Human Health Risk Assessment Workshop

April 27, 2011

Vieques, Puerto Rico

Workshop Agenda

6:00 – 6:15	Welcome
6:15 – 6:30	Introductions and Workshop Goals
6:30 – 7:30	Overview of Human Health Risk Assessment Protocol Steps and Examples
7:30 – 7:45	Break
7:45 – 9:00	Continued Risk Assessment Discussion and Wrap-up

Workshop Contributors

- Michael Sivak – USEPA
- Rich Henry – USFWS
- Katarina Rutkowski – PREQB Technical Support Contractor
- Barrie Selcoe – Navy Technical Support Contractor

Goals of Workshop

- To provide a broad overview of the human health risk assessment (HHRA) process as it applies to Vieques sites.
- Describe basic parts of HHRA
- Answer your questions

CERCLA HHRA Process for Vieques

--Michael

Vieques Master Plans – Overview

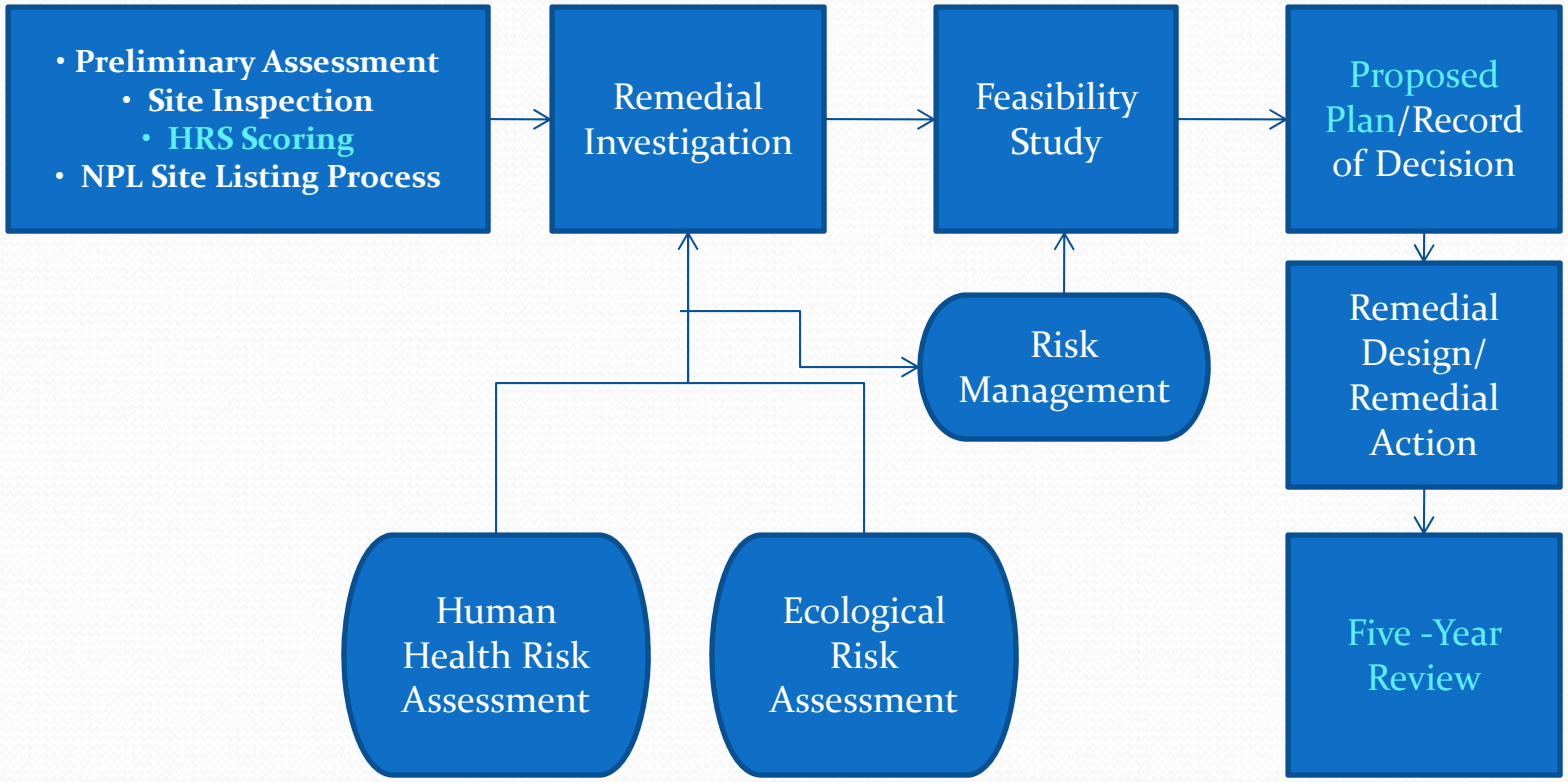
"Master Standard Operating Procedures, Protocols, and Plans, Environmental Restoration Program, Vieques, Puerto Rico"
April 2010

- Provides a blueprint for consistent data collection and risk assessments for all Vieques sites
- Includes methodologies for conducting
  - Ecological risk assessments
  - Human health risk assessments
  - Sampling methods for soil, groundwater, surface water, and sediment
- Updated as needed

Why Do We Need a HHRA Protocol Specific to Vieques?

- Consistent approach & process applied to all sites
- Tailored to the people, food sources, and activities specific to the island.

CERCLA Remedial Process



CERCLA = Comprehensive Environmental Response, Compensation, and Liability Act

Blue = step with formal public input; white = step with informal public input

Baseline Human Health Risk Assessment

- HHRA identifies and characterizes the potential current and future risks a site poses
- Provides a basis for taking an action under CERCLA
- Can help set clean up goals

Baseline Human Health Risk Assessment

- In accordance with CERCLA, answers 2 main questions:
  1. What are the potential health risks based on current land use, if no action is taken?
  2. What might be the potential risks be for future land uses, if no action is taken?
     - How might the land/groundwater/surface water/sediment be used differently in the future?
     - Might people be exposed under different scenarios?

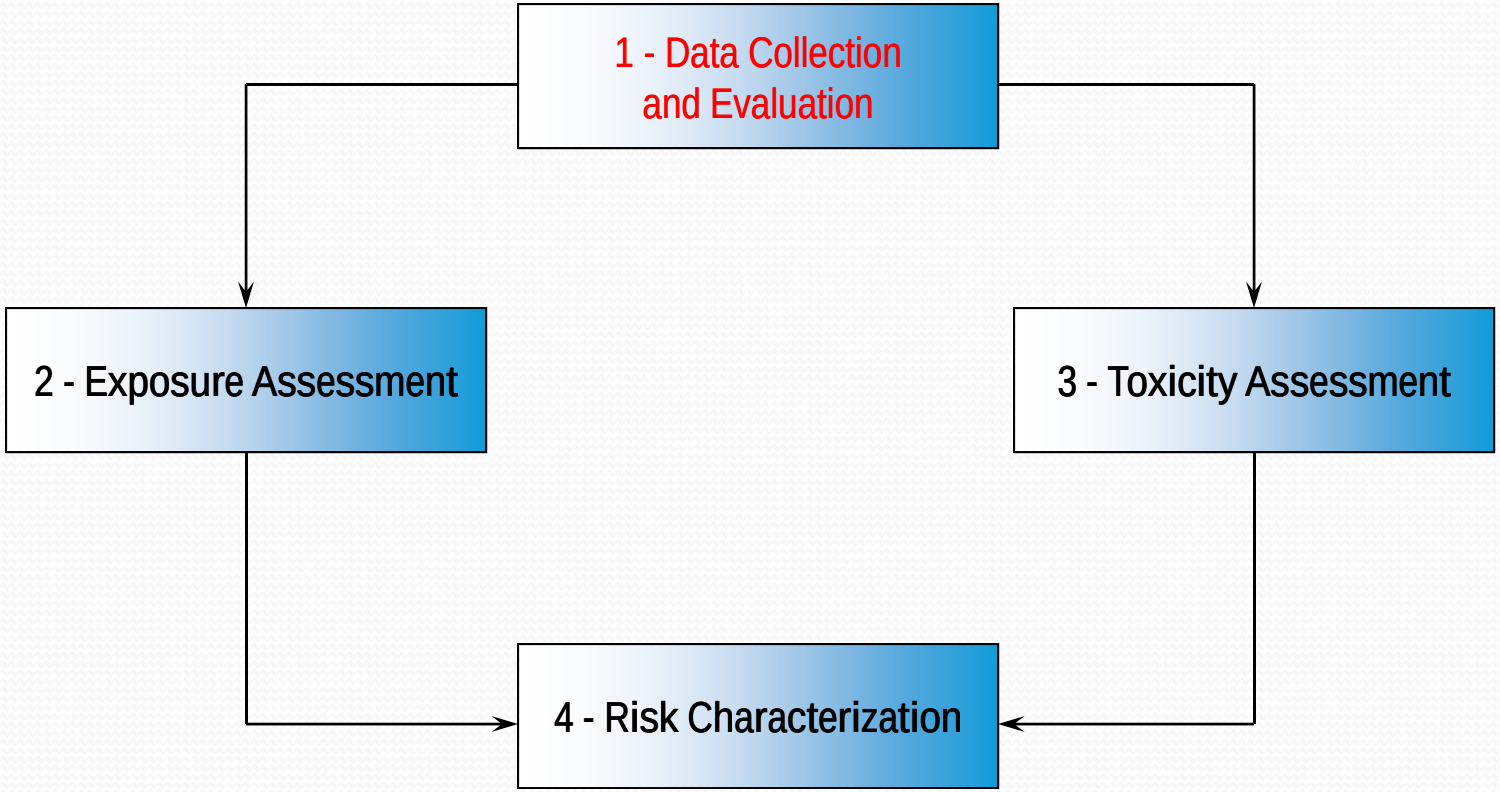
What HHRA Doesn't Do

- Predict a certain individual's health
- Address risk from exposures unrelated to historic Navy releases associated with a particular site
- Address overall health conditions on Vieques

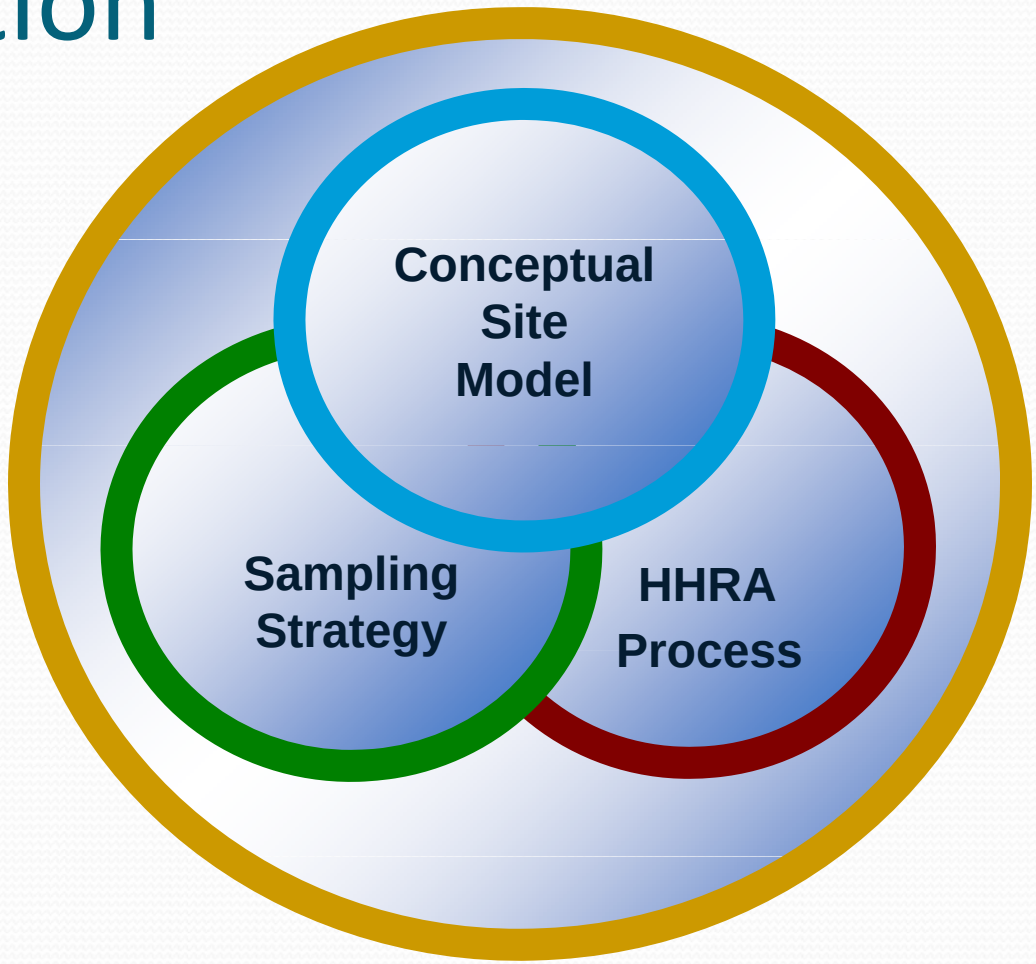
HHRA 4-Step Process

--Barrie

HHRA 4-Step Process

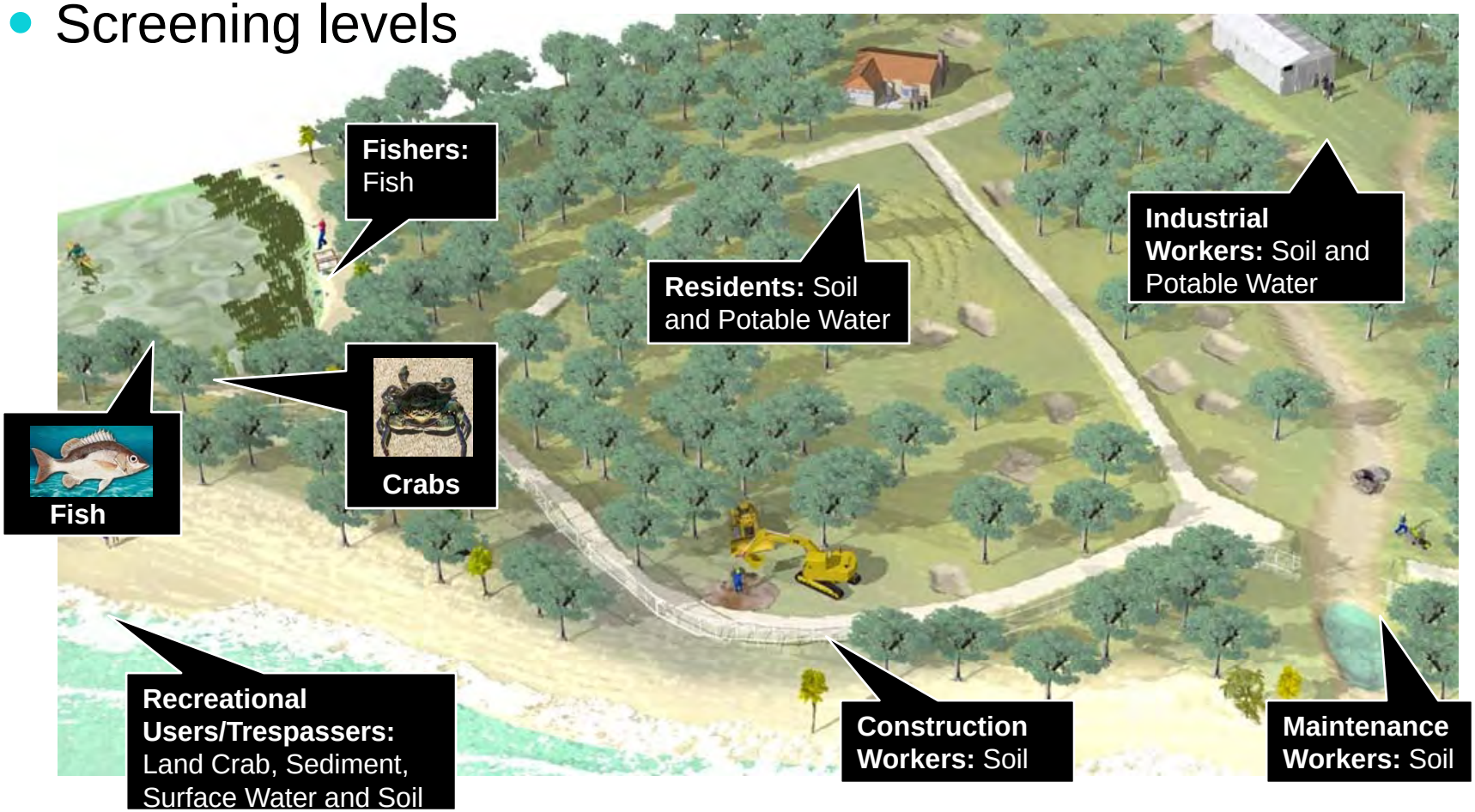


Step 1 – Data Collection & Evaluation



Planning for Step 1 - CSM

- Potential exposure scenarios (current/future)
- Data needs for HHRA
- Screening levels



Planning for Step 1 - Coordination with Team Members

- Land Stewardship on Former Navy Lands
  - Municipality of Vieques, Dept of Interior, Puerto Rico Conservation Trust
    - Exposure areas
    - Future land uses
    - Exposure scenarios
- Ecological Risk Assessors
  - Edible fish species
- Field Team
  - Samplers & Chemists
  - Analytical detection limits, sampling locations

Planning for Step 1 - Community Involvement (RAB)

- Review of Draft Sampling and Analysis Plans
  - Conceptual Site Model
    - Land Uses
    - Who might be exposed to the site (receptors)
    - What types of activities might be occurring

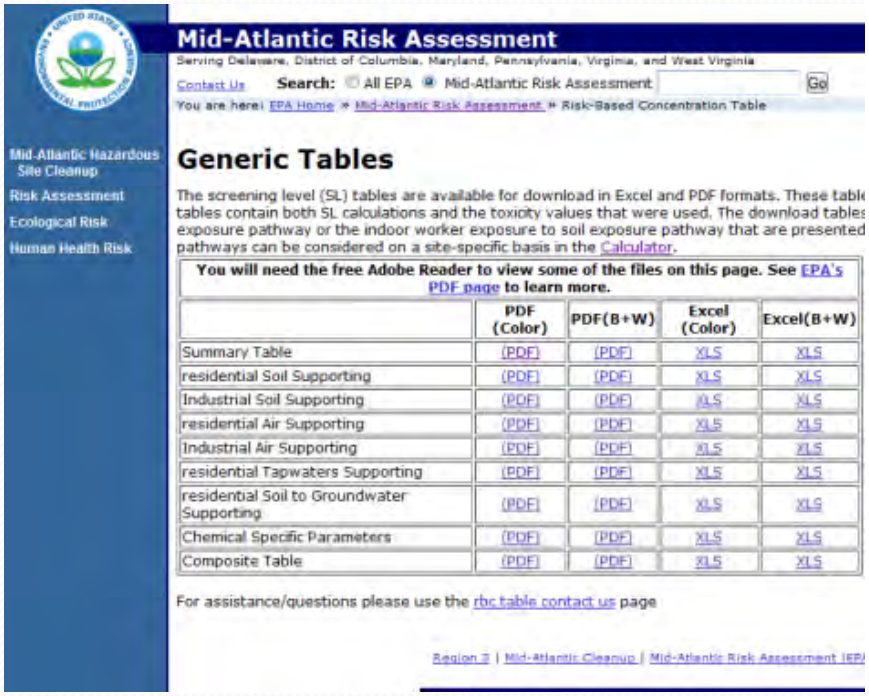
Step 1 – Compile Data

- Historic and new data
- Some data may be eliminated
  - older data if newer available from same area
  - areas excavated
  - field screening data
- Group data by:
  - exposure area, soil depth
  - surface water body

Step 1 – Evaluate Sample Data

- EPA Regional Screening Levels – for all CERCLA sites
  - http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/index.htm
  - Health-protective levels by land use
    - Soil
    - Groundwater
    - Surface Water
    - Sediment
- Identify COPCs
  - Maximum detected conc.
  - More inclusive than exclusive
  - Evaluate further in HHRA

COPC = chemical of potential concern



Mid-Atlantic Risk Assessment

Serving Delaware, District of Columbia, Maryland, Pennsylvania, Virginia, and West Virginia

Contact Us Search: All EPA Mid-Atlantic Risk Assessment Go

You are here: EPA Home » Mid-Atlantic Risk Assessment » Risk-Based Concentration Table

Mid-Atlantic Hazardous Site Cleanup
Risk Assessment
Ecological Risk
Human Health Risk

Generic Tables

The screening level (SL) tables are available for download in Excel and PDF formats. These table tables contain both SL calculations and the toxicity values that were used. The download tables exposure pathway or the indoor worker exposure to soil exposure pathway that are presented pathways can be considered on a site-specific basis in the Calculator.

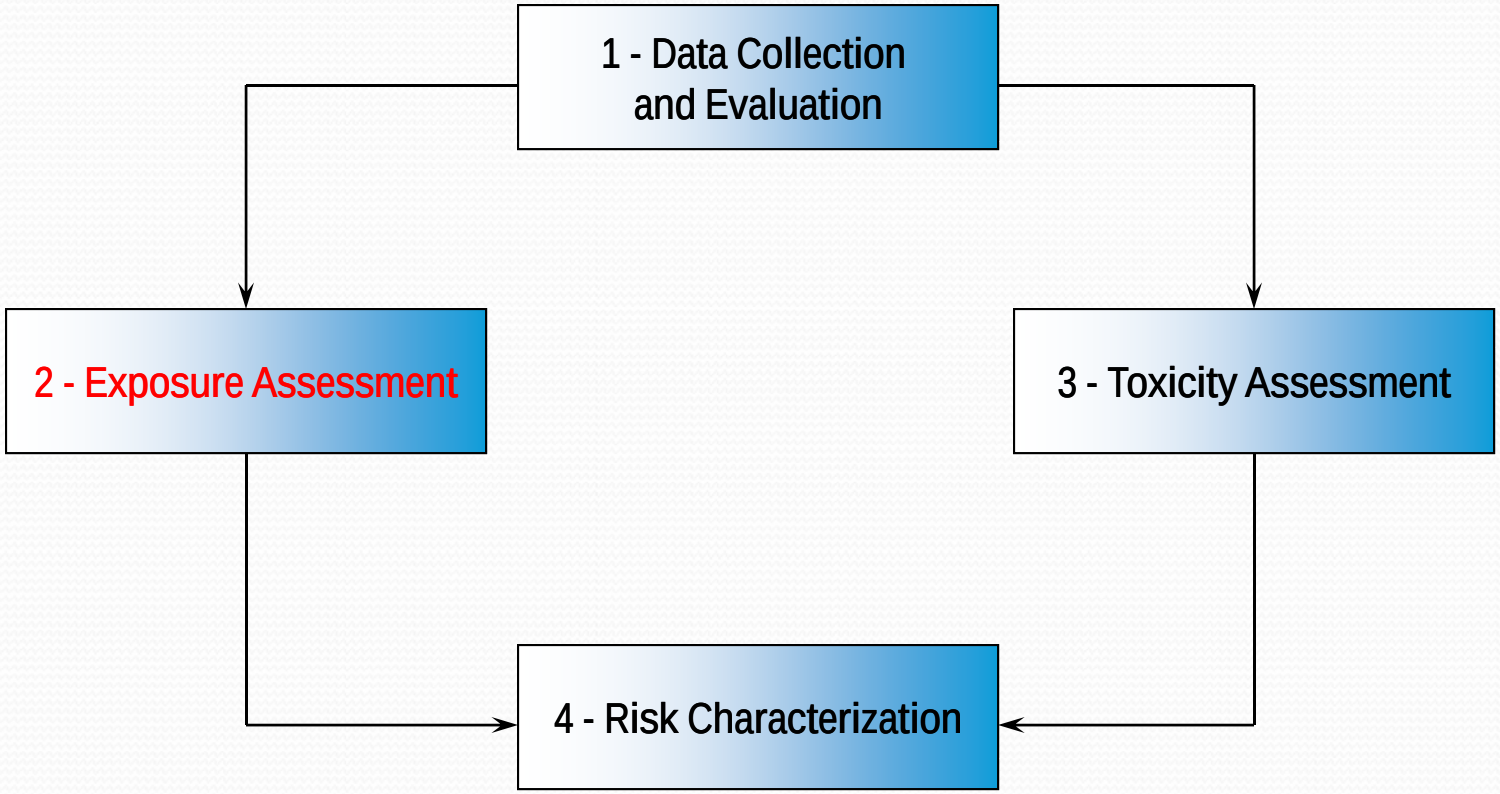
You will need the free Adobe Reader to view some of the files on this page. See EPA's PDF page to learn more.

	PDF (Color)	PDF(B+W)	Excel (Color)	Excel(B+W)
Summary Table	(PDF)	(PDF)	XLS	XLS
residential Soil Supporting	(PDF)	(PDF)	XLS	XLS
Industrial Soil Supporting	(PDF)	(PDF)	XLS	XLS
residential Air Supporting	(PDF)	(PDF)	XLS	XLS
Industrial Air Supporting	(PDF)	(PDF)	XLS	XLS
residential Tapwaters Supporting	(PDF)	(PDF)	XLS	XLS
residential Soil to Groundwater Supporting	(PDF)	(PDF)	XLS	XLS
Chemical Specific Parameters	(PDF)	(PDF)	XLS	XLS
Composite Table	(PDF)	(PDF)	XLS	XLS

For assistance/questions please use the rbc table contact us page

Region 3 | Mid-Atlantic Cleanup | Mid-Atlantic Risk Assessment (EPA

2rd Step in HHRA Process

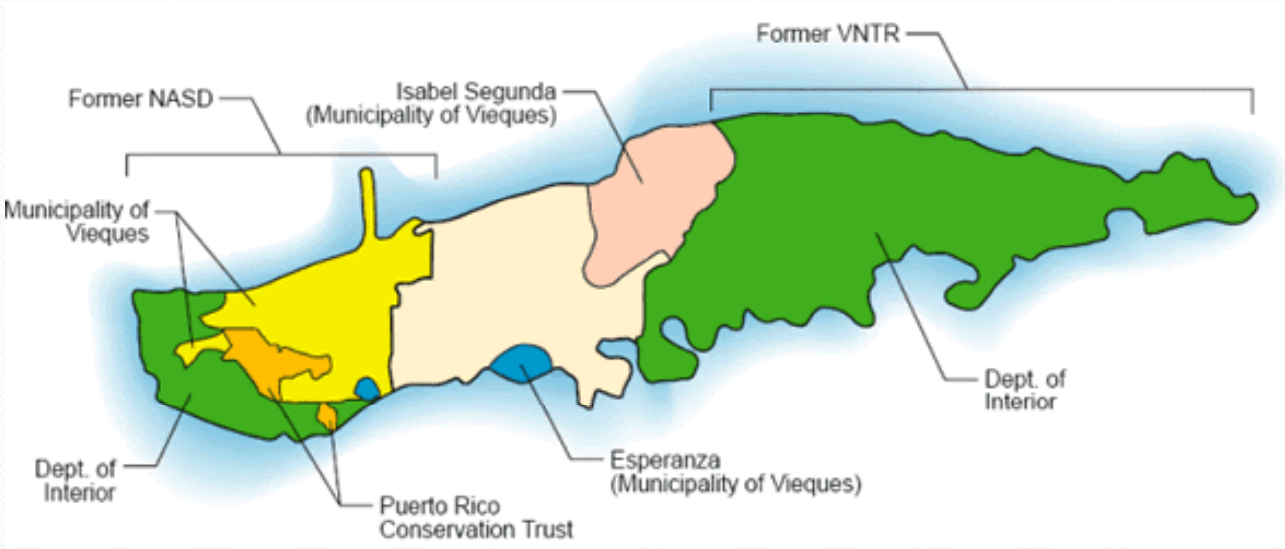


Land Uses

--Rich

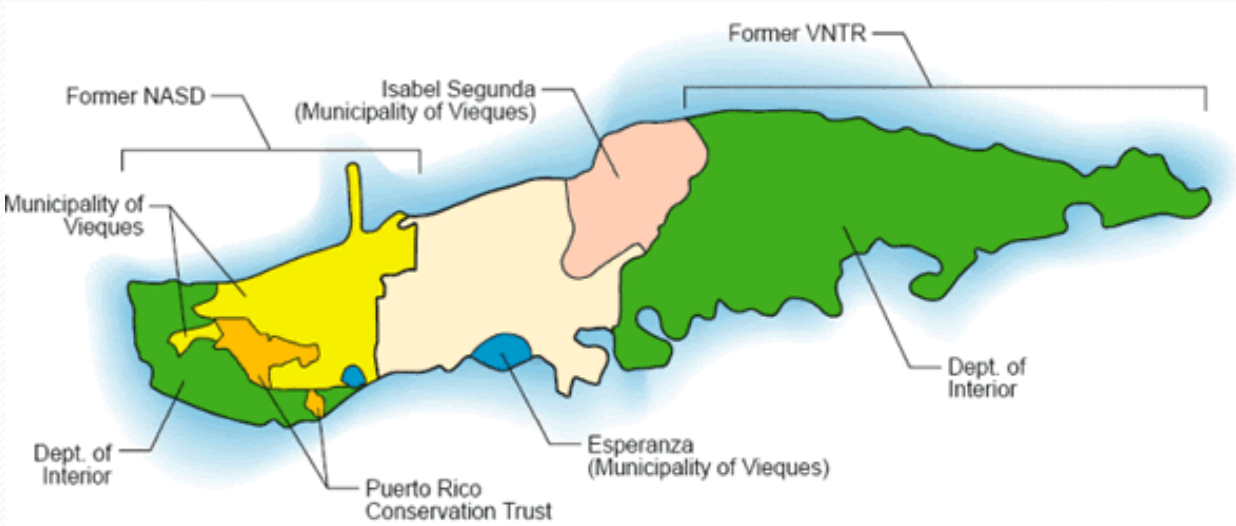
Former Navy Land Stewardship

- Municipality of Vieques – yellow
- Department of the Interior – green
- Puerto Rico Conservation Trust – orange



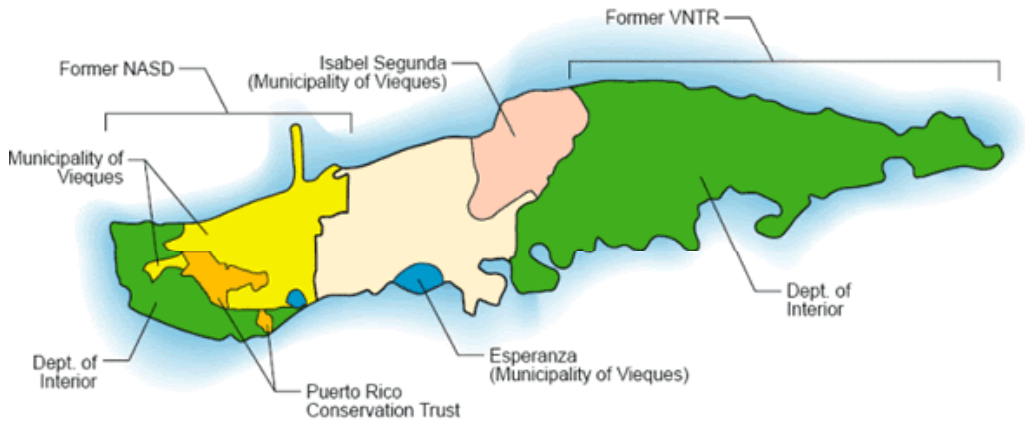
Municipality of Vieques – Land Uses

- Promote economic development & provide employment opportunities
- Residential
- Commercial/industrial
- Recreation



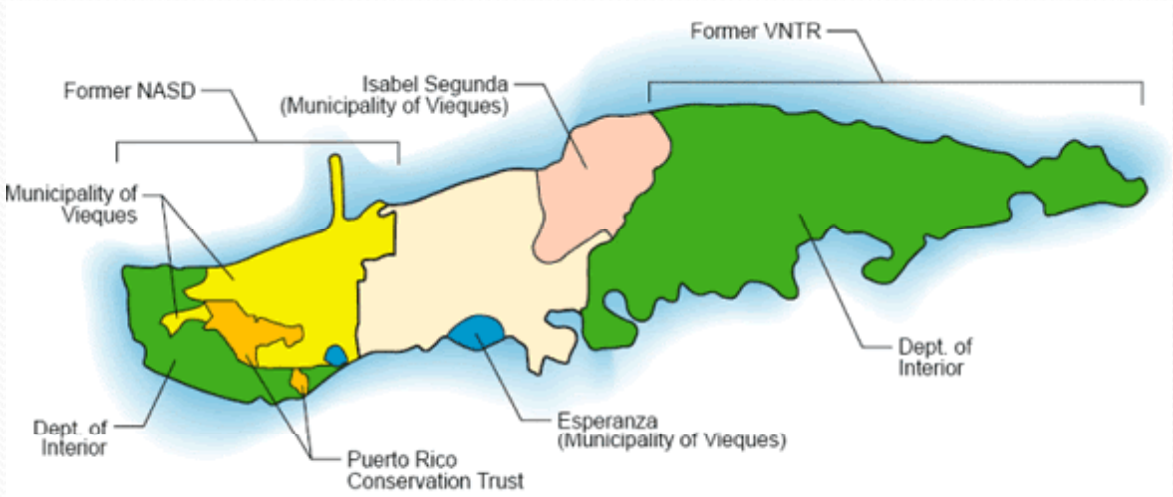
Department of Interior – Land Uses

- Vieques National Wildlife Refuge
  - Conservation, management, and where appropriate, restoration of the fish, wildlife, and plant resources and their habitats
  - Biological studies
  - Recreation
  - Wilderness area



Puerto Rico Conservation Trust – Land Uses

- Long-term protection and preservation of natural resources
- Conservation
- Biological studies
- Education
- Recreation



Exposure Scenarios & Exposure Factors

--Katarina

Exposure Scenarios

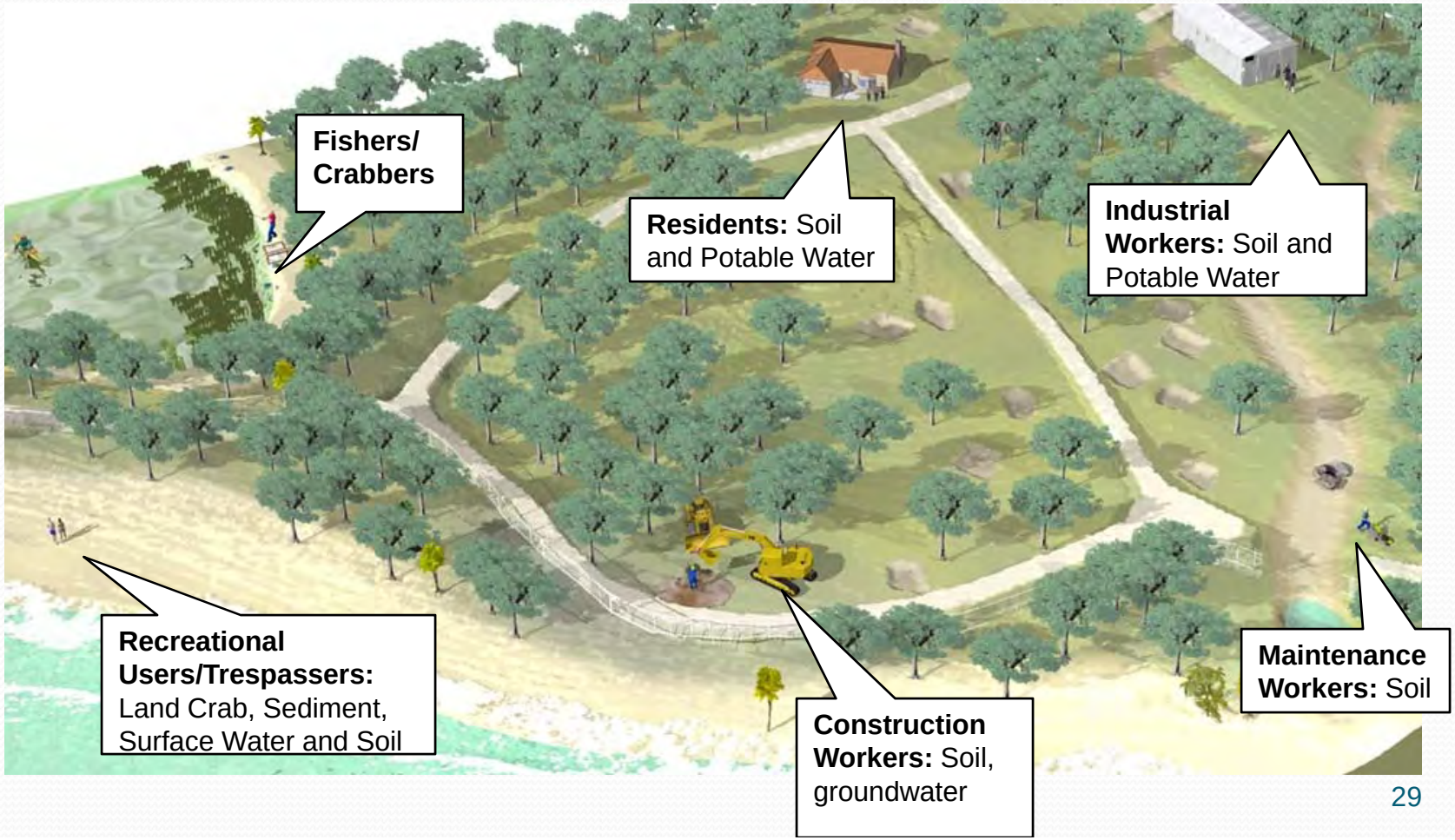
Exposure scenarios identify:

- Who might be exposed at a site
- How they may be exposed
- How much they may be exposed

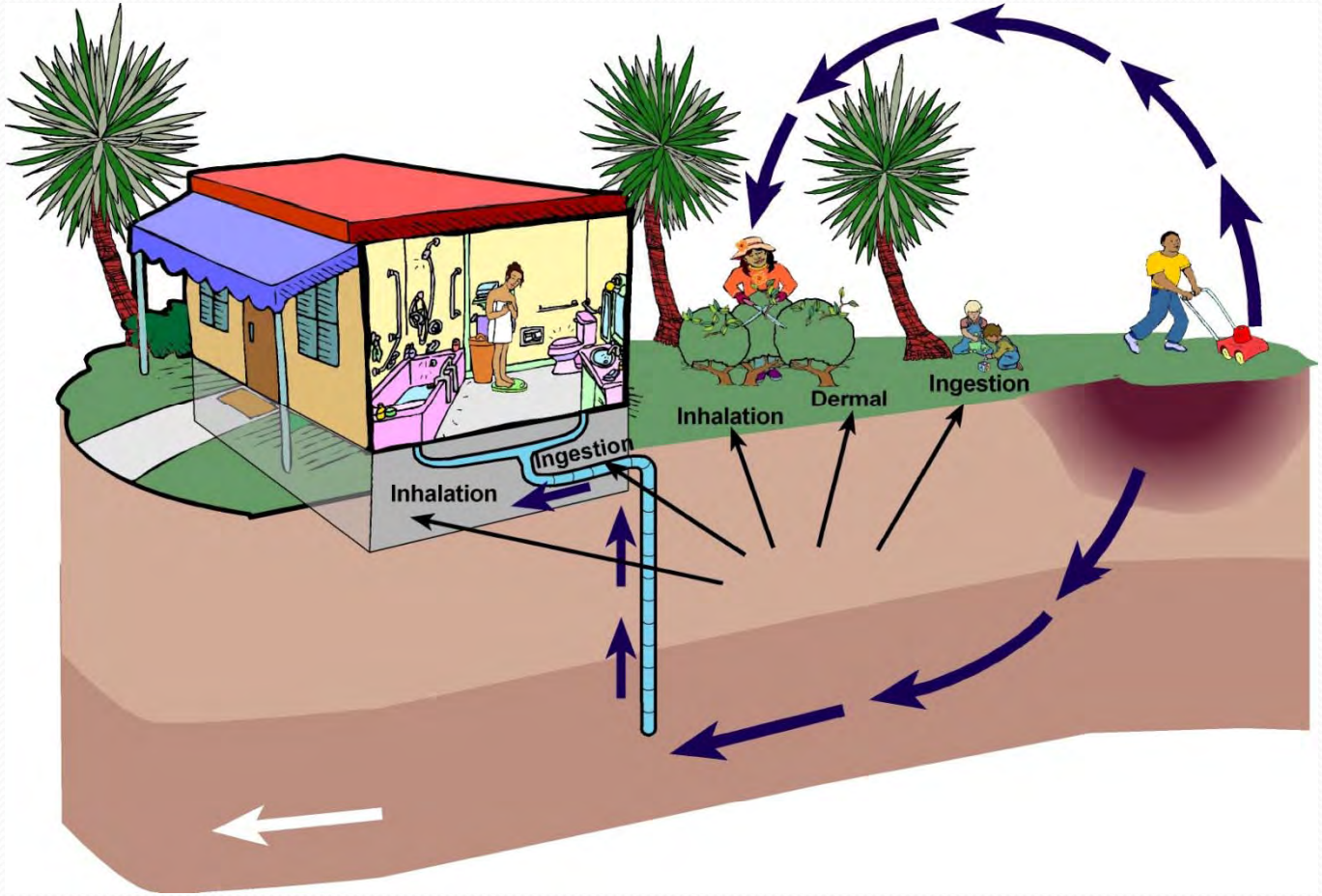
Who May Be Exposed

- Residents – Generic EPA
- Industrial Workers – Generic EPA
- Maintenance Workers – Vieques-specific
  - Volunteers/researchers/students
- Recreational Users – Vieques-specific
  - Visitors/trespassers
- Construction Workers – Generic EPA
- Fishers/Crabbers – Vieques-specific

Who May Be Exposed



How Exposure Occurs



How Much Exposure Occurs

Based on:

- Levels of chemicals identified at the site in each media
- How much soil, groundwater, surface water and/or sediment a person is exposed to
- How often a person is exposed
- Length of time a person is exposed

Levels Identified at Site

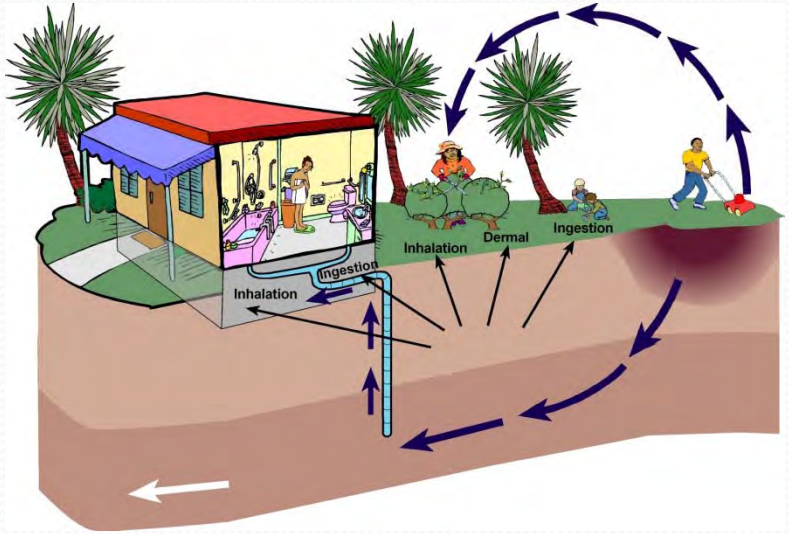
- Data from site investigations
- Conservative estimate of average concentration for each chemical
- Measured or modeled

Exposure Parameters

- Generic: EPA's Exposure Factors Handbook or other EPA guidance
- Vieques-specific: based on island-specific data or best professional judgment
- Values selected to represent reasonable maximum exposure
  - Highest exposure that is reasonably expected to occur at a site

Receptor Exposure Scenarios

- Residents
  - Generic EPA exposure scenario
  - Adults and children
  - Assumes daily exposure to chemicals for 350 days per year for 30 years
    - Soil (200 mg/day [6 yrs], 100 mg/day [24 yrs])
    - Groundwater (2 L/day)
  - Very conservative
    - If residential exposure is acceptable, site poses no unacceptable risks for all uses



Receptor Exposure Scenarios

- Recreational Users
  - Vieques-specific exposure scenario
  - Adults, youths and children
  - Assumes exposure to chemicals for 2 days per week
    - Adults – 24 years
    - Youths – 10 years
    - Children – 6 years

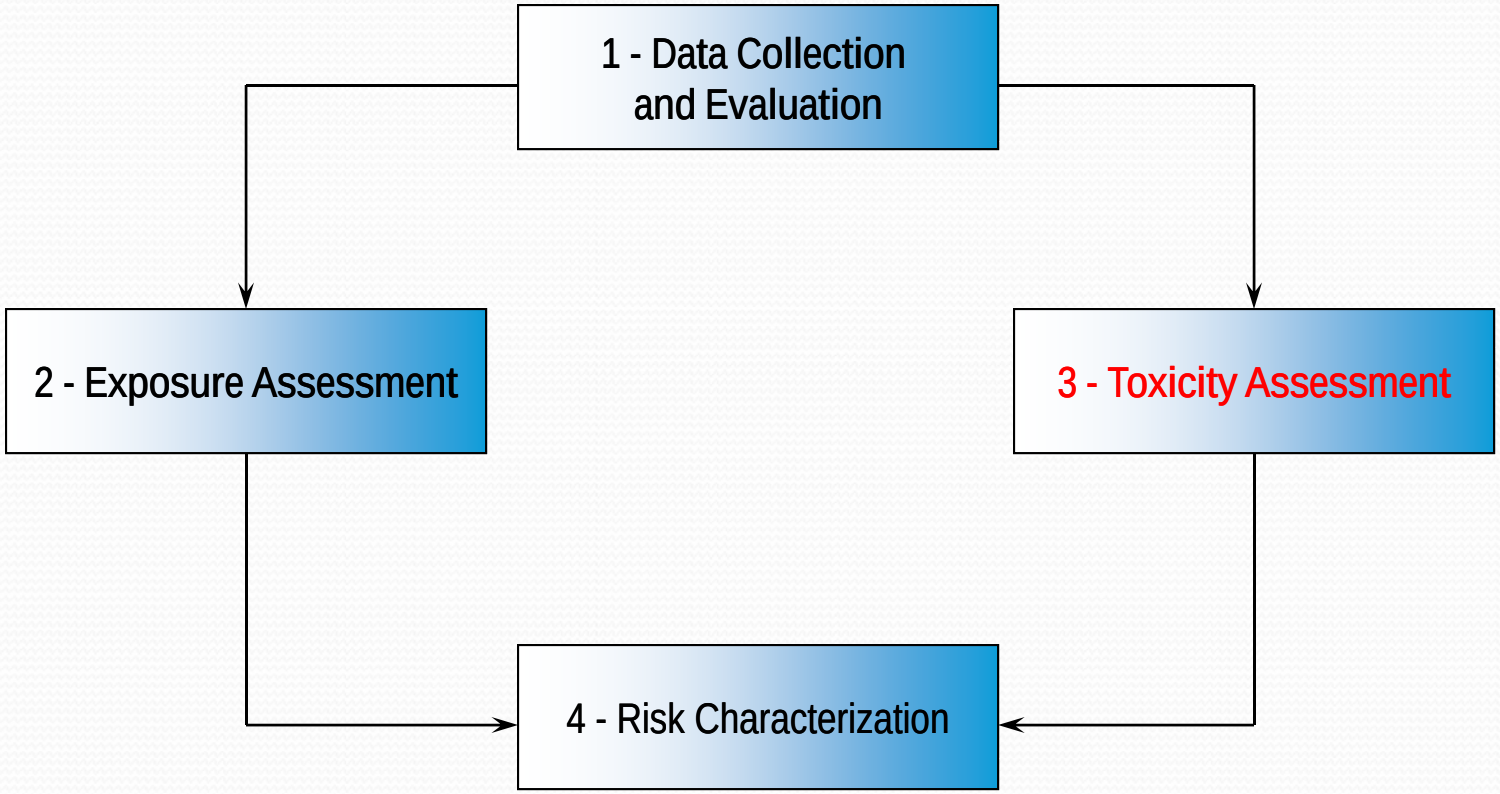
Receptor Exposure Scenarios - Community Involvement

- Draft Final Sampling and Analysis Plans
  - Conceptual Site Model
    - Land Uses
    - Who might be exposed to the site (receptors)
    - What types of activities might be occurring

Toxicity Assessment

--Barrie

3rd Step in HHRA Process



Toxicity Assessment

- What adverse health effects are likely associated with exposure to a chemical?
- How much of chemical can someone be exposed to without developing an adverse health effect?
  - Noncancer effects (kidney or liver damage, reproductive effects, central nervous system impacts, etc.)
  - Cancer

Toxicity Values for HHRA

- Developed by agencies
- Peer-reviewed by experts
- Protective for the entire population, including sensitive populations
  - Children
  - Elderly
  - Those with compromised health
- Includes EPA safety factors (uncertainty, susceptibility)

Toxicity Value Sources – 3 Tiers

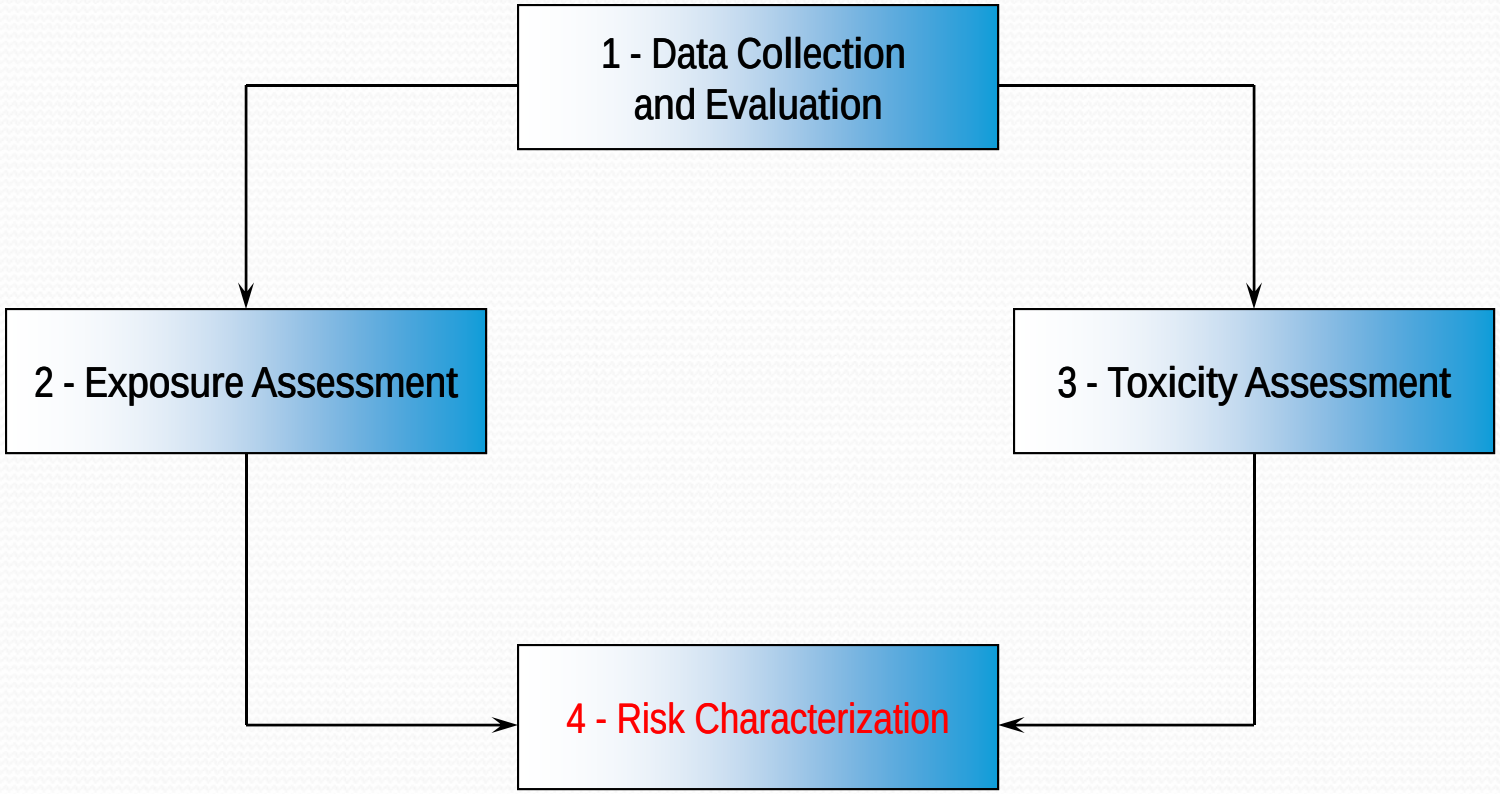
1. EPA database used world-wide; highest level of peer-review: http://www.epa.gov/iris
2. EPA database not as extensively peer-reviewed:

   http://hhpprtv.ornl.gov/
3. Other sources approved by EPA:
   - California EPA
   - New Jersey DEP
   - Others

Risk Characterization

--Michael

4th Step in HHRA Process



Risk Characterization

- Cancer risks and noncancer health effects (hazards)
- Background contribution
- Uncertainty analysis

Risk Characterization

- Cancer Risks
- Noncancer Health Effects
- Specific to exposure scenarios and receptors in exposure assessment of HHRA

Risk Characterization

- Example – Hypothetical site with benzene and barium impacts in soil
  - Benzene – cancer & noncancer effects
  - Barium – noncancer effects only

Risk Characterization

- Hypothetical Cancer Risks for Hypothetical Resident - Benzene
  - Calculated cancer risk estimate for hypothetical future resident is 5 in a million (5E-06 or 5 x 10^{-6} or 0.000005)
    - If 1 million people were exposed to the site contaminants for 24 hours per day for 350 days per year for 30 years, 5 people may develop cancer attributable to the site
  - Risk and hazard estimates are for defined exposure scenarios

Risk Characterization

- Hypothetical Noncancer Hazards for Hypothetical Resident - Benzene & Barium
  - Calculated noncancer hazard for hypothetical resident is 2.4
  - Hazard above 1 indicates a potential for an adverse health effect for a hypothetical resident
    - The higher the value is above 1, the greater the level of concern that adverse noncancer health effects would occur

Role of Background

- Risk Characterization takes into account the contribution from background
  - Chemicals attributable to background are presented separately in risk characterization
  - CERCLA sites not remediated below background levels
  - Vieques-specific background data
    - 2nd study with RAB participation in sampling locations
  - Follows EPA Guidance "*Role of Background in the CERCLA Cleanup Program*"
    - http://www.epa.gov/oswer/riskassessment/pdf/role.pdf

Types of Background

- Naturally occurring
  - Chemical concentrations present in the environment that have not been influenced by humans (metals)
- From human activity (anthropogenic)
  - Not present as a result of a CERCLA release
    - Examples
      - Agriculture
      - Industry
      - Automobiles

Uncertainty Analysis

- Identifies areas of uncertainty for each step in the risk assessment and how they were addressed
- Risk assessment is designed to be protective of public health:
  - Have site conditions and land uses been adequately characterized?
    - Team coordination, historical records, analytical suites
  - Is an adult or child really going to be exposed to the extent evaluated in the risk assessment?
    - Conservatively assume daily residential exposure
  - What about chemicals with no toxicity information?
    - Use of Surrogates

Risk Management

--Michael

Risk Assessment → Risk Management

HHRA does

- Predicts cancer risks and adverse health effects
- CERCLA law defines if the risk is unacceptable.

HHRA does not

- Guarantee that cancer risks and adverse health effects will occur if risks are unacceptable

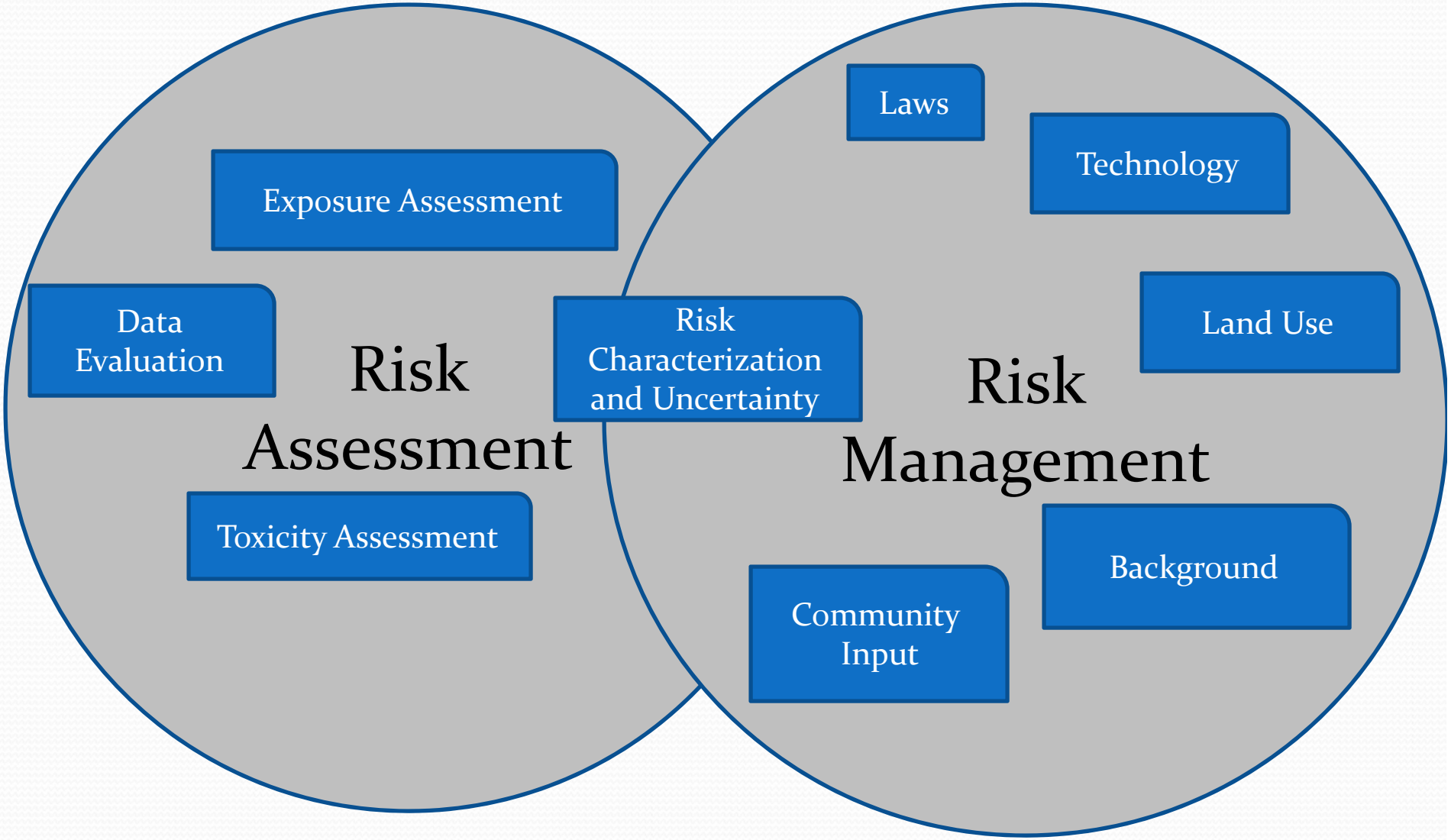
Acceptable Risk

- Established by Congress in CERCLA regulations
- Used at all Superfund sites across the country
- Cancer Risk
  - Acceptable risk range is 1 additional incidence of cancer in an exposed population of 10,000 to 1,000,000
- Noncancer Health Hazard
  - If hazard is less than 1, adverse noncancer effects are not expected

Risk Management

- Risk Management is a decision-making process to determine whether to take action for a site
- Risk managers involved in decision-making
  - USEPA, PREQB, USFWS, Navy
- Formal public input at Proposed Plan stage
  - Informal public input and RAB input welcome throughout the process

Risk Assessment → Risk Management



Possible Outcomes

- No Further Action: Estimated cancer risks and noncancer hazards are within EPA's acceptable limits as identified by Congress
- Response Action: Estimated cancer risks and/or noncancer hazards exceed EPA's acceptable limits as identified by Congress; response is needed to manage potential risks or exposures to be protective of human health & the environment

Discussion

ATSDR

- Public Health Assessment (PHA)
  - Evaluates available information about hazardous substances to determine whether populations could be harmed from contacting those substances
  - Recommends actions to protect public health
- Can provide physician training and consultation
  - Evaluates past and current exposures to estimate potential health effects across the Island, regardless of source
  - In contrast, a Superfund HHRA evaluates current and potential future exposures to estimate health risks for a specific site