OVERVIEW

Risk Assessment in Superfund
Review of Deterministic Risk Assessment
Motivations for Conducting a Probabilistic Risk Assessment
Probabilistic Risk Assessment Overview
Technical and Policy Recommendations
ORIGINS OF RISK ASSESSMENT
FOR SUPERFUND

Defining Risk Assessment
RISK ASSESSMENT IS CONTEXTUAL

Engineering/Structural

Ecological

Financial/Business

Human Health

Security: Vulnerability and Threat
WHY IS RISK ASSESSMENT IMPORTANT?

“Risk is a common metric that lets us distinguish the environmental heart attacks and broken bones from indigestion or bruises.”

EPA Administrator William K. Reilly
Aiming Before We Shoot:
The Quiet Revolution in Environmental Policy
Address to the National Press Club
September 26, 1990
EPA DEFINITION OF RISK ASSESSMENT

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

Risk Assessment:
Qualitative and quantitative evaluation of the risk posed to human health and/or the environment by the actual or potential presence and/or use of specific pollutants.

From EPA’s “Terms of Environment” Glossary
OVERVIEW

Planning and Scoping (data collection and evaluation)

Toxicity Assessment (hazard ID and dose response)

Exposure Assessment

Risk Characterization

http://www.epa.gov/oswer/riskassessment/risk_superfund.htm
MOTIVATING EXAMPLE

The town of Kemical has detected “badmium” in its water supply at a level of 0.65 mg/liter.

An investigation found the water supply could have been contaminated for the past 30 years.

- Does badmium pose a risk to the health of the residents of Kemical?
- Should EPA take action to clean up the badmium contamination?
- How much badmium does EPA need to clean up to protect the people of Kemical?
PLANNING AND SCOPING

Planning and Scoping (data collection and evaluation)

Toxicity Assessment (hazard ID and dose response)

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http://www.epa.gov/oswer/riskassessment/risk_superfund.htm
Planning & Scoping looks at the “big picture” of data collection and information needed for the risk assessment on the Superfund site.

Addresses the Questions:
- What contaminants are present at the site?
- What concentration?
- Where are they?

Data Collection & Evaluation
- Site History
- Develop a sampling and analysis plan for site investigation
- Identify Chemicals of Potential Concern (COPCs) & Relevant Toxicity Values
TOXICITY ASSESSMENT

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TOXICITY ASSESSMENT

**Toxicity Assessment**: the investigation of how toxic a contaminant may be to human health
- Relies on published, peer reviewed toxicity data
- IRIS, PPRTVs, etc.

Tries to address:
- What kind of harm are you dealing with?
- What health effects may occur?
- How much exposure is needed to cause harm?

**Hazard Identification**: the process of determining whether a chemical can cause adverse health effects, and what those effects might be.
I think you need to make clear here that we rely on published, peer review toxicity values, with IRIS being the primary source. Toxicity assessment is not a site-specific decision.

Scozzafava, MichaelE, 10/11/2016
EXPOSURE ASSESSMENT

Planning and Scoping
(data collection and evaluation)

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EXPOSURE ASSESSMENT

Identifying the pathways by which toxicants may reach individuals, estimating how much of a chemical an individual is likely to be exposed to, and estimating the number likely to be exposed

(EPAs Terms of Environment)

Addresses the Questions:
• Who is exposed?
• How are they getting exposed?
• How much are they exposed to?
• How long are they exposed?
EXPOSURE ASSESSMENT

Identify:

- Source of contamination
  - What media are contaminated?

- Potential receptors
  - Adults, Children
  - Residential, Commercial
  - Sensitive Populations

- Pathways for exposure
  - Inhalation
  - Ingestion
  - Dermal Contact
slide is very small/hard to see
Scozzafava, MichaelE, 10/11/2016
SIMPLIFIED EXPOSURE EQUATION

Chronic Daily Intake = \( \frac{\text{Concentration} \cdot \text{Contact Rate} \cdot \text{Exposure Duration}}{\text{Body Weight} \cdot \text{Averaging Time}} \)

Where do these numbers come from?

- Concentration: Measured concentration on the site
- Contact Rate: Defaults from exposure factors handbook – 2.5L water/day, 100mg soil/day
- Exposure Duration: Cancer, 70 years
- Body Weight: Default from Exposure Factors Handbook, 70kg
- Averaging Time: Cancer, 70 years x 365 days/year
RISK CHARACTERIZATION

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RISK CHARACTERIZATION

Estimate the potential for human health (or ecological effects) occurring from exposure to a stressor, and evaluate the uncertainty involved

- Which contaminants are causing risks to human health?
- Which exposure pathways are creating risk?

Typical steps:
1. Review information
2. Quantify Risk (equations from RAGS)
3. Combine risks across exposure pathways
4. Consider site specific studies
5. Summarize Results
Target Risk Range (Cancer)
- The superfund remedial program has a target cancer risk range of $10^{-4}$ to $10^{-6}$
- This range is considered to be protective
RISK CHARACTERIZATION

Hazard Index (Non-Cancer)

- Sum of hazard quotients for multiple substances over multiple exposure pathways
- Hazard Quotient: ratio of site specific chemical exposure over a reference dose (at which no adverse health effects are likely to occur)

\[ HQ = \frac{Daily \ Intake}{Reference \ Dose} \]
The town of Kemical has detected “badmium” in its water supply at a level of 0.65 mg/liter. An investigation found the water supply could have been contaminated for the past 30 years. The slope factor of “badmium” is 0.15 (mg/kg-day)$^{-1}$.

What is the cancer risk?

$$Cancer\ Risk = Chronic\ Daily\ Intake \cdot Slope\ Factor$$

$$Chronic\ Daily\ Intake = \frac{Concentration \cdot Contact\ Rate \cdot Exposure\ Duration}{Body\ Weight \cdot Averaging\ Time}$$

$$1.04 \cdot 10^{-4} \text{ is within the acceptable risk range, but fairly high.}$$
UNCERTAINTY

Uncertainty Analysis
- Explore uncertainties in risk estimates
- Minimize underestimation of potential risk

Typical Superfund Uncertainty
- Environmental sampling
- Laboratory analysis
- Dose-response toxicity assessment
- Exposure assessment
MOTIVATION

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very qualitative
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Typical Superfund Uncertainty
- Environmental sampling
- Experimental Design
- Laboratory analysis
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- Exposure assessment

very qualitative
MOTIVATION

Uncertainty Analysis
- Explore uncertainties in risk estimates
- Minimize underestimation of potential risk

Typical Superfund Uncertainty
- Environmental sampling, Experimental Design
- Laboratory analysis, QA/QC, replicates
- Dose-response toxicity assessment
- Exposure assessment

very qualitative
MOTIVATION

Uncertainty Analysis
- Explore uncertainties in risk estimates
- Minimize underestimation of potential risk

Typical Superfund Uncertainty
- Environmental sampling - Experimental Design
- Laboratory analysis - QA/QC, replicates
- Dose-response toxicity assessment 
- Exposure assessment

very qualitative
MOTIVATION

Uncertainty Analysis
- Explore uncertainties in risk estimates
- Minimize underestimation of potential risk

Typical Superfund Uncertainty
- Environmental sampling - Experimental Design
- Laboratory analysis - QA/QC, replicates
- Dose-response toxicity assessment - Explicit Uncertainty Factors
- Exposure assessment

very qualitative
EXPOSURE UNCERTAINTY & VARIABILITY

Exposure Assumptions

- Exposure Durations
  - Acute
  - Short-Term
  - Sub Chronic
  - Chronic

- Exposure Scenarios
- Behaviors
- Physical Characteristics
- Contact Rates

CDI = \frac{\text{Concentration} \times \text{Contact Rate} \times \text{Exposure Duration}}{\text{Body Weight} \times \text{Averaging Time}}

- Concentration: Measured concentration on the site
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- Exposure Duration: Cancer, 70 years
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EXPOSURE UNCERTAINTY & VARIABILITY

Exposure Assumptions

- **Exposure Durations**
  - Acute
  - Short-Term
  - Sub Chronic
  - Chronic
- **Exposure Scenarios**
  - Residential, Commercial
- **Behaviors**
- **Physical Characteristics**
- **Contact Rates**

...so what is this value?

\[
CDI = \frac{\text{Concentration} \cdot \text{Contact Rate} \cdot \text{Exposure Duration}}{\text{Body Weight} \cdot \text{Averaging Time}}
\]

- Concentration: central tendency
- Contact Rate: 90th percentile adult intake
- Exposure Duration: Cancer, lifetime
- Body Weight: average adult weight
- Averaging Time: Cancer, every day for life.
PROBABILISTIC RISK ASSESSMENT (PRA)

Quantify Uncertainty in Exposure & Risk
- Replace point estimates with site specific, relevant distributions
- Use Monte Carlo simulation to develop a risk distribution
- Use the risk distribution to better understand population wide risk

However…
- Still follows RAGS guidance
- Does not incorporate uncertainty in dose-response
- Not a tool to get a higher cleanup level
DETERMINISTIC VS. PROBABILISTIC RISK

\[
\begin{align*}
\text{Concentration in environment} & \times \text{Exposure Duration} \times \text{Ingestion or Inhalation Rate} \times \text{Toxicity Factor} = \text{RISK} \\
\text{Central tendency (average) values for all parameters} & = \left[ c \right] \times \left[ e \right] \times \left[ i \right] \times \left[ t \right] = \text{Yields a reasonable estimate for average or typical individual} \\
\text{High-end values for some or all parameters} & = \left[ C \right] \times \left[ E \right] \times \left[ I \right] \times \left[ T \right] = \text{Yields estimate that is likely biased high (conservative)}
\end{align*}
\]
BENEFITS OF PRA

Risk assessments have a lot of poorly characterized variability and uncertainty – PRA quantitatively and explicitly describes the distribution of risk.

Helps stakeholders understand how different parameter assumptions affect conclusions.

“Apples to Apples” incorporation of parameter assumptions.

May be particularly appropriate for:

- Dealing with environmental justice issues raised by inter-individual variability
- Data rich sites
- Exploring the impact of exposure assumptions
- Helping decide between different risk management decisions
RISK ASSESSMENT OVERVIEW

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- Exposure Assessment
- Risk Characterization

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PROBABILISTIC RISK ASSESSMENT

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PLANNING AND SCOPING

All Stakeholders should agree to use probabilistic risk assessment

Why are you doing a PRA?

What percentiles are you using for decision making?

What are your decision criteria?

Before starting, identify:

- Parameters with **variability** (eg. age of current population)
- Parameters with **uncertainty** (eg. age composition of future population)
- **Variable and uncertain** parameters (eg. chemical concentration)
EXPOSURE ASSESSMENT

Exposure Terms:
- Relevant distributions – national or site specific
  - Exposure Factors Handbook
  - NHANES
  - Peer reviewed publications
  - Site Specific Data
- Point estimates for the deterministic risk assessment should be drawn from the same distributions as are used in the PRA

Chemical Concentrations:
- Exposure Point Concentration – upper bound on the mean
- Parametric Distribution – fit a distribution to site data
- Non-parametric Distribution – bootstrap from site data
RISK CHARACTERIZATION

Monte Carlo Simulation using standard risk equations

Repeated random sampling used to generate simulated data for a mathematical model

- Generate random draws from defined probability distributions
- Incorporate samples into risk assessment equations
- Develop distribution for risk

Risk equations draw randomly from exposure distributions

May require multiple rounds of refinement
PRA PROCESS (RAGS III)

**Planning and Scoping**
- Identify site characteristics
- COPCs & Sampling
- Define Risk Levels

**Deterministic Risk Assessment**
- Define Exposure Unit & Pathways
- Calculate Point Estimate of Risk

**1-D Monte Carlo Simulation: Variability**
- Identify Probability Distributions
- Simulate Risk Distribution

**2-D Monte Carlo Simulation: Uncertainty & Variability**
- Bayesian Statistics, Microexposure Event Analysis, Geospatial Methods…
**PRA PROCESS**

After each tier is a decision making point:

"*Do I have sufficient data to make a risk management decision?*

- Review uncertainty and sensitivity analysis
- Identify data gaps/needs
- Communicate with all stakeholders

Before starting the next tier:

- Is refining the current tier sufficient?
- Refine the work plan
- Collect additional data

*This is an iterative process*
EPA Guidance states that a tier 3 assessment is a 2-D Monte Carlo Simulation

- **Mathematical Definition:** “A two-dimensional Monte-Carlo simulation is a Monte-Carlo simulation where the distributions reflecting variability and the distributions representing uncertainty are sampled separately in the simulation, so that variability and uncertainty in the output may be assessed separately.”

- RAGS III lumps other statistical techniques in with 2D MC simulation
REPORTING THE RESULTS OF A PRA

Is there unacceptable risk at your site?

Transparent explanation of decision points

Baseline, Deterministic Risk Assessment

Risk Distribution from PRA

Sensitivity Analysis:
- Multiple Simulations with range of uncertainty
- Distribution of RME
- Correlation between variables – Pearson or Spearman Rank
EXAMPLE: 1D MCA

PRA uses the same equations as a deterministic risk assessment:

\[
\text{Chronic Daily Intake} = \frac{\text{Concentration} \times \text{Contact Rate} \times \text{Exposure Duration}}{\text{Body Weight} \times \text{Averaging Time}}
\]

\[
\text{Cancer Risk} = \text{Chronic Daily Intake} \times \text{Slope Factor}
\]

<table>
<thead>
<tr>
<th>Variable</th>
<th>Type of Input</th>
<th>Case 1: Base</th>
<th>Case 2: More uncertainty</th>
<th>Case 3: Longer exposure</th>
</tr>
</thead>
<tbody>
<tr>
<td>Concentration</td>
<td>Point Estimate</td>
<td>.65 mg/L</td>
<td>.65 mg/L</td>
<td>.65 mg/L</td>
</tr>
<tr>
<td>Contact Rate</td>
<td>Distribution</td>
<td>Normal, (\mu = 1, \sigma = .25)</td>
<td>Normal, (\mu = 1, \sigma = .25)</td>
<td>Normal, (\mu = 1, \sigma = .25)</td>
</tr>
<tr>
<td>Exposure Duration</td>
<td>Distribution</td>
<td>T-Lognormal, (\mu = 10, \sigma = 2.5)</td>
<td>T-Lognormal, (\mu = 10, \sigma = 5)</td>
<td>T-Lognormal, (\mu = 15, \sigma = 5)</td>
</tr>
<tr>
<td>Body Weight</td>
<td>Distribution</td>
<td>Normal, (\mu = 70, \sigma = 10)</td>
<td>Normal, (\mu = 70, \sigma = 10)</td>
<td>Normal, (\mu = 70, \sigma = 10)</td>
</tr>
<tr>
<td>Averaging Time</td>
<td>Distribution</td>
<td>365 x ED</td>
<td>365 x ED</td>
<td>365 x ED</td>
</tr>
<tr>
<td>Slope Factor</td>
<td>Point Estimate</td>
<td>0.15 (mg/kg-day)(^{-1})</td>
<td>0.15 (mg/kg-day)(^{-1})</td>
<td>0.15 (mg/kg-day)(^{-1})</td>
</tr>
</tbody>
</table>
RESULTS: CASE 1 — BASE CASE

Histogram of Monte Carlo Results

Cumulative Distribution Function

Mean: $8.31 \cdot 10^{-6}$  
$95^{th}$ Percentile: $1.64 \cdot 10^{-5}$  
Max: $3.75 \cdot 10^{-5}$
RESULTS: CASE 2 — MORE UNCERTAINTY

Histogram of Monte Carlo Results

Cumulative Distribution Function

Mean: $8.12 \cdot 10^{-6}$
95th Percentile: $1.86 \cdot 10^{-6}$
Max: $5.8 \cdot 10^{-5}$
RESULTS: CASE 3 — LONGER EXPOSURE

Histogram of Monte Carlo Results

Cumulative Distribution Function

Mean: $1.23 \cdot 10^{-5}$

95th Percentile: $2.52 \cdot 10^{-5}$

Max: $5.75 \cdot 10^{-5}$
SENSITIVITY

Scenario 1

Scenario 2

Scenario 3
RESULTS

1-D Monte Carlo Simulation, Qualitative Sensitivity Analysis

- Maximum 95\textsuperscript{th} percentile of Risk: $2.52 \cdot 10^{-5}$
- Minimum 95\textsuperscript{th} percentile: $1.86 \cdot 10^{-6}$
- **All values were within risk range**

Compare to point estimate – $1.04 \cdot 10^{-4}$

Questions to consider:

- Did the sensitivity analysis flag any parameters for further evaluation?
- How comfortable are we with our parameter estimates?
- Is a 2D simulation necessary?
...SO WHAT CAN I DO WITH A PRA?

Inform Uncertainty Analysis

Inform Risk Management Decisions

Decide Cleanup Levels, provided you have

▪ Extensive supporting evidence for distributions & decision points
▪ Clear case of what PRA adds over a deterministic risk assessment
RECOMMENDATIONS

Technical Considerations
Mathematical Issues
Policy
Resources
TECHNICAL CONSIDERATIONS

Conducting a PRA is not a trivial exercise

Understand why you’re doing a PRA

Software: (not an EPA endorsement)

- Excel
- Proprietary Software (Oracle Crystal Ball, Palisade’s @Risk)
- Open Source – R (`mc2d`), Python

Consult with the project team to make sure everyone is able to collaborate on analysis
MATH/STAT CONSIDERATIONS

Choosing distributions:
- Site specific data
- Peer reviewed national data sets

Parametric Distributions
- Fit a distribution to relevant data
- Provide statistical support for decision
- Some may take on negative values – be aware and address that!

Empirical Distributions
- Empirical data needs sufficient sample size for boot strapping
- Be wary of truncating or manipulating distributions
MATH/STAT CONSIDERATIONS

Variable correlation

- Empirically, many risk parameters are correlated
- Explicitly incorporate this into the model

**Example:** Body Weight & Consumption

95th percentile: 0.044

95th percentile: 0.036
DON’T SIMPLIFY EARLY: $f(E(x)) \neq E(f(x))$
POLICY REMINDERS

Follow Risk Assessment Guidance for Superfund (RAGS)
Toxicity Assessment (dose response) is not probabilistic
Deterministic Risk Assessment is always the first step
Submit a work plan for review before starting
Early engagement

Iterative process
- Communicate results to stakeholders at each tier (or sooner!)
- Revisit assumptions and inputs as necessary

Transparency
- Provide stakeholders with simulation code
- Present input distributions up front
- Report the full risk distribution
- Conduct a robust sensitivity analysis
RESOURCES

Superfund:
- Risk Assessment Guidance for Superfund (A, B, C, D, E, F)
- RAGS III: Probabilistic Risk Assessment
- OSWER Directive 9200.1-120
- PRG for Radionuclides

Other EPA resources:
- Exposure Factors Handbook
- Risk Assessment Forum PRA whitepaper
- EPA Office of the Science Advisor PRA FAQ

Non-EPA:
- NAS Science & Decisions (Silver Book)
- mc2d (R): tools for Two-Dimensional Monte Carlo Simulations
Superfund PRG guidance on Radiation Risk Assessment

◆ *Radiation Risk Assessment at CERCLA Sites: Q&A (5/2014) OSWER Directive 9200.4-40*
  
  » PRA may be used to provide quantitative estimates of the uncertainties in the risk assessment.
  
  » PRA may be used as a supplement to, not instead of, deterministic (point estimate) methods.

◆ Retains guidance from 1999
  
  » Radiation Risk Assessment at CERCLA Sites: Q&A (12/99) OSWER Directive 9200.4-31P