DON RAB/TRC
Training Workshop

Risk Assessment

Presenter:
Ihor Hlohowskyj, PhD
Argonne National Laboratory

Topic Objectives

- Provide RABs with an understanding of how human health and ecological risk assessments are conducted.
- To educate RABs about background chemical levels and how they are used in risk assessments and cleanup remedy selection.
- To give RABs enough information to know how to ask the right questions to get helpful information from technical people.

Topic Outline

- Overview of general risk assessment process
  - Goals and objectives
- Navy approaches for ecological and human health risk assessment
  - Navy policy and consistency with CERCLA
- Risk assessment approaches
  - Problem formulation, effects and exposure assessment methods, and risk characterization

Topic Outline, cont'd

- Alternative evaluation
  - Associated risks to human health and the environment
- Background chemical levels
  - Role in risk assessment and remedy selection

What is Risk Assessment?

Something we all do

Involves collecting and analyzing information

To determine likelihood that something *(bad)* will happen

crossing the street

eating left overs

smoking, eating fries

getting married

A Hazard Alone

Does Not Represent a Risk

Risk Requires Exposure

Someone or Something Has to Be Exposed

Level of Risk Depends on Two Factors

RISK = HOW MUCH IS TAKEN IN x HOW TOXIC IT COULD BE

Concentration of the material in the environment as measured by our sampling

+

Amount of our exposure (*how much, how often, how long) as established/determined by the risk assessment*

For humans, generally estimated from animal studies

For biota, estimated from laboratory and field studies

What Do Risk Assessments Do?

Look at conditions as they are today, and as they may be in the future

human health	***ecology***
possibility we could get cancer or other health effects from exposures to hazards *(chemicals, radiation, diseases)*	possible adverse effects to animals/plants *(individuals, populations, habitats, ecosystems)* from exposures to stressors *(chemical, physical, biological)*

Outcome of the risk assessment helps us make decisions:

- **Does something need to be done?**
- **If so, what?**

Risk Assessments Address "Who, What, When, Where, & How?"

DON RAB/TRC Training Workshop

Starting point source	Can move through environmental media	To reach receptors	And possibly cause effects
Hazard or Concern	Soil Ground Water Surface Water Air	Humans, Animals, Plants	Human Health/ Ecological Risks
What, how much, where ?	Where, when, how much ?	Who, what, where ?	What could happen?

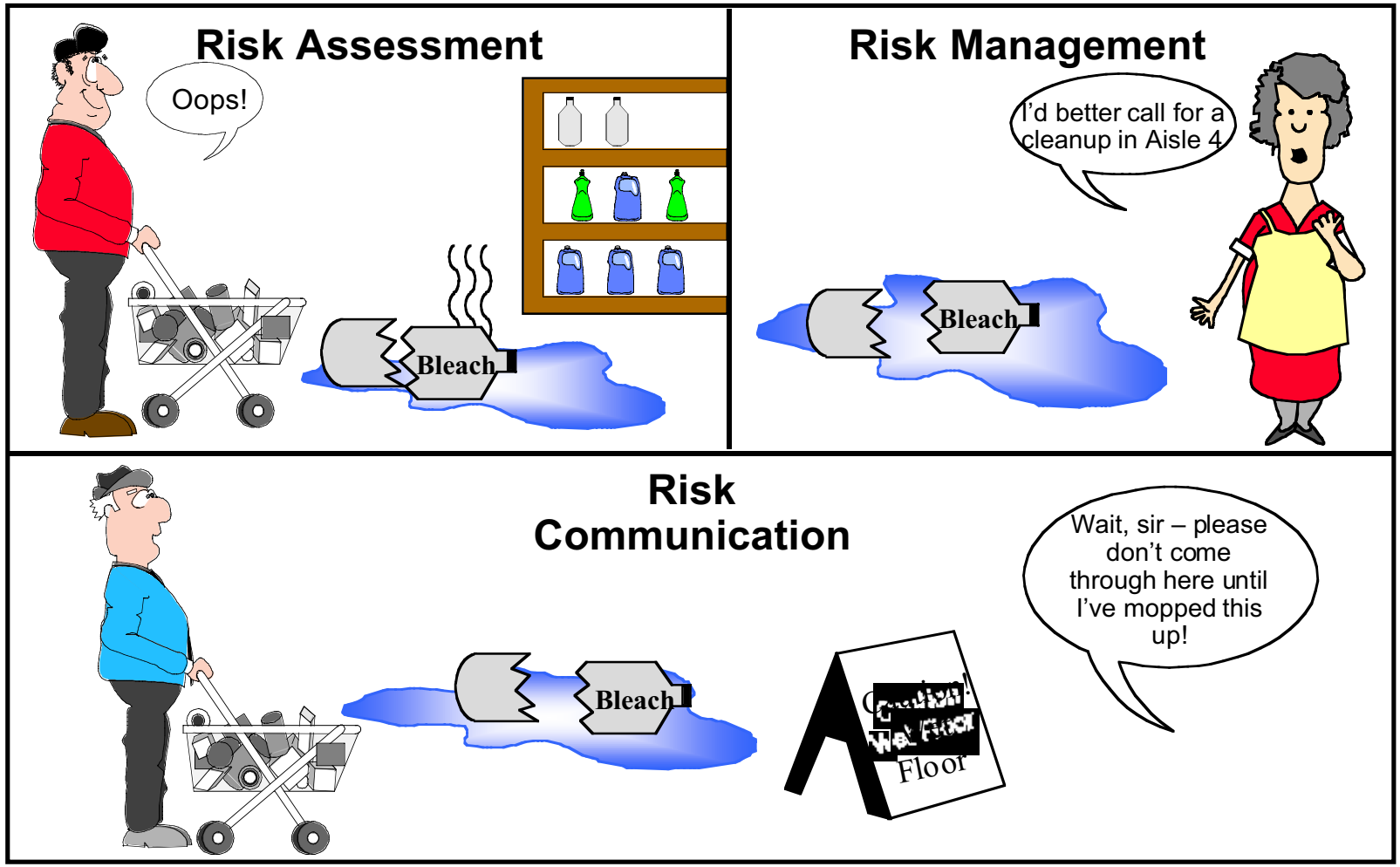
General Risk Assessment Objectives

1. Estimate risks to help see if/what action may be needed
   - Is there a human health or ecological risk?
   - What hazard poses the greatest risk?
   - Which exposures are most important?
   - Which groups or individuals are most at risk?
   - What risks can be attribute to the environment vs a given hazard?

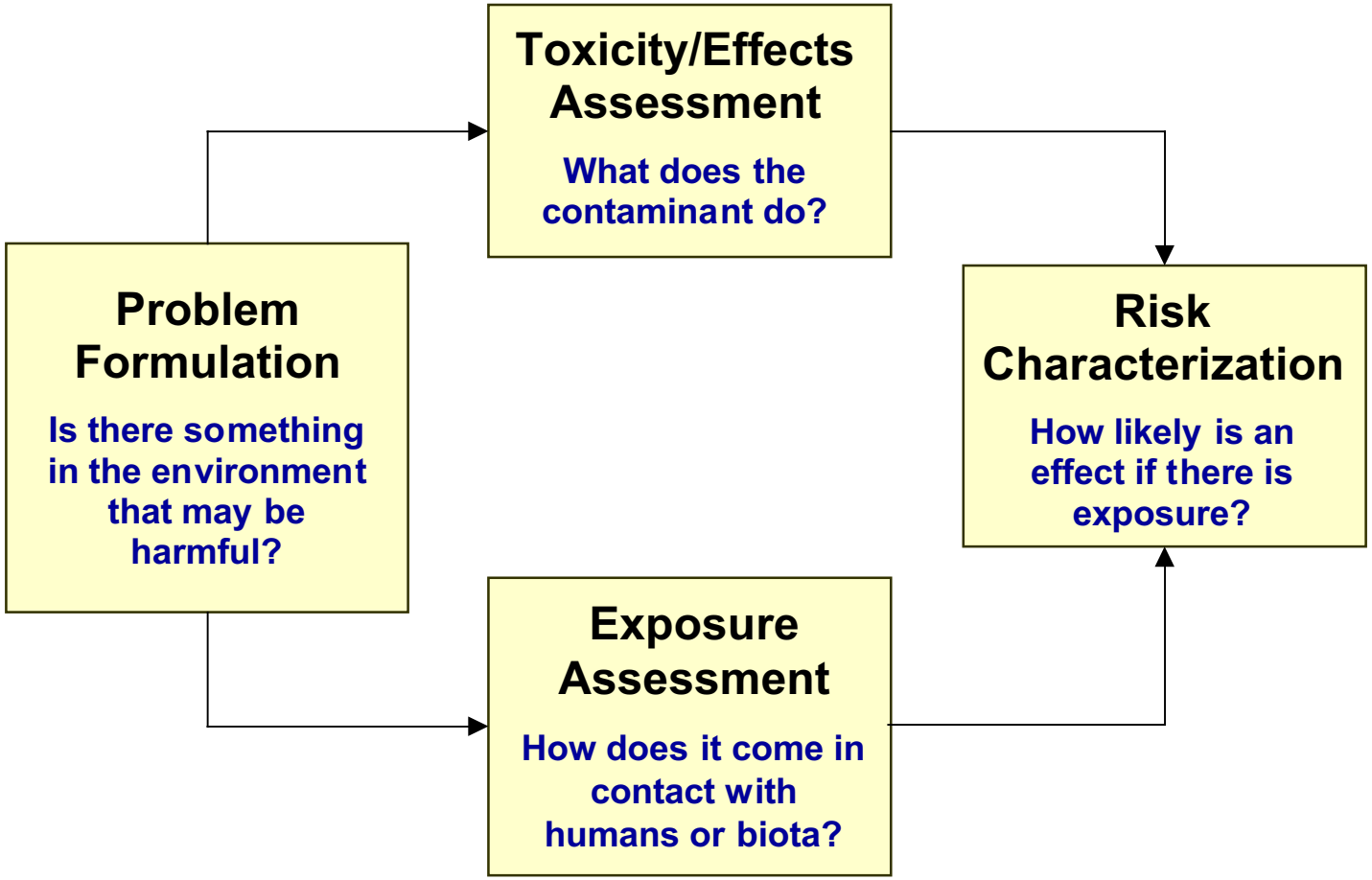
2. Provide a basis for determining what levels can be safe if left alone
   - How much of a given stressor can remain in the environment?

3. Apply a consistent process for estimating health and ecological risks
   - So different response options can be evaluated in a similar manner

Risk Assessment is Just One Part of Risk Analysis



Four Steps of Risk Assessment

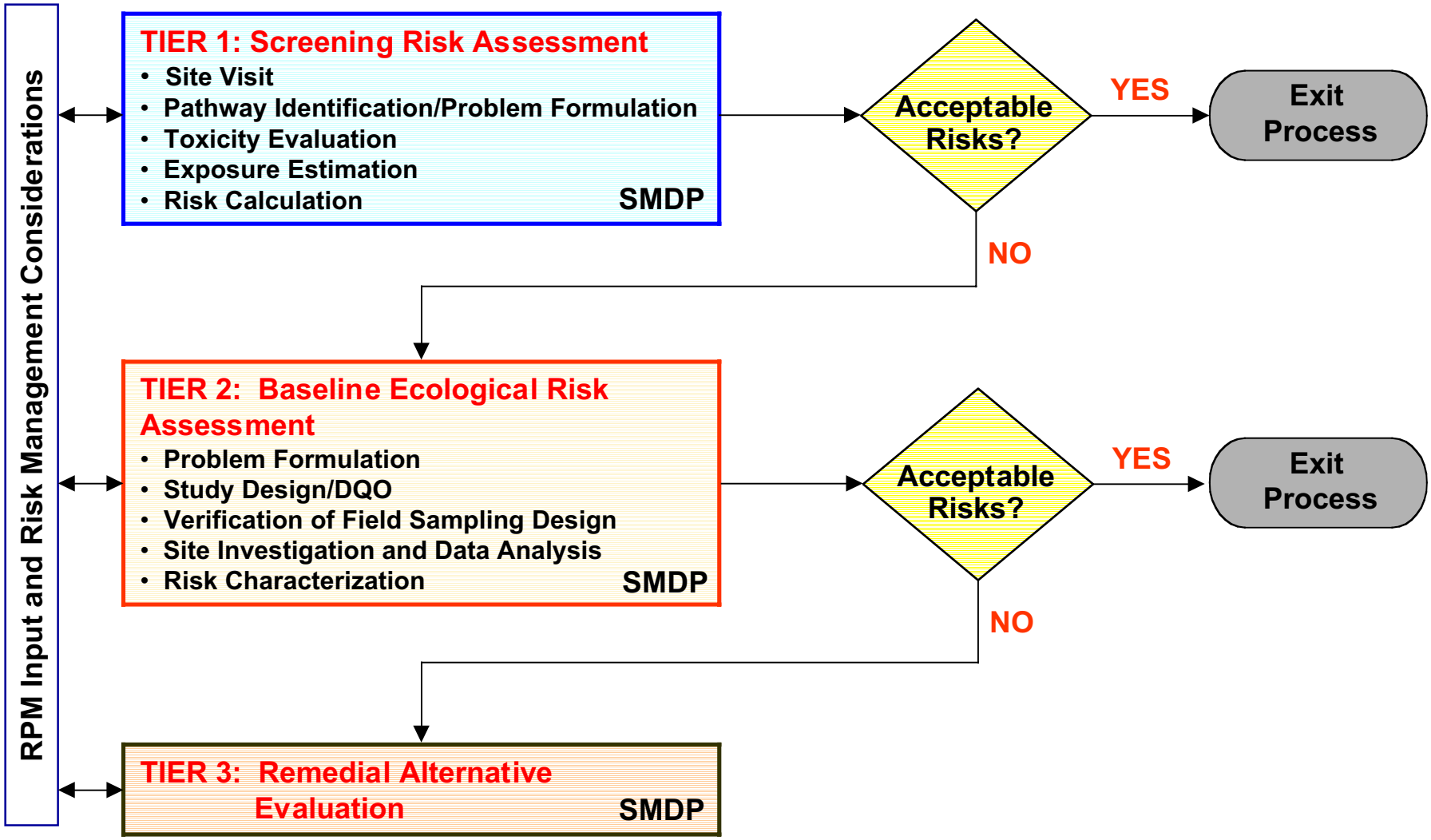


Common to both human health and ecological risk assessments

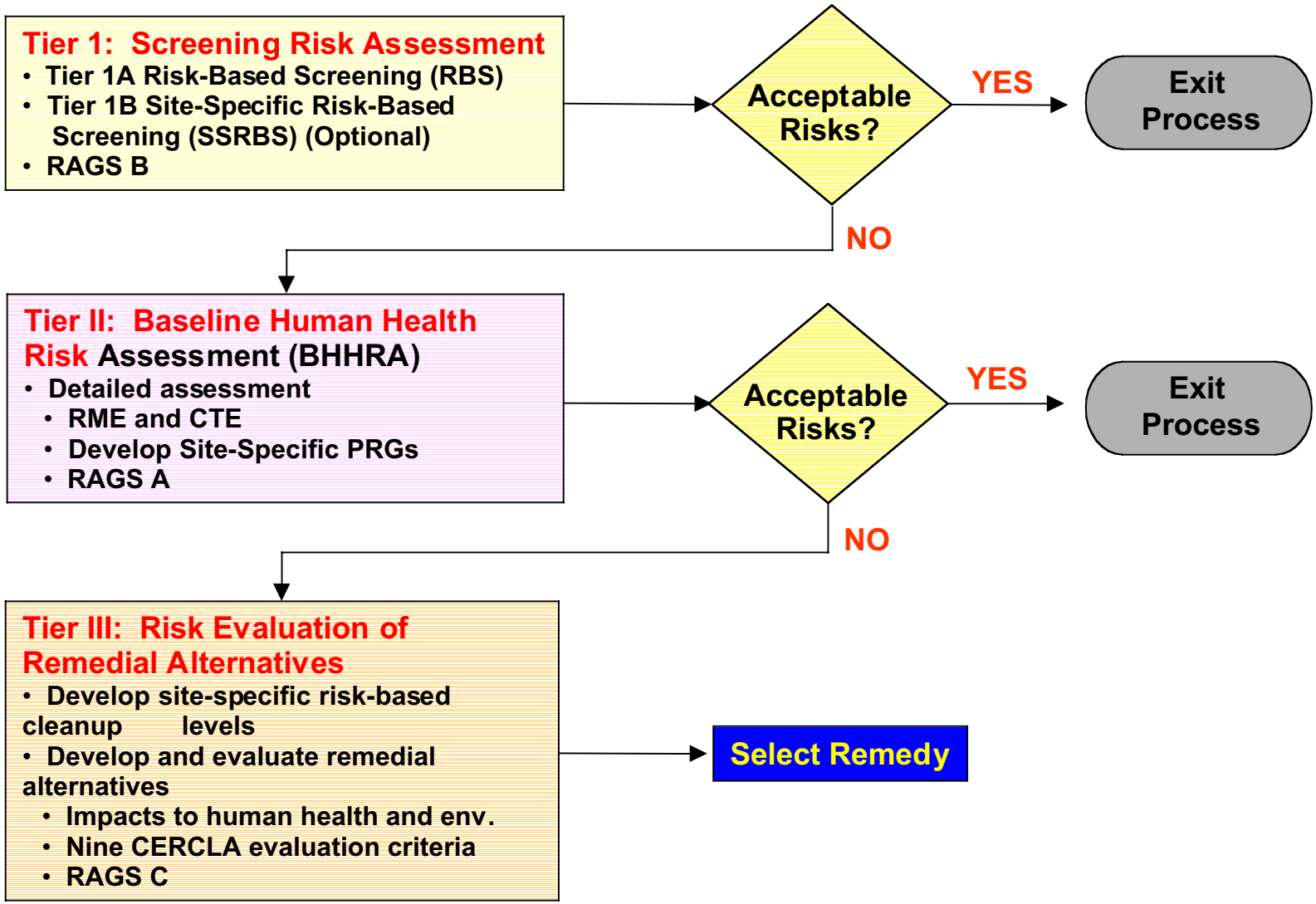
The Navy Tiered Approach to Risk Assessment

- Phased approach with different layers of assessment complexity:
  - Tier 1: Screening level assessment
  - Tier 2: Baseline risk assessment
  - Tier 3: Risk evaluation of remedial alternatives, including no-action
- Outcome of each tier leads to risk management decisions
- Tiers 1 and 2 include exit criteria

Navy Approach for Ecological Risk Assessment



Navy Approach for Human Health Risk Assessment



How Similar are Ecological and Human Health Risk Assessments?

Assessment Parameter	Human Health Risk Assessment	Ecological Risk Assessment
Tissue/Whole Body Analyses	Limited	Yes
Standard Exposure Factors	Readily Available	Limited Availability
Receptors	Single Species	Multiple Species
Spatial Scale	Species Independent	Species Dependent
Temporal Scale	Important	Important

Tier 1: Screening Risk Assessment

- Both human health and ecological risk assessments begin with Tier 1 Screening Risk Assessments
  - Relatively straightforward and simple
  - Employ very conservative assumptions
    - assume maximum exposures and effects
    - typically over-estimate exposure and effects
      - provides confidence when eliminating COPCs from further evaluation
  - Typically use existing data
    - little or no new data collection

Tier 2: Baseline Risk Assessments

- A more rigorous assessment than the Tier 1 SRA, and includes:
  - Development of a more detailed problem formulation and conceptual site model
  - Design of site specific studies for data collection/analysis
  - Risk estimates based on realistic assumptions and site-specific data
  - Risk characterizations for current and future land use

Tier 3: Remedial Alternatives Evaluation

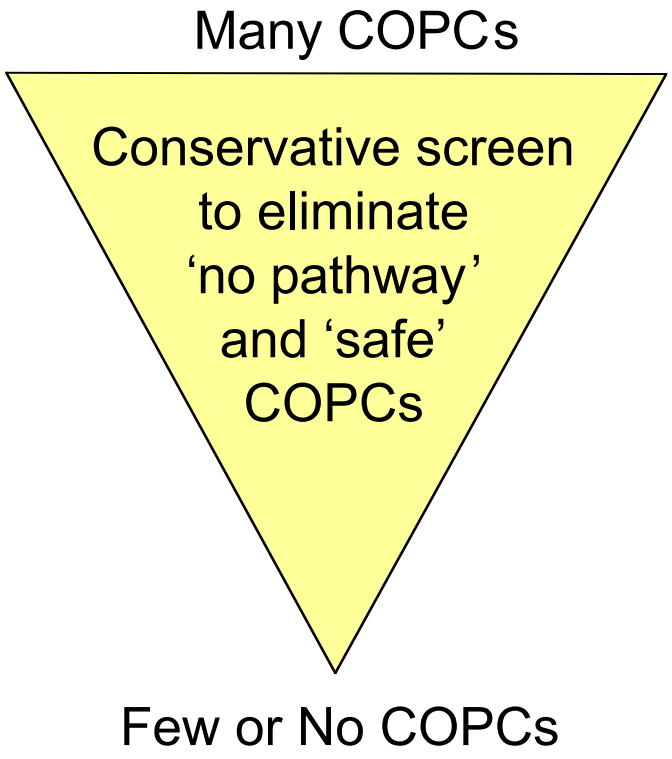
- Both risk assessment processes end (if appropriate) with Tier 3, which evaluates alternatives with regard to:
  - Effectiveness of risk reduction
  - Impacts related to implementation and operation
  - Residual risks
- Tier 3 is done to ensure to the extent possible that:
  - Selected alternative is protective of both ecological resources and human health

Tier 1: Screening Risk Assessment

- Tier 1 evaluates potential for risks and need for further evaluation or action
- Compares maximum site concentrations to “safe” screening values
  - This ratio is the Hazard Quotient (HQ)
- If site concentrations are above “safe” levels then additional evaluation or action needed
- If site concentrations below “safe” levels then no further action needed

Role of the Tier 1 Screening Risk Assessment

- Eliminate those constituents for which complete exposure pathways **do not** exist
- Eliminate those constituents that are present at levels less than the "**safe**" concentration
- Retain those constituents as COPCs that exceed the "**safe**" concentration
- If appropriate, drop site altogether



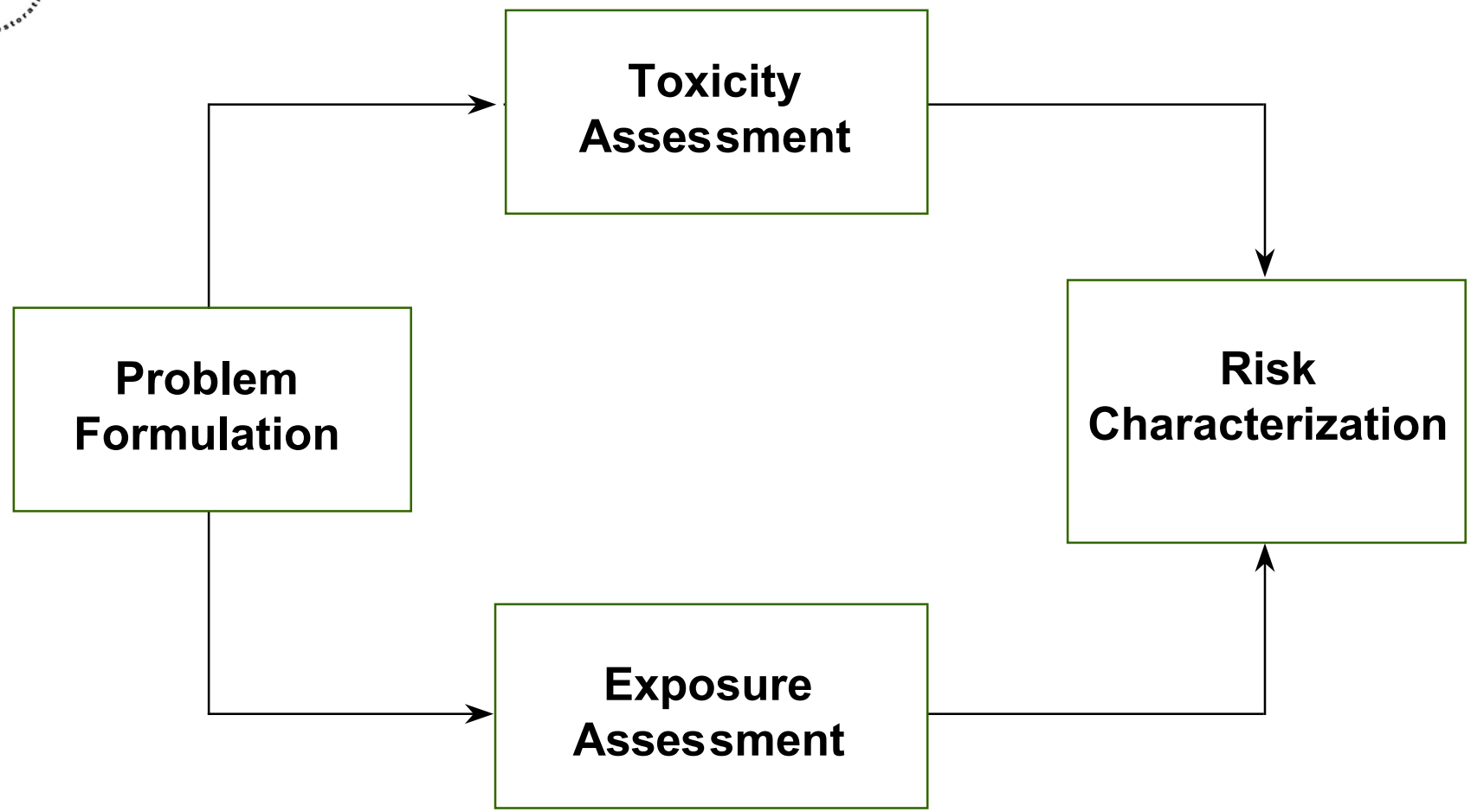
Tier 1 Decision Criteria

- Potential risks are negligible (acceptable): HQs below 1.0
  - No need for additional risk assessment or remediation from an ecological perspective
- Insufficient data available, proceed to Tier 2
- Potential for unacceptable risks indicated: HQs above 1.0, proceed to Tier 2
- Potential for unacceptable risks indicated: HQs above 1.0, proceed directly to remediation

Tier 2: Baseline Risk Assessment

- The baseline risk assessments focus detailed, site-specific evaluations on specific receptors of concern:
  - For human health - different subpopulations
    - adults and children
    - residential, recreational, worker, visitor
  - For ecological resources
    - assessment endpoints
    - species, populations, communities, habitats

Four Components of a Baseline Risk Assessment



Baseline Risk Assessment Exit Criteria

- COPCs at the site **do not pose unacceptable risks** to human health and/or ecological resources
  - No further evaluation and no remediation needed
  - Site exits the risk assessment process
- COPCs at the site **do pose unacceptable risks** to human health and/or ecological resources
  - Further evaluation in the form of remedy development and evaluation is appropriate
  - Site proceeds to Tier 3

Problem Formulation

- Problem formulation identifies the objectives and goals of the assessment
  - Refines information on COPC fate & transport and exposure pathways
  - Identifies assessment endpoints and human populations potentially at risk
  - Refines conceptual site model, including risk hypotheses

Problem Formulation Looks at COPC Fate & Transport and Exposure Pathways

Contaminant Source → Release Mechanism → Transport Medium → Exposure Point → Exposure Route → Receptor

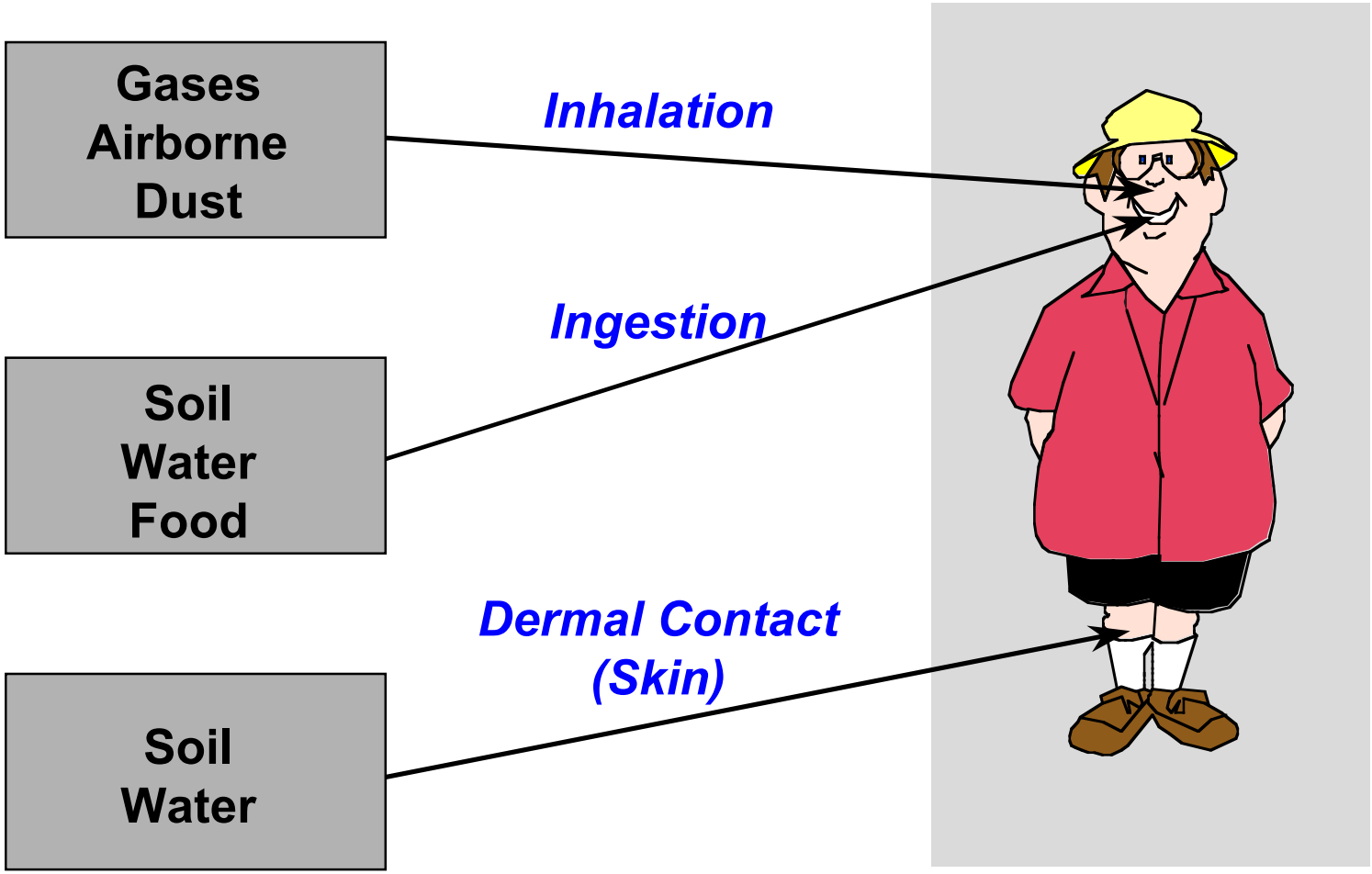
A Complete Exposure Pathway:

Contaminated Surface Soil → Fugitive Dust → Air → Residence → Inhalation → Resident

An Incomplete Exposure Pathway:

Contaminated Surface Soil → Fugitive Dust → Air → Work Site →

What Is an Exposure Route?



What Is an Exposure Scenario?

- The Who? What? Where? When? and How often? that describe an exposure
  - Receptor (resident, worker, recreational visitor?)
  - Location of exposure – also referred to as the exposure point or contact point (at home, at work, at a park?)
  - Activities during exposure (sleeping, typing, hiking?)

Human Health Receptors

- One species but multiple groups may be of interest
  - Adults and children
  - Residential, industrial, recreational
  - Specific group of interest determined by current and future land use
    - screening assessment considers everyone to be residential
    - baseline becomes site-specific
  - Consider cancer and non-cancer effects

Ecological Assessment Endpoints

- Assessment Endpoint: "An explicit expression of the actual environmental value that is to be protected." (EPA)
  - What we are concerned about protecting

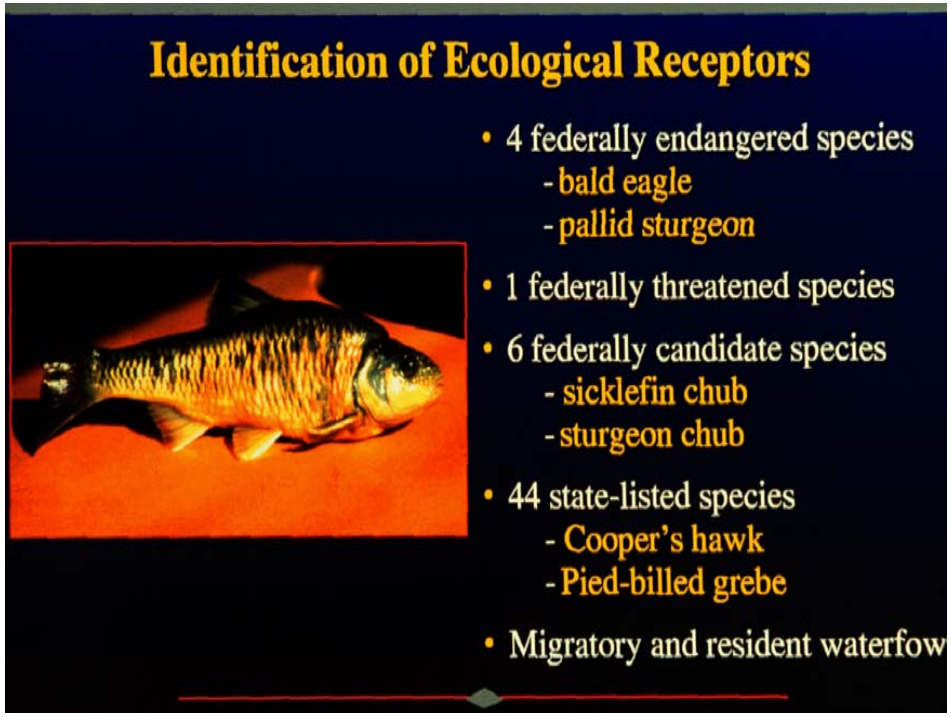
Ecological Assessment Endpoints

- Two elements needed to define an assessment endpoint
  - Identification of the valued ecological resource
    - species, functional group, a community, or ecosystem
  - The characteristic that is potentially at risk
    - survival, growth, reproduction, nutrient cycling, abundance and distribution, diversity

How Do We Evaluate Assessment Endpoints?

Select Representative Biota

- Ecologically important species
- Species protected under federal or state law
- Economically important species
- Societal species
- Populations, communities, habitats



Example: Ecological Assessment Endpoints

- Example: Potentially contaminated wetland
  - Heavily used by nesting waterfowl (ducks and geese)
  - We know there is a COPC that affects reproduction in birds
- Maintaining successful waterfowl reproduction at levels similar to those at nearby areas that don't receive site COPCs
  - The valued ecological resource is waterfowl
  - The characteristic potentially at risk is reproduction

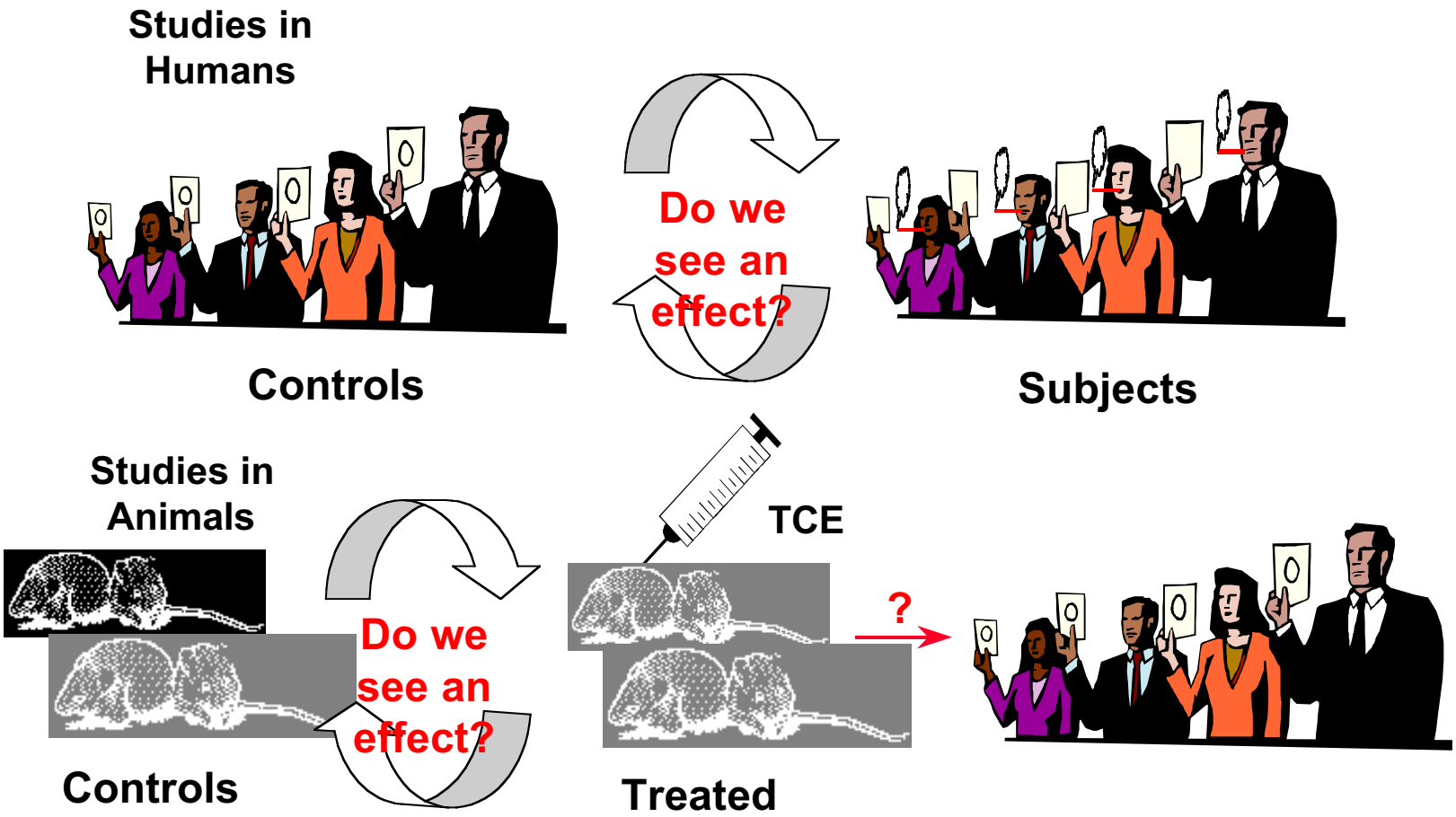
Some Basic Toxicological Concepts

- There are two categories of toxic agents
- Carcinogens
  - Exposure results in increased risk of cancer
  - Believed to act via a “nonthreshold” mechanism of action
    - no exposure that does not result in a response
    - a risk would be associated with any exposure level
- Noncarcinogens
  - Exposure may affect growth, reproduction, mortality, development, etc.
  - Believed to act via a “threshold” mechanism of action
    - there is a level of exposure (i.e., a threshold) below which it is unlikely to have an effect.

What is a Toxicity Value?

- A measure of relative toxic potency
- Human health
  - Reference dose (RfD)
    - for noncarcinogens
    - an estimate of the "safe dose", in units of mg/kg-d
  - Slope factor (SF)
    - for carcinogens
    - derived from slope of the dose-response curve
- Ecological
  - No Observed Adverse Effects Level (NOAEL)
    - highest reported concentration with no effect
  - Lowest Observed Adverse Effect Level (LOAEL)
    - lowest concentration that still causes an effect

Hazard Identification: Is It Toxic?



Toxic Potency Varies Over Several Orders of Magnitude

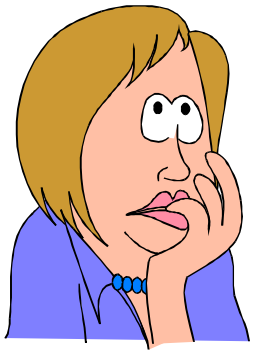
Compound	Oral LD50 (mg/kg)
Salt	3,000
Aspirin	1,000
DDT	100
Arsenic	48
Nicotine	1
Dioxin	0.001
Botulinus toxin	0.0001

All Risk Assessments Use a Conceptual Site Model (CSM)

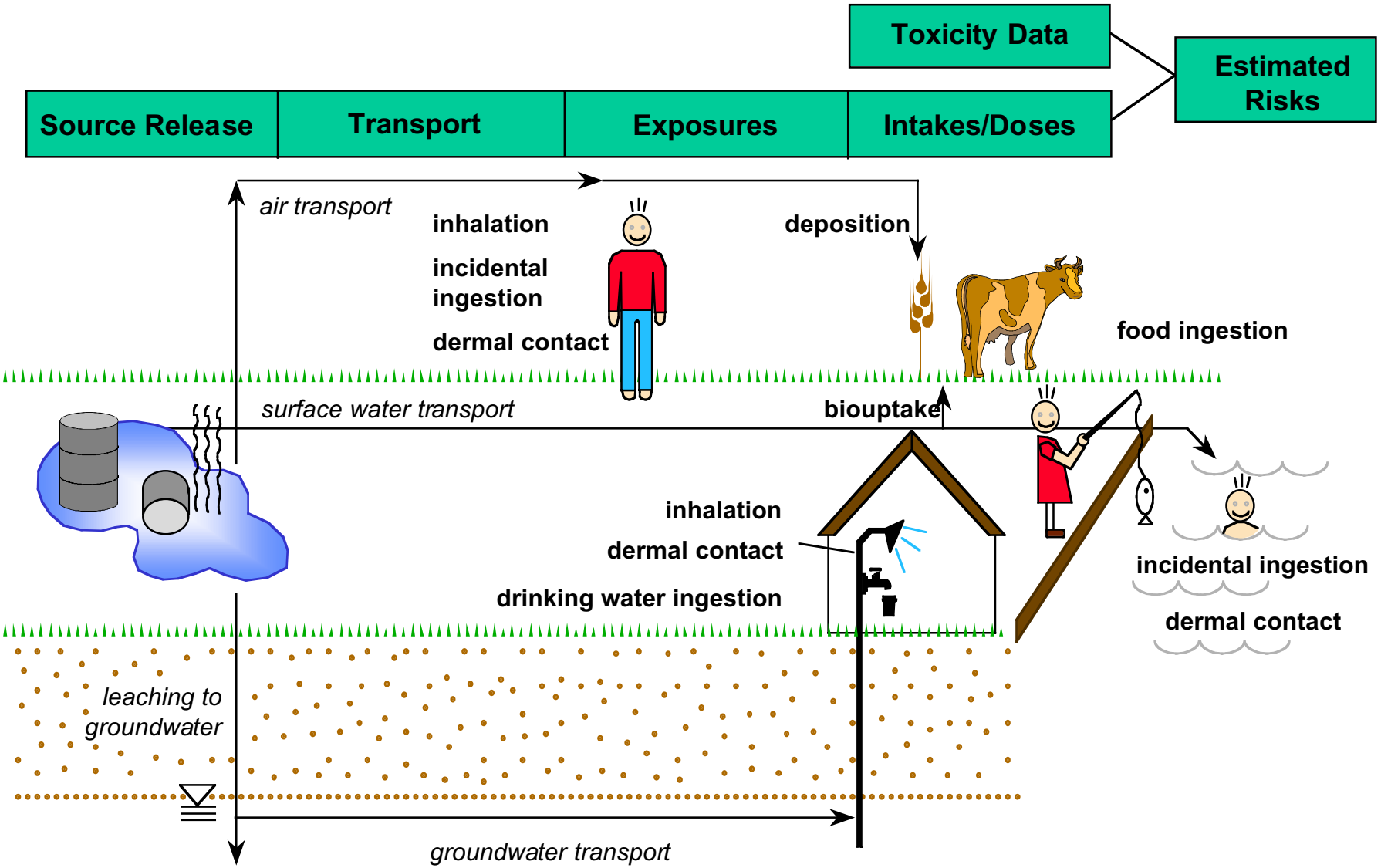
- A description of the source, environmental fate and transport of the site COPCs
  - Where are they, and where and how are they moving
- A description of the known and/or suspected exposures
  - Who/what are we most concerned about, and where/how are they being exposed
- A set of risk hypotheses
  - Describing the relationships among the stressors, the resources of concern, and the environment
- A diagram depicting these relationships

Risk Hypotheses

- Critical - serves as the foundation for the assessment
  - “Our explanation of the situation and what we think is going on”
  - Specific assumptions about potential risk to assessment endpoints
  - Developed using professional judgment and available data/information

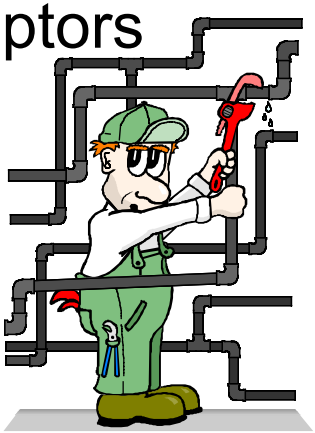


Example Conceptual Site Model



Study Design: Effects and Exposure Assessments

- Risk assessments employ both ***exposure*** and ***effects*** assessments
  - *Exposure assessment* measure/estimate actual or potential exposure of each receptor to each COPC
  - goal is to link COPCs in the environment to receptors
- *Effects assessment* quantitatively links COPC concentrations to adverse effects in receptors
- *The number and types of studies will depend on:*
  - *Assessment endpoints and human receptors*
  - *Measurement endpoints*
  - *COPCs*



Measurement Endpoints

- Measurement endpoint is an ecorisk term
- Can be defined as a measurable ecological characteristic related to the assessment endpoint
  - what aspect of the assessment endpoint are you going to evaluate in order to determine risks or impacts?

Example:

***Contaminant* - PCB**

Assessment endpoint - maintenance of predatory bird populations at levels similar to populations not exposed to PCB

Measurement endpoint - PCB levels in food and model the dose, which can be compared to critical dose levels

Exposure Assessment

- For ecological risk assessments, three general approaches:
  - Tissue analysis
  - Biomarkers
  - Dose modeling
- For human health risk assessment, typically one approach
  - Dose modeling
- These approaches do NOT identify effects

Tissue Analysis and Biomarkers

- Similar evaluations
  - Both involve collecting biota and looking for evidence of COPC exposure

- Tissue analysis
  - Measures COPC concentrations in tissues of exposed biota
- Biomarkers
  - Look for changes in physiology o biochemistry
    - enzyme activity in tissues
    - genetic changes
    - presence of tumors or lesions
    - changes in body functions (e.g., breathing rate)

Modeling: Estimating Contaminant Doses

- Predict exposure by modeling contaminant intake
  - Food and water ingestion
  - Ingestion of contaminated soil and sediment
  - Direct uptake through body surfaces
  - Inhalation
- Similar approach for both humans and biota

How Do We Calculate Contaminant Intake?

Generic equation for estimating intake by humans:

$$\text{Intake} = \frac{\text{Contaminant Concentration} \times \text{Intake Rate} \times \text{Exposure Time} \times \text{Exposure Frequency} \times \text{Exposure Duration}}{\text{Body Weight} \times \text{Averaging Time}}$$

For contaminant i:

$$I_i = \frac{C_i \times IR \times ET \times EF \times ED}{BW \times AT}$$

Calculating Contaminant Intake (cont'd)

$$I_i = \frac{C_i \times IR \times ET \times EF \times ED}{BW \times AT}$$

C_i = COPC Concentration at Exposure Point

- estimated for each COPC in each environmental medium (soil, water, and air)
- either calculated from the sampling data or modeled

Calculating Contaminant Intake (cont'd)

$$I_i = \frac{C_i \times IR \times ET \times EF \times ED}{BW \times AT}$$

IR = Intake Rate

- depends on the route of exposure (e.g., inhalation) and exposure medium (e.g., air)
  - ingestion of food, soil, sediment, water
  - inhalation
  - dermal contact with soil, sediment, water

Calculating Contaminant Intake (cont'd)

$$I_i = \frac{C_i \quad 5 \quad IR \quad 5 \quad ET \quad 5 \quad EF \quad 5 \quad ED}{BW \quad 5 \quad AT}$$

ET x EF x ED = Total Duration of Exposure

- ET = exposure time (in hours/day or hours/event)
  For how many hours is the receptor exposed?
- EF = exposure frequency (in days/year or events/year)
  Over how many days a year does the exposure occur?
- ED = exposure duration (in years)
  Over how many years does the exposure occur?

Calculating Contaminant Intake (cont'd)

$$I_i = \frac{C_i \times IR \times ET \times EF \times ED}{BW \times AT}$$

BW = body weight of the receptor

AT = averaging time (in days)

for carcinogens: 25,550 days (70 years)

for noncarcinogens: 365 d/yr x ED

Ecological Dose Modeling

Dose = Concentration in food, soil, water, air X Species-Specific Exposure Factors

Models may include:

- Food/water ingestion
- Ingestion of soil
- Ingestion of sediment
- Root uptake by plants
- Dermal uptake

Exposure factors include:

- Diet Composition
- Body Weight
- Habitat Size
- Food and Water Ingestion Rates
- Root Uptake Rates

Effects Assessment

- Effects assessment links COPC concentrations to adverse effects in the receptors
- For ecological risk assessments there are three general approaches
  - Literature reviews
  - Toxicity testing
  - Field studies
- For human health assessments, one approach
  - Evaluation of existing data bases and literature

Literature Reviews

- Wealth of effects information available from a variety of sources
- For human health
  - IRIS, HEAST, ATSDR
  - Very standardized and widely accepted
- For ecological risks
  - EPA, FWS, Environment Canada, etc.
  - Scientific literature
  - More diverse and not as widely accepted
  - Often difficult to find species-specific information

Toxicity Testing

- Directly evaluate toxicity of site media
- Expose test organism to contaminated media and observed predetermined response
  - Survival, growth, and/or reproduction, behavior
  - Can test individual contaminants or media containing mixtures of contaminants
  - Short-term (acute) and long-term (chronic) tests

Field Studies

- Identify whether ecological effects are actually occurring under existing site conditions
- Field studies may include:
  - Collection of specimens
  - Physical and chemical habitat evaluations
  - Remote sensing

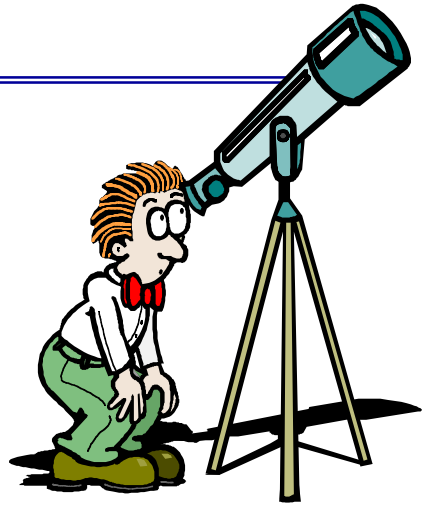
- Field data may include:
  - Biodiversity, biomass, abundance
  - Presence/absence of tolerant or sensitive species
  - Population structure, growth rates, reproductive success

Field Studies Require Use of a Reference Site

- Observed field results may not be result of exposure to site COPCs:
  - Non-site factors could be producing observed effect
  - Natural variability in the biota
  - Natural variability in the environment (climate)

- Reference site provides baseline for comparison of results from contaminated areas
  - Should be as physically and ecologically similar to the contaminated site as possible

Risk Characterization



- Final phase of the risk assessment:
  - Evaluates evidence linking COPCs with potential adverse ecological effects.
  - Goal is to use the results of the exposure and effects assessments to:
    - estimate risks to the assessment endpoints or human receptors identified in problem formulation

Ecological Risk Characterization

- Ecological risks are estimated using one of three general approaches:
  - Calculate a hazard quotient (HQ) using modeling and site-specific data
  - Identify no-effect and low-effect concentration ranges from site-specific data
  - Combine different lines of evidence with professional judgement

Risk Calculation Using the Quotient Method

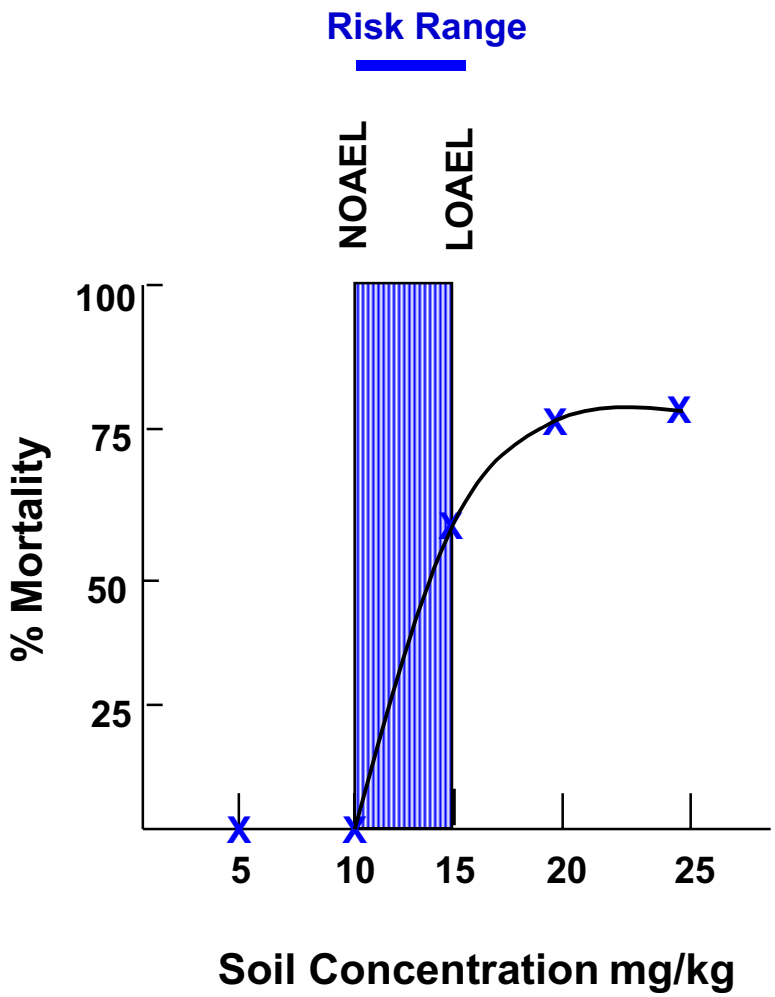
Risks estimated using simple calculation:

$$HQ = \frac{\textit{Exposure Value}}{\textit{Toxicity Value}}$$

- the exposure and toxicity values can be ***either*** an environmental concentration ***or*** a dose
- HQ values > 1.0 indicate potential risk
- HQ values $\leq$ 1.0 indicate acceptable risk

A separate HQ is calculated for each COPC/receptor pair

Site-Derived Risk Ranges



Lines-of-Evidence Approach

Situation	Chemicals Present	Toxicity	Alteration of Benthic Community	Possible Conclusion
1	+	+	+	Strong evidence for contaminant-induced degradation
2	-	-	-	Strong evidence that there is no contaminant-induced degradation
3	+	-	-	Contaminants not bioavailable or below toxic levels
4	-	+	-	Unmeasured contaminant or conditions with potential for degradation
5	-	-	+	Alteration not due to contaminants
6	+	+	-	Contaminants stressing the system
7	-	+	+	Unmeasured contaminants causing degradation
8	+	-	+	Toxicity tests are insufficiently sensitive or alteration not due to contaminants

Ecological Significance

- Most critical aspect of the risk characterization
- The interpretation of ecological significance considers:
  - Where is the greatest impact likely to occur?
  - What is the expected magnitude of the impact?
  - What does the impact mean ecologically?
  - How are the magnitude and likelihood of occurrence of the impact related?
  - What is the expected duration of the impact?

Human Health Risk Characterization

- Human health risks are estimated using two general approaches:
  - For non-carcinogens calculate a hazard quotient (HQ) using modeling and site-specific data
  - For carcinogens calculate a risk number that identifies likelihood of getting cancer

How Do We Quantify Risks from Noncarcinogens?

Calculate HQ as: $$HQ = \frac{I}{RfD}$$

Where:

HQ	=	Hazard quotient from chemical
I	=	Intake of chemical
RfD	=	Reference dose for chemical

- HQ > 1 indicate potential unacceptable risk for noncarcinogenic effects
- HQ $\leq$ 1 indicate an acceptable level of risk

How Do We Quantify Risks from Carcinogens?

For a single contaminant,

$$\text{Risk} = I \times SF$$

Where:

Risk	=	Risk from chemical
I	=	Intake of chemical
SF	=	Slope factor for chemical

How Do We Express Cancer Risk?

1/10	0.1	10^{-1}
1/100	0.01	10^{-2}
1/1,000	0.001	10^{-3}
1/10,000	0.0001	10^{-4}
1/100,000	0.00001	10^{-5}
1/1,000,000	0.000001	10^{-6}

What Do the Numbers Mean?

- A 1×10^{-6} risk is equivalent to a one-in-a-million excess risk of cancer from a given level of exposure to a chemical
  - Each individual exposed to a COPC has a one-in-a-million chance of getting cancer from that particular exposure
    - because of that COPC, we would expect to see one additional case of cancer in a population of one million people who are all exposed under the same circumstances

- Cancer risk is described as "excess" because it is over and above the existing background risk of cancer
  - In the same population of one million people, the number of background cancer cases ranges from approximately 250,000 to 333,000

Tier 3: Evaluation of Remedial Alternatives

- Evaluation of remedial action alternatives (including no-action)
- Based on the Nine CERCLA Evaluation Criteria
  - **Threshold Criteria:** must be met for an alternative to to acceptable
  - **Primary Balancing Criteria:** must be balanced, emphasizing long-term effectiveness and reduction of contaminant toxicity, volume, or mobility
  - **Modifying Criteria:** need to be “considered”

Tier 3: Evaluation of Remedial Alternatives

- Identify a remedy that:
  - Reduces exposure and risks to acceptable levels
  - Strike balance between human health and ecological concerns
  - Cost-effective
  - Environmentally benign
  - Acceptable to the public

Ecological Evaluations: Tier 2 vs. Tier 3

- Different focus of each tier, but address the same set of resources
- Tier 2 evaluations
  - Focus is on risks posed by current and future site conditions (environmental COPC concentrations)
- Tier 3 evaluations
  - Impacts of implementation
  - Protectiveness
  - Residual risks

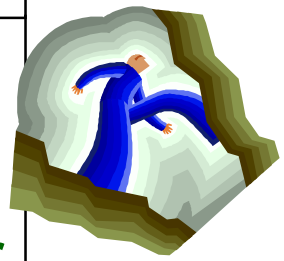
Land Use, Risk, and Remedial Alternatives

Land Use

Residential
Commercial/industrial
Recreational
Wildlife area

Exposed Individual

Resident
Worker
Recreational user
Ecological receptor



Exposure Scenario

Routes of exposure *(e.g., breathing, eating, drinking)*
Exposure parameters *(e.g., how often, how long)*

Risk → **Remedial Alternative**

CERCLA Remedy Selection Criteria

Threshold Criteria

1. Overall protectiveness of human health and the environment
2. Compliance with ARARs

Primary Balancing Criteria

3. Long-term protectiveness and permanence
4. Reduction of toxicity, mobility, or volume
5. Short-term effectiveness
6. Implementability
7. Costs (relative to overall effectiveness)

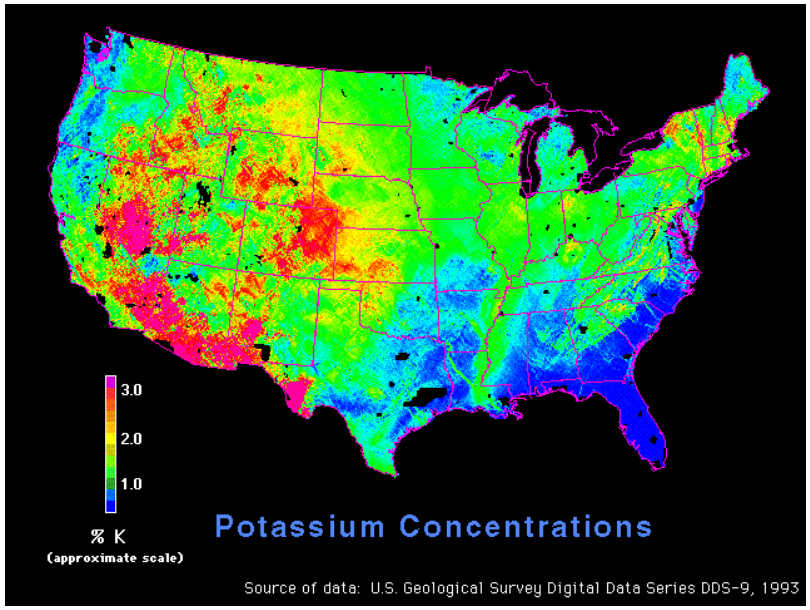
Modifying Criteria

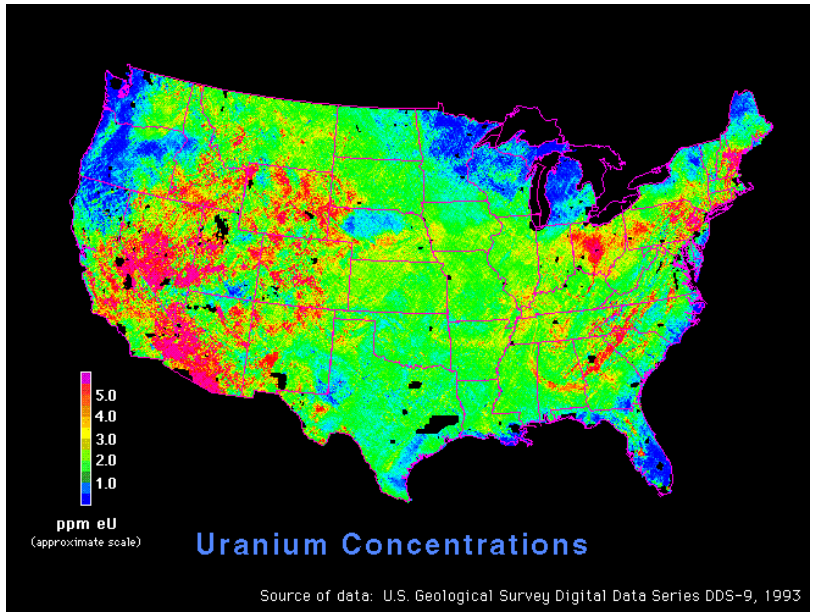
8. State acceptance
9. Community acceptance

What About Background?

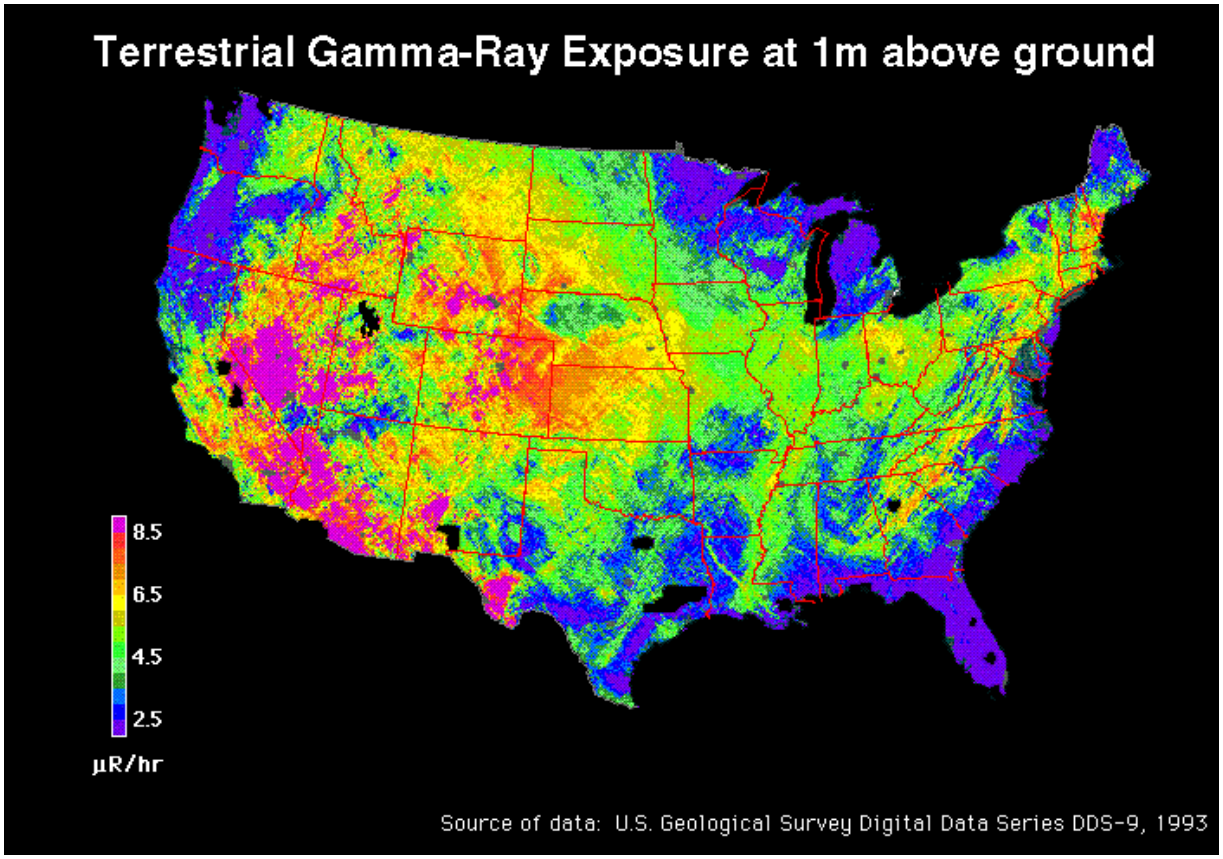
- Chemical concentrations in environmental media are a function of a number of factors
  - Underlying geology (natural)
  - Human activities (anthropogenic)
  - Natural fate and transport mechanisms (natural and anthropogenic)
- Important to identify background levels of site COPCs

Terrestrial Background Levels: Potassium and Uranium





Terrestrial Background Radiation



What if We Don't Consider Background?

- May assign risks to site concentrations that are not the result of site releases
  - Conduct cleanup when not appropriate
- May develop cleanup goals that are below background
- May identify cleanup for sites receiving non-site inputs
  - Cleanup successful but levels return

Background Considerations Under CERCLA

- CERCLA recognizes importance of identifying and considering background
- In risk assessments
  - During screening, eliminate COPCs that are present at levels < background
- During remedy development and selection
  - Don’t clean to below background

How Do We Determine Background?

- Number of guidance documents available from EPA
  - Collect and analyze samples from areas as similar to your site as possible
    - same geology and soils
    - same topography
    - typically upgradient locations for surface water and groundwater
    - defensible scientific design
      - sufficient sample size
      - appropriate statistics

Navy Policy for Consideration of Background

- Navy recently issued policy for considering background
  - Fully consistent with CERCLA
  - Sites need to consider background in risk assessments and remedy development and evaluation
  - Cleanup levels below background are not appropriate

Summary

- Navy uses tiered approaches for human health and ecological risk assessments
  - Tier 1 Screening Risk Assessment
  - Tier 2 Baseline Risk Assessment
  - Tier 3 Evaluation of Remedial Alternatives
- Human and ecological risk assessments share common framework
  - Problem Formulation
  - Effects and Exposure Assessment
  - Risk Characterization

Summary

- Variety of methods for evaluating effects and exposure
  - Primarily modeling for human health
  - Modeling and studies with biota for ecological risks
- Human health risks focus on potential for cancer and non-cancer effects, while ecological risks focus on noncancer effects
  - Ecorisk assessments often include directly measured exposure and effects

Summary

- Remedy evaluation focuses on balancing benefits and impacts to human health and the environment
- Background levels play an important role in risk evaluation, remedy development, and cleanup levels