) - toxicity information for contaminants

American Society for Testing and Materials, Risk-Based Corrective Action (www.ucop.edu/facil/eps/astm.html) - information on the use of risk-based Corrective Action concepts as developed by ASTM

Elements to Consider When Drafting EPA Risk Characterizations, March 1995
(www.epa.gov/ORD/spc/rcelemen.html)

Tool for Evaluating Risk Expertise

