Risk Assessment 101

Learning the Basics & Understanding Challenges in Conducting Risk Assessments

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Presentation Overview

What is Risk Assessment?

Human Health Risk Assessment

- Hazard Identification
- Exposure Assessment
- Toxicity Assessment
- Risk Characterization

Ecological Risk Assessment

- Quick overview

Risk Assessment Benefits

Tiered Approach to Risk Assessment

What is Risk Assessment?

Human Health Risk Assessment (HHRA)

- The process to estimate the nature and probability of adverse health effects in humans who may be exposed to chemicals in contaminated environmental media, now or in the future.

Ecological Risk Assessment (ERA)

- The process for evaluating how likely the environment might be impacted from exposure to one or more environmental stressors, such as chemicals, land-use change, disease, and invasive species.

HHRA History

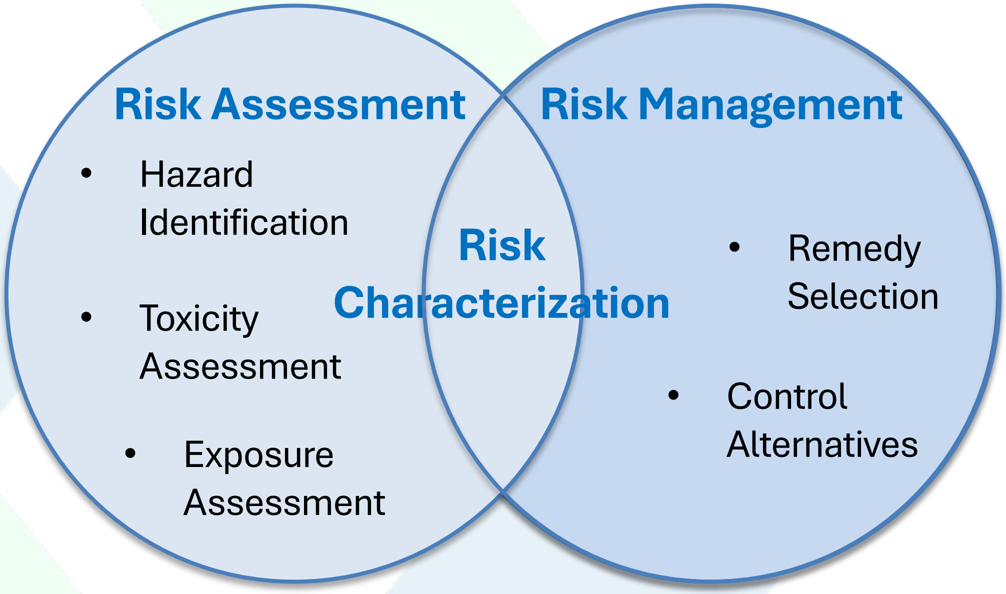
EPA introduces **Risk Assessment Guidance for Superfund (RAGS),** Part A in 1989, which provides guidance on human health evaluation activities conducted during the baseline risk assessment, which is the 1st step of the RI/FS. Parts B and C are released in 1991 and provide guidance on deriving risk-based Preliminary Remediation Goals (PRGs) (Part B) and remedial alternatives (Part C).

- **1971** – EPA announces national air quality standards for 6 common pollutants
- **1985** – EPA creates the **Integrated Risk Information System (IRIS)** database for chemical toxicity
- **1988** – EPA makes the IRIS database public
- **1989** – EPA publishes **RAGS, Part A** and Exposure Factors Handbook; EPA develops method to **estimate Inhalation Reference Concentration (RfC)**
- **1991** – EPA publishes **RAGS, Parts B and C**
- ***1993*** – EPA publishes air quality criteria document for oxides of nitrogen
- **1994** – EPA publishes updated methods for assessing toxicity of inhaled chemicals
- **1995** – EPA releases benchmark does guidelines for assessing noncancer health risk; ASTM publishes Standard on **Risk-Based Corrective Action (RBCA)** Applied at Petroleum Release Sites
- **1998** – EPA publishes **RAGS, Part D** (updated in 2001) to standardize reporting
- **2004** – EPA publishes **RAGS, Part E** to evaluate dermal exposure, which is an update of EPA's 1992 interim report "Dermal Exposure Assessment: Principles and Applications"
- **2009** – EPA publishes **RAGS, Part F** to address human health risk associated with inhalation exposure

Risk Assessment Overview

Risk Assessment…

- analyzes the potential for adverse effects on receptors
  - (e.g. humans, bugs, bunnies)
- aids in developing corrective action goals
- focuses remedial action where needed



Why Conduct a Risk Assessment?

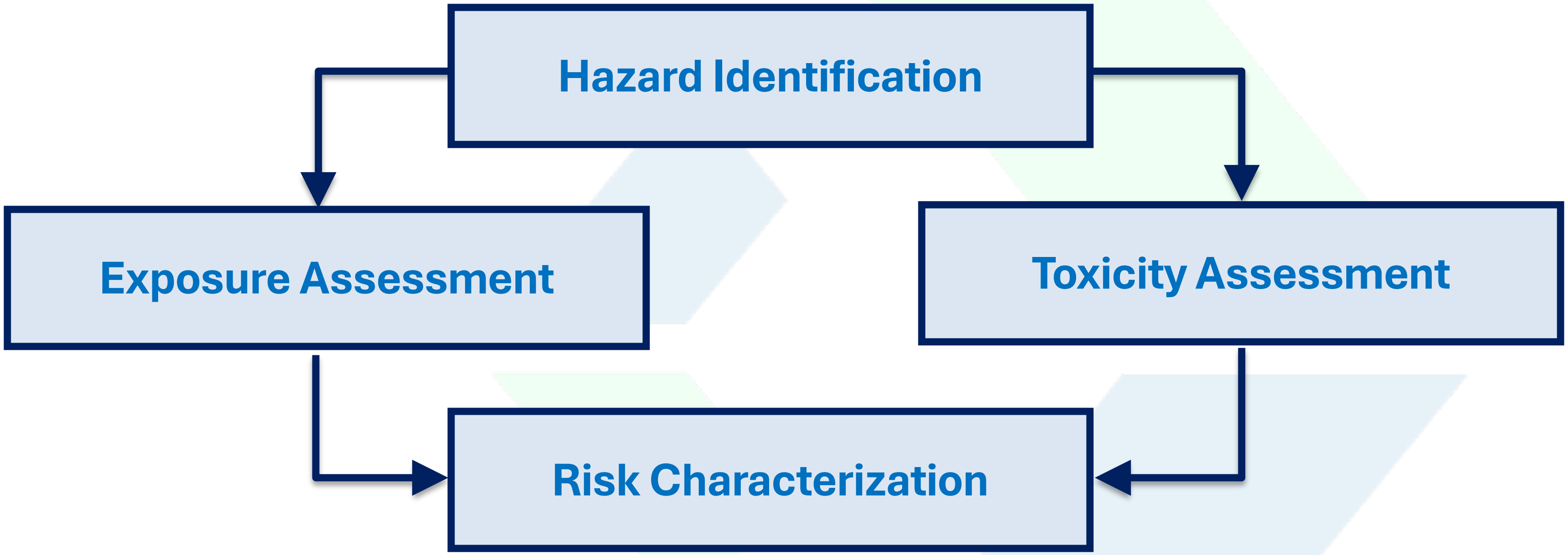
Advantages of Using Risk-Based Approach to Remedy Evaluation

- Well-established protocols
- Track record for acceptance
- Voluntary approach
- Small expenditure compared to remediation costs
- Ensures human health and environmental protection

Value-Added for Stakeholders

- Consistency
- Reasonably Conservative
- Technically defensible
- Transparent

The HHRA Process



Elements of HHRA

- Hazard Identification
- Exposure Assessment
- Toxicity Assessment
- Risk Characterization

Hazard Identification

Purpose

- Gather and analyze relevant data
- Identify potential chemical(s) of concern

Hazard Identification Questions

- What data are available?
- What chemicals are present on site?
- In what concentrations?
- What are the Chemicals of Potential Concern (COPC)?

  COPC = Concentration > Tier 1 Generic Screening Level

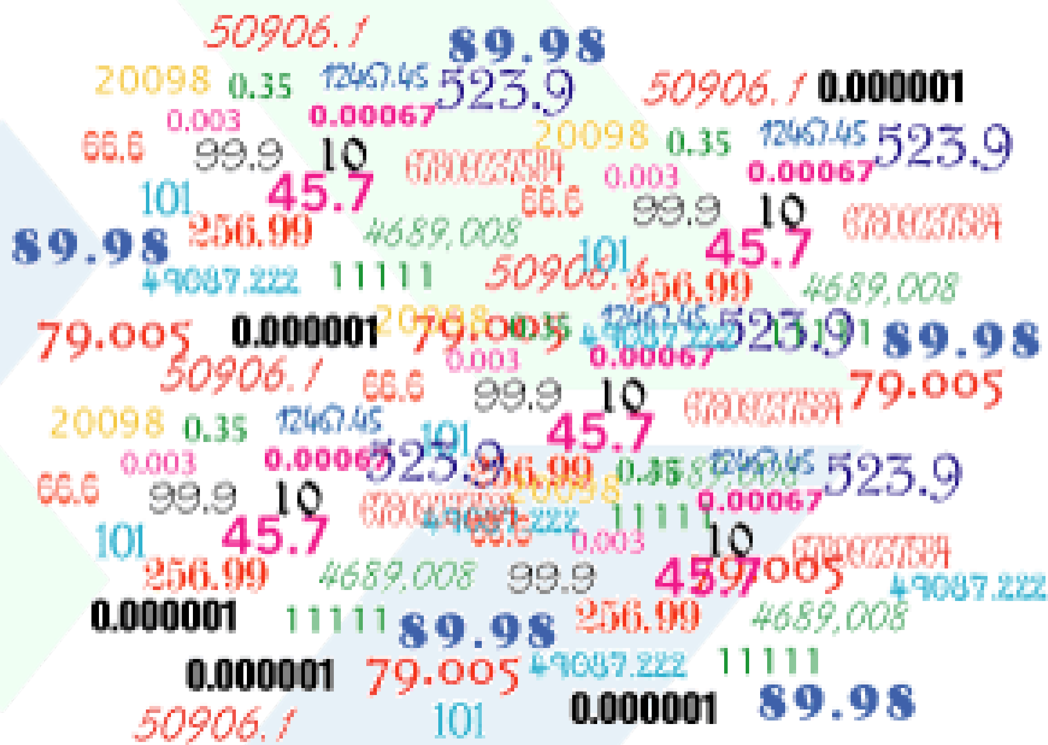
Hazard Identification

- Answers these questions:
  - Which media are affected?
  - What COPCs are identified for each medium?
  - What concentrations are measured in each medium?

Hazard Identification

Compile / review available data by each environmental medium

This is usually the first critical look at holistic dataset!!



Hazard Identification/ Data Adequacy Determination

- **Are data adequate to define the nature of contamination?**
  - Analyte list appropriate based upon site history and/or current land use
  - Number of samples collected appropriate to estimate a representative concentration for each medium (e.g., calculation of Exposure Point Concentration or EPC)
- **Are data adequate to define the extent of contamination?**
  - Migration pathways, including LNAPL migration potential, presence of biodegradation products (e.g., petroleum metabolites)
  - Horizontal and vertical delineation (e.g., nested soil gas data to create vertical profile)
- **Are data adequate to evaluate exposure scenarios?**
  - Too few samples where receptors may be located
  - Wrong medium sampled based on exposure pathway [e.g., soil data collection for vapor intrusion (VI) evaluation]
- **Are data adequate to assess the applicability of remedial technologies?**

Hazard Identification / Data Adequacy Evaluation

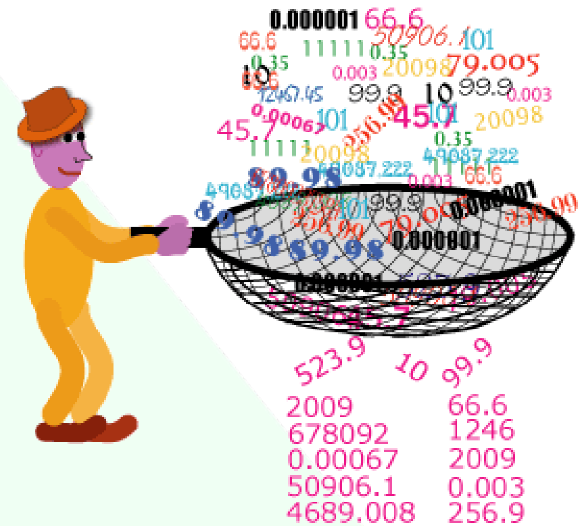
Objective - Verify that data are appropriate to use and representative of current conditions

- **Requirements for Statistical Analysis** – rule of thumb = 10 samples, with min 6 detects. For some media (i.e., surface water, not necessary)
- **Temporal Variability Analysis** – summer vs winter conditions (VI evaluation)
- **Historical Data Use** – how old is too old re historical data (hint, depends on the medium)
- **Spatial Variability Analysis** – determination of localized hot spot (may require additional data collection)

Hazard Identification – COPC Screening

Objective – Identify COPC for each medium

- **Requires identification of appropriate screening criteria** – review current/future site use to determine whether residential or industrial screening levels apply
- **Background comparison** – incorporation into COPC selection process, if allowed
- **Appropriate site concentration to screen** – older, non-representative groundwater data or excavated/remediated samples should be removed from dataset



Exposure Assessment

» **Objectives of Exposure Assessment:**

- Identify and estimate COPC potentially affecting human health
- **Site Characterization Elements:**
  - **Physical setting**: soil, surface water, groundwater, meteorology
  - **Exposed populations**: current/future land use and receptor activities (e.g., day care, school, hospital, resident, office)

- **Who is potentially exposed to COPCs?**
  - workers, recreational users, residents, etc.
- **How might they be exposed to COPCs?**
  - Direct vs indirect contact
- **How much are receptors exposed to on a daily basis?**
  - Average Daily Dose (ADD)

Exposure Assessment – Conceptual Site Model (CSM)

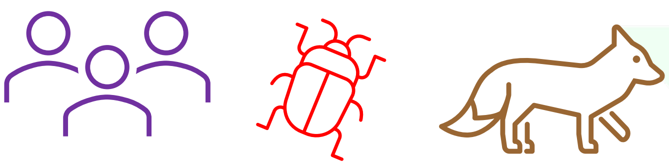
Conceptual Site Model Elements

- source release
- migration pathway
- exposure media
- receptors/exposure pathways

Potential Sources: leaking tanks, air emissions, historical operations, etc.

Potential Migration Pathways: airborne emissions, vapor intrusion, leaching to groundwater, groundwater lateral transport, etc.

Potential Exposure Media: indoor/outdoor air, soil, groundwater, surface water, sediment, etc.



Potential Receptors: indoor/outdoor workers, residents, recreational users, etc.

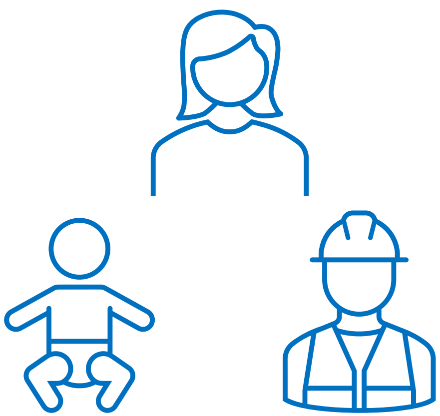
Potential Exposure Pathways: inhalation, ingestion, or dermal contact

- Exposure can be by direct contact (ingesting or touching soil impacts) or indirect contact (inhaling airborne particulates from soil impacts)

Exposure Assessment

Potential Receptors

- Resident (Adult and young child)
- Occupational worker
- Construction worker
- Utility/Excavation worker
- Trespasser
- Off-site receptors



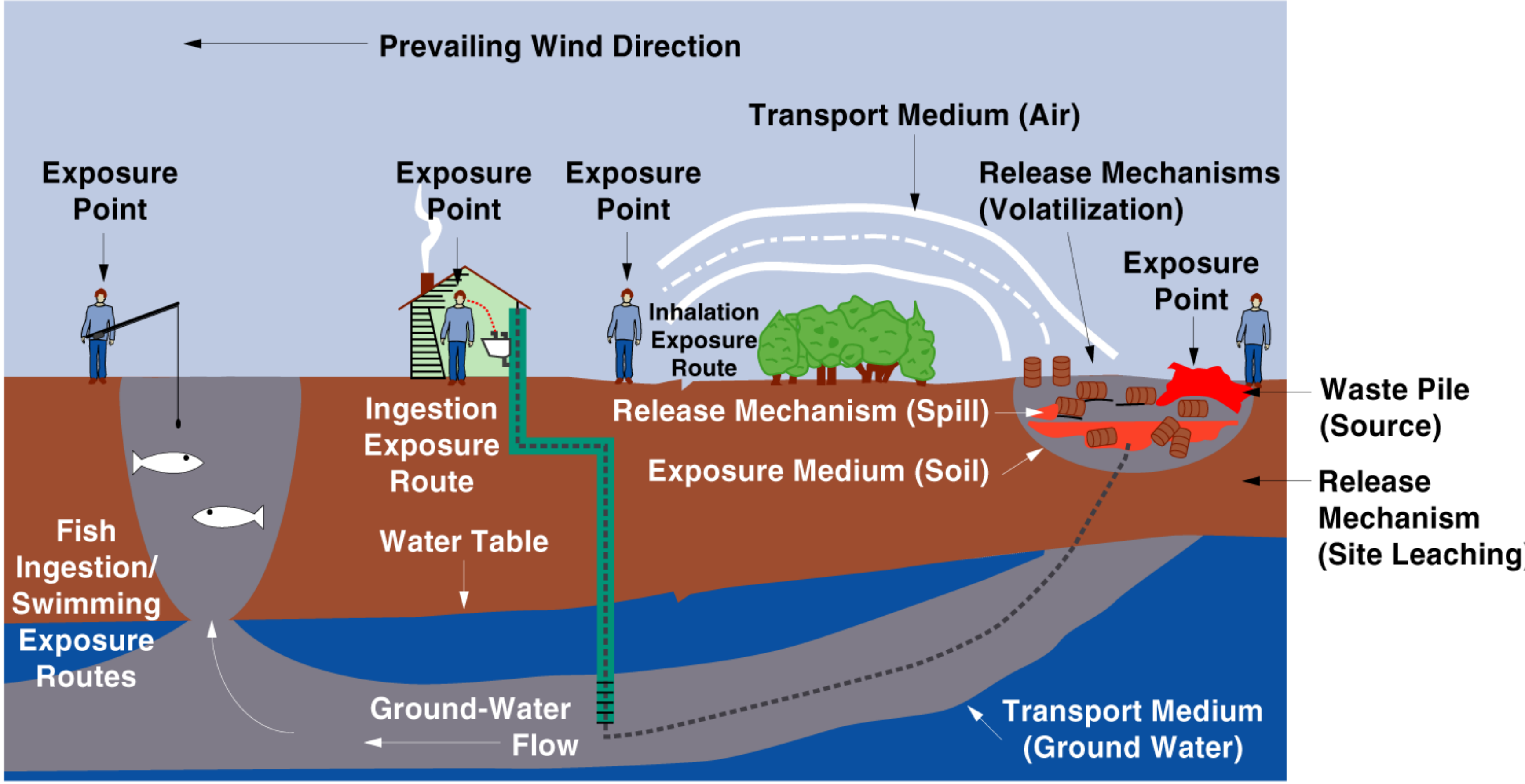
Example Migration Pathways

- Vapor Intrusion into Buildings from Groundwater, Soil, LNAPL
- Groundwater Volatilization in Excavation Trench
- Soil Particulate/Vapor into Ambient air
- Soil Leaching to Groundwater
- Plant Uptake from Soil
- Fish/Benthic Invert Uptake from Surface Water /Sediment
- Livestock Uptake from Plants

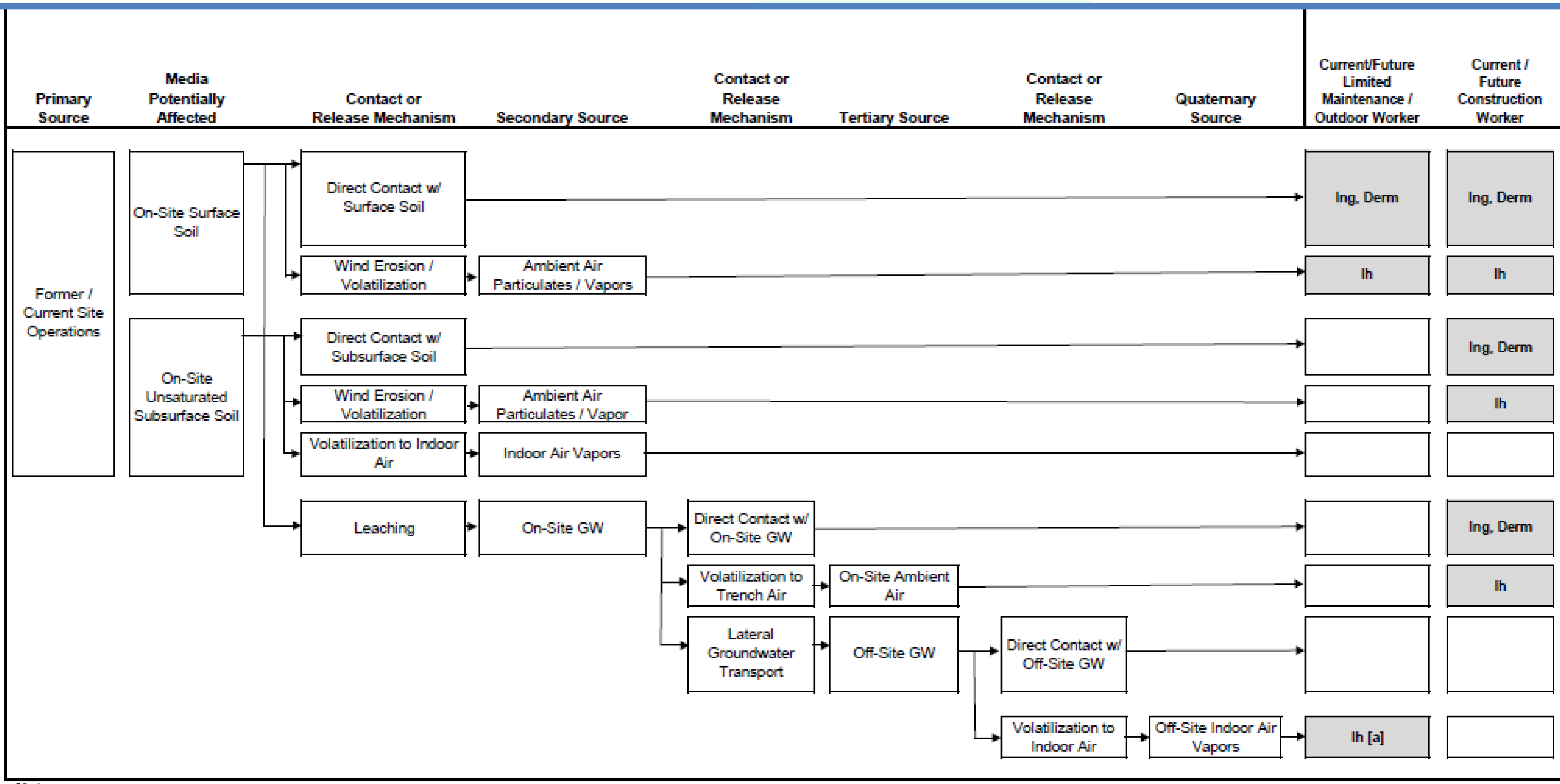
Example Exposure Pathways

- **Soil:**
  - Ingestion, dermal contact, inhalation of soil particulates and volatiles
  - Soil leaching to groundwater
  - Plant uptake from soil; ingestion of homegrown produce and further uptake by terrestrial animals/livestock
  - Ingestion of livestock
- **Groundwater:**
  - Ingestion of drinking water and household use dermal contact (washing dishes, showering)
  - Incidental ingestion and dermal contact with exposed groundwater (construction worker)
  - Inhalation of groundwater volatiles into excavation trench (construction worker)
  - Inhalation of groundwater volatiles into indoor air
- **Surface Water:**
  - Ingestion and dermal contact with surface water
  - Aquatic (fish) uptake from surface water
  - Ingestion of fish

Exposure Assessment -CSM



Exposure Assessment -CSM



Notes:

[a] There is one occupied building (storage building) located within SWMU-C that is used as an office space

Derm = Dermal Contact

GW = groundwater

Ih = Inhalation

Ing = Ingestion

Sed = sediment

SW = surface water

Shaded box = potentially complete and significant exposure pathway.

Unshaded box = potentially complete, but insignificant exposure pathway.

Blank box (no text) = incomplete exposure pathway

Exposure Assessment – Estimating Dose

Average Daily Dose (ADD) expressed as mass of contaminant per unit body weight over time (mg/kg-day).

$$ADD = \frac{C_{soil}\, x IRsoil\, x EF\, x ED\, x AAF\, x CF}{BW\, x AT}$$

Csoil = Soil Exposure Point Concentration

- Intended to represent the upper range of the average concentration in an environmental media available for exposure
- 95% upper confidence limit (95% UCL) on the mean or the maximum observed concentration

C_{soil} – concentration in soil (mg/kg)

IR_{soil} – soil ingestion rate (mg/day)

EF – exposure frequency (days/year)

ED – exposure duration (years)

AAF – gi absorption adjustment factor (unitless)

CF – conversion factor (10^6 mg/kg)

BW – body weight (kg)

AT – averaging time (years x 365 days/year)

Toxicity Assessment

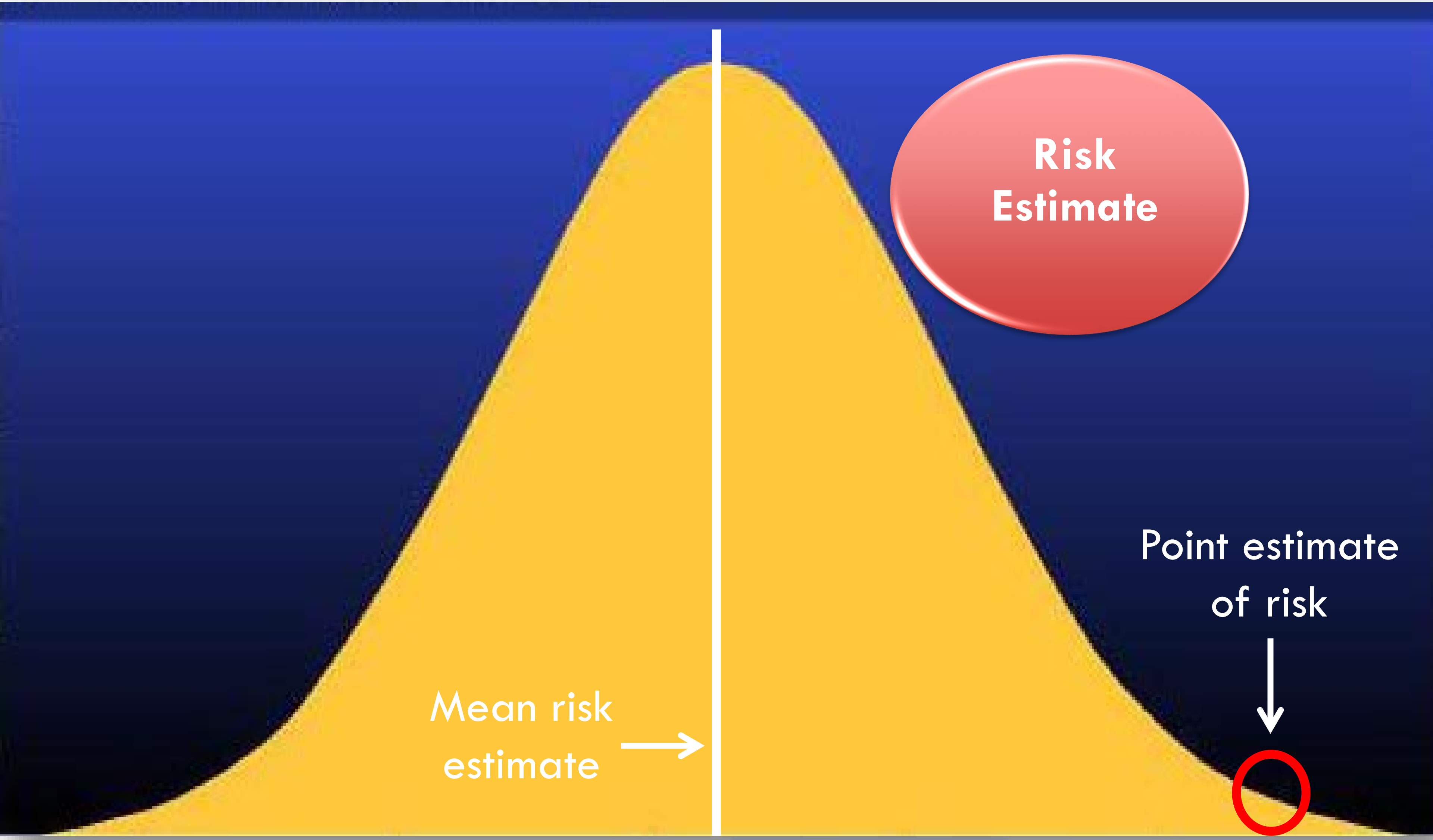
- What adverse effects can a chemical cause?
- What dose causes adverse chemical effect?
  - **Carcinogenic**
    - Assumes carcinogens exhibit intrinsic risk
    - Oral Slope Factor (SF) and Inhalation Unit Risk (IUR) = toxicity value used to quantify cancer risk
  - **Noncarcinogenic**
    - Assumes noncarcinogens exhibit a "threshold" effect
    - Oral Reference Dose (RfD) and Inhalation Reference Concentration (RfC) = toxicity value used to quantify the threshold dose to illicit noncarcinogenic effect

Toxicity Assessment

- **What adverse effects can a chemical cause?**
  - Is different based on exposure pathway (ingestion, dermal contact, inhalation)

- **At what dose does chemical cause adverse effect?**
  - Carcinogenic Adverse Effects
    - Exposure to carcinogen may stop, but cancer risk continues throughout lifetime
  - Noncarcinogenic Adverse Effects
    - Causes non-cancer effects (e.g., skin irritation, dizziness, nausea) during exposure period only

Step 4: Risk Characterization



Risk Characterization

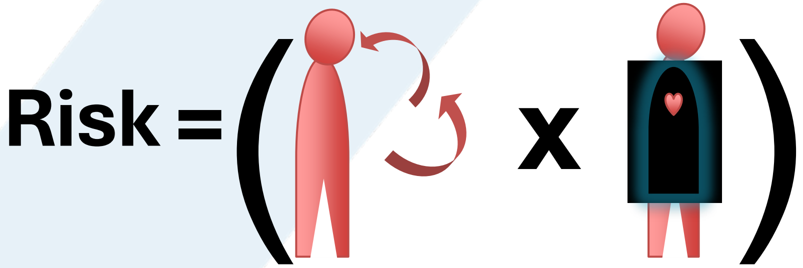
- Cancer risk assessment: probability of contracting cancer over lifetime due to specific exposure
  - Cancer risk = ADD $\times$ CSF
  - Risk range: one-in-one-million (10^{-6}) to one-in-ten-thousand (10^{-4})
  - Outcome:
    - Cancer risk > risk range – further evaluation in FS
    - Cancer risk within range is acceptable (depends on regulating agency)

Risk Characterization

Answers the question:

- *What is the nature and magnitude of health risk?*

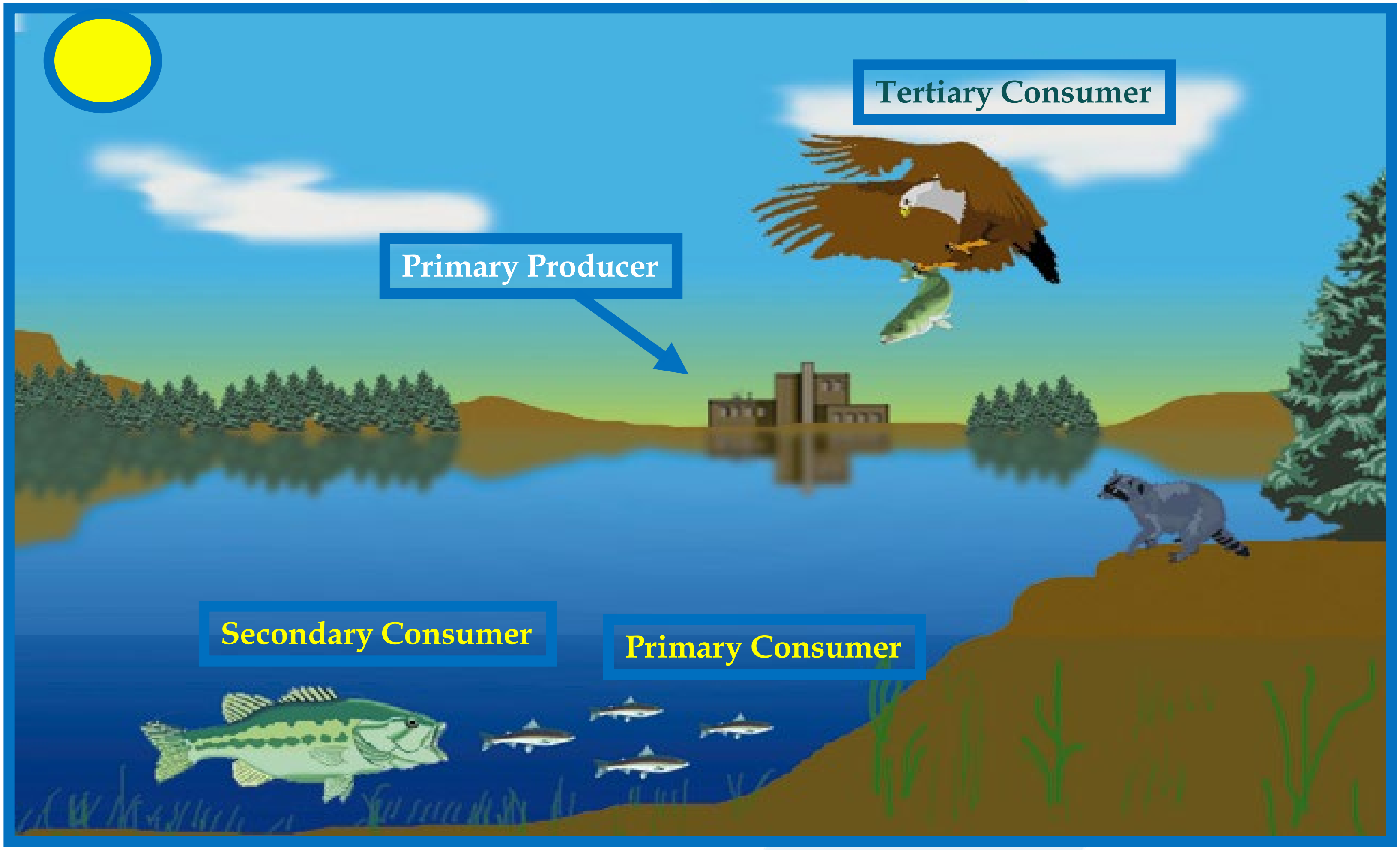
- Each chemical risk is estimated by multiplying exposure (estimate of dose) by chemical's toxicity data (acceptable dose) = risk (probability)



Uncertainty Evaluation

- Presentation of risk estimates should always include discussion of uncertainty
- Environmental risk estimates **are not** precise predictor of health impacts/disease
- Accuracy is dependent on how closely assumptions reflect actual conditions
- Accuracy is implied in risk estimates

Ecological Risk Assessment - CSM



What is Ecological Risk?

Evaluates the likelihood that adverse ecological effects may occur or as a result of exposure to one or more stressors

- A process to evaluate contaminant risk to biota present at a site
  - ***Similar*** to human health risk assessment in the quantification of risk and the development of Cleanup Levels
  - ***Different*** from human health in that the list of things to protect is potentially infinite, and what is important to protect is agreed upon by stakeholders
  - A process of focusing resources iteratively to identify and describe the environmental issues that really matter

Ecological Risk Assessment - Elements

The process systematically evaluates and organizes data, information, assumptions, and uncertainties to understand and predict the relationships between stressors and ecological effects in a manner that is useful for environmental decision making.

- The elements of an ecological risk assessment consist of:
  - planning and scoping
  - problem formulation
  - evaluating toxicity
  - assessing exposures
  - characterizing risks

Risk Assessment Benefits

- Identify data gaps
- Develop a relationship for risk evaluation with the regulator/ community
- Identify appropriate remedy/ remedies
- Use data to tell story

Why Conduct a Risk Assessment?

REGULATORY REQUIREMENT

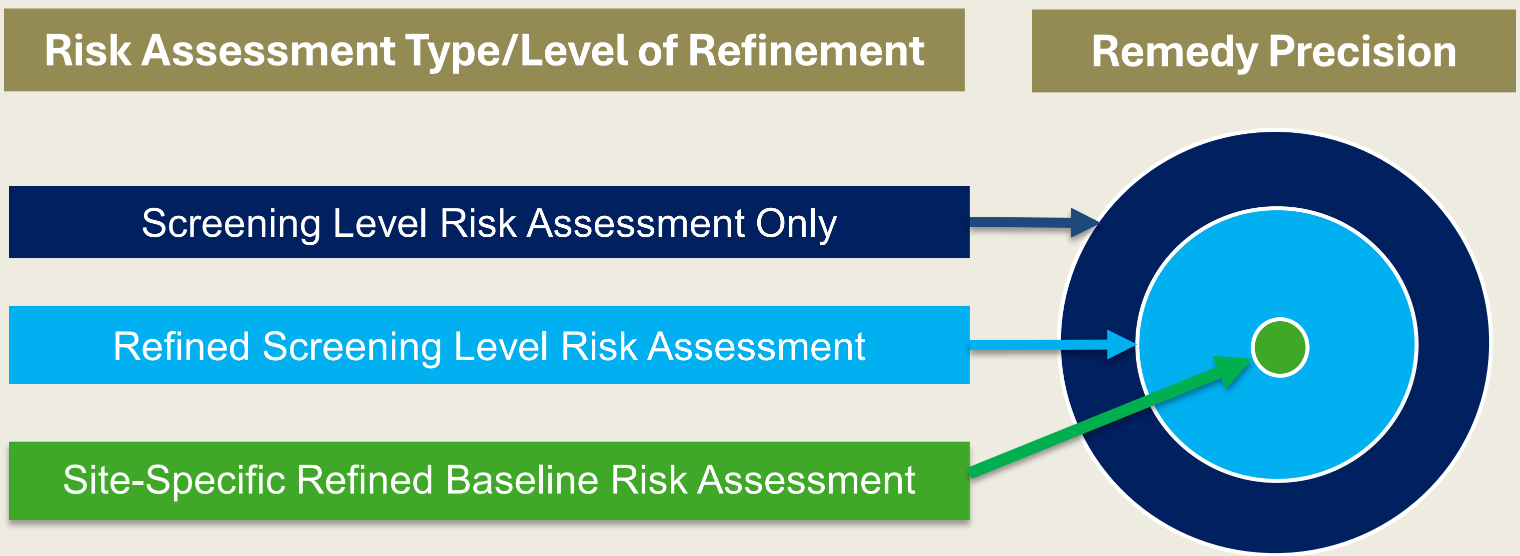
COMMUNITY INTEREST

STRATEGIC UNDERSTANDING

When to Conduct a Risk Assessment – the Value of Thinking Ahead

- Using Existing Data to Establish CSM / Data Gaps
- Prior to Data Collection to Establish Strategic Sampling Plan
- As Data are Collected – Screening and Hotspot Evaluation
- Regulatory Risk-Based Goals
- Risk-Base Remedy Selection

Magnitude of Remedy



Tiered Approach to Risk Assessment

The Tiered Risk Assessment process helps avoid the following pitfalls:

- Prescribing Tier 1 Screening as remedial action standards – tiered approach allows additional data collection, understanding actual exposure at site to refine site characterization, risks, and risk-based remediation goals (RBRGs)
- Doing remediation before determining site-specific corrective action goals
- Unnecessary additional costs to cleanup site

Tier 1 Evaluation

Tier 1 = Conservative exposure assumptions (low cost)

- **Exposure pathway analysis**
  - No exposure = no risk = no further action
- **Identify or Generate RBSL for human exposure pathways**
  - Tier 1 screening levels established using conservative, default exposure assumptions to ensure no potential risk is missed
- **Compare site concentration (max detect) to Tier 1 RBSLs (lookup table of screening levels):**
  - Site concentration ≤ Tier 1 RBSLs; no further action required
  - Site concentrations > Tier 1 RBSLs; conduct Tier 2 Evaluation or remediate to achieve Tier 1 goals

Tier 1 Outcome

- **List of COPCs for Tier 2 Evaluation**
  - Identify those chemicals/pathways that are not a concern (require no further action)
- **Knowledge of potential exposure pathways and media of concern**
- **Identify any data gaps**
  - Focus on locations where more data may be needed
  - Continue to update understanding of CSM with additional data

Tier 2 Evaluation

Tier 2 = Site-specific exposure assumptions (moderate cost)

- **Refinement of Tier 1 Evaluation**
  - Collect additional data, as needed
  - Incorporate site-specific data, including f&t inputs

- **Develop Tier 2 SSTLs for chemicals and exposure pathways that pose unacceptable risk**

- **Compare Site Concentrations (e.g., EPC) to Tier 2 SSTLs**
  - EPC = 95% Upper Confidence Limit on the Mean (95% UCL)
  - Point of Exposure (POE) may require fate and transport modeling

Tier 2 Outcome

- **Calculate Site-Specific Tier 2 SSTLs for COPCs identified in Tier 1**
  - Potential concern for COPC individually exceeding:
    - Target risk range of 1E-04 to 1E-06 for potential carcinogens (depends on regulating agency and land use)
    - Target organ-specific hazard index (HI) of 1 noncarcinogens

- **If Site Remediated to Tier 2 SSTLs, Risk Posed by Remaining Contamination is Health-Protective**

Tier 3 Evaluation

Tier 3 = Probabilistic exposure assumptions (high cost)

- Quantitative Probabilistic Risk Assessment
  - Additional data and/or assessment methods may be used (e.g., fate and transport modeling; Monte Carlo statistical simulation)
- Increased specificity, typically requiring more site-specific data and/or more sophisticated methods
- Used at the most complex sites only and requires experienced risk assessors

Your Site: Initial Site Assessment

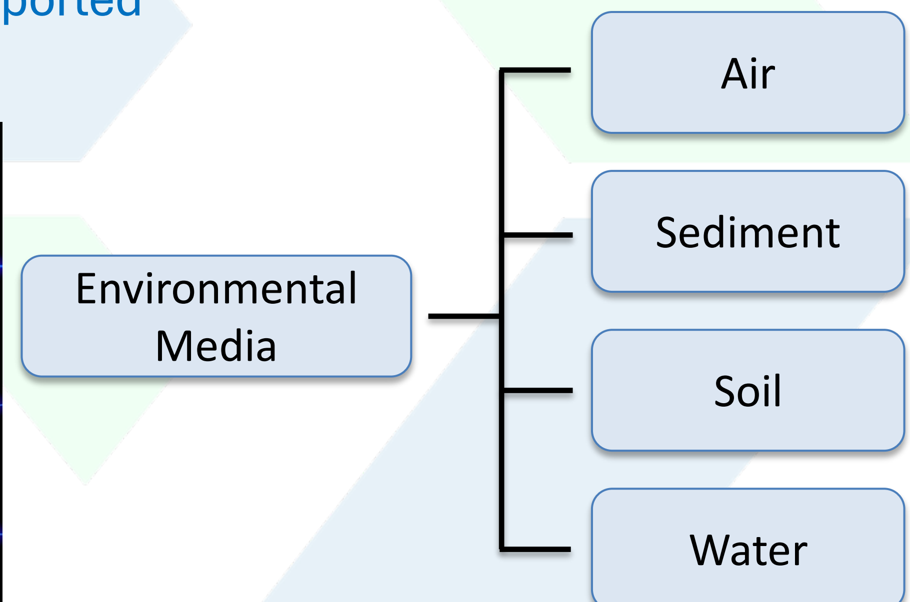
Planning and Scoping Stage

- Review available information (regulatory requirements, history, current/future use, any historical data)
- Develop a preliminary CSM

Data Evaluation

Collect Site Data

- Identify media to sample
- Identify how many samples to collect
- Identify constituents to analyze
- Identify analytical methods for the lab
- Identify how data should be reported



Data Evaluation

TRC

Data Quality Levels (DQLs)

- Most conservative risk-based screening levels to be used
- Lower of HHRA and ERA values
- Goal: for laboratory reporting limits to meet the DQLs
- Not possible in all instances - alert regulatory agency

HH Screening Criteria for DQLs

- US EPA Regional Screening Levels (RSLs)
  - Updated every 6 months
  - Includes latest toxicity information available
  - Includes latest human health risk-based screening levels for soil, water, leaching, air

"The *RSLs are not cleanup standards and should not be used as cleanup levels.* *The RSL tables provide comparison values for residential and commercial/industrial exposures to soil, air, and tap water (drinking water). The unified use of the RSLs, to screen chemicals at Superfund sites, promotes national consistency."* – Regional Screening Levels for Chemical Contaminants at Superfund Sites

Data Evaluation

Exposure point Concentrations = conservative estimate of the average chemical concentration in an environmental medium

Measured

- generally lower of maximum detected and the 95% Upper Confidence Limit (95%UCL)
- 95% UCL statistical approach – currently use ProUCL

Statistics

- Requires n = 10, minimum of 6 detects to run statistics
- 10< n <20 – adequate estimate of 95%UCL
- n>20 - good estimate of 95% UCL

Data Collection Issues

Data Collection Issues

- Ensure all data end users are involved in sample collection design, including:
  - nature and extent, exposure, and evaluation of treatment technologies
- Collect adequate fate and transport parameters to characterize migration potential
  - foc, porosity, bulk density, etc.
- Data quality levels (DQLs)
  - Appropriate detection limits required to meet screening levels

Fate and Transport

Fate and Transport in the Environment

- **fate = chemical change** (chemically, physically, or biologically)
- **transport =** movement in the environment can be through 1 or more medium)

Types of Fate and Transport

- Vapor Intrusion of subsurface media (groundwater/unsaturated soil/soil gas) into indoor air
- Windblown or construction activities lead to airborne soil particulates or soil volatiles
- Leaching of unsaturated soil impacts downward into groundwater
- Downgradient lateral transport of groundwater

Fate and Transport Evaluates

- How contaminants have moved or will move beyond the source area
- How contamination could migrate, and exposures could occur beyond the sampled areas.

Data to Support Fate and Transport

Data Necessary to Support Fate and Transport

- **Unsaturated Zone**
  - foc
  - air-filled porosity
  - pH
  - Soil bulk density
  - fixed gases (O_2, CO_2, CH_4)
    - VI bioattenuation

- **Saturated Zone**
  - hydraulic gradient and conductivity
  - foc, water-filled porosity, pH

- **Surface Water**
  - 7Q1O flow
  - water chemistry

Risk Assessment Cost-Benefit Analysis

Predicts hypothetical risk to potential receptors

- **Tier 1-** least costly risk assessment step, but results in conservative conclusions
- **Tier 2 -** adds costs to risk assessment, but, potentially results in lower remediation costs
- **Tier 3 -** adds more costs to risk assessment, but results in most accurate risk and/or cleanup levels based on site conditions, with lowest remediation costs

Tier 1, Tier 2, Tier 3 are all health-protective!

Thank you

Questions?

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Risk Assessment Resources

RAIS Online Risk Assessment Resource - RAIS has a lot of tools and databases, including chemical properties, fate and transport / uptake modeling, as well as residential, indoor worker, outdoor worker, construction, recreator, farmer exposure assumptions. Available at: https://rais.ornl.gov/

USEPA Risk Assessment Resources

USEPA, 1989. Risk Assessment Guidance for Superfund (RAGS) Volume I Human Health Evaluation Manual Part A. EPA/540/1-89-002. December 1989.

USEPA, 1991. Risk Assessment Guidance for Superfund, Volume I— Human Health Evaluation Manual (Part B, Development of Risk-based Preliminary Remediation Goals). Washington D.C.: Office of Emergency and Remedial Response. U.S. EPA/540/R-92/003. December 1991.

USEPA, 1994. Region 8, Superfund Technical Guidance. Evaluating and Identifying Contaminants of Concern for Human Health. United States Environmental Protection Agency, Hazardous Waste Management Division, Superfund Management Branch, Technical Section. September 1994.

USEPA, 1996. Soil Screening Guidance: User's Guide (EPA/540/R-96/018) and Technical Background Guidance.

USEPA, 2002a. Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites OSWER 9355.4-24. December.

USEPA, 2002b. Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites

USEPA, 2004. Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual, Part E: Supplemental Guidance for Dermal Risk Assessment. Final. Office of Superfund Remediation and Technology Innovation, Washington, D.C. EPA/540/R/99/005. July.

USEPA, 2006a. Guidance on Systematic Planning Using the Data Quality Objectives Process. Office of Environmental Information, Washington, DC. EPA/240/B-06/001. February.

USEPA, 2006b. On the Computation of a 95% Upper Confidence Limit of the Unknown Population Mean Based Upon Data Sets with Below Detection Limit Observations. Office of Research and Development. EPA/600/R-06/022. March.

USEPA, 2009. Risk Assessment Guidance for Superfund (RAGS), Volume I: Human Health Evaluation Manual, Part F: Supplemental Guidance for Inhalation Risk Assessment. Final. EPA-540-R-070.002. January 2009.

USEPA, 2011. USEPA's Exposure Factors Handbook, 2011 Edition. National Center for Environmental Assessment, Office of Research and Development, Washington D.C. EPA/600/R-09/052F. September 2011.

USEPA, 2014a. USEPA's Human Health Evaluation Manual, Supplemental Guidance: Update of Standard Default Exposure Factors. Office of Solid Waste and Emergency Response, Washington, D.C. OSWER Directive 9200.1-120. February 6, 2014.

USEPA, 2014b. Determining Groundwater Exposure Point Concentrations, Supplemental Guidance. Office of Solid Waste Emergency Response, Washington, C.D. OSWER Directive 9283.1-42. February.

USEPA 2023a. Regional Screening Levels (RSLs) User's Guide. Available at: https://www.epa.gov/risk/regional-screening-levels-rsls-generic-tables. November.

USEPA. 2023b. Regional Screening Levels (RSLs) Generic Tables. Available at: https://www.epa.gov/risk/regional-screening-levels-rsls-users-guide. November.

USEPA, 2024a. Regional Screening Level (RSL) Calculator available online at: https://epa-prgs.ornl.gov/cgi-bin/chemicals/csl_search

USEPA, 2024b. Integrated Risk Information System (IRIS) database. Available online at: www.epa.gov/iris