# Risk Assessment and Risk-Based Cleanup

Paducah Citizens' Advisory Board

March 18, 2010

Presented by:

Rich Bonczek, Portsmouth/Paducah Project Office

# Why is Risk Assessment Used at Paducah?

***Use of risk assessment specifically called-out in FFA***

- Remedial Investigation/Feasibility Study Work Plans are required to describe plan for completing baseline risk assessment (XI)(1).
- Feasibility Study is required when baseline risk assessment shows: (XII)
  - cumulative carcinogenic risk is >$10^{-6}$ or
  - cumulative noncarcinogenic hazard quotient >1 or
  - have adverse environmental impact.
- Proposed Plans for final action, but not for interim action, require complete baseline risk assessments (XIV)(A)(1) and (XIV)(B).
- Comprehensive Site Operable Units (i.e., Ground Water Operable Unit and Surface Water Operable Unit) reports must include baseline risk assessment for risk remaining after response actions complete. (XIII)(B)(1)
- Final Comprehensive Site Operable Unit must include evaluation of residual risks. (XIII)(B)(2).

# Why is Risk Assessment Used at Paducah?

***SMP Uses Risk-based Approach***

- Site Cleanup Objectives
- Risk-based Prioritization

***Two Methods Documents Implement SMP Strategy***

- Methods for Conducting Risk Assessment and Risk Evaluations at the Paducah Gaseous Diffusion Plant, Paducah, Kentucky. Volume 1. Human Health
- Methods for Conducting Risk Assessment and Risk Evaluations at the Paducah Gaseous Diffusion Plant, Paducah, Kentucky. Volume 2. Ecological

***Developed to integrate the requirements found in federal regulation, EPA guidance, and guidance received in comments.***

# What is Risk Assessment?

***A process used to:***

- Organize information
- Analyze information

***Provides estimates of harm from exposure to a agent.***

***We do risk assessments every day when selecting how to act or react!***

# An Every Day Risk Assessment!

**Let's Buy a Lottery Ticket**

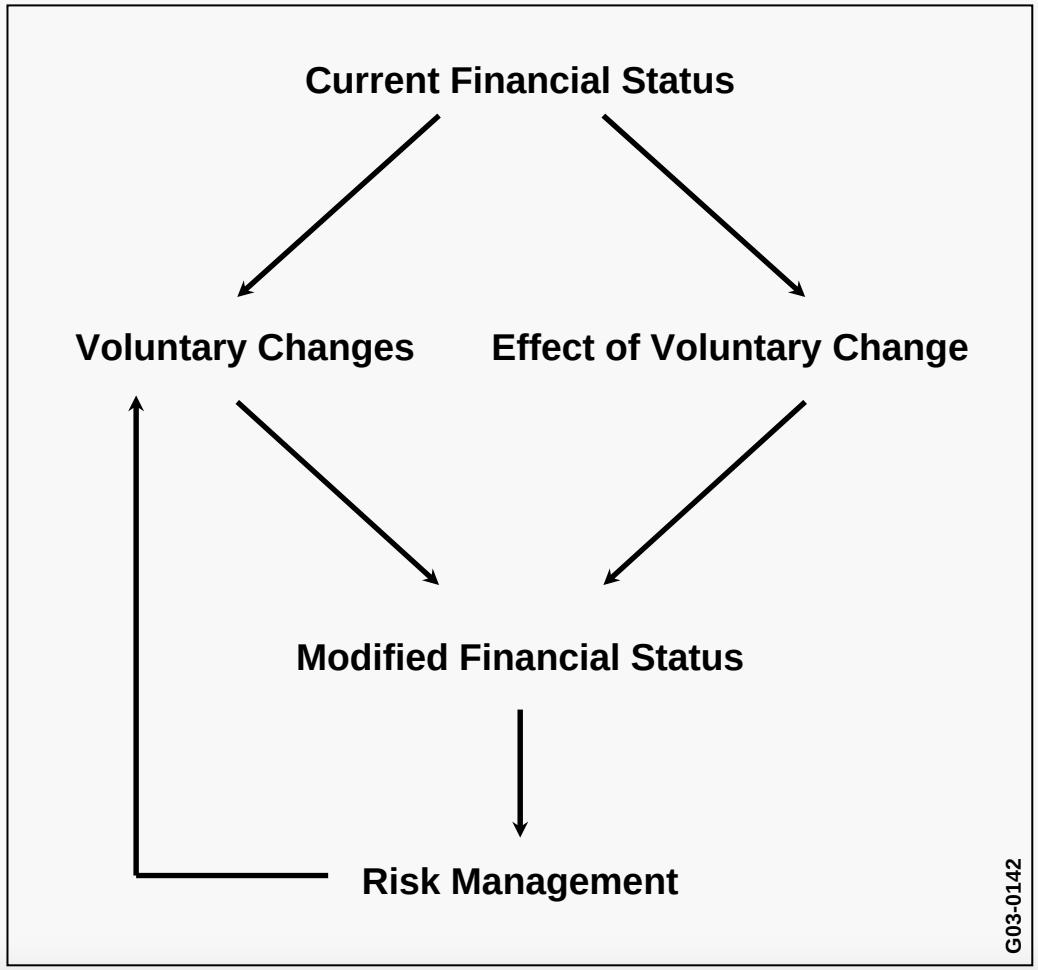
**Expectation is to win!**

**How much to spend?**

**What is the chance of winning?**

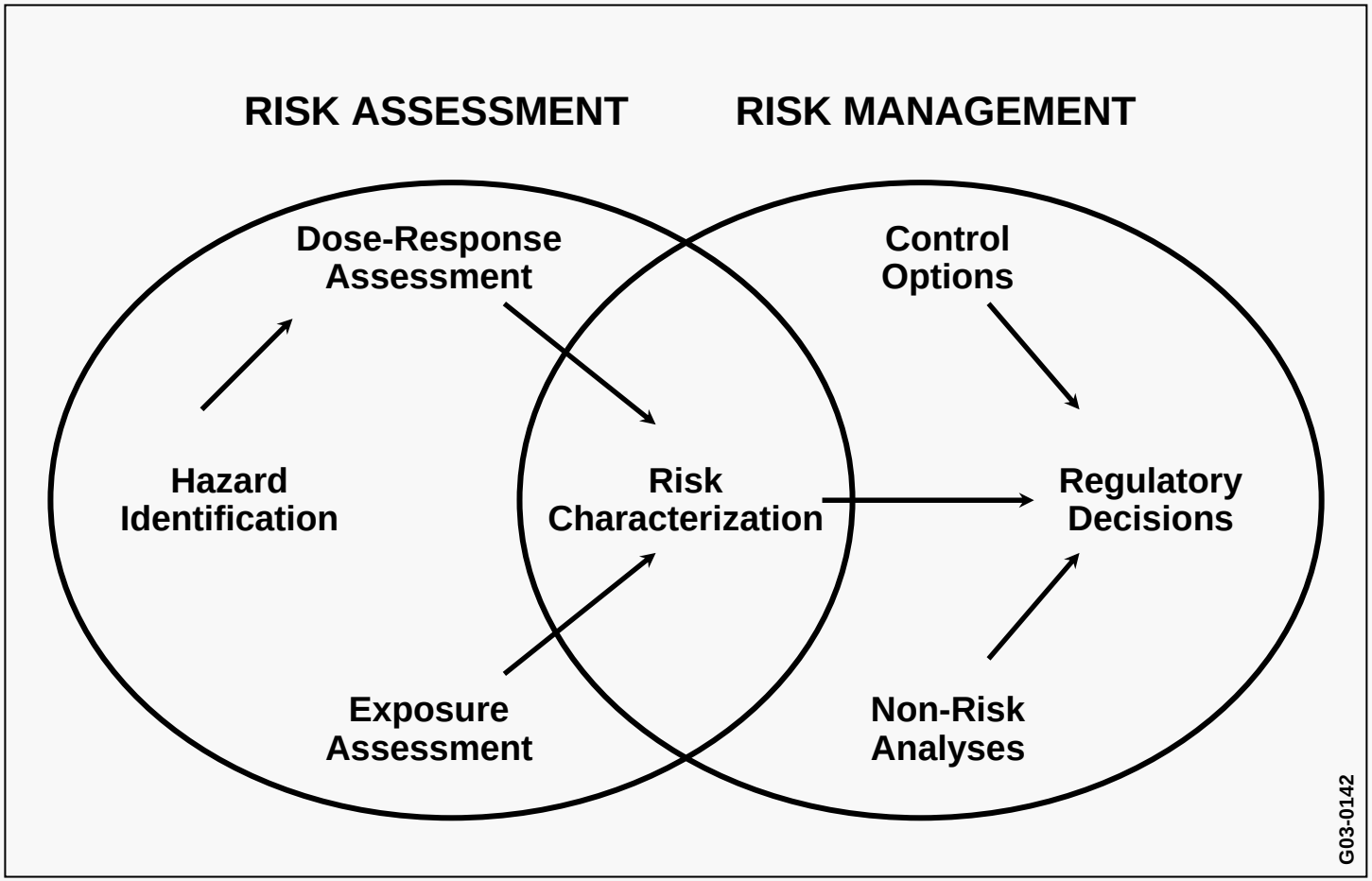
**Can you increase your chances of winning?**

**Once result is obtained, resulting risk is managed! (Buy another ticket?)**



# Can You Paradigm?

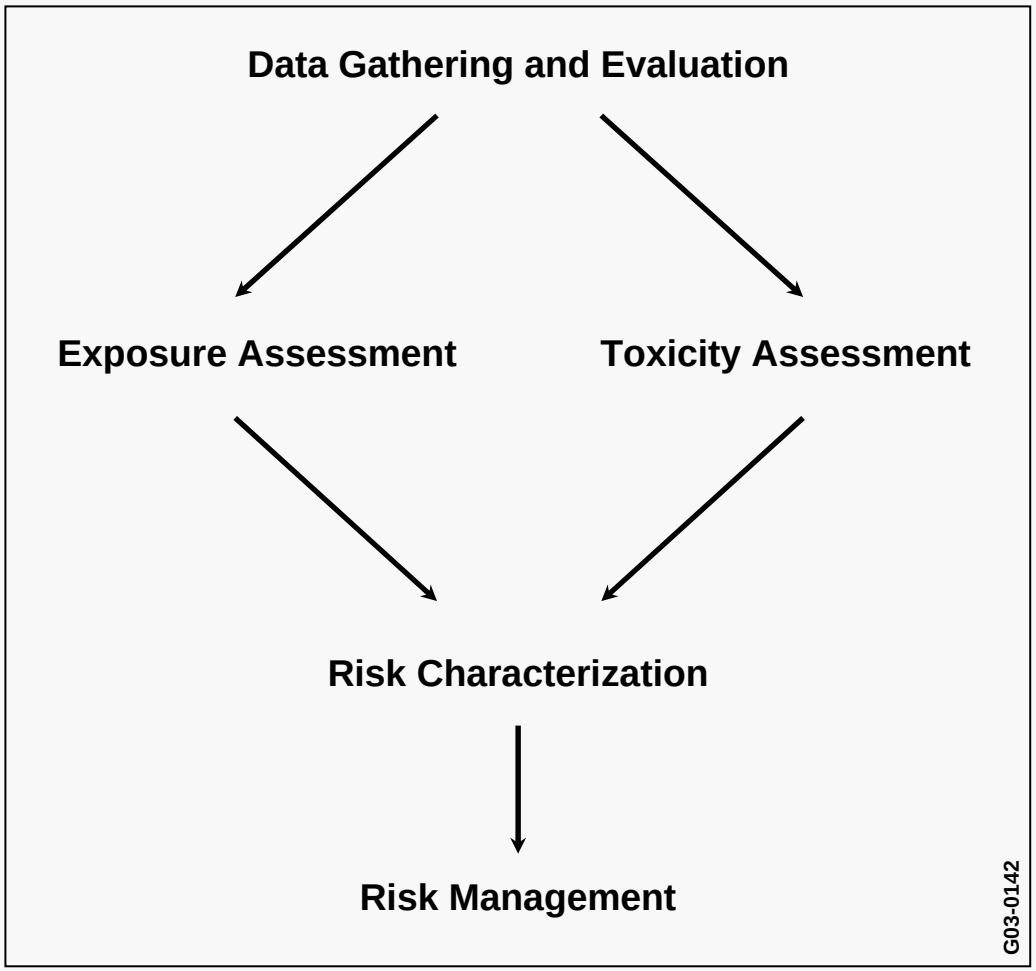
**How is this similar to the everyday example?**




**National Academy of Sciences Risk Paradigm**

# EPA's Risk Assessment Paradigm

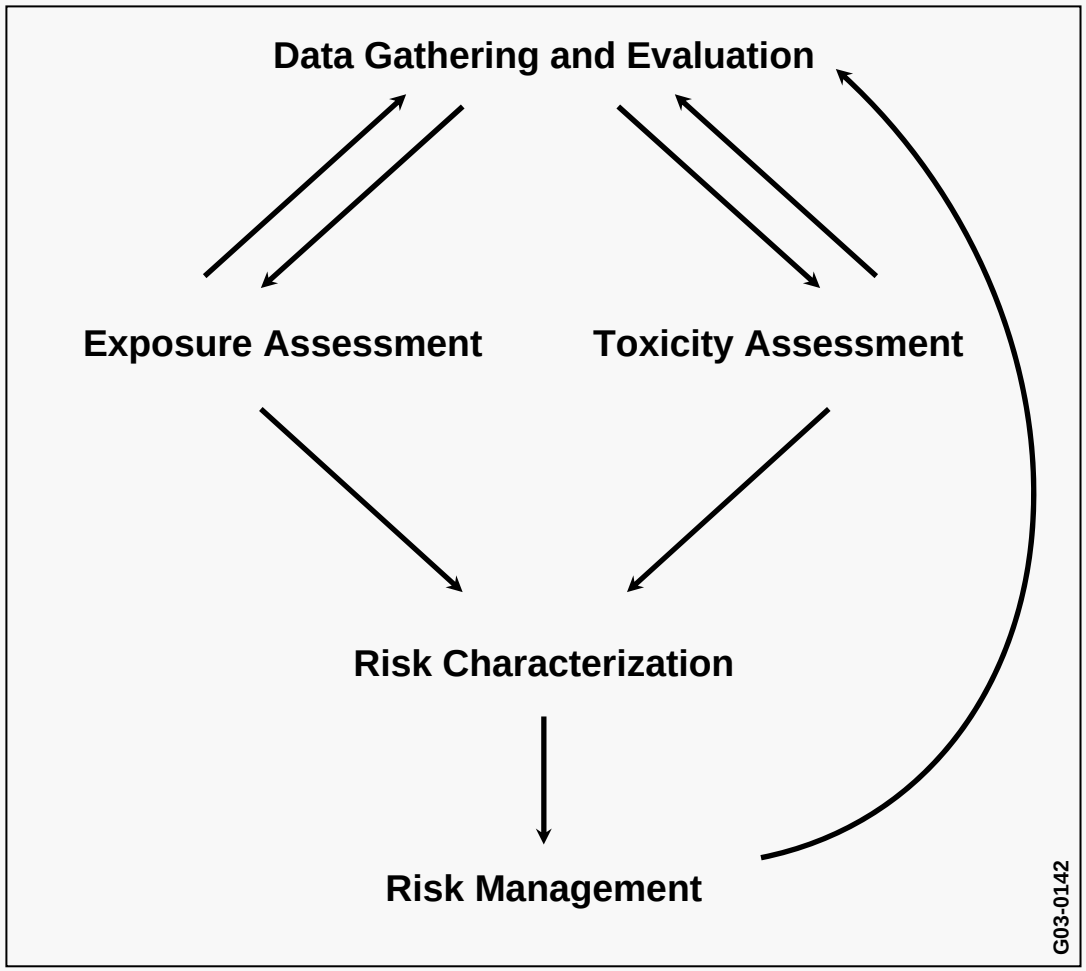
**Let's Flip It and Simplify!**




**EPA Environmental Risk Paradigm (from "RAGS")**

# EPA's Risk Assessment Paradigm

**Add Some Feedback Loops!**




**EPA Environmental Risk Paradigm (from "RAGS")**

# The Parts Defined!

***Data Gathering and Evaluation:***

Demonstrate the presence of a harmful agent

==> How much is there?

***Exposure Assessment:***

Calculate projected rate of contact by receptor

==> What is the dose or intake?

***Toxicity Assessment:***

Demonstrate relationship between level of exposure and injury

==> What harm does the agent cause?

***Risk Characterization:***

Calculate measure of expected effect by integration toxicity and exposure assessments

==> What is the risk?

# The Parts Defined!

***Risk Management***

- ***Control Options:***

  Actions that may be taken to reduce effects

  ==> Methods to reduce risk?

- ***Non-risk Inputs:***

  Consideration of social and economic consequences

- ***Regulatory Decision:***

  Response action decision

  ==> What is done!

***Risk Management is where the "rubber meets the road!"***

# Some Additional Detail on Parts

## *Data Gathering and Evaluation – Analyze Contamination*

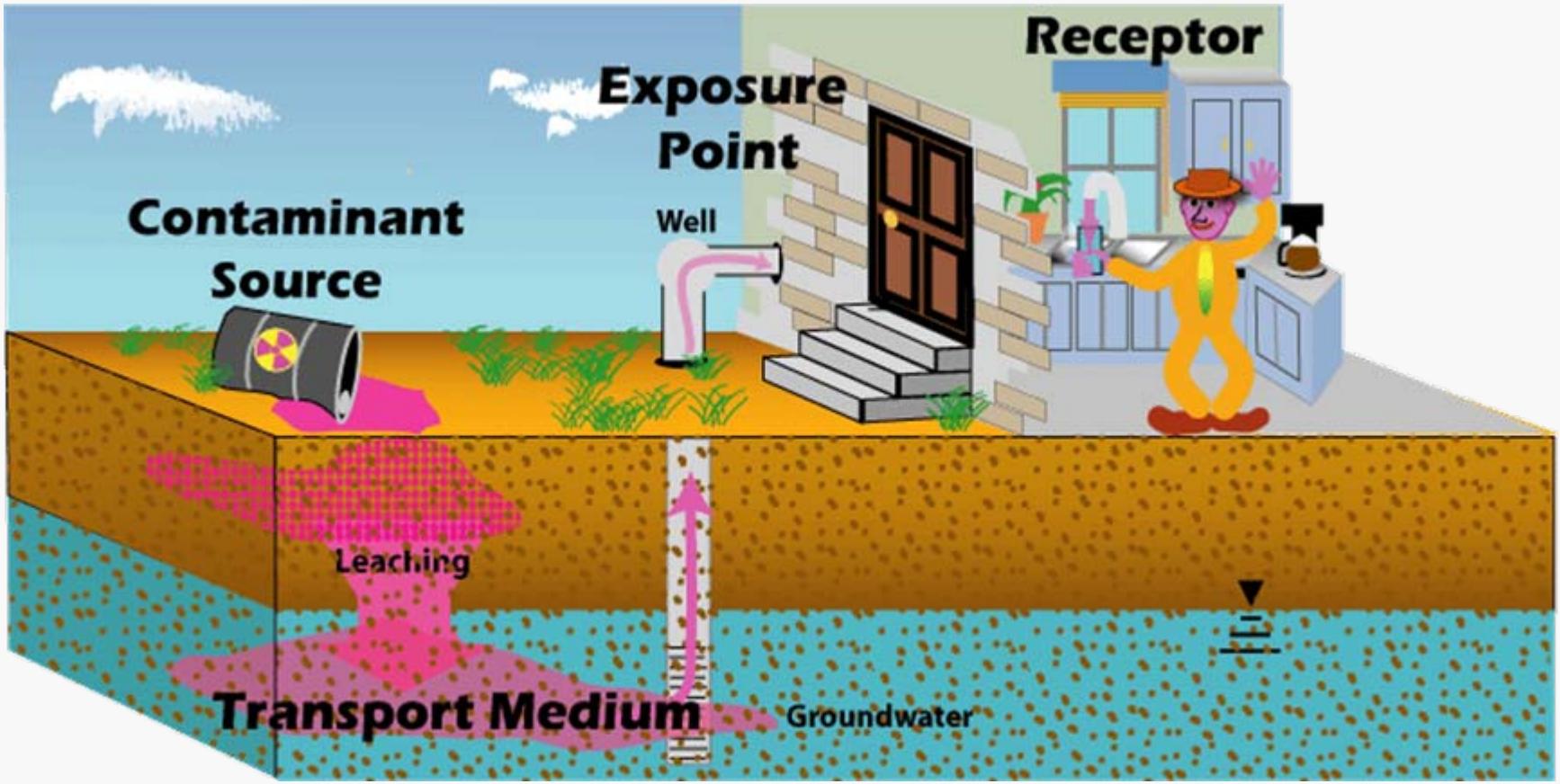
- Is sampling of sufficient quality and representative of site conditions?
- Is contamination present in samples? (Compare to background)
- Is contamination present at concentrations that could cause harm? (Above *de minimis levels*)
- End up with "Contaminants of Potential Concern" or "COPCs"

## *Exposure Assessment – Estimate Dose*

- Develop conceptual site model
  - How could exposure occur?
  - Who may be exposed?
- Calculate dose or intake by integrating contaminant concentrations and rate of exposure

$$\text{Intake} = \text{Concentration} \times \left[ \frac{\text{Contact Rate} \times \text{Exposure Frequency}}{\text{Body Weight}} \times \frac{1}{\text{Averaging Time}} \right]$$

# An Example Conceptual Site Model



# Some Additional Detail on Parts

***Toxicity Assessment – Assess Potential Health Effects***

- **Cancer effects:**
  - Potential for cancer to occur in response to exposure to a contaminant.
  - Toxicity value is called a slope factor.
- **Non-cancer effects:**
  - Potential for injury to occur in response to exposure to a contaminant.
  - Toxicity value is called a reference dose (RfD).

# Some Additional Detail on Parts

***Risk Characterization - Calculating cancer risk***

- Integrate contaminant intake with slope factor.
- Results are in terms of probability

$$\text{Cancer Risk} = \text{Slope Factor} \times \text{Intake}$$

***Risk Characterization - Calculating hazard***

- Integrate contaminant intake with reference dose.
- Results reported as fractions or multiples of reference dose.

$$\text{Hazard} = \frac{\text{Intake}}{\text{Reference Dose}}$$

# Interpretation of Risk Results

***Benchmarks for Cancer Risk***

- $<1 \times 10^{-6}$ (probability is less than 1 in 1 million)

  Cancer risk is at *de minimis* levels; cleanup likely not needed.

- $>1 \times 10^{-4}$ (probability is greater than 1 in 10 thousand)

  Cancer risk is at an elevated level; cleanup likely needed.

- $>1 \times 10^{-6}$ but $< 1 \times 10^{-4}$ (probability is greater than 1 in 1 million but less than 1 in 10,000)

  Cancer risk is in "gray area;" evaluate options for cleanup.

$10^{-6}$ to $10^{-4}$ is called, "EPA's acceptable risk range for site-related exposures to carcinogens."

# Comparison of Cancer Risks

| Cancer-causing Agent or Situation | Approximate Lifetime Risk of Cancer | Scientific Notation |
|---|---|---|
| Exposure to Sun (skin cancer) | 1 in 3 | 3E-01 |
| Cigarette smoking (pack a day or more) | 8 in 100 | 8E-02 |
| Natural radon in indoor air in home | 1 in 100 | 1E-02 |
| Outside radiation (radon and cosmic rays) | 1 in 1,000 | 1E-03 |
| Second-hand cigarette smoke | 7 in 1,000 | 7E-03 |
| Human-made chemicals in indoor air in home | 2 in 10,000 | 2E-04 |
| Outdoor air in industrialized area | 1 in 10,000 | 1E-04 |
| Human-made chemicals in drinking water* | 1 in 100,000 | 1E-05 |
| Human made chemicals in food | 1 in 100,000 or less | ≤ 1E-05 |
| a) 2 oz. peanut butter per week from aflatoxin | 8 in 100,000 | 8E-05 |
| b) One meal per year of small lake trout from Lake Michigan | 1 in 100, 000 | 1E-05 |
| Chemical exposure at most uncontrolled hazardous-waste sites | 1 in 10,000 to 1 in 1,000,000 | 1E-04 to 1E-06 |

From U.S. EPA Region 5 report *Environmental Risk: Your Guide to Analyzing and Reducing Risk* (EPA 905/9-91/017, October 1991). Available at http://www.epa.gov/reg5oopa/reisk/htm.

# Interpretation of Risk Results

***Benchmarks for Hazard***

- < 1 (hazard is below threshold level)

  Hazard is at *de minimis* levels; cleanup likely not needed.

- > 1 (hazard is above threshold level)

  Hazard is at an elevated level; evaluate options for cleanup.

# Identifying the Problems

## *Contaminants of Concern (COCs)*

- COPCs that have an unacceptable level of risk or hazard within a scenario that has an unacceptable level of risk or hazard are COCs.
- Cleanup goals are developed for COCs during risk management.

## *Cleanup Goals*

- Specific to the cleanup action that is selected.
- Integrate exposure and concentration.

# Putting It All Together – An Example

***Site Description***

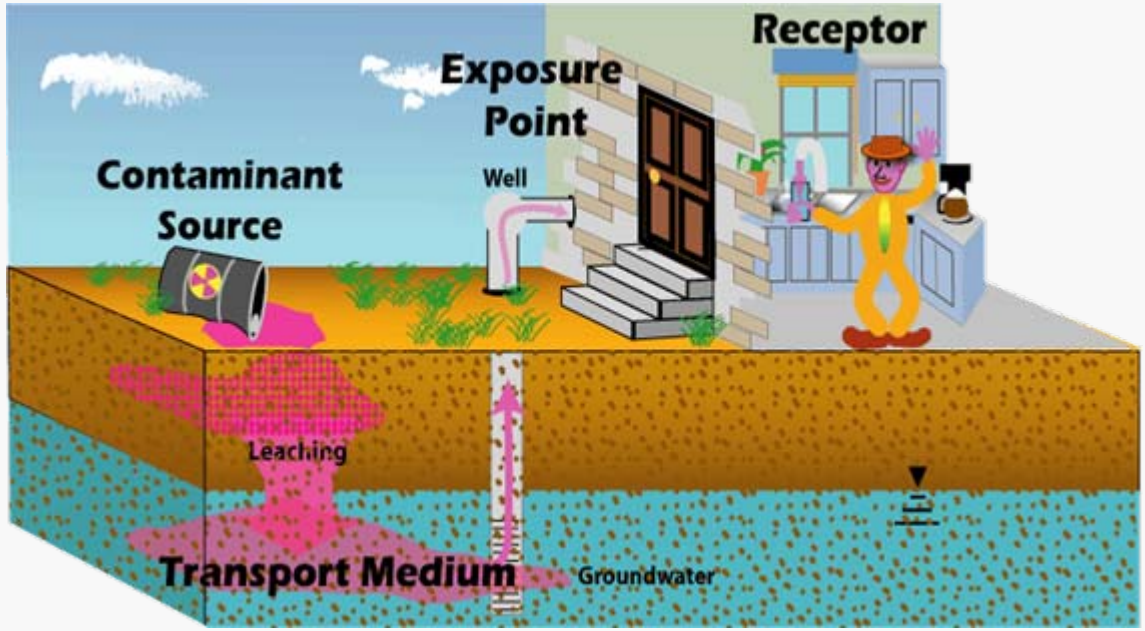
- Spill of solvent (trichloroethene) occurred.
- Over time, trichloroethene migrated to groundwater.
- Trichloroethene detected in groundwater at the spill site and in neighboring wells.
- Trichloroethene detected in soils at spill areas.

***Sampling Shows (Data Gathering and Evaluation)***

- Trichloroethene in groundwater (at well) averages 30 micrograms/liter.
- Trichloroethene in soil (at source) averages 200 milligrams/kilogram.

# Putting It All Together – An Example

**Receptor is adult that:**
- **Drinks from the well**
- **Contacts contaminated soil**




**Some "exposure paramenters:"**
- **Water ingestion – 2 liters/day**
- **Incidental soil ingestion – 100 mg/day**
- **Days per year exposed – 350 days/year**
- **Years exposed – 30 years**
- **Body weight of adult – 70 kg (154 lbs)**

**Trichloroethene toxicity factors**
- **Slope Factor = 0.322 [mg/(kg X day)]$^{-1}$**
- **Reference Dose = 0.0003 mg/(kg X day)**

**(Source 2010 Paducah Risk Methods Document)**

# Putting It All Together – An Example

***Use Equations for Intake, Cancer Risk, and Hazard Calculation***

$$\text{Intake} = \text{Concentration} \times \left[ \frac{\text{Contact Rate} \times \text{Exposure Frequency}}{\text{Body Weight}} \times \frac{1}{\text{Averaging Time}} \right]$$

$$\text{Cancer Risk} = \text{Slope Factor} \times \text{Intake}$$

$$\text{Hazard} = \frac{\text{Intake}}{\text{Reference Dose}}$$

# Putting It All Together – An Example

## *Cancer Risk and Hazard Results*

**Exposure to Drinking Water**

- **Cancer Risk = $1.1 \times 10^{-4}$**
- **Hazard = 3**

**Exposure to Soil (Incidental Ingestion)**

- **Cancer Risk = $3.7 \times 10^{-5}$**
- **Hazard = 0.9**

**Trichloroethene is a COC for Soil and Groundwater**

**Risk Management would determine appropriate actions to address this risk and hazard.**

- **Reduce Trichloroethene Concentrations**
- **Reduce Rates of Exposure**

# Resources

- EPA's Superfund Risk Assessment Page: http://www.epa.gov/oswer/riskassessment/risk_superfund.htm
- EPA's Soil Screening Guidance: http://rais.ornl.gov/calc_start.shtml
- EPA's Regional Screening Tables: http://epa-prgs.ornl.gov/cgi-bin/chemicals/csl_search
- DOE's Risk Assessment Information System: http://rais.ornl.gov/