1

Starting Soon: Issues and Options in Human Health Risk Assessment – A Resource When Alternatives to Default Parameters and Scenarios are Proposed

Poll Question

- Decision Making at Contaminated Sites: Issues and Options in Human Health Risk Assessment (RISK-3, 2015) http://www.itrcweb.org/risk-3
- Download PowerPoint file
  - CLU-IN training page at http://www.clu-in.org/conf/itrc/risk3/
  - Under “Download Training Materials”
- Using Adobe Connect
  - Related Links (on right)
    - Select name of link
    - Click “Browse To”
  - Full Screen button near top of page

Follow ITRC

Poll Questions as training class starts:

On projects with site-specific risk assessments, what topics have you encountered that were not covered in the guidance document that you usually use? (select all that apply)

Including institutional controls

Addressing data gaps

Choosing among toxicity values

Justifying site-specific exposure factors

Working with probabilistic risk assessment

None of the above

I have not worked on projects with site-specific risk assessments

What other topics have you encountered that were not covered in the guidance document that you usually use? (short answer)

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Welcome – Thanks for joining this ITRC Training Class

Issues and Options in Human Health Risk Assessment – A Resource When Alternatives to Default Parameters and Scenarios are Proposed

Sponsored by: Interstate Technology and Regulatory Council (www.itrcweb.org)
Hosted by: US EPA Clean Up Information Network (www.cluin.org)

Many state and local regulatory agencies responsible for the cleanup of chemicals released to the environment have adopted regulations, guidance and policies that define default approaches, scenarios, and parameters as a starting point for risk assessment and the development of risk-based screening values. Regulatory project managers and decision makers, however, may not have specific guidance when alternative approaches, scenarios, and parameters are proposed for site-specific risk assessments, and are faced with difficult technical issues when evaluating these site-specific risk assessments. This ITRC web-based document is a resource for project managers and decision makers to help evaluate alternatives to risk assessment default approaches, scenarios and parameters.

ITRC's Decision Making at Contaminated Sites: Issues and Options in Human Health Risk Assessment (RISK-3, 2015) guidance document is different from existing ITRC Risk Assessment guidance and other state and federal resources because it identifies commonly encountered issues and discusses options in risk assessment when applying site-specific alternatives to defaults. In addition, the document includes links to resources and tools that provide even more detailed information on the specific issues and potential options. The ITRC Risk Assessment Team believes that state regulatory agencies and other organizations can use the RISK-3 document as a resource or reference to supplement their existing guidance. Community members and other stakeholders also may find this document helpful in understanding and using risk assessment information.

After participating in this ITRC training course, the learner will be able to apply ITRC's Decision Making at Contaminated Sites: Issues and Options in Human Health Risk (RISK-3, 2015) document when developing or reviewing site-specific risk assessments by:

-- Identifying common issues encountered when alternatives to default parameters and scenarios are proposed during the planning, data evaluation, toxicity, exposure assessment, and risk characterization and providing possible options for addressing these issues

-- Recognizing the value of proper planning and the role of stakeholders in the development and review of risk assessments

-- Providing information (that includes links to additional resources and tools) to support decision making when alternatives to default approaches, scenarios and parameters are proposed

ITRC offers additional documents and training on risk management. ITRC's Use of Risk Assessment in Management of Contaminated Sites (RISK-2, 2008) and associated Internet-based training archive highlight variation of risk-based site management and describes how to improve the use of risk assessment for making better risk management decisions. ITRC's Examination of Risk-Based Screening Values and Approaches of Selected States (RISK-1, 2005) and associated Internet-based training archive focus on the process by which risk-based levels are derived in different states.

ITRC (Interstate Technology and Regulatory Council) www.itrcweb.org

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ITRC Training Program: training@itrcweb.org; Phone: 402-201-2419

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- Course time is 2¼ hours
- This event is being recorded
- Trainers control slides
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- Questions and feedback
  - **Throughout training:** type in the “Q & A” box
  - **At Q&A breaks:** unmute your phone with #6 to ask out loud
  - **At end of class:** Feedback form available from last slide
    - **Need confirmation of your participation today?** Fill out the feedback form and check box for confirmation email and certificate

Although I’m sure that some of you are familiar with these rules from previous CLU-IN events, let’s run through them quickly for our new participants.

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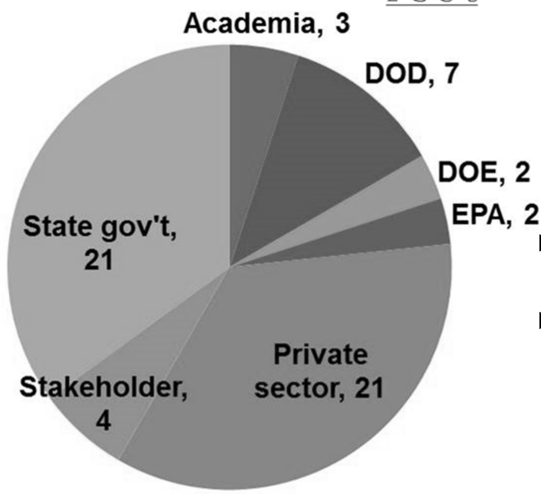
- Host organization
- ITRC Risk Team



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Meet the ITRC Trainers

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Read trainer bios at https://clu-in.org/conf/itrc/risk3/

Diana Marquez is an Associate Toxicologist with Burns & McDonnell in Kansas City, MO and has worked for the company since June 1995. She serves as the company's National Practice Leader for Risk Assessment Services. She has over twenty years of risk assessment experience and has worked with a wide variety of sites under CERCLA, RCRA, and state-led programs. She has successfully completed work nationwide for both human health risk assessments and the determination of site-specific cleanup levels. She has direct experience working with large PRP groups on complex sites that require careful negotiations with regulators. Through this experience, she has gained in-depth knowledge of state and federal regulations. She authored 15+ publications on risk assessment, risk-based corrective actions, and vapor intrusion. Diana earned a bachelor's degree in biology from Villanova University in Villanova, PA in 1991 and a master's degree in toxicology from University of New Mexico in Albuquerque, NM in 1992.

Barrie Selcoe is a Principal Technologist with Jacobs in Houston, Texas. Barrie has worked at Jacobs since 2018, specializing in human health risk assessment. She is responsible for planning and overseeing human health risk-based activities at hazardous waste sites across the U.S. and internationally. She utilizes numerous federal (USEPA and Department of Defense) and state guidance documents in risk assessment projects, and is involved in all stages of site planning, investigation and reporting, cleanup level identification, and remedial action planning. She has been involved in risk assessments in 40 states and about 20 countries. She has worked on risk assessments incorporating incremental sampling and site-specific bioaccessibility studies. She has provided risk assessment services for numerous Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA)/Superfund sites, Resource Conservation and Recovery Act (RCRA) facilities, state-program sites, voluntary actions, and international projects. She has prepared risk assessments for various types of sites, including industrial and commercial facilities, industrial and municipal landfills, bulk fuel terminals, rivers, U.S. Department of Defense facilities, and residential areas. Prior to Jacobs (which purchased CH2M in 2018), she worked as a human health risk assessor for 19 years with CH2M, 7 years with Philip Environmental, and 3 years with O'Brien & Gere Engineers. Since 2012, Barrie has contributed as a team member on ITRC's Risk Assessment team, Bioavailability in Contaminated Soil team, TPH Risk Evaluation at Petroleum-Contaminated Sites team, and PFAS team. She earned a bachelor's degree in microbiology from San Diego State University in San Diego, California in 1986, and a Master's of Public Health from the University of Pittsburgh Graduate School of Public Health in Pittsburgh, Pennsylvania in 1999.

Vivek Mathrani has been a Staff Toxicologist in the Human and Ecological Risk Office at the California Department of Toxic Substances Control (DTSC) since January 2010. He works out of DTSC's regional office in Berkeley, CA. He provides human health risk assessment and toxicology support to DTSC's Brownfields and Environmental Restoration Program and Safer Consumer Products Program. Prior to DTSC, Vivek spent three years as an exposure assessor in the California Department of Pesticide Regulation's Worker Health and Safety Branch. Vivek's doctoral dissertation work dealt with inflammation signaling pathways and airway remodeling under inhalation of ozone and particulate matter. His past involvement with ITRC includes membership on the Environmental Molecular Diagnostics, Green and Sustainable Remediation, and Risk Assessment teams. Vivek earned his doctorate and master's degrees in Pharmacology and Toxicology from the University of California, Davis in 2006. He earned a bachelor's degree in Chemistry from the California Institute of Technology in Pasadena in 2000. Vivek also earned certification as a Diplomate of the American Board of Toxicology in 2010.

Kevin Long is a Principal Consultant in Terraphase's Princeton, NJ office. Since 2000, he has applied risk assessment and risk management strategies to support site characterization, risk management, and redevelopment at hazardous waste and brownfield sites under Superfund, RCRA, and various state and provincial cleanup programs. Working on such projects, he has helped to control unacceptable human exposures at dozens of sites, including those that may pose an imminent and substantial danger to human health. Such projects have involved addressing contamination in all sorts of environmental media and, in many cases, have required complex exposure assessment, fate and transport modeling, statistical analysis, risk management design, and risk communication. He has been a member of the ITRC Risk Assessment team since 2012. Kevin earned a bachelor's degree in 2000 and master's degree in 2006, both in Civil and Environmental Engineering, from Princeton University in Princeton, NJ.

Emily Strake is a consultant with Langan Engineering and Environmental Services, Inc. in Warrington, Pennsylvania. She provides technical expertise in the areas of risk assessment and environmental chemistry. Since 2000, Emily has worked assessing chemical data and the potential adverse health effects to humans from exposure to hazardous contaminants in soil, sediment, groundwater, surface water, ambient and indoor air, and various types of animal, fish, and plant materials. She routinely applies environmental cleanup guidance and policies associated with multiple federal and state agencies, and has been the primary author or key contributor of risk assessment reports and screening evaluations for projects governed under USEPA RCRA and CERCLA, and state programs in California, Delaware, Pennsylvania, New Jersey, Connecticut, Oregon, New York and Maryland. Additionally, she has broad experience in the development of preliminary remediation goals and site-specific action levels, and has performed assessments to focus areas of investigation and identify risk-based alternatives for reducing remediation costs. She has been active in the ITRC Risk Assessment Team since 2012. Emily completed an undergraduate degree in chemistry in 2000 from Cedar Crest College in Allentown, PA and earned a Master's of Business Administration in 2012 from The University of Scranton in Scranton, PA.

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Poll Question – Knowledge and Experience

Poll Question

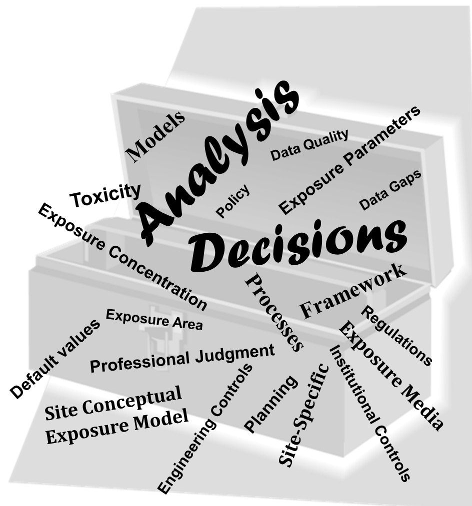
- How much knowledge and experience do you have with risk assessments using site-specific values and parameters in place of default values and lookup tables?
  - None – new to risk assessment
  - Have used or reviewed site-specific parameters or exposure pathways in a limited way
  - Have used or reviewed many site-specific parameters, approaches and processes in risk assessment
  - Have used or reviewed site-specific risk assessment extensively

No associated notes.

7

Why Develop Guidance

- Use of risk assessment in decision making is widely accepted
- Site-specific risk assessment can be complex
- Decision makers are faced with technical issues when applying professional judgment



No associated notes.

8

When working with risk assessments, do you have questions about…

- Situations that don't fit the default approach in guidance documents?
- Equations and assumptions that you don't recognize or aren't in your guidance document?
- Technical validity/defensibility of the calculations?

No associated notes.

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RISK-3
Not Your Typical Risk Guidance

Decision Making at Contaminated Sites: Issues and Options in Human Health Risk Assessment

- Not a "how to" guide for risk assessments
- Focuses on key technical issues
- Provides "options" for resolving each issue
  - Alternatives
  - Recommendations
  - Solutions
  - Approaches

No associated notes.

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When Would I Use the RISK-3 Document?

- Intended to address "non-standard" situations that might not be covered in guidance documents.
- Example:
  - Off-site groundwater receptors

Photo Source: D. Marquez, used with permission

No associated notes.

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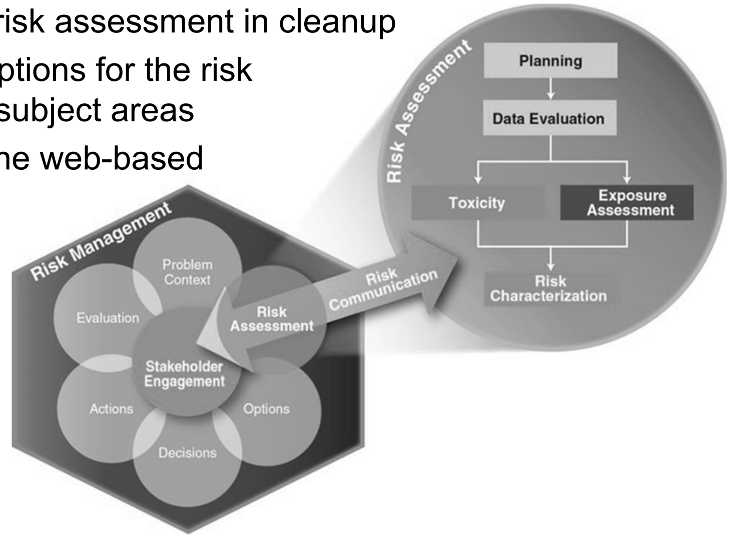
How can the RISK-3 document help me?

- If you are a project manager
  - More informed consumer of risk assessment results
  - Confidence to spot misapplications and mistakes
  - Review selection of values
  - Understand language of risk assessment
- If you are a risk assessor
  - Help make your work and conclusions understandable to a general audience
  - Provide a one-stop reference for addressing technical issues
  - Help make better decisions about alternatives or options for values and parameters in a risk assessment

No associated notes.

Presentation Overview

- Overview of risk assessment in cleanup
- Issues and options for the risk assessment subject areas
- How to use the web-based document



Adapted from "Framework for Environmental Health Risk Management." (Commission 1997)

Figure Source: Adapted from Commission, Presidential/Congressional. 1997a. "Framework for Environmental Health Risk Management. Final Report, Volume 1." Washington, D.C.: The Presidential/Congressional Commission on Risk Assessment and Risk Management. http://www.riskworld.com/riskcommission/default.html.

13

What is Risk Assessment? (Chapter 1)

- Overview of risk assessment

Risk = Toxicity x Exposure

- What is the risk to human health?
- What chemicals and exposures are driving the risk?

- What are the chemical's health effects?
- What is the relationship between exposure and health effects?

- How will people contact the chemical?
- What is the magnitude, frequency and duration of contact?

No associated notes.

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Use of Risk Assessment in Site Cleanups (Chapter 2)

- Tailor risk assessment to needs of project
  - What is goal of the risk assessment?
  - How complex is the site?
  - Can goals be achieved using a screening level approach or is a site-specific risk assessment warranted?
- What approach should be used?
  - Baseline risk assessment
  - Forward versus backward calculations
  - Tiered approach
  - Deterministic or probabilistic approaches

No associated notes.

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Baseline Risk Assessment

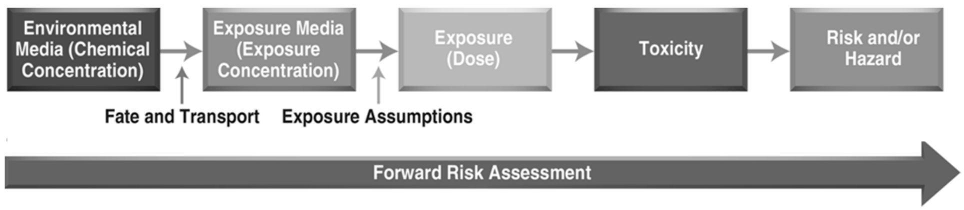
- An analysis of the risks caused by a release in the absence of any actions to control or mitigate the exposure
- Conducted to quantify potential risks posed by chemicals in environmental media and determine if these risks require action

ITRC RISK-3 Section 2.3

No associated notes.

16

Forward vs Backward



Estimate Site Risks

Estimate Screening Levels

ITRC RISK-3 Section 2.1

No associated notes.

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Tiered Approach to Risk Assessment

Risk Assessment	Tier 1	Tier 2	Tier 3
Site-Specificity of Exposure Variables			
Cost of the Risk Assessment	$$	$$$	$$$$
Uncertainty and Bias in Resulting Cleanup Levels			
Cost of Remediation (often but not always)	$$$$	$$$	$$

ITRC RISK-3 Section 2.2

No associated notes.

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Deterministic or Probabilistic Risk Assessment

- Deterministic
  - Uses a single value for each input parameter
  - Can use established default assumptions or site-specific information
  - Single number result – simplifies decision making
- Probabilistic
  - Uses statistically derived distributions of input values to calculate a range of risk
  - Supports a quantitative uncertainty analysis
  - Range of results – better understand uncertainty

ITRC RISK-3 Section 2.4

No associated notes.

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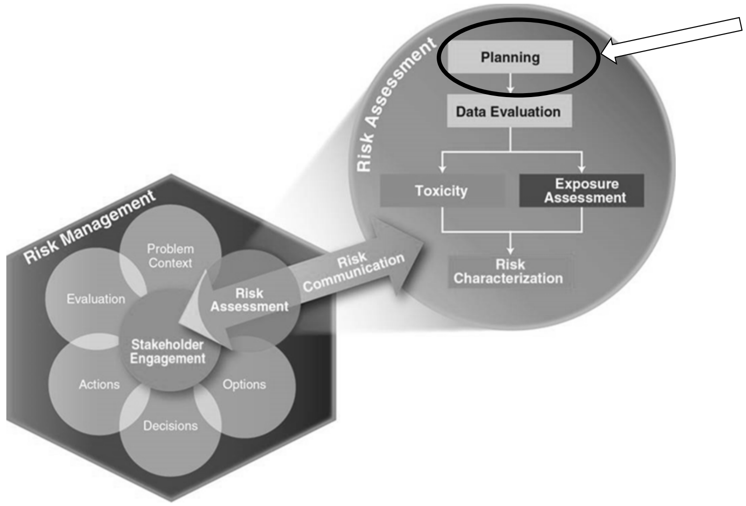
Planning (Chapter 3)



No associated notes.

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Overview of Chapter 3

- Chapter organized around 3 general issues:
  1. Scoping and technical approach – "fit for purpose"
  2. Conceptual site model
  3. Data & information
- Site-specific & thorough
- Alternate approaches
  - Not default
  - Where allowed

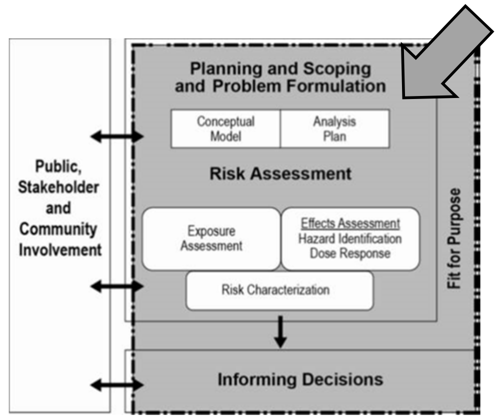

Figure source: USEPA 2012. Draft *Framework for Human Health Risk Assessment to inform Decision Making*

Figure source: USEPA. 2012c. Human Health Risk Assessment (Web Page), Science and Technology, EPA Risk Assessment. United States Environmental Protection Agency. http://www2.epa.gov/risk/human-health-risk-assessment

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Poll Question – Identifying Appropriate Stakeholders

Poll Question

- Have you worked on a project where stakeholders were engaged only AFTER the risk assessment was written, and addressing their concerns caused major risk assessment rewrites?
    - Yes, almost every time
    - Yes, a few times
    - No

No associated notes.

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Identify Appropriate Resources

- **Issue**: Identifying appropriate resources for the risk assessment
  - **Option** – Engage all appropriate stakeholders during planning
- Stakeholders
  - People or agencies
  - Indian Tribes and Native Americans
  - Interested or affected
  - Concerns, input, and insight
  - More accepting of decisions when engaged

ITRC RISK-3 Section 3.1.1.3

No associated notes.

Communicate Throughout the Project

- **Issue**: Communicating during the risk assessment planning & implementation process
  - **Option** – Engage resources & other stakeholders early and throughout the process
- Risk assessor input: investigation and risk assessment scope and approach, exposure scenarios, data needs, cleanup goals

ITRC RISK-3 Section 3.1.2.2

Photo Source: J. Martin, used with permission

Example site in Puerto Rico.

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Identify the Regulatory Context

- **Issue**: Identify the appropriate regulatory context
  - Option – Establish the regulatory jurisdiction in which the site is located & lead agency
  - Option – Understand the pertinent regulations, policies, and guidance
- Regulatory program affects
  - Scope
  - Assumptions
  - Interpretation

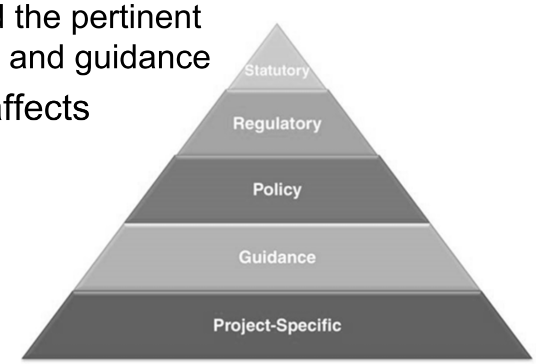

Figure 3-1. Regulatory context hierarchy

ITRC RISK-3 Section 3.1.3

Figure 3-1. Regulatory context hierarchy

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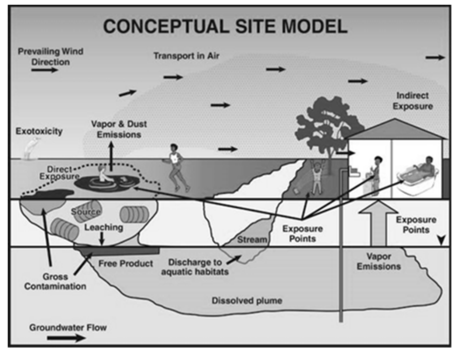
Use a Site-Specific CSM

- **Issue**: What if you have a generic or inadequate conceptual site model (CSM)?
  - **Option** – Prepare a site-specific CSM during planning & refine throughout the project
- Planning tool for data needs
  - Media
  - Locations
  - Depths
- Update iteratively
  - Exposure scenarios
  - Exposure points
  - Receptors



ITRC RISK-3 Section 3.2.1

Figure Source: ITRC 2012 ISM-1

Figure Source: ITRC. 2012 Incremental Sampling Methodology. ISM-1. Washington, D.C.: Interstate Technology & Regulatory Council. http://www.itrcweb.org/Ism-1/Executive_Summary.html.

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Poll Question – Institutional Controls and Engineering Controls

Poll Question

- Have you reviewed a risk assessment where institutional controls (ICs) or engineering controls (ECs) were incorporated into the risk assessment?
    - Yes – ICs only
    - Yes – ECs only
    - Yes – both ICs and ECs
    - No

Example ICs: legal restrictions preventing digging, groundwater use, or residential land use

Example ECs: soil vapor barrier, concrete barrier, clean fill cover

Many states and programs have guidance on this issue; be aware of applicable guidance.

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Incorporating ICs, ECs, or Remedial Action May be Useful

- **Issue**: Determining whether to include ICs, ECs, or planned remedial action in the CSM
  - **Option** – Incorporate ICs or ECs
- Typical baseline risk assessment – no further action
- Discuss during planning; if allowed, incorporate to evaluate:
  - Risk under land use control (for example, industrial)
  - Residual risk outside excavation
- Other ITRC documents:
  - An Overview of Land Use Control Management Systems (ITRC BRNFLD-3, 2008) – see http://www.itrcweb.org/GuidanceDocuments/BRNFLD-3.pdf
  - Long Term Contaminant Management Using ICs (ITRC IC-1, 2016) – see http://institutionalcontrols.itrcweb.org

ITRC RISK-3 Section 3.2.3.1

Former ITRC teams prepared guidance documents titled “An Overview of Land Use Control Management Systems” in 2008 and “Long Term Contaminant Management Using Institutional Controls” – on ITRC website.

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Example – IC Incorporated into CSM

- Former industrial facility; metal waste residue piles
- Planning stage - incorporate ICs
  - Current site zoning & reasonably foreseeable site use
  - Residential use unlikely

ITRC RISK-3 Section 3.2.3.1 Photo Source: B. Selcoe, used with permission

Example site in Illinois.

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Example – IC Not Incorporated into CSM

- Pond sediments impacted by PCBs
- IC = agencies prohibit wading, swimming, fishing
- Planning stage – do not consider ICs
- Risk assessment will assess scenarios and need for ICs (might modify based on risk assessment results)

ITRC RISK-3 Section 3.2.3.2

Photo Source: B. Selcoe, used with permission

Example site in Wisconsin.

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The Amount of Data Needed for Risk Assessment Varies by Site

- **Issue**: Determining the adequacy of data & information for the risk assessment
  - **Option** – Incorporate risk assessment data needs during project planning
- Consider:
  - Media
  - Concentration ranges
  - Number of samples
  - Proximity to sources
  - Analytes & detection limits
  - Age of data

ITRC RISK-3 Section 3.3.1.1

No associated notes.

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Example - Data Needs Evaluated During Project Planning

- Impacted creek downstream from a former smelter
- Planning stage – site visit with PMs & risk assessors; sediment deposition areas, proximity to receptors, accessibility, play areas, edible-size fish
- Used to develop data needs

ITRC RISK-3 Section 3.3.1.1

Photo Source: B. Selcoe, used with permission

Example site in Illinois.

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Many More Issues Addressed in Chapter 3

- Data and information (Section 3.3)
  - Assessing hot spots
  - Determining whether the data set is representative of the exposure areas
  - Recognizing biases in the data set that will affect risk estimates
  - Selecting analytical parameters
  - Addressing background concentrations in the risk assessment

No associated notes.

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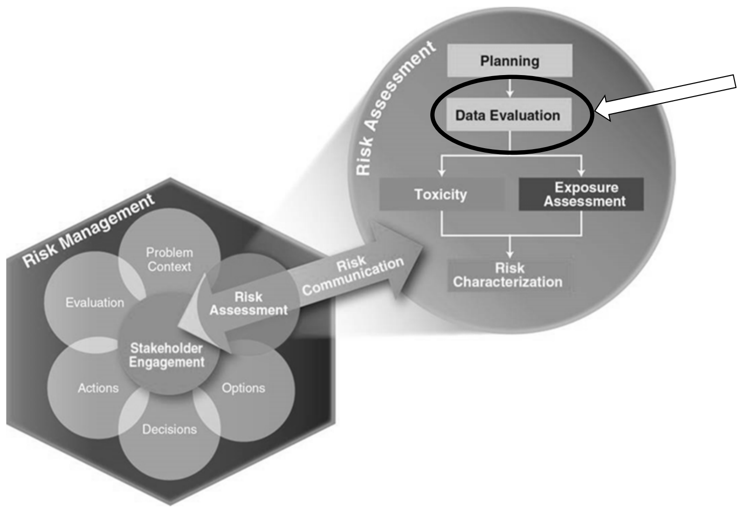
Data Evaluation (Chapter 4)



No associated notes.

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Overview of Chapter 4

- Chapter organized around 5 general issues:
  1. Data gaps
  2. Data usability
  3. Data reduction concerns
  4. Data visualization and analysis
  5. Data screening and chemical selection process
- Alternate approaches (not default, where allowed)

No associated notes.

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Identify Which Data Gaps Should be Filled

- **Issue**: Identifying & filling data gaps
  - **Option** – Determine if additional data changes the risk assessment results
  - **Option** – Collect additional data to address the gap
- Uncertainty inherent in all sampling & risk assessment efforts
  - Not all data gaps are significant
  - Significant when insufficient for evaluating exposure and risk

ITRC RISK-3 Section 4.1.1

No associated notes.

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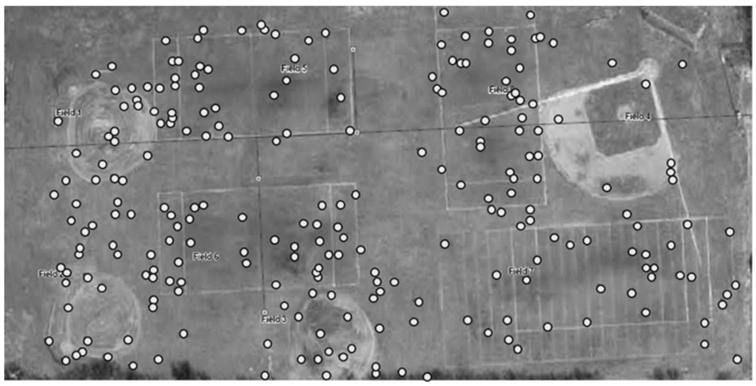
Example – Not all Data Gaps are Significant

- Impacted soil from adjacent industrial site
- Planning stage – site layout; incremental & discrete sampling
- "Data gaps" near center but concentration gradient from source
- Data near site center would not change conclusions



○ = *sampling location*

Photo Source: CH2M Hill, used with permission

No associated notes.

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Sometimes Data Gaps Cannot be Filled

- **Issue**: Addressing permanent data gaps
  - **Option** – Assume the concentrations present
- Potential approaches
  - Estimate concentrations
  - Surrogate exposure area
  - Professional judgment from similar sites
  - Conservative risk management decision

ITRC RISK-3 Section 4.1.2

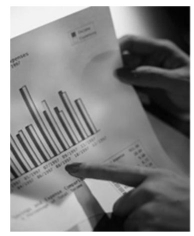
Photo Source: B. Selcoe, used with permission

No associated notes.

38

Visualize Site Data for Better Understanding

- **Issue**: Accurately displaying & visualizing data
  - **Option** – Use common data visualization tools, considering the limitations of the tool
- Can reveal site-specific data patterns not portrayed by tables.
- Project needs may warrant multiple tools
- Various data visualization tools discussed; pros/cons – see guidance
- 2 examples:
  - Probability Plots
  - 2-dimensional maps



ITRC RISK-3 Section 4.4.1

No associated notes.

39

Probability Plots Reveal Distribution & Outliers

- Probability plot (quantile plot)
- USEPA's ProUCL software
- Pros: Provides data distribution type & statistical outliers
- Cons: No concentration locations or temporal information

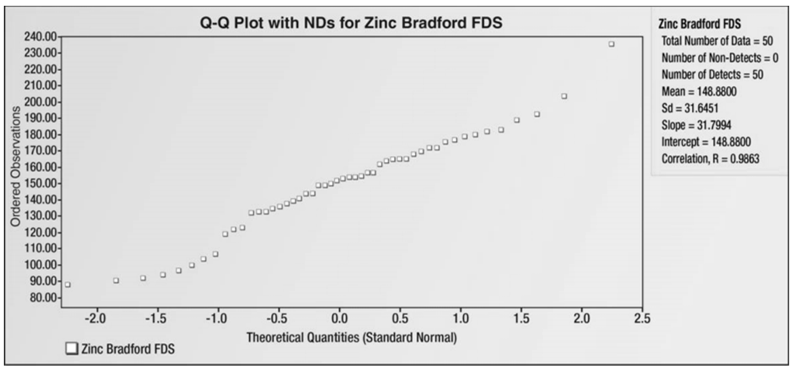


Figure 4-3. Q-plot example developed using USEPA's ProUCL statistical software package

ITRC RISK-3 Section 4.4.1

Data Source: Bradford et al 1996 and Solt 2010

Figure 4-3 from the RISK-3 document Data Source: from

Bradford, G.R., A.C. Change, A.L. Page, D. Bakhtar, J.A. Frampton, and H. Wright. 1996. "Background Concentrations of Trace Metals and Major Elements in California Soils." Kearny Foundation of Soil Science, Division of Agriculture and Natural Resources, University of California.

Solt, M.J. 2010. Multivariate Analysis of Lead in Urban Soil in Sacramento, CA, California State University, Sacramento.

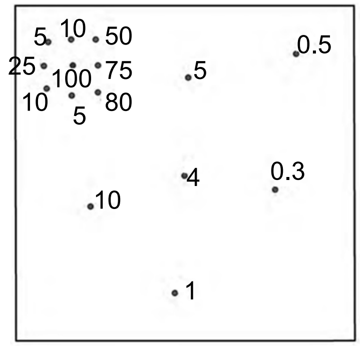
Q-plot example developed using USEPA's ProUCL statistical software package.

See the ITRC GSMC-1 document for information about ProUCL www.itrcweb.org/gsmc-1, Appendix D.14

40

2-D Maps Reveal Spatial Distribution

- 2-D map
- Pros: Provides spatial distribution of concentrations and location of highest detected concentration
- Cons: No temporal information



• = *sampling location*

Figure 6-10. Hypothetical exposure area with clustered data.

ITRC RISK-3 Section 4.4.1

Figure 6-10. Hypothetical exposure area with clustered data.

41

Select Conservative Screening Levels for Site Exposures

- **Issue**: Identifying appropriate screening levels
  - **Option** – Select applicable screening values consistent with the CSM and regulatory framework
- Screening levels
  - Conservative for site scenarios
  - Identify chemicals for further evaluation
  - Vary based on assumptions, risk targets, background
  - Are not cleanup levels
- Plan for changes in screening levels
  - Values may change
  - Exposure scenarios may change

ITRC RISK-3 Section 4.5.1

No associated notes.

42

Example – Screening Levels (SLs) are Conservative for the CSM

- Shallow creek in residential area; no edible-size fish
- Exposure scenario – wading
- Sediment - residential soil SLs
- Surface water – drinking water SLs

ITRC RISK-3 Section 4.5.1.1

Photo Source: B. Selcoe, used with permission

Example site in Illinois.

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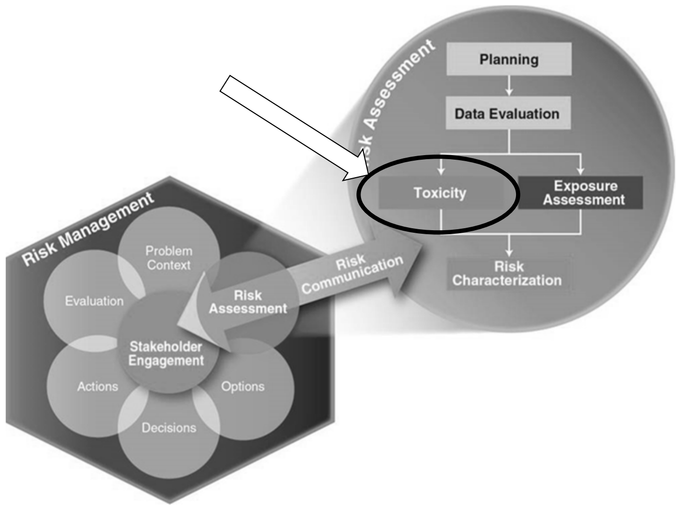
Many More Issues Addressed in Chapter 4

- Data Usability (Section 4.2)
  - Measurement units
  - Data representativeness
- Data Reduction Concerns (Section 4.3)
  - Duplicate samples
  - Pooling data
  - Non-detects
- Data Screening and Chemical Selection Processes (Section 4.5)
  - Chemicals with missing screening values
  - Consideration of background

No associated notes.

Toxicity (Chapter 5)



No associated notes.

45

Toxicity Assessment Overview

Risk = Toxicity x Exposure

Toxicity:
- What are the chemical's health effects?
- What is the relationship between exposure and health effects?

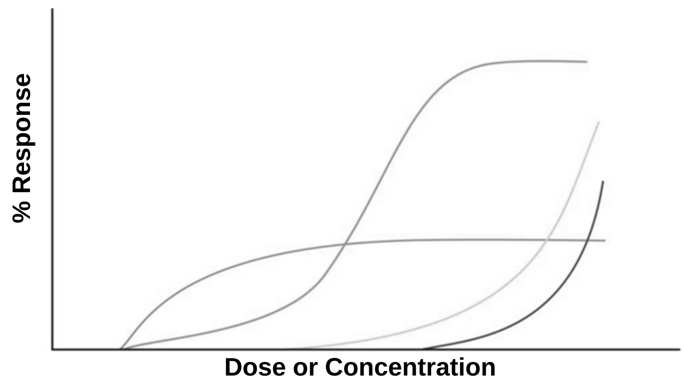
Exposure:
- How will people contact the chemical?
- What is the magnitude, frequency and duration of contact?

No associated notes.

46

Dose Response

- Relationship between the exposure and health effects



ITRC RISK-3 Appendix B

Source: NCEA, USEPA 2010

USEPA. 2010. "Overview of IRIS Human Health Effect Reference and Risk Values." Reading Packet HBA 202. Basics of Human Health Risk Assessment (HBA) Course Series. Washington, D.C.: United States Environmental Protection Agency.

NCEA - National Center for Environmental Assessment (www.epa.gov/ncea)

Toxicity Issues Encountered

- Toxicity values may be selected from multiple sources
  - e.g. tetrachloroethylene
- Toxicity values are reassessed and updated
  - e.g. trichloroethylene
- A toxicity value may not be adopted nor established
  - e.g. TPH

	SF_O	IUR	RfD_o	RfC_i
Contaminant	$(mg/kg\text{-}day)^{-1}$	$(mg/m^3)^{-1}$	mg/kg-day	mg/m^3
Tetrachloroethylene	2.1E-03	2.6E-07	6.0E-03	4.0E-02
Trichloroethylene	4.6E-02	4.1E-06	5.0E-04	2.0E-03
Total Petroleum Hydrocarbons (Aromatic Low)			4.0E-03	3.0E-02

USEPA Regional Screening Levels Table excerpt.

USEPA. 2015. USEPA Regional Screening Levels (RSL) Table.

USEPA. 2014e. USEPA Regional Screening Levels (RSL) User's Guide (November 2014) and Generic Tables. http://www2.epa.gov/risk/regional-screening-table-users-guide-june-2015

48

Sources of Toxicity Values

- Issue: Choosing among toxicity values from multiple sources
  - Adequate protection of human health?
  - Acceptance of assessment by regulatory agency?

ITRC RISK-3 Section 5.1.1

No associated notes.

Sources of Toxicity Values

- Options:
  - 2003 USEPA guidance
    - Tier 1 – USEPA's Integrated Risk Information System
    - Tier 2 – USEPA's Provisional Peer Reviewed Toxicity Values
    - Tier 3 – Other Sources – additional USEPA and non-USEPA sources, including toxicity values prepared by states and other agencies
  - Use USEPA guidance supplemented with 2007 Environmental Council of the States (ECOS) guidance
  - Use state agency toxicity values or hierarchy
    - For PCE, California did not adopt 2012 revised, less stringent IRIS values
  - Consult experts in toxicology

ITRC RISK-3 Appendix A

No associated notes.

50

Poll Question – Updated Toxicity Values

Poll Question

- Do you use EPA's hierarchy of toxicity values in your risk assessments?
  - Yes, always
  - No, we have another method
  - It depends
  - Don't know

No associated notes.

51

Updated Toxicity Values

- Issue: Change in toxicity value (e.g. trichloroethylene)

Noncancer Toxicity Value	State of CA (2009)	U.S. EPA (2011)	Relative Protectiveness
Reference Concentration (RfC; $\mu g/m^3$)	600	2	300-fold

- U.S. EPA TCE RfC = Accelerated Response Action Level (RAL)
- 10^{-5} Lifetime Cancer Risk is >2x RAL
- New decision criterion for vapor intrusion risk management

No associated notes.

52

Toxicity Value Unavailable

- Issue: Toxicity value is not readily available
  - e.g. perfluoroalkylated substances
- Options:
  - Determine if the value is needed to guide risk management decision
    - Is the contaminant co-located with another hazard?
    - Is the exposure pathway significant?

ITRC RISK-3 Section 5.1.2

No associated notes.

53

Toxicity Value Unavailable

- Options: (continued)
  - Use a surrogate value intended for
    - Different time frame (e.g. subchronic for chronic) or
    - Exposure route (e.g. oral for inhalation)
  - Superfund Health Risk Technical Support Center
    - Identify a value and develop a PPRTV
    - Identify a surrogate chemical
      - for example, Benzene for low-range aromatic TPH
    - (513) 569-7300
    - http://www.epa.gov/superfund/health/research.htm

No associated notes.

54

Additional Toxicity Issues in Chapter 5

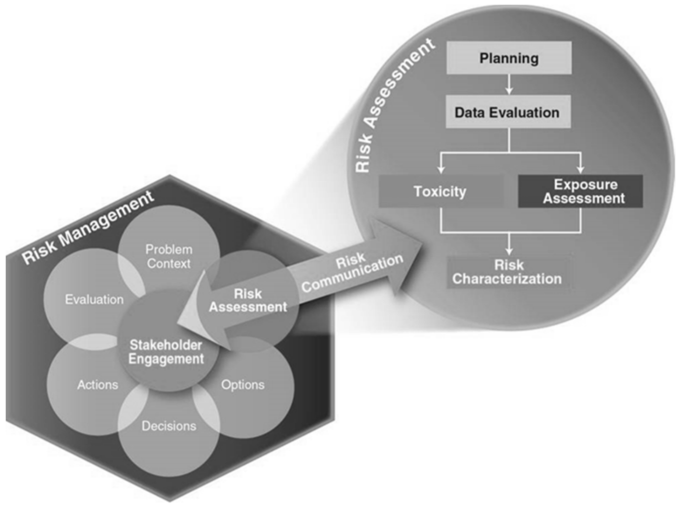
- Assessing toxicity of chemical groups and mixtures
- Assessing toxicity of mutagenic carcinogens
- Addressing toxicity of lead
- Understanding uncertainty in toxicity values

No associated notes.

55

Questions & Answers

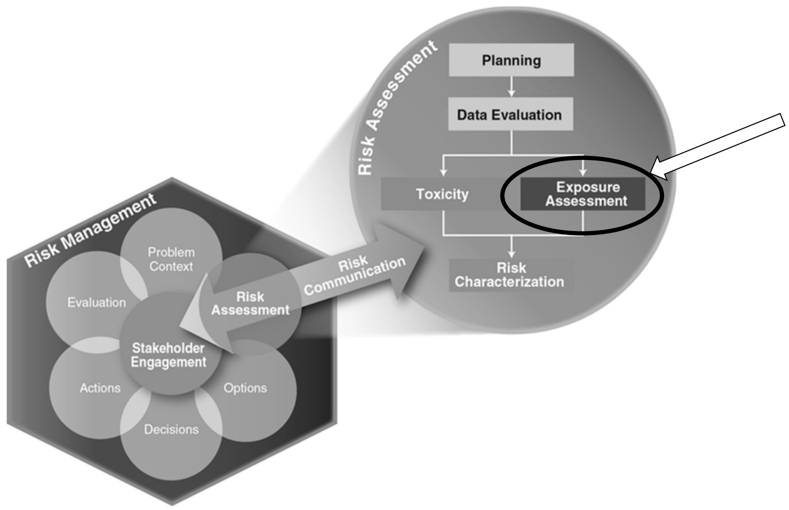
Follow ITRC



No associated notes.

56

Exposure Assessment (Chapter 6)



No associated notes.

57

Exposure Assessment Overview (Chapter 6)

$$\text{Risk} = \text{Toxicity} \times \text{Exposure}$$

- What are the chemical's health effects?
- What is the relationship between exposure and health effects?

- How will people contact the chemical?
- What is the magnitude, frequency and duration of contact?

No associated notes.

58

Exposure Assessment Overview (Chapter 6)

- Issues
  - Justifying site-specific exposure factors
  - Prorating exposure factors
  - Bioavailability
  - Exposure areas vs. exposure patterns
  - Exposure concentrations (modeling vs. measuring)
  - Modeling (for example, accounting for limited mass)
  - Uncertainty in estimating exposure concentrations
  - Site-specific exposure vs. background exposure

No associated notes.

59

Exposure Areas/Exposure Units

- **Issue**: Exposure areas often not representative of actual exposure patterns
  - Based on default exposure areas
  - Based on operational units or areas of concern

ITRC RISK-3 Section 6.2.1

No associated notes.

60

Poll Question – Exposure Area Basis

Poll Question

- Have you ever prepared or reviewed a risk assessment in which the area or unit of exposure was arbitrary?
  - Yes
  - No

No associated notes.

61

Exposure Areas/Exposure Units

- **Issue**: Exposure areas often not representative of actual exposure patterns
  - Based on default exposure areas
  - Based on operational units or areas of concern

Receptor Activity + Exposure Media → Exposure Area/Unit

No associated notes.

Exposure Areas/Exposure Units

- Different receptors will have different activity patterns and thus different exposure areas

No associated notes.

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Exposure Areas/Exposure Units

- Different receptors will have different activity patterns and thus different exposure areas
- Consistency between estimates of the exposure concentrations and the exposure patterns of the receptor(s) being evaluated
- Risk assessment may not adequately answer the site-specific risk management questions

No associated notes.

64

Exposure Areas/Exposure Units

- **Issue**: Exposure areas often not representative of actual exposure patterns
  - **Option** – Establish exposure areas based on known or anticipated uses

ITRC RISK-3 Section 6.2.1.1

No associated notes.

65

Exposure Areas/Exposure Units

Establish Exposure Areas Based on Known or Anticipated Uses

Conceptual Model for Potential Human Exposure

Example for Pathway-Exposure CSM

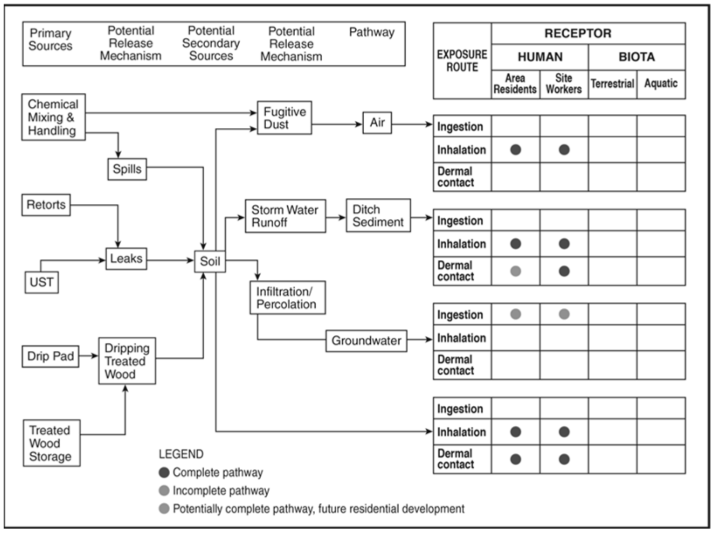


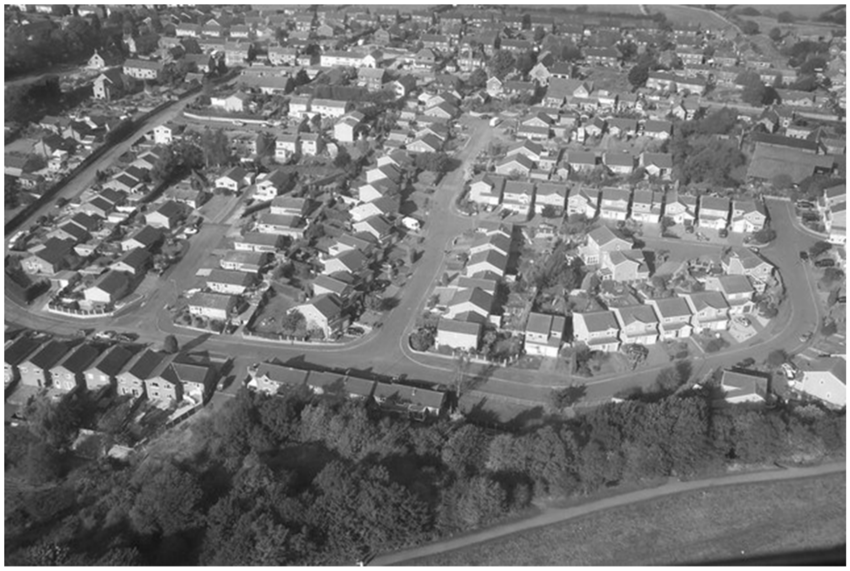
Figure Source
DTSC 2008

Figure source: DTSC. 2008. Proven Technologies and Remedies Guidance – Remediation of Metals in Soil. Sacramento, CA: California Environmental Protection Agency, Department of Toxic Substances Control. http://www.dtsc.ca.gov/PublicationsForms/upload/Guidance_Remediation-Soils.pdf.

66

Exposure Areas/Exposure Units

Establish Exposure Areas Based on Known or Anticipated Uses



No associated notes.

Exposure Areas/Exposure Units

- **Issue**: Exposure areas often not representative of actual exposure patterns
  - **Option** – Point-by-point risk calculations

ITRC RISK-3 Section 6.2.1.2

No associated notes.

68

Exposure Areas/Exposure Units

Point-By-Point Risk Calculations

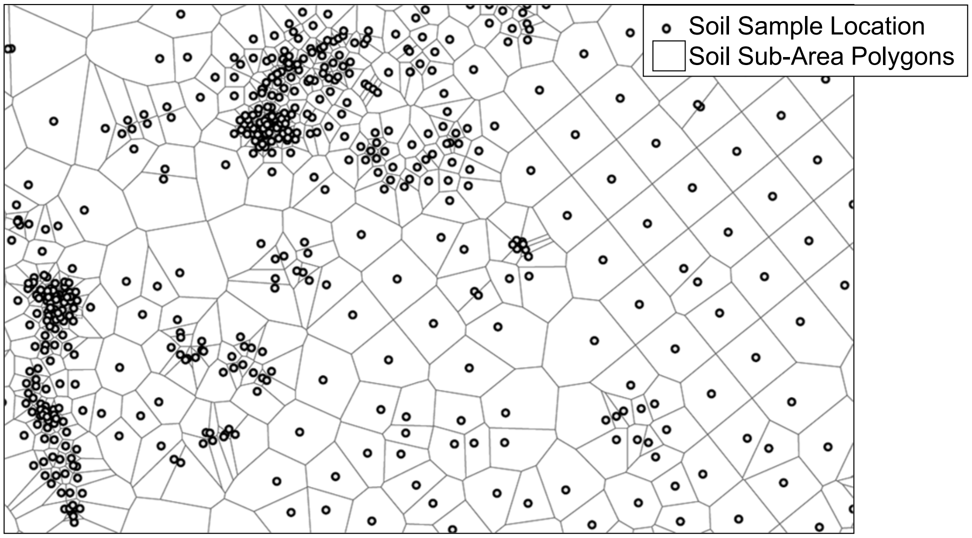


Figure 6-7. Soil sampling locations as individual exposure areas (represented by Thiessen polygons).

Figure 6-7. Soil sampling locations as individual exposure areas (represented by Thiessen polygons).

69

Exposure Areas/Exposure Units

Point-By-Point Risk Calculations

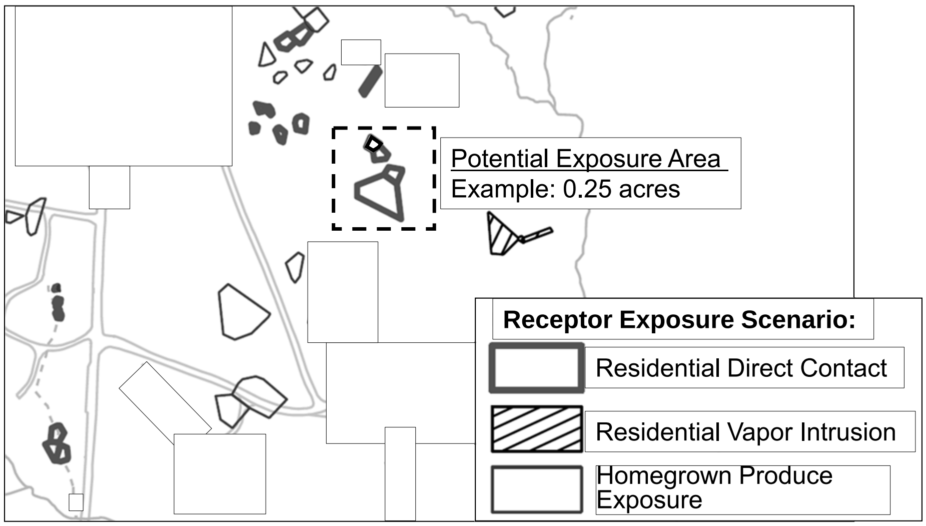


Figure 6-8. Locations potentially warranting further assessment or risk management.

Figure 6-8. Locations potentially warranting further assessment or risk management.

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Exposure Factors

- **Issue**: Justifying site-specific exposure factors
  - Exposure not routinely encountered
  - Default exposure factors not been established

ITRC RISK-3 Section 6.1.1

No associated notes.

71

Poll Question – Default exposure factors not available

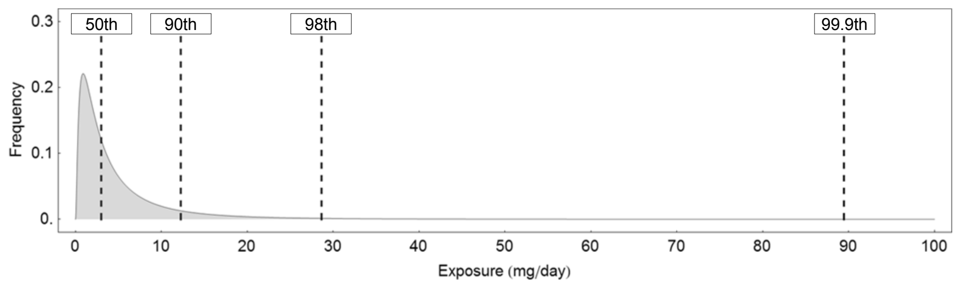
Poll Question

- Have you ever prepared or reviewed a risk assessment which involved the evaluation of exposures for which default exposure factors were not available?
  - Yes
  - No

No associated notes.

Exposure Factors

- **Issue**: Justifying site-specific exposure factors
  - **Option** – Probabilistic exposure assessment



ITRC RISK-3 Section 6.1.1.3

No associated notes.

73

Exposure Factors

- **Issue**: Justifying site-specific exposure factors

No associated notes.

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Exposure Factors

Justifying Using Probabilistic Exposure Assessment

$$\text{dose} = C \cdot \left(\frac{IR \cdot EF \cdot ED}{BW \cdot AT} \right)$$

Dose	=	mg chemical per kg body weight per day
C	=	contaminant concentration (mg/L)
IR	=	intake rate (L/day)
EF	=	exposure frequency (days/year)
ED	=	exposure duration (years)
BW	=	body weight (kg)
AT	=	averaging time (days)

No associated notes.

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Exposure Factors

Justifying Using Probabilistic Exposure Assessment

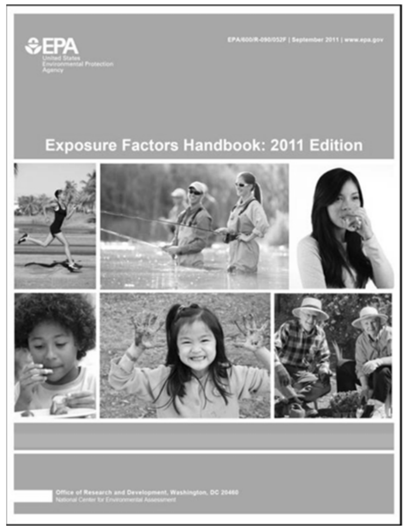
$$\text{dose} = C \cdot \left(\frac{IR \cdot EF \cdot ED}{BW \cdot AT} \right)$$

No associated notes.

76

Exposure Factors

Justifying Using Probabilistic Exposure Assessment



USEPA Exposure Factors Handbook, 2011

available from: http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252

USEPA. 2011c. *Exposure Factors Handbook: 2011 Edition*. EPA/600/R-09/052F. Washington, D.C.: United States Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252

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Exposure Factors

Justifying Using Probabilistic Exposure Assessment

Table 3-93. Estimated Water Ingestion During Water Recreation Activities (mL/hr)

Activity	Surface Water Study				Swimming Pool Study			
	N	Median	Mean	UCL	N	Median	Mean	UCL
Limited Contact Scenarios								
Boating	316	2.1	3.7	11.2	0	-	-	-
Canoeing	766				76			
no capsize		2.2	3.8	11.4		2.1	3.6	11.0
with capsize		3.6	6.0	19.9		3.9	6.6	22.4
all activities		2.3	3.9	11.8		2.6	4.4	14.1
Fishing	600	2.0	3.6	10.8	121	2.0	3.5	10.6
Kayaking	801				104			
no capsize		2.2	3.8	11.4		2.1	3.6	10.9
with capsize		2.9	5.0	16.5		4.8	7.9	26.8
all activities		2.3	3.8	11.6		3.1	5.2	17.0
Rowing	222				0			
no capsize		2.3	3.9	11.8		-	-	-
with capsize		2.0	3.5	10.6		-	-	-
all activities		2.3	3.9	11.8		-	-	-
Wading/splashing	0	-	-	-	112	2.2	3.7	1.0
Walking	0	-	-	-	23	2.0	3.5	1.0
Full Contact Scenarios								
Immersion	0	-	-	-	112	3.2	5.1	15.3
Swimming	0	-	-	-	114	6.0	10.0	34.8
TOTAL	2,705				662			

N = Number of participants.
UCL = Upper confidence limit (i.e. mean +1.96 × standard deviation).
\- = No data.

Source: Dorevitch et al. , 2011.

Table from USEPA 2011

USEPA. 2011c. *Exposure Factors Handbook: 2011 Edition*. EPA/600/R-09/052F. Washington, D.C.: United States Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252

Exposure Factors

Justifying Using Probabilistic Exposure Assessment

Table 3-55. Total Tap Water Intake (mL/day) for Both Sexes Combined[a]

Age (years)	Number of Observations	Mean	SD	SE of Mean	Percentile Distribution								
					1	5	10	25	50	75	90	95	99
<0.5	182	272	247	18	*	0	0	80	240	332	640	800	*
0.5 to 0.9	221	328	265	18	*	0	0	117	268	480	688	764	*
1 to 3	1,498	646	390	10	33	169	240	374	567	820	1,162	1,419	1,899
4 to 6	1,702	742	406	10	68	204	303	459	660	972	1,302	1,520	1,932
7 to 10	2,405	787	417	9	68	241	318	484	731	1,016	1,338	1,556	1,998
11 to 14	2,803	925	521	10	76	244	360	561	838	1,196	1,621	1,924	2,503
15 to 19	2,998	999	593	11	55	239	348	587	897	1,294	1,763	2,134	2,871
20 to 44	7,171	1,255	709	8	105	337	483	766	1,144	1,610	2,121	2,559	3,634
45 to 64	4,560	1,546	723	11	335	591	745	1,057	1,439	1,898	2,451	2,870	3,994
65 to 74	1,663	1,500	660	16	301	611	766	1,044	1,394	1,873	2,333	2,693	3,479
≥75	878	1,381	600	20	279	568	728	961	1,302	1,706	2,170	2,476	3,087
Infants (ages <1)	403	302	258	13	0	0	0	113	240	424	649	775	1,102
Children (ages 1 to 10)	5,605	736	410	5	56	192	286	442	665	960	1,294	1,516	1,954
Teens (ages 11 to 19)	5,801	965	562	7	67	240	353	574	867	1,246	1,701	2,026	2,748
Adults (ages 20 to 64)	11,731	1,366	728	7	148	416	559	870	1,252	1,737	2,268	2,707	3,780
Adults (ages ≥65)	2,541	1,459	643	13	299	598	751	1,019	1,367	1,806	2,287	2,636	3,338
All	26,081	1,193	702	4	80	286	423	690	1,081	1,561	2,092	2,477	3,415

[a] Total tap water is defined as "all water from the household tap consumed directly as a beverage or used to prepare foods and beverages."
* Value not reported due to insufficient number of observations.
SD = Standard deviation.
SE = Standard error.

Source: Ershow and Cantor, 1989.

Table from USEPA 2011

USEPA. 2011c. *Exposure Factors Handbook: 2011 Edition*. EPA/600/R-09/052F. Washington, D.C.: United States Environmental Protection Agency, Office of Research and Development, National Center for Environmental Assessment. http://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252

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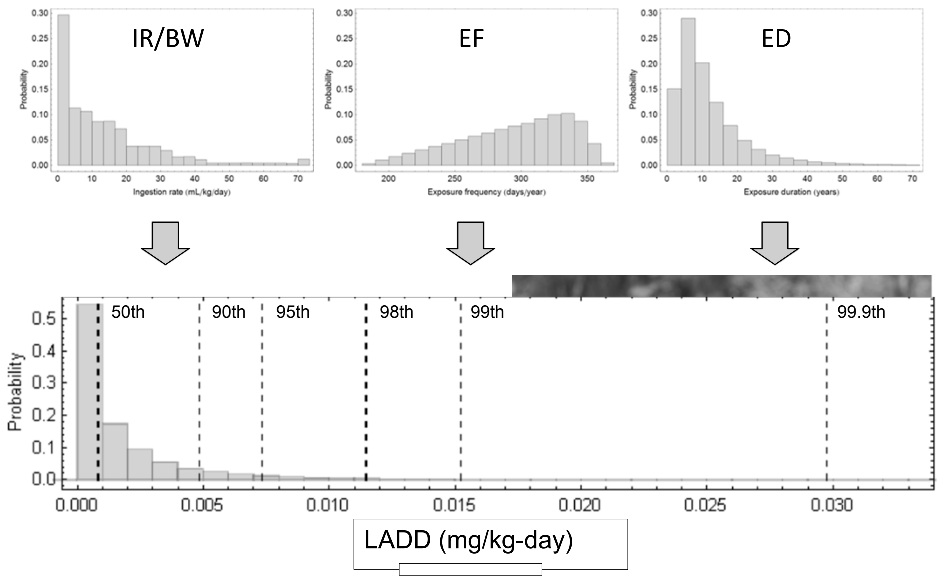
Exposure Factors

Justifying Using Probabilistic Exposure Assessment



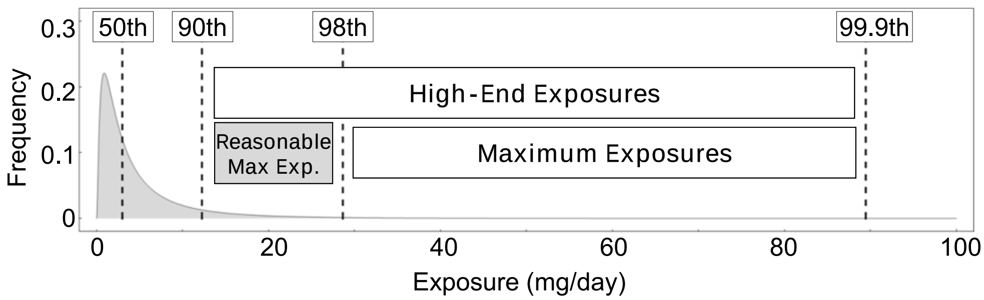
No associated notes.

80

Exposure Factors

Justifying Using Probabilistic Exposure Assessment

- "Reasonable Maximum Exposure" or RME, which is defined as "conservative but within a realistic range of exposure." - National Contingency Plan (NCP)



For more information see USEPA 2004. "An Examination of EPA Risk Assessment Principles and Practice"

USEPA. 2004a. *An Examination of EPA Risk Assessment Principles and Practices*. EPA/100/B-04/001. Washington D.C.: United States Environmental Protection Agency, Office of Science Advisor Staff Paper. http://itrcweb.org/FileCabinet/GetFile?fileID=6879

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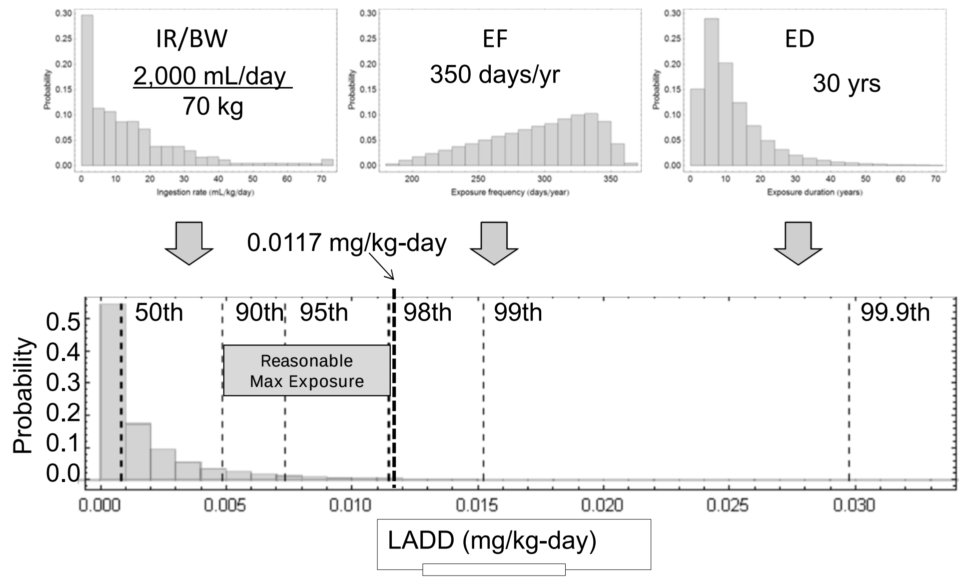
Exposure Factors

Justifying Using Probabilistic Exposure Assessment



No associated notes.

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Exposure Factors

Justifying Using Probabilistic Exposure Assessment

- **Issue**: Justifying site-specific exposure factors
  - **Option** – Probabilistic exposure assessment
  - To determine reasonable "values" to use for each exposure factor
  - Demonstrate that use of these values would result in exposure within 90-98% (reasonable maximum exposure)

No associated notes.

83

Exposure Concentrations

- **Issue**: Conservative fate and transport models
  - Infinite source mass assumptions
  - Uniform distribution of contamination
  - No contaminant attenuation
  - Instantaneous equilibrium partitioning

ITRC RISK-3 Section 6.2.3

No associated notes.

84

Exposure Concentrations

- **Issue**: Conservative fate and transport models
  - **Option** – Use mass balance check
  - Chemical concentration distribution should be well defined
  - Likely will require additional field data

ITRC RISK-3 Section 6.2.3.2

No associated notes.

85

Exposure Concentrations

Using Mass Limited Check

Mass Balance (Limit) Check

- Estimates mass to which receptor exposed (over period of exposure)
- Total mass in contaminated source area
- Mass of exposure can’t exceed mass in source

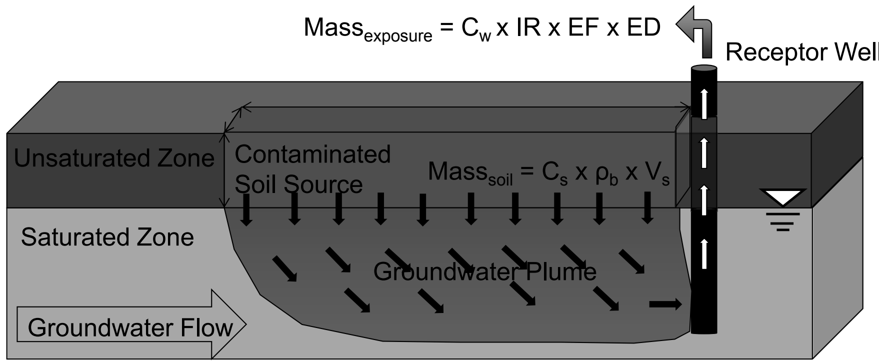

Figure 6-9. Soil migration to groundwater – mass limited check.

Figure 6-9. Soil migration to groundwater – mass limited check.

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Exposure Concentrations

- **Issue**: Accounting for uncertainty
  - Exposure concentration intended to be average “site-related” concentrations routinely contacted by receptor
  - Based upon actual monitoring data
  - Arithmetic average (mean) concentration may not provide defensible estimate of true average concentration

ITRC RISK-3 Section 6.2.4

No associated notes.

87

Exposure Concentrations

- **Issue**: Accounting for uncertainty
  - **Option** – Upper confidence limits on mean

  - Provides conservative estimate of the average exposure concentration
  - Accounts for uncertainty given limited data

ITRC RISK-3 Section 6.2.4.1

No associated notes.

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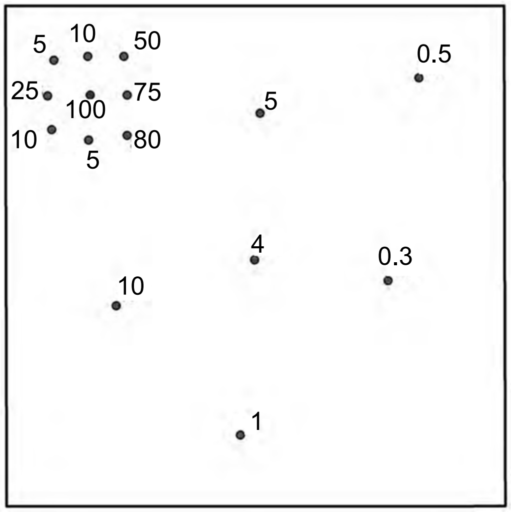
Exposure Concentrations



Hypothetical Exposure Area

$$dose = C \cdot \left(\frac{IR \cdot EF \cdot ED}{BW \cdot AT} \right)$$

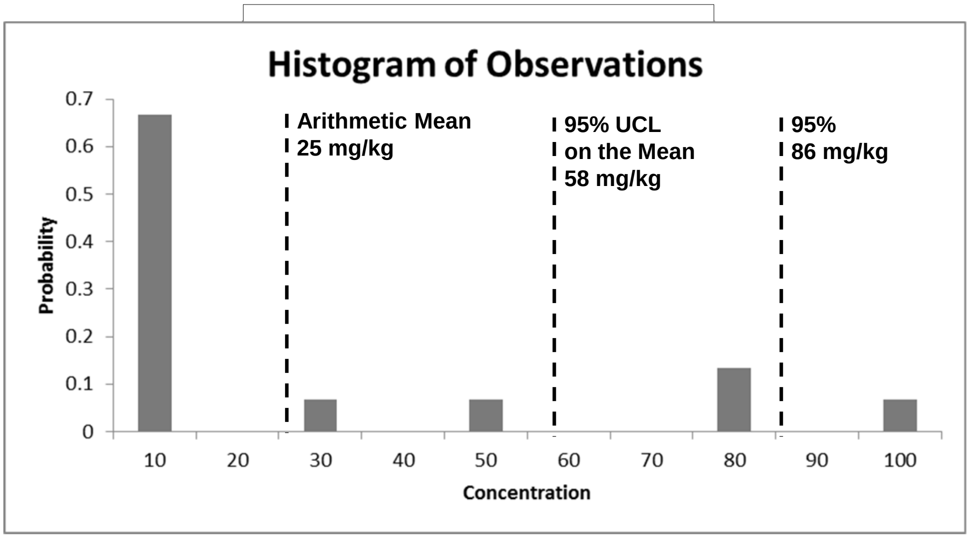
Dose = mg chem/kg body weight per day
C = contaminant concentration (mg/kg)
IR = intake rate (kg/day)
EF = exposure frequency (days/year)
ED = exposure duration (years)
BW = body weight (kg)
AT = averaging time (days)

What is the average concentration in this area?

Hypothetical exposure area example

Exposure Concentrations

Upper Confidence Limits on the Mean

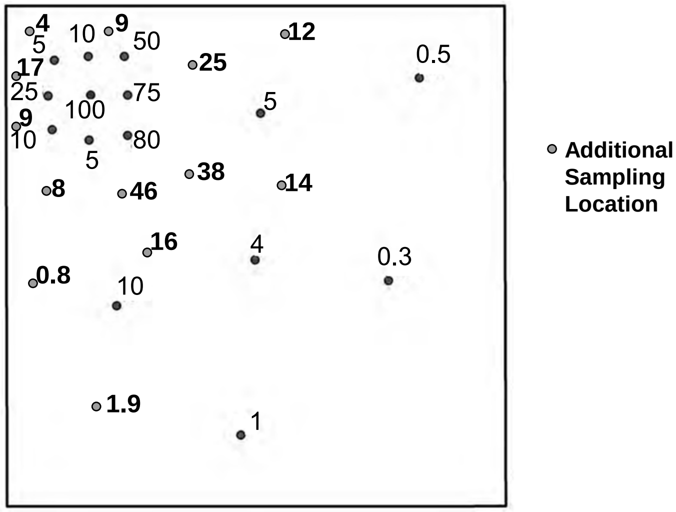


Based on 15 Samples

No associated notes.

90

Exposure Concentrations



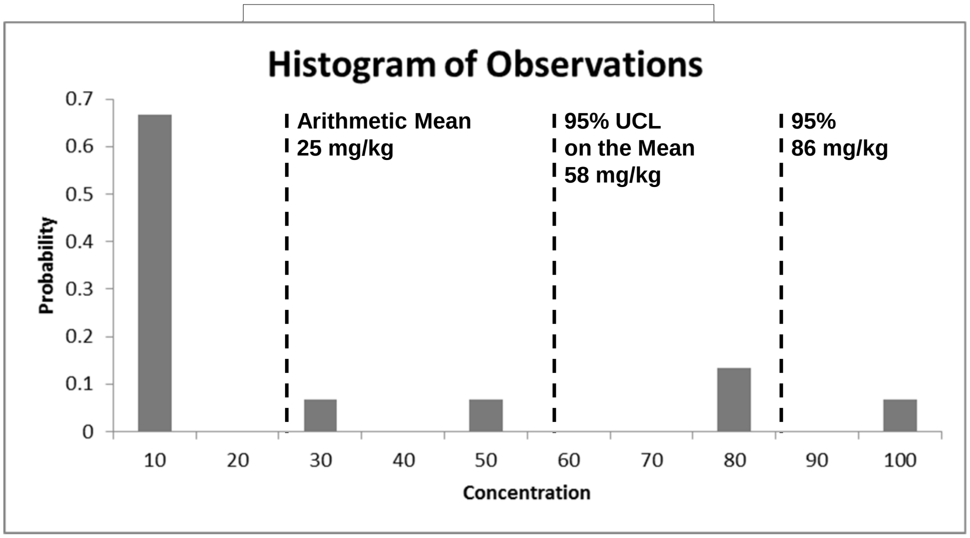
Hypothetical Exposure Area

No associated notes.

91

Exposure Concentrations

Upper Confidence Limits on the Mean



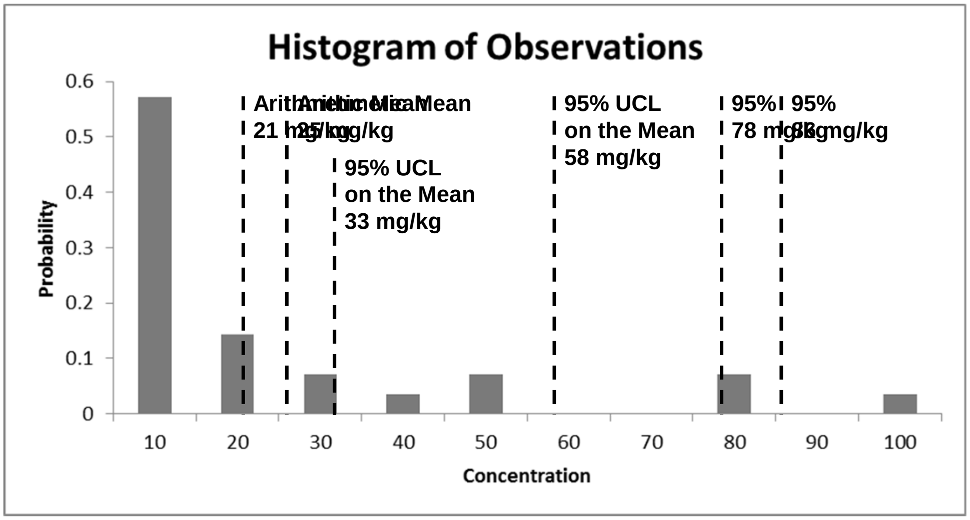
Based on 15 Samples

No associated notes.

92

Exposure Concentrations

Upper Confidence Limits on the Mean



Based on 28 Samples

No associated notes.

93

Exposure Concentrations

- **Issue**: Accounting for uncertainty
  - **Option** – Area-weighted averaging

  - Used to estimate appropriate exposure concentrations
  - Where data are unevenly distributed, UCLs on the mean may not provide reasonable estimates of exposure concentration
  - Statistical methods can assess the uncertainty in area-weighted averages (e.g., nonparametric bootstrap method with weighted bootstrap resampling)

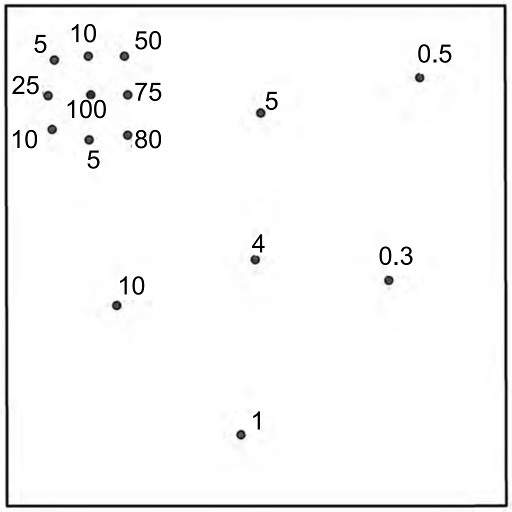
ITRC RISK-3 Section 6.2.4.2

No associated notes.

94

Exposure Concentrations

Area-Weighted Average



Hypothetical Exposure Area

No associated notes.

95

Exposure Concentrations

Area-Weighted Average

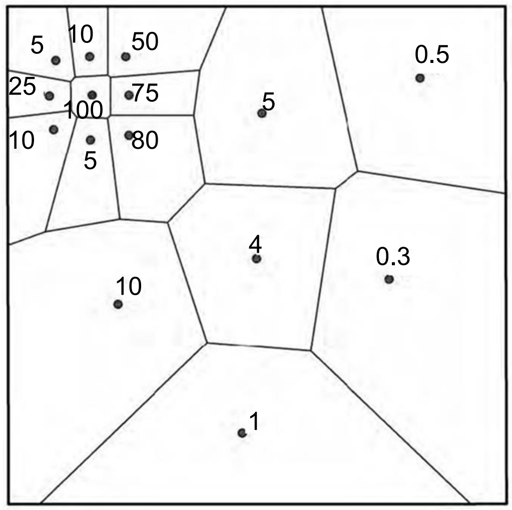
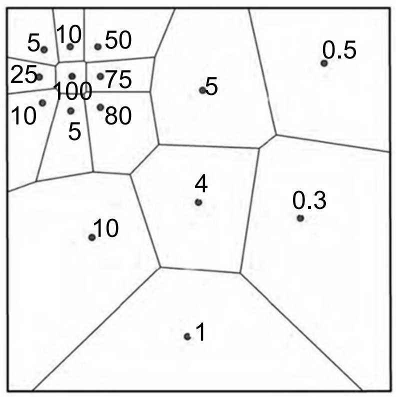


Figure 6-11. Hypothetical Exposure Area with Thiessen Polygons

Figure 6-11. Hypothetical one-acre exposure area with Thiessen polygons.

Exposure Concentrations

Area-Weighted Average



Hypothetical Exposure Area

95% UCL on the mean = 58 mg/kg

Sample Location	Concentration (mg/kg)	Area (acres)	Area x Concentration
1	1	0.34	0.34
2	10	0.05	0.53
3	5	0.04	0.18
4	10	0.02	0.21
5	50	0.06	2.87
6	75	0.03	2.18
7	100	0.01	1.31
8	24	0.02	0.47
9	5	0.05	0.23
10	80	0.07	5.65
11	5	0.20	1.00
12	0.5	0.24	0.12
13	0.3	0.39	0.12
14	4	0.18	0.71
15	10	0.32	3.20
	Totals:	2.0	19.12
	Area Weighted Average:		9.48

No associated notes.

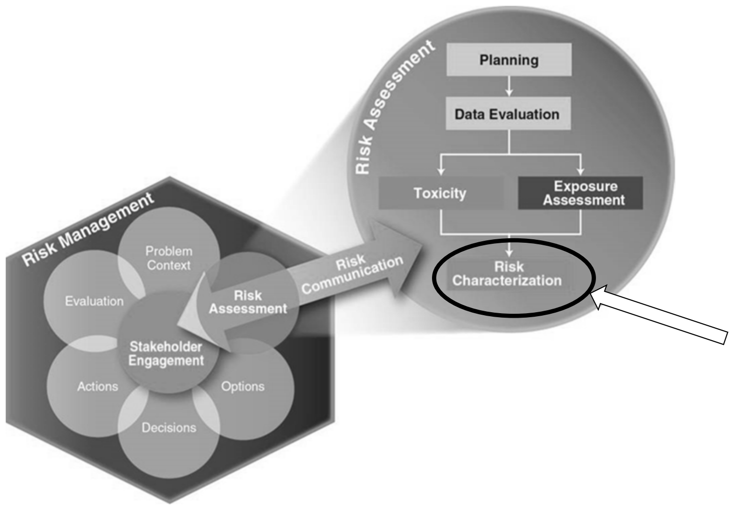
97

Exposure Assessment Overview (Chapter 6)

- Issues
  - Justifying site-specific exposure factors
  - Prorating exposure factors
  - Bioavailability
  - Exposure areas vs. exposure patterns
  - Exposure concentrations (modeling vs. measuring)
  - Modeling (for example, accounting for limited mass)
  - Uncertainty in estimating exposure concentrations
  - Site-specific exposure vs. background exposure

No associated notes.

Risk Characterization (Chapter 7)



No associated notes.

99

Risk Characterization Overview (Chapter 7)

- Integration of information from the toxicity assessment and exposure assessment to draw an overall conclusion about risk
- Provides: Basis for the calculations

$$\text{Risk} = \text{Toxicity} \times \text{Exposure}$$

Toxicity:

- What are the chemical's health effects?
- What is the relationship between exposure and health effects?

Exposure:

- How will people contact the chemical?
- What is the magnitude, frequency and duration of contact?

No associated notes.

100

Presentation of Risk Results

- **Issue**: Unclear presentation of risk results
  - **Option** – Organized and systematic presentation
  - Identify chemicals and pathways contributing most significantly to the risks
  - Provide an understanding of the uncertainties and bias inherent in the evaluation
  - Presentation of results should include:
    - Risk for each chemical
    - Risk by route of exposure
    - Risk by medium
    - Total risk

ITRC RISK-3 Section 7.2.1.1

No associated notes.

101

Example – Construction Worker Scenario

- Exposure media include soil and groundwater
- Chemicals include arsenic and benzo(a)pyrene “B(a)P”

No associated notes.

102

Example – Construction Worker Scenario

- Potentially complete exposure pathways include:
  - Incidental ingestion of soil
  - Dermal exposure to soil
  - Dermal contact with groundwater

No associated notes.

103

Risk Results For Each Chemical

- Presentation of results should include:
  - Risk for each chemical from soil ingestion

Chemical	RME Soil Concentration mg/kg	ADD mg/kg-day	Oral RfD mg/kg-day	HQ	LADD mg/kg-day	CSF $(mg/kg\text{-}day)^{-1}$	Cancer Risk
Arsenic	9.14E+00	6.44E-06	3.00E-04	0.02	9.20E-08	1.50E+00	1E-07

RME = Reasonable Maximum Exposure
ADD = Average Daily Dose
RfD = Reference Dose
HQ = Hazard Quotient
LADD = Lifetime Average Daily Dose
CSF = Cancer Slope Factor

No associated notes.

Risk Results By Route of Exposure

- Presentation of results should include:
  - Risk by route of exposure:
    - Soil ingestion

Chemical	RME Concentration in Soil mg/kg	ADD mg/kg-day	Oral RfD mg/kg-day	HQ	LADD mg/kg-day	Oral CSF $(mg/kg\text{-}day)^{-1}$	Cancer Risk
Arsenic	9.14E+00	6.44E-06	3.00E-04	0.02	9.20E-08	1.50E+00	1E-07
B(a)P	6.03E+00	4.25E-06	NA	--	6.07E-08	7.30E+00	4E-07

    - Dermal exposure to soil

Chemical	RME Concentration in Soil mg/kg	ADD mg/kg-day	Dermal RfD mg/kg-day	HQ	LADD mg/kg-day	Dermal CSF $(mg/kg\text{-}day)^{-1}$	Cancer Risk
Arsenic	9.14E+00	6.37E-07	3.00E-04	0.002	9.11E-09	1.50E+00	1E-08
B(a)P	6.03E+00	1.82E-06	NA	--	2.60E-08	7.30E+00	2E-07

No associated notes.

105

Risk Results by Medium

- Presentation of results should include:
  - Risk by medium

Soil

Chemical	Incidental Ingestion of Soil		Dermal Exposure to Soil		Total Hazard and Risk	
	HQ	Cancer Risk	HQ	Cancer Risk	HQ	Cancer Risk
Arsenic	0.02	1E-07	0.002	1E-08	0.02	1E-07
B(a)P	--	4E-07	--	2E-07	--	6E-07
				TOTAL	0.02	7E-07

Groundwater

Chemical	Dermal Exposure to Groundwater		Total Hazard and Risk	
	HQ	Cancer Risk	HQ	Cancer Risk
Arsenic	0.1	5E-05	0.1	5E-05
B(a)P	--	2E-05	--	2E-05
		TOTAL	0.1	7E-05

No associated notes.

106

Presentation of Total Risk

- Presentation of results should include:
  - Total Risk

Chemical	Incidental Ingestion of Soil		Dermal Exposure to Soil		Dermal Exposure to Groundwater		Total Hazard and Risk	
	HQ	Cancer Risk	HQ	Cancer Risk	HQ	Cancer Risk	HI	Cancer Risk
Arsenic	0.02	1E-07	0.002	1E-08	0.1	5E-05	0.1	5E-05
B(a)P	--	4E-07	--	2E-07	--	2E-05	--	2E-05
						TOTAL	0.1	7E-05

$$\text{Cumulative Risk} = \sum_i \text{Risk}_i \qquad \text{HI} = \sum_i \text{HQ}_i$$

No associated notes.

107

Alternatives To Default Assumptions

- **Issue**: Default assumptions
  - **Option** – Alternatives to default assumptions
  - Excerpt of Table D-1

Table D-1: Common risk assessment defaults and potential site-specific options

Component of Risk Assessment	Route of Exposure	Chemicals	Common Default	Possible Options
Characterization	All	All	Maximum detected or UCL on biased samples	Soil/Sediment - perform Outlier test, address hot spot separately, calculate exposure point concentration that is true to the data distribution (area-weighted averages) Groundwater - use more reasonable/average exposure point concentration, use data from most recent rounds (where stabilized)
Characterization	All	PAHs, dioxins, pesticides, metals (commonly As)	All concentrations are presumed site-related	Utilize site-specific or literature values to quantitatively account for background contribution. Determine whether site-related using lines of evidence approach.
Exposure	All	All	Residential exposure may be possible anywhere	Selection of future land use through access planning documents or interview planners, evaluate feasibility of deed restrictions, identify areas of relatively lower concentrations

ITRC RISK-3 Section 7.1.1.1 and Appendix D

No associated notes.

108

Account For Background

- **Issue**: Default assumptions
  - **Option** – Account for background

Background arsenic in groundwater

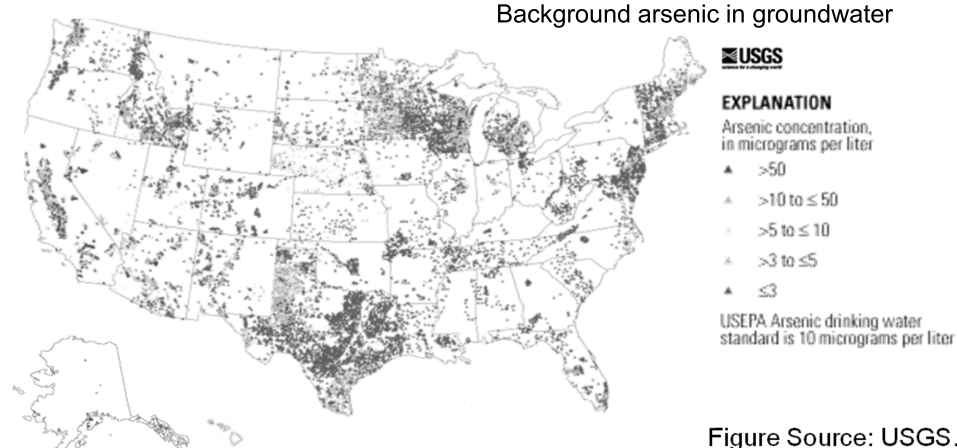


Figure Source: USGS.
Available from http://water.usgs.gov/nawqa/trace/arsenic/

Figure Source: USGS.
Available from http://water.usgs.gov/nawqa/trace/arsenic/

See also

http://pubs.usgs.gov/fs/2000/fs063-00/fs063-00.html

109

Account For Background

- Presentation of risk without background arsenic

Chemical	Incidental Ingestion of Soil		Dermal Exposure to Soil		Dermal Exposure to Groundwater		Total Hazard and Risk	
	HQ	Cancer Risk	HQ	Cancer Risk	HQ	Cancer Risk	HI	Cancer Risk
Arsenic	0.02	1E-07	0.002	1E-08	0.1	5E-05	0.1	5E-05
B(a)P	--	4E-07	--	2E-07	--	2E-05	--	2E-05
Total							0.1	7E-05
Risk Attributable To Background Arsenic							0.08	3E-05
Total Risk Without Background (Site Risk)							0.04	4E-05

- Qualitatively discuss background contribution to total risk

No associated notes.

110

Poll Question – Uncertainty

Poll Question

- Have you reviewed a risk assessment with a generic or incomplete uncertainty section?
  - Yes, frequently
  - Yes, a few times
  - No

No associated notes.

111

Uncertainty and Bias

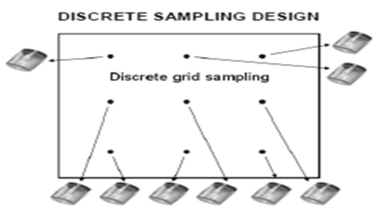
- Uncertainty refers to a lack of knowledge of how well the calculated results represent the actual risks
  - Unknown amount of variability
  - Can lead to over- or under-estimation of potential risk
- Protective bias can be used to address uncertainty
  - Shifts all results in a “conservative” direction

ITRC RISK-3 Section 7.3.1

No associated notes.

Uncertainty and Bias

- **Issue**: Unclear presentation of uncertainty and bias in the risk results
  - **Option** – Provide information so that uncertainties and bias can be understood
  - **Option** – Provide detailed consideration of toxicological assumptions
  - **Option** – Provide detailed consideration of exposure assumptions
  - **Option** – Include multiple descriptors of risk



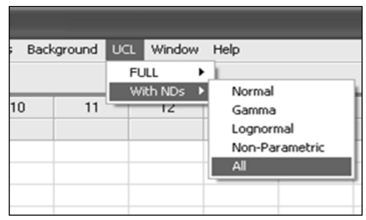


Figure Sources: ITRC 2012, ISM-1; USEPA 2010, ProUCL

Figure sources:

USEPA. 2010. ProUCL Version 4.1.00 Technical Guide (Draft). EPA/600/R-07/041. Washington, DC: United States Environmental Protection Agency. http://www.epa.gov/osp/hstl/tsc/ProUCL_v4.1_tech.pdf.

ITRC. 2012. Incremental Sampling Methodology. ISM-1. Washington, D.C.: Interstate Technology & Regulatory Council. http://www.itrcweb.org/Ism-1/Executive_Summary.html.

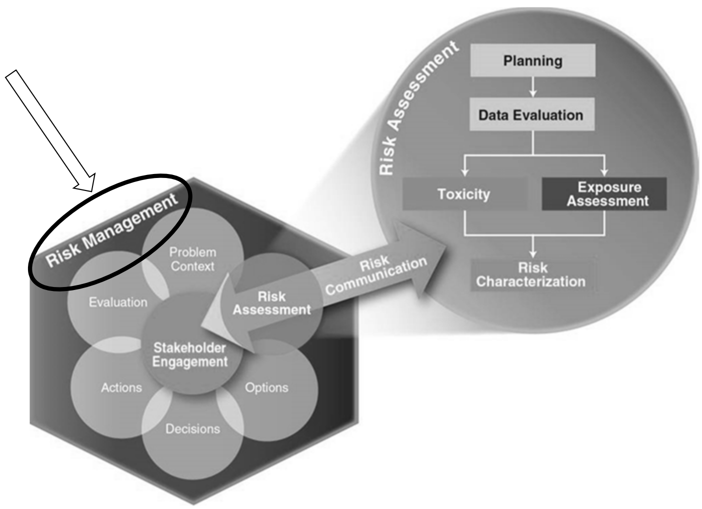
113

Other Issues Addressed in Chapter 7

- Summation of risk results for multiple media or pathways
- Considerations for probabilistic risk assessment
- Resources and tools
  - Tools available to calculate risk
    - Spatial Analysis and Decision Assistance http://www.sadaproject.net
    - Army Risk Assessment Modeling System http://el.erdc.usace.army.mil/arams/arams.html
    - EPA Regional Screening Level (RSL) Calculator http://epa-prgs.ornl.gov/cgi-bin/chemicals/csl_search
    - Risk Assessment Information System (RAIS) Contaminated Media (Risk) Calculator http://rais.ornl.gov

No associated notes.

Risk Management (Chapter 8)



No associated notes.

115

Risk Management Overview (Chapter 8)

- The process of identifying, evaluating, selecting, and implementing actions to reduce risk to human health
  - Science
  - Policy
  - Professional judgment
  - Social, Political and Economic Concerns

Figure 8-1. Risk management process.
Source: Adapted from Commission 1997

Figure Source: Adapted from Commission, Presidential/Congressional. 1997. "Framework for Environmental Health Risk Management. Final Report, Volume 1." Washington, D.C.: The Presidential/Congressional Commission on Risk Assessment and Risk Management. http://www.riskworld.com/riskcommission/default.html.

116

Poll Question – Changes in Land Use

- Have the land use assumptions for your projects ever changed after the risk assessment was completed?
  - Yes, frequently
  - Yes, a few times
  - No

No associated notes.

117 **Risk Assessment to Inform Risk Management**

- **Issue**: Accounting for changes in scientific consensus or land use
  - **Option** – Have ongoing communication between Project Managers and Risk Assessors

ITRC RISK-3 Section 8.2.1

No associated notes.

118

Risk Assessment to Inform Risk Management

- **Issue**: Accounting for changes in scientific consensus or land use
  - **Option** – Perform a qualitative or semi-quantitative reevaluation
    - Focus on issues pertinent to a specific risk management decision
    - Small changes may not need to be updated

ITRC RISK-3 Section 8.2.1.2

No associated notes.

119

Uncertainty in Numerical Risk Estimates

- **Issue**: Full consideration of uncertainty in numerical risk estimates
  - **Option** – Probabilistic uncertainty evaluation

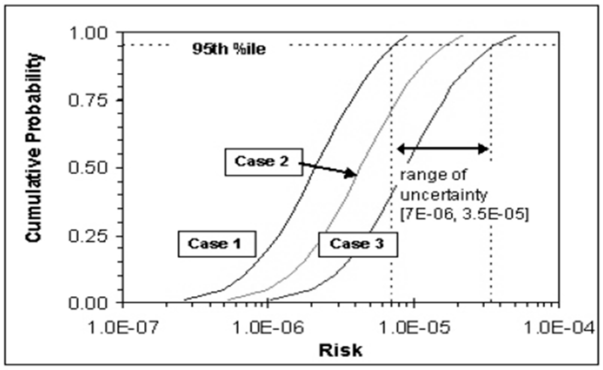


Figure Source: USEPA 2001 Risk Assessment Guidance for Superfund Volume III Part A. Figure 3-3

ITRC RISK-3 Section 8.2.2.3

USEPA. 2001c. *Risk Assessment Guidance for Superfund (RAGS), Volume III, Part A: Process for Conducting Probabilistic Risk Assessment*. EPA 540/R-02/002. Washington, D.C.: United States Environmental Protection Agency, Office of Emergency and Remedial Response. http://itrcweb.org/FileCabinet/GetFile?fileID=6872

120

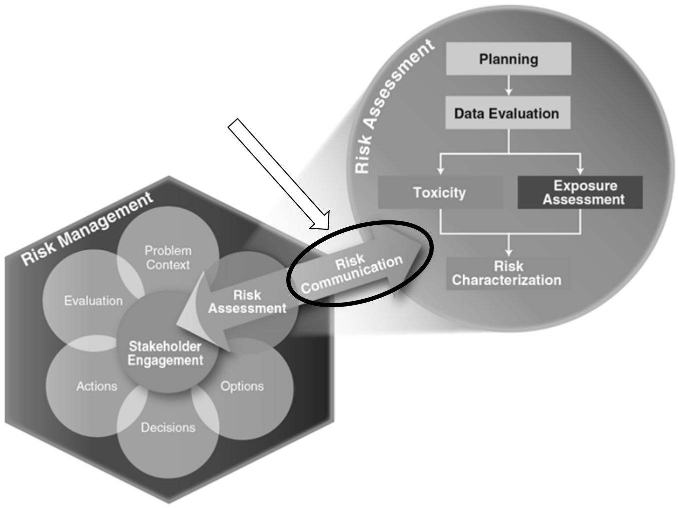
Other Issues Addressed in Chapter 8

- Risk management in project planning
- Other factors in risk management
  - Use guidance to identify other factors
  - Apply sustainability as the organizing principle for risk management
  - Facilitate stakeholder acceptance
- Resources and tools

No associated notes.

121

Risk Communication (Chapter 9)



No associated notes.

122

Risk Communication (Chapter 9)

- Goal is for all stakeholders to have a common understanding of how the risk assessment effectively support risk management decisions
- Designed to be iterative and to inform the risk assessment and risk management decisions
- Interwoven and important element of the risk assessment process

No associated notes.

123

Risk Communication (Chapter 9)

- Issues
  - When to Soliciting Stakeholder Input
  - Risk Perception and Interpretation Create Challenges
  - Identifying Effective Presentation Strategies

No associated notes.

124

Risk Communication

- **Issue**: Risk Perception and Interpretation Create Challenges

  Option – Be aware of, and address, possible differences in perceived risks

ITRC RISK-3 Section 9.2.1.1

No associated notes.

125

Risk Communication

- **Issue**: Risk Perception and Interpretation Create Challenges
  - Subjective context of the perceiver (qualitative personal views) as important as (quantified) risk in influencing perception of hazard
  - Must not underestimate the importance and validity of risk perception

No associated notes.

126

Risk Communication

Be Aware of Risk Perceptions

MORE RISK, LESS FEAR ⟷ *MORE FEAR, LESS RISK*

1:200	Risk of Being Hospitalized	1:6,000,000
1:30,000	Risk of Being Killed	1:600,000,000

No associated notes.

127

Risk Communication

Be Aware of Risk Perceptions

- Numerical Risk Estimates
  - Voluntary/involuntary
  - Dreaded or catastrophic event
- Personal Context
  - Equity
  - Fairness
  - Control
  - Levels of Trust in the Institution or Industry
  - Familiarity

No associated notes.

128

Risk Communication

- **Issue**: Risk Perception and Interpretation Create Challenges

  Option – Use effective risk communication methods

ITRC RISK-3 Section 9.2.1.2

No associated notes.

129

Risk Communication

Use Effective Risk Communication Methods

- Accept and involve the public as a legitimate partner
- Plan carefully and evaluate your efforts
- Listen to the public's specific concerns
- Be honest, frank, and open
- Coordinate and collaborate with other credible sources
- Meet the needs of the media
- Speak clearly and with compassion

ITRC RISK-3 Section 9.2.1.2

USEPA. 1988.
Seven Cardinal Rules of Risk Communication.

USEPA. 1988b. *Seven Cardinal Rules of Risk Communication*. OPA-87-020. Washington, D.C.: United States Environmental Protection Agency. http://itrcweb.org/FileCabinet/GetFile?fileID=6889

130

Risk Communication

- **Issue**: Identifying Effective Presentation Strategies

  Option – Develop an appropriate message for communication with the public

ITRC RISK-3 Section 9.3.1.1

No associated notes.

131

Risk Communication

Develop and Appropriate Message

Message Mapping

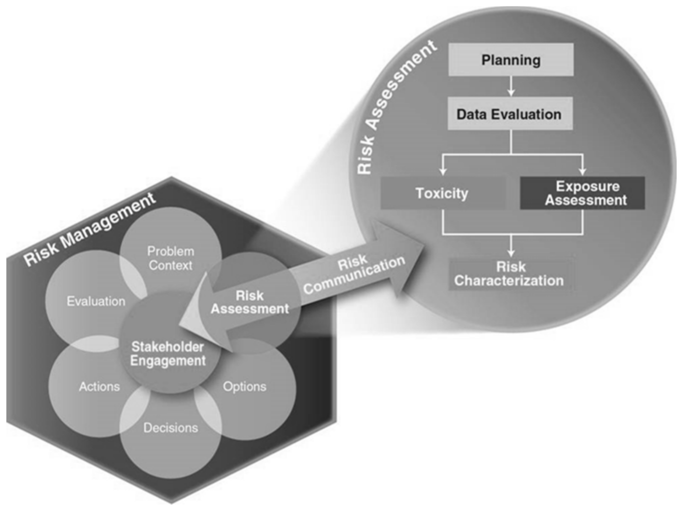
1. Identify stakeholders
2. Elicit stakeholder concern(s)
3. Identify common concern(s)
4. Develop key message(s)
5. Develop supporting information
6. Test the message
7. Plan for delivery

ITRC RISK-3 Section 9.3.1.1

USEPA. 2007. Effective Risk and Crisis Communication During Water Security Emergencies.

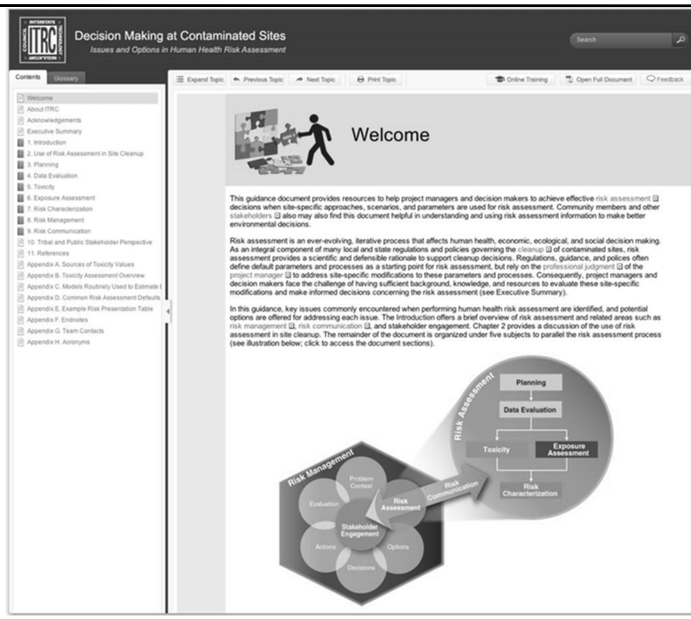
USEPA. 2007g. *Effective Risk and Crisis Communication During Water Security Emergencies*. EPA/600/R-07/027. Washington, D.C.: United States Environmental Protection Agency. http://itrcweb.org/FileCabinet/GetFile?fileID=6884

Summary and Wrap-up



No associated notes.

How do I use this document?

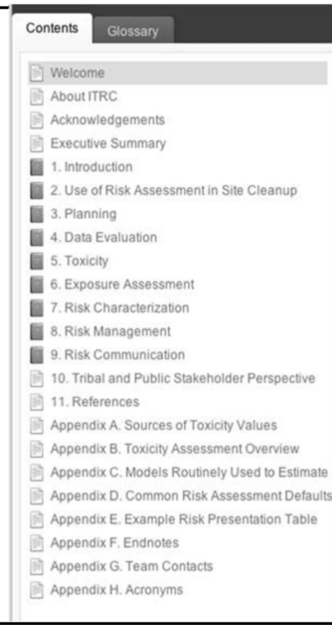


No associated notes.

134

Navigating the Document

- Contents bar organized by chapter



No associated notes.

Navigating the Document

- Contents bar organized by chapter
- Chapter organized by topic

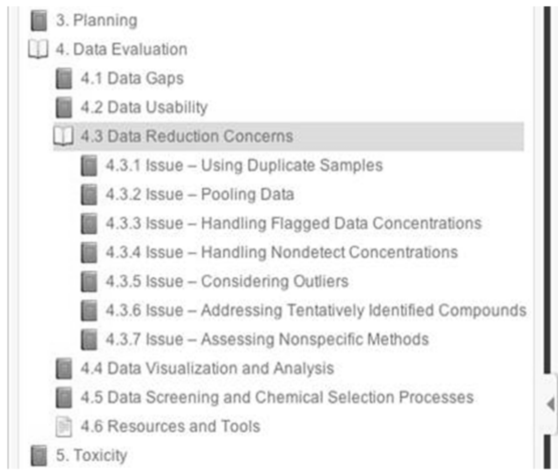
Executive Summary
1. Introduction
2. Use of Risk Assessment in Site Cleanup
3. Planning
4. Data Evaluation
   4.1 Data Gaps
   4.2 Data Usability
   4.3 Data Reduction Concerns
   4.4 Data Visualization and Analysis
   4.5 Data Screening and Chemical Selection F
   4.6 Resources and Tools
5. Toxicity
6. Exposure Assessment
7. Risk Characterization
8. Risk Management

No associated notes.

136

Navigating the Document

- Contents bar organized by chapter
- Chapter organized by topic
- Topic organized by issue



No associated notes.

Navigating the Document

- Contents bar organized by chapter
- Chapter organized by topic
- Topic organized by issue
- Issue followed by options

No associated notes.

Navigating the Document

- Contents bar organized by chapter
- Chapter organized by topic
- Topic organized by issue
- Issue followed by options
- Glossary tab

No associated notes.

139

Summary

- Challenges for both risk assessors and project managers
  - Variability between programs
  - Sites can be complex
  - Applying risk assessments to different situations
- These challenges translate to a number of key issues with one or more possible options to address these issues

No associated notes.

140

Summary

- The RISK-3 web-based document
  - Organizes these key issues in topic areas specific to the risk assessment process
  - Provides potential options and sources of additional information
- The electronic web-based format allows a user to drill down through a dense and technically-challenging topic to core concepts
- You can view or download the document for free at itrcweb.org

No associated notes.

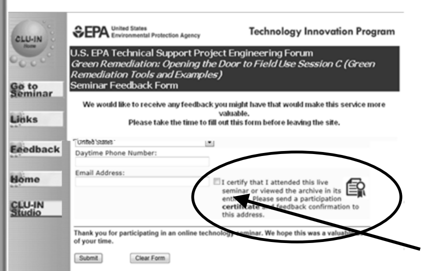
141

Thank You

Follow ITRC

- 2nd question and answer break
- Links to additional resources
  - **http://www.clu-in.org/conf/itrc/risk3/resource.cfm**
- Feedback form – *please* complete
  - **http://www.clu-in.org/conf/itrc/risk3/feedback.cfm**

Poll Question



View Your Participation Certificate (PDF)

Need confirmation of your participation today?

Fill out the feedback form and check box for confirmation email and certificate.

Links to additional resources: http://www.clu-in.org/conf/itrc/risk3/resource.cfm

Your feedback is important – please fill out the form at: http://www.clu-in.org/conf/itrc/risk3/feedback.cfm

The benefits that ITRC offers to state regulators and technology developers, vendors, and consultants include:

✓Helping regulators build their knowledge base and raise their confidence about new environmental technologies

✓Helping regulators save time and money when evaluating environmental technologies

✓Guiding technology developers in the collection of performance data to satisfy the requirements of multiple states

✓Helping technology vendors avoid the time and expense of conducting duplicative and costly demonstrations

✓Providing a reliable network among members of the environmental community to focus on innovative environmental technologies

How you can get involved with ITRC:

✓Join an ITRC Team – with just 10% of your time you can have a positive impact on the regulatory process and acceptance of innovative technologies and approaches

✓Sponsor ITRC's technical team and other activities

✓Use ITRC products and attend training courses

✓Submit proposals for new technical teams and projects