Risk Based Corrective Action and Risk Based Decision Making

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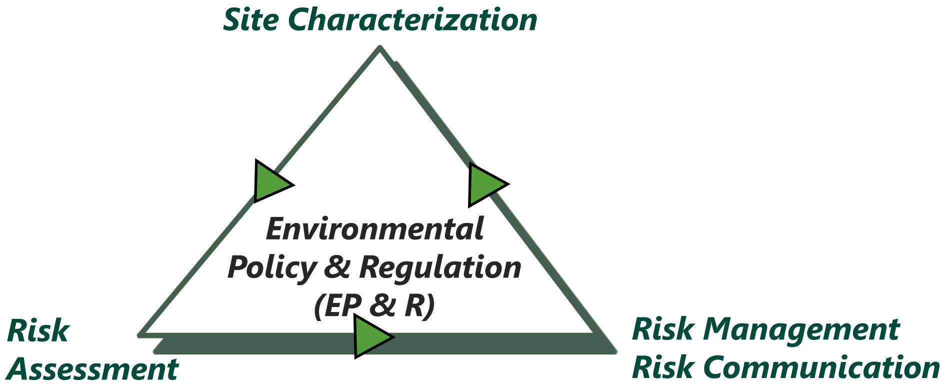
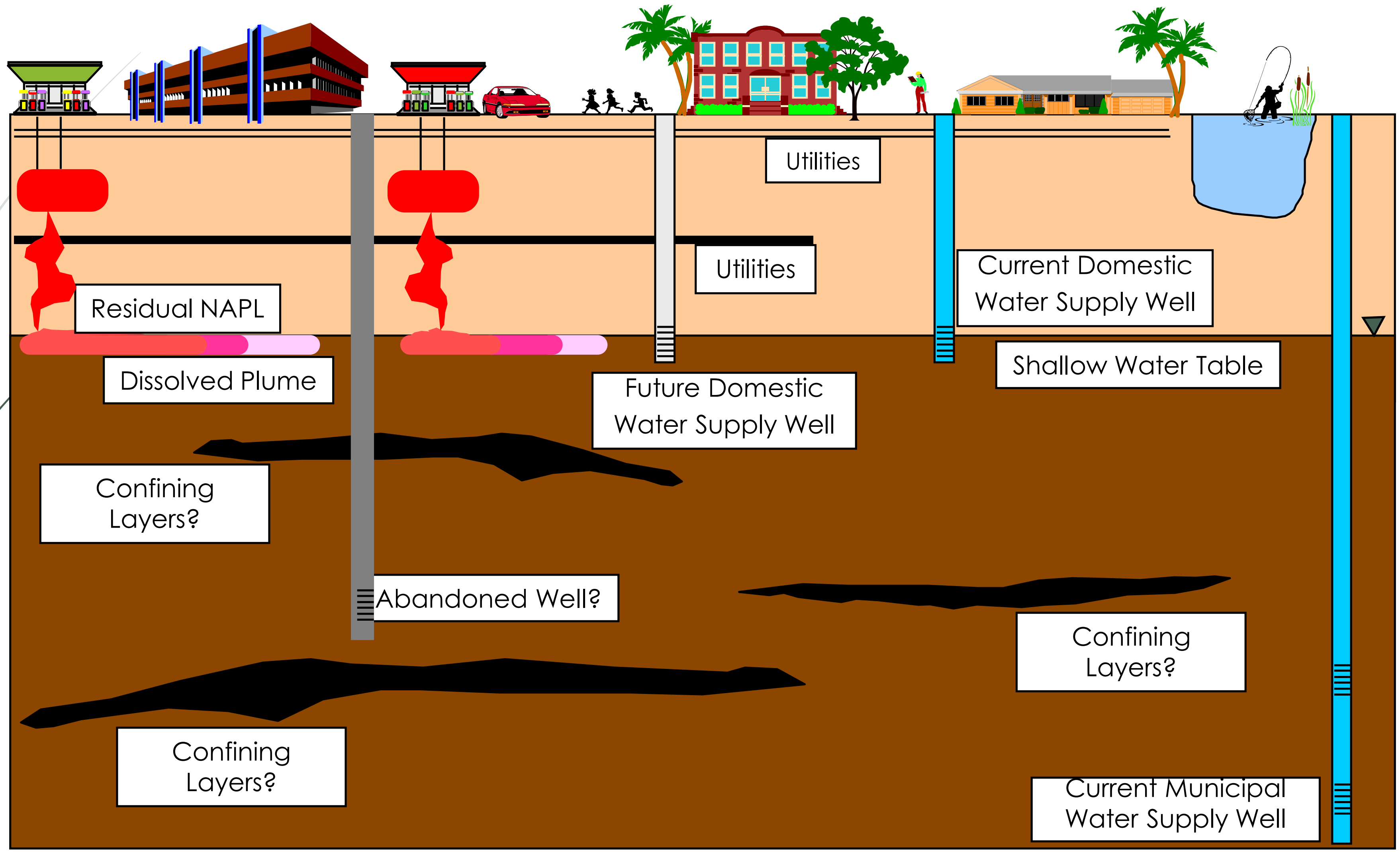


Course Objectives

Understand RBCA to better manage contaminated sites

- RBCA
- Brief history
- What is RBCA……..and what it is not

A General Site Model



Gas Station

Hydrocarbon Contamination Refinery, Tank Farm & Residential Area

Manufacturing Facility/Airport Expansion

What do these sites have in common?

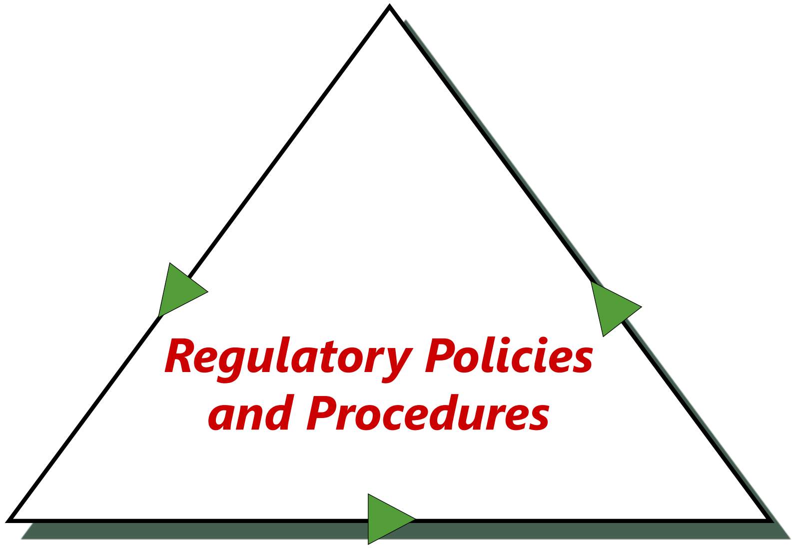
- Touched by chemicals (contaminants?)

- Regulatory closure is required to “move forward”

- Various drivers for “moving forward”:
  - Current/future threat to human health and the environment
  - Sale of property
  - Development of property
  - Neighboring property issues

RBCA and Activities Required at Contaminated Sites

Site Characterization



Risk Assessment
- Explosive Conditions
- Human Health
- Environment
- Nuisance conditions

Risk Management
- Cleanup
- Institutional controls

What to Characterize?

SOURCE →	**MEDIA** →	**RECEPTOR LOCATION**
LANDFILL	SATURATED ZONE	WATER USE WELL
LEAKING TANK	UNSATURATED ZONE	AMBIENT AIR
RESIDUAL CONC. IN GW	SURFACE STREAM	CONC. IN PRODUCE
OIL WATER SEPARATOR	ATMOSPHERE	INDOOR AIR

Natural attenuation processes reduce the concentrations during migration
Models can estimate the (i) mass of chemicals released from the source and (ii) their movement through various media to reach the receptor.

Data For Site Characterization (SC)

- Source characteristics (size, location, COCs)
- Characteristics of media (soil, groundwater, surface water, soil vapor, indoor & ambient air)
- Spatial and temporal variation in concentrations (soil, groundwater, surface water, soil vapor…..)
- Current and future land use and buildings

Collect data to (i) develop SCM, or (ii) answer a specific question that will help make a decision (DQO Process)

Do not collect data just because….

Objective of Data Collection/Site Characterization (SC)

- Size of problem (Delineate impacts)
- Estimate site-specific risk
- Confirm stability of impacts
- Implement management options
- Understand fundamental processes that affect chemical behavior (fate and transport properties and processes)

Number of samples is a professional decision

Conceptual Model

- A narrative description of site characteristics with tables and figures that provides a foundation for understanding a site and the distribution of chemicals in space and time

- Identifies general and specific physical conditions that influence contaminant transport and receptor exposure

- Identifies environmental issues that need to be investigated (and those issues that do not need to be addressed)

- Used to select and design the best options for remediation

- Provides a framework for the entire project and a communication tool for the regulators, PRPs, and other stockholders

SCM is the cornerstone of good RBDM

Basis For Risk Assessment

- Site-specific data
- Toxicity of chemicals
- Behavior of chemicals in the environment (fate and transport modeling)
- Complete routes of exposure (ingestion, inhalation, and dermal contact)
- Receptor characteristics (residential, non-residential, and construction worker)
- Regulatory program & policies

RA Two Questions

Ideally would like to clean properties to pristine conditions, however extensive experience suggests:

- Technology nor resources exist to clean sites to pristine conditions
- Not necessary to clean to pristine conditions

Risk assessment can answer two questions:

- What is the risk at a site?
- How clean is clean, i.e. develop cleanup/target levels?

Application of Risk Assessment (RA)

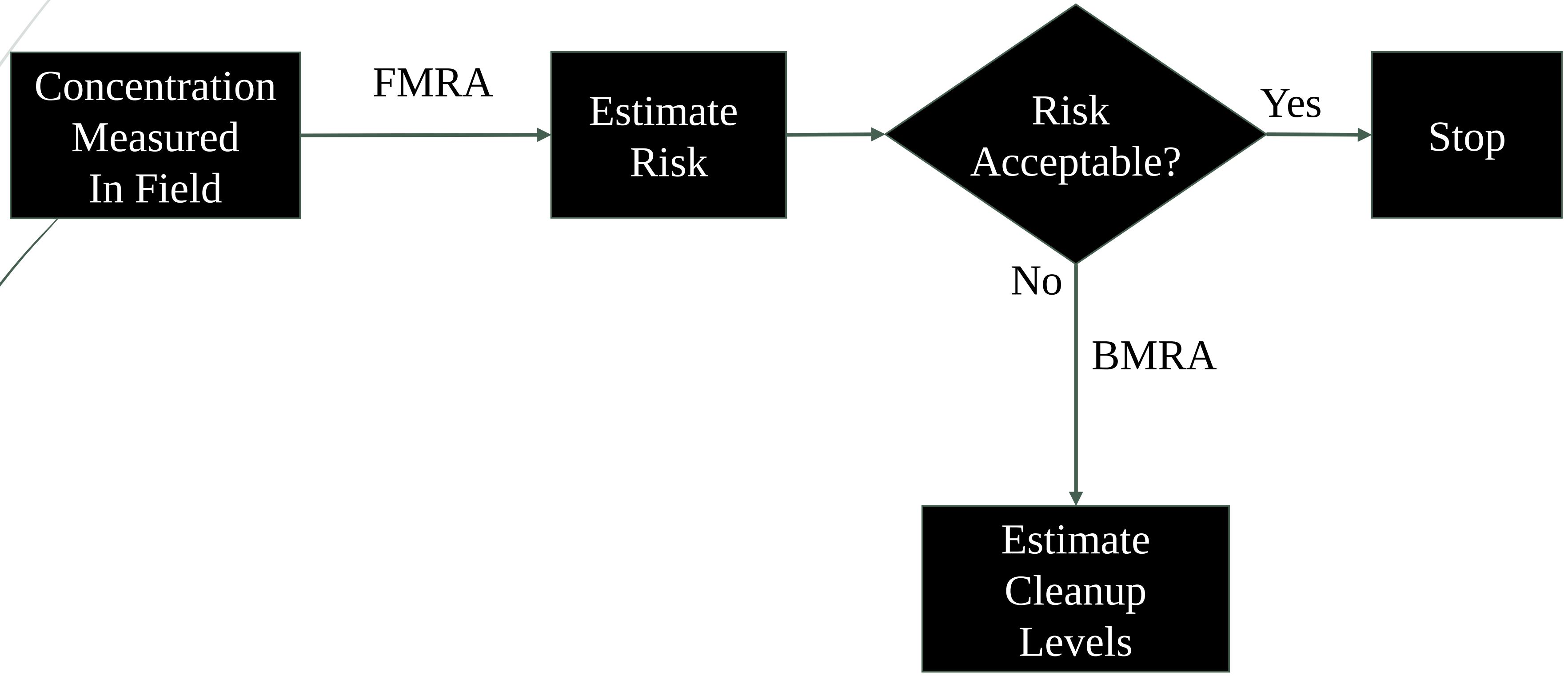
Risk Assessment is a scientific and regulatory process used to:

1. **Estimate risk based on site-specific factors and concentrations: F*orward mode of RA***

2. Estimate cleanup levels based on site-specific factors and acceptable risk standards: B*ackward mode of RA*

FMRA and BMRA are a key part of RBCA process

Summary: Forward Mode and Backward Mode Risk Assessment



Risk Management (RM)

Risk Management (RM) follows RA and is used to:

1. Decide whether calculated risk is acceptable
2. Develop cleanup levels
3. Remediate site to cleanup levels or use institutional controls to manage risk

RM includes technical and non-technical considerations such as policy choices, cost, stakeholder agreements, risk perception, institutional controls, etc.

Risk Management (RM) Tools

- Engineered treatment systems
  - Pump & treat
  - Soil Vapor Extraction
  - Enhanced bio-degradation
  - Dual-phase extraction
- Land use controls
  - Land use restrictions
  - Water use restrictions
- Engineered controls
  - Capping
  - Slurry walls
  - Ventilation systems
- Information and training

Institutional Controls
An Important Risk Management Tool

- Allow productive and safe use of property
- Ensures that the assumptions used in risk assessment remain valid
- Knowledge of impacted sites is not lost
- Provides long-term protection for risk based remedies

Outcome of RBCA Process

If correctly implemented, RBCA can provide a clear path forward for the site. These include:

- No further action needed (clean-up levels achieved and plume is stable)
- Additional data collection to demonstrate (i) plume is stable, and (ii) cleanup levels have been achieved
- Remediation (passive or active) to meet specific target levels

A Fundamental Paradigm Shift

- **Conventional Approach**:
  - How much chemical mass can we remove?
- **RBCA Approach**:
  - How much chemical mass can we safely leave behind?
  - How do we ensure that future generations are aware of the chemical left behind so there are no surprises?

History of Risk Assessment

- RAGS (1990)
- Soil Screening levels (1996)
- ASTM RBCA (1995)
- ORBCA (1996)
- Vapor Intrusion (2001, 2002 and 2015)
- PRGs (early 2000), now RSLs
- Many federal (DOD, guidance documents)

RA is a part of RBCA but RA is not RBCA

RBCA is a comprehensive decision making process

Exposure Assessment

Two Parts of Exposure Assessment (EA)

- **Part 1: Qualitative Considerations**
  - Objective: the development of an exposure model (EM) for the site
  - An EM lists all complete and incomplete exposure pathways

- **Part 2: Quantitative Considerations**
  - Objective: the estimation of dose for each chemical of concern (COC) for all complete exposure pathways

The following slides explain EA and COCs

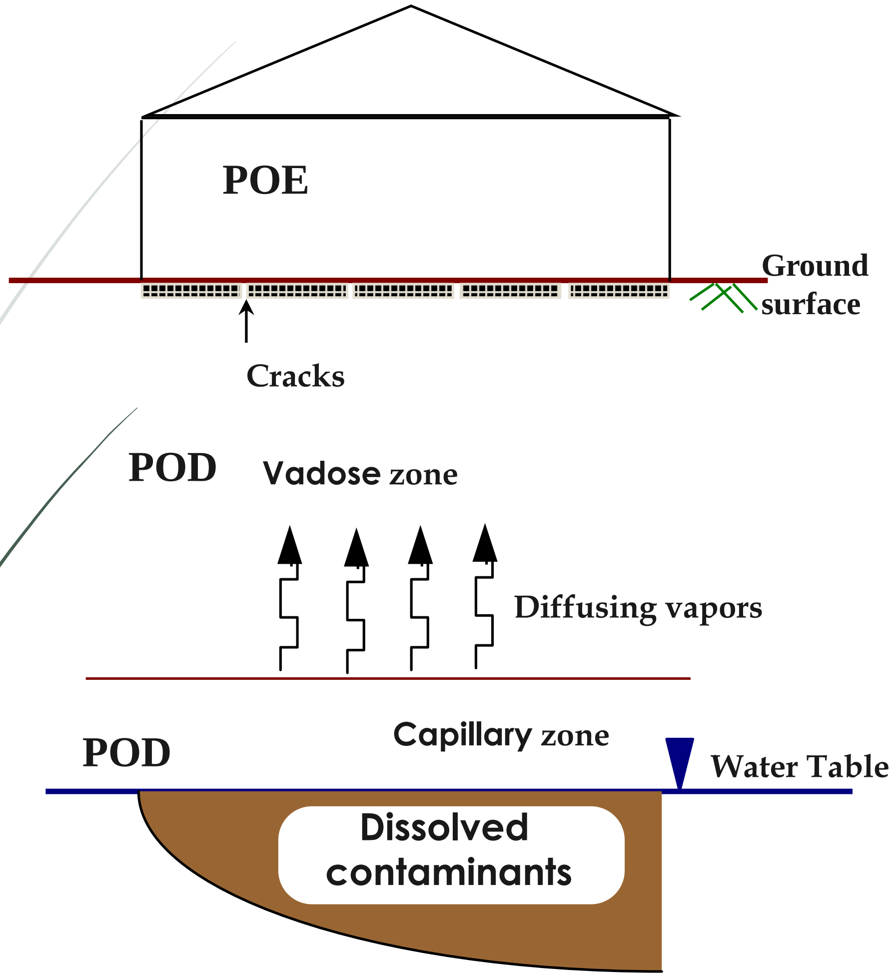
Complete and Incomplete Exposure Pathway

A complete exposure pathway consists of four components:

1. **Source** of chemicals
2. **Mechanism** for release of chemicals from source
3. **Migration** through media to the receptor
4. **Contact** with receptor

If any one component is missing, exposure pathway is incomplete

Example Pathway: Indoor Vapor Intrusion from Groundwater



Complete Pathway:

Source: Residual chemicals in groundwater
Release: Volatilization
Media: Capillary fringe, vadose zone, and cracks
Contact: Inhalation

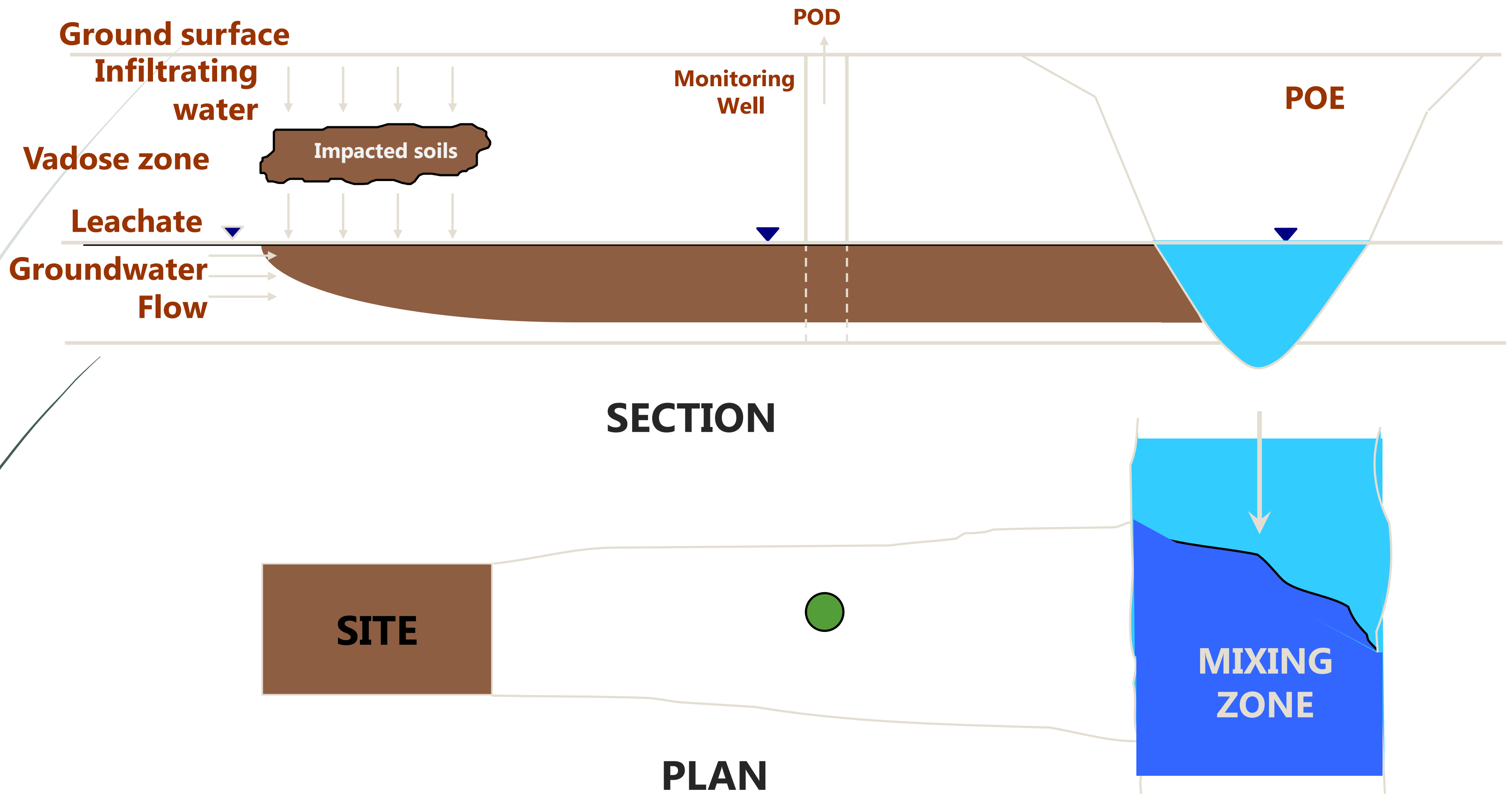
Pathway Incomplete if:

No Source: Groundwater is clean
No Release: Chemical is non-volatile
No Migration: Vapor barrier exists below building
No Contact: No receptors or personal air supply

One approach to risk management is to make the pathway incomplete by eliminating one of the elements

Petroleum hydrocarbon vapors biodegrade in vadose zone

Example Pathway: Migration from Soil to Groundwater to Surface Water Body

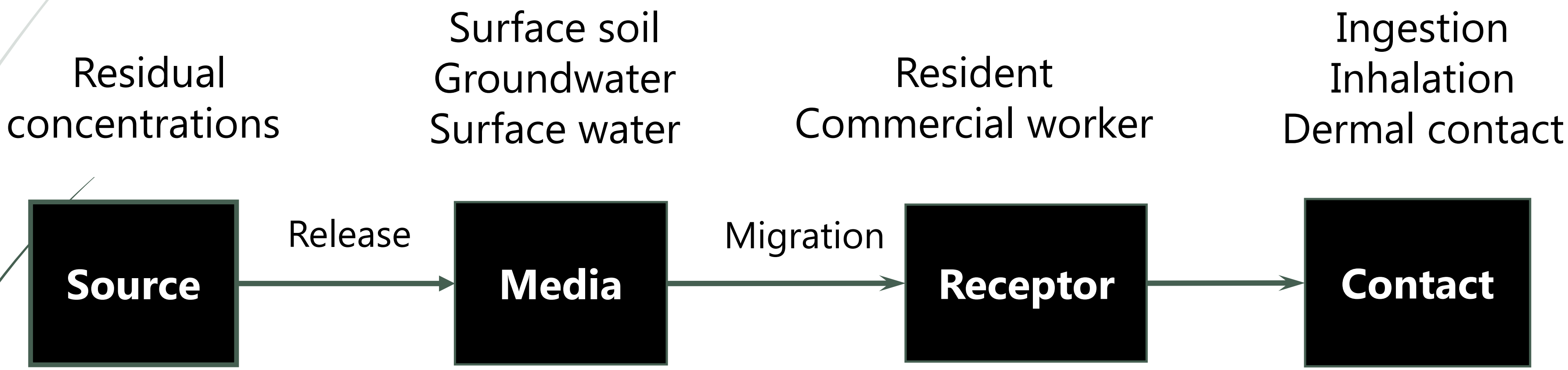


Site Conceptual Exposure Model (SCEM) Complete Exposure Pathways

Receptor	Exposure Pathway
Current On-site Indoor Worker	• Indoor inhalation of vapors from subsurface soil • Indoor inhalation of vapor from groundwater
Future On-site Indoor Worker	• Outdoor inhalation of vapors from subsurface soil • Outdoor inhalation of vapor from groundwater • Ingestion of water by domestic use of groundwater • Dermal contact with water by domestic use of groundwater
Current On-site Outdoor Worker	• Dermal contact with surficial soil • Accidental ingestion of surficial soil • Outdoor inhalation of vapors and particulates from surficial soil • Outdoor inhalation of vapors from subsurface soil • Outdoor inhalation of vapors from groundwater
Future On-site Outdoor Worker	• Dermal contact with surficial soil • Accidental ingestion of surficial soil • Outdoor inhalation of vapors and particulates from surficial soil • Outdoor inhalation of vapors from subsurface soil • Outdoor inhalation of vapors from groundwater • Ingestion of water by domestic use of groundwater • Dermal contact with water by domestic use of groundwater

The primary drivers are protection of groundwater and indoor vapor intrusion

Elements of Exposure Pathway



Quantitative Exposure Assessment Objective

Estimate dose for each chemical for all current and potential future receptor(s) by all complete exposure pathways

$$\text{Dose} = \frac{\text{mg of chemical}}{\text{kg of body weight per day}}$$

Dose has to be estimated for all complete exposure pathways identified in the exposure model

Calculations are not required fro the incomplete pathways

Quantitative Exposure Assessment

Dose depends on:

- POE concentration
- Exposure factors that depend on exposure pathway and receptor and include:
  - Amount of media that comes in contact with the receptor
  - Frequency and duration of contact
  - Physiological factors

Dose Equation: Ingestion of Water

$$\text{Dose}\,(\text{mg/kg-day}) = \frac{CW \times IR \times EF \times ED}{BW \times AT}$$

CW = <u>Representative</u> concentration in water at <u>POE</u> (mg/L)
IR = Ingestion rate (L/day)
EF = Exposure frequency (days/year)
ED = Exposure duration (years)
BW = Body weight (kg)
AT = Averaging time (days)

For carcinogenic health effects, AT = 70 years and dose is referred to as the lifetime average daily intake (LADI)

For non-carcinogenic health effects, AT = the exposure duration and dose is referred to as the chronic daily intake (CDI)

Calculations are simple, most common error are with units!

Exposure Factors

- Include human physiological & behavioral factors.
- Typically not measured at the site, literature/default values are used
- Typically default values are conservative

Use of Fate and Transport Models in RA

- Calculation of dose requires POE concentration.
- There are many situations where POE concentration is not available and cannot be measured
- In such situations it is necessary to estimate concentration based on alternative concentrations, e.g. at the source concentration or between the source and POE
- Fate and transport (F&T) models are used to relate the POE concentration with the source concentration

Schematic of Fate and Transport Models

SOURCE	**MEDIA**	**RECEPTOR LOCATION**
LANDFILL	SATURATED ZONE	WATER USE WELL
LEAKING TANK	UNSATURATED ZONE	AMBIENT AIR
RESIDUAL CONC. IN GW	SURFACE STREAM	CONC. IN PRODUCE
OIL WATER SEPARATOR	ATMOSPHERE	INDOOR AIR

F&T models can be used to estimate the concentration at the POE based on the source and the media through which chemicals migrate

Quantitative Toxicity Measures
Non-carcinogenic Effects

- Reference Dose, RfD (mg/kg-day)
  - An estimate (with uncertainty spanning perhaps an order of magnitude) of a daily exposure to the human population (including sensitive subgroups) that is likely to be without risk of adverse effects during a lifetime
- Reference Concentration, RfC (mg/m^3)
  - An estimate (with uncertainty spanning about an order of magnitude) of a continuous inhalation exposure to the human population (including sensitive subgroups) that is likely to be without an appreciable risk of harmful effects during a lifetime.
- (Route to Route Extrapolation: Not recommended)

$$RfD\ (\mathrm{mg/kg} \bullet \mathrm{day}) = RfC\ (\mathrm{mg/m^3}) \times \frac{20\ \mathrm{m^3/day}}{70\ \mathrm{kg}}$$

Quantitative Toxicity Measures
Carcinogenic Effects

- **Slope Factor/Potency Value, SF (mg/kg•day)-1**
  - **Slope factor is a conservative estimate of risk per unit intake over a lifetime assumes a linear dose response curve (risk per unit dose)**

- **Unit Risk, URF (mg/m^3)-1**
  - **The conservative estimate of lifetime cancer risk due to continuous exposure to a chemical of mg/m3 in air (risk per unit concentration).**

Route to route extrapolation, not recommended:

$$SF\ (\text{mg/kg} \bullet \text{day})^{-1} = URF\ (\mu\text{g/m}^3)^{-1} \times 1000\ \frac{\mu\text{g}}{\text{mg}} \times \frac{70\ \text{kg}}{20\ \text{m}^3/\text{day}}$$

Risk Characterization: Non-Carcinogenic Health Effects

$$\text{Hazard Quotient (HQ)} = \frac{\text{Dose}}{\text{Reference Dose}}$$

- **HI is the sum of HQs**
- **Calculation of HQ/HI for each chemical and each receptor is the end of risk assessment**

Risk assessment is followed by risk management

Risk Characterization: Carcinogenic Health Effects

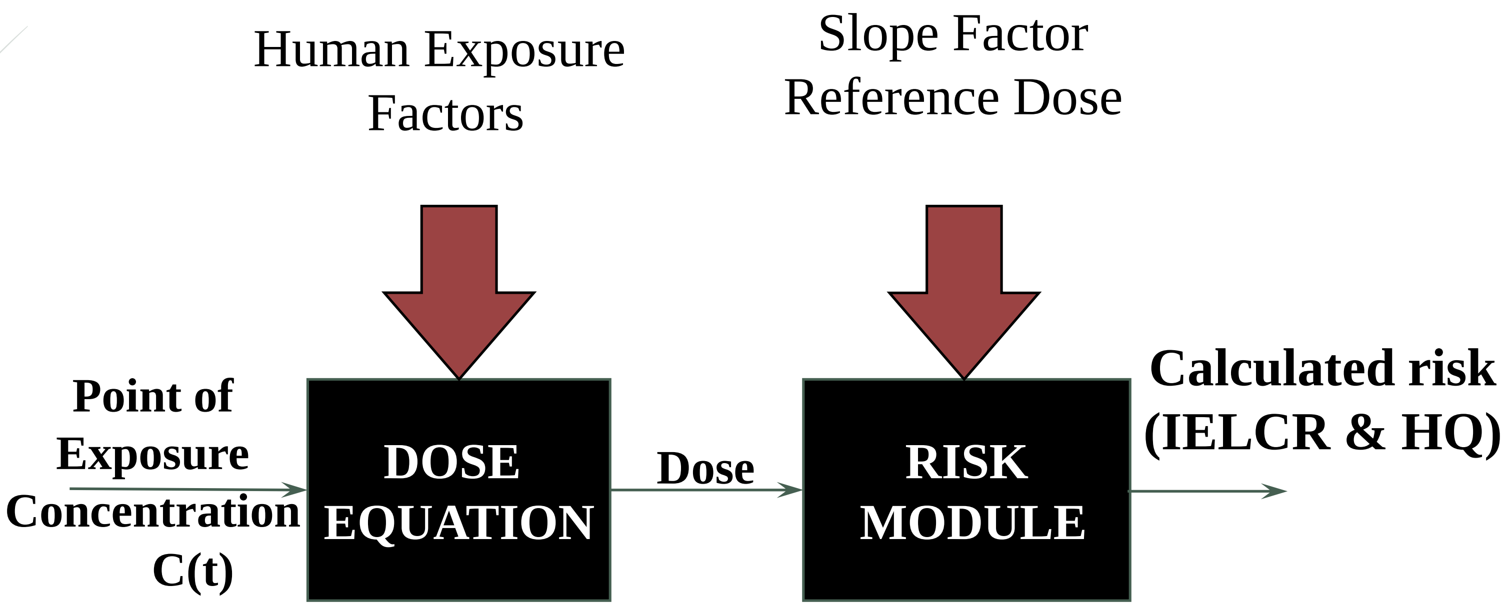
IELCR* = Dose x Slope Factor

If IELCR > acceptable risk, need for risk management

If IELCR < acceptable risk, no action required from a human health risk perspective.

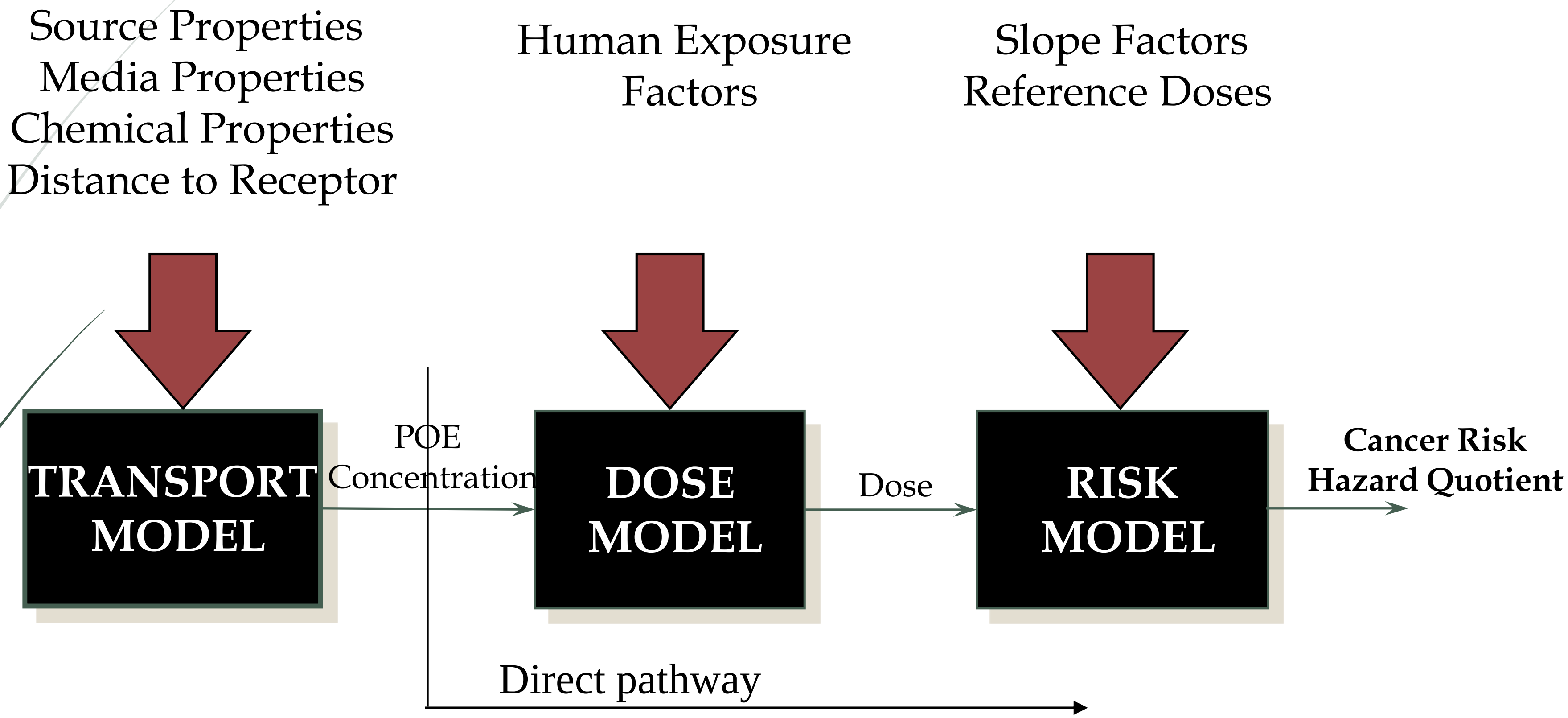
*Individual Excess Lifetime Cancer Risk

Estimation of Risk Direct Exposure Pathway



Calculated risk has to be compared with the acceptable risk to make a decision about risk management

Estimation of Human Health Risk by Indirect Exposure Pathway



Forward And Backward Modes Of Risk Assessment
Indirect Routes Of Exposure

Forward Mode - Is risk below regulatory acceptable level? →

Model/Data		Default or Site-Specific		EPA/State Databases		Default or Site-Specific		EPA/State Databases		?
Concentration other than point of exposure	X	Media Parameters	X	Chemical Specific Properties	X	Exposure Factors	X	Toxicity	=	Risk
?		Default or Site-Specific		EPA/State Databases		Default or Site-Specific		EPA/State Databases		Policy

← Backward Mode - Are the representative site concentrations below the estimated clean-up levels?

Characteristics of Tiers

- All tiers provide the regulatory mandated acceptable risk level
- All tiers require the similar inputs to develop target levels
- RM-1 levels are developed using conservative default assumptions and factors by the regulatory agency
- RM-2 levels/cumulative risk is based on site-specific data

Key Aspects of Risk-Based Decision Making

- **Site Conceptual Model**
  - Establishes the framework for site management
- **Site Conceptual Exposure Model**
  - Establishes the framework for RA
- **Quantitative Target Levels**
  - Establishes measurable goals
- **Tiered Approach**
  - Ensures efficient use of resources
- **Upfront Involvement of Concerned Parties**
  - Enhances acceptability of results

Summary of RBCA Process

- **Process: SA, RA, RM, involvement of stake holders**
- **Outcome: A definitive path forward**
- **Benefit: If implemented & documented correctly, reduces the financial and regulatory uncertainty required to close site or achieve a no further action determination**

Common Misconceptions

- RBCA is a “do nothing” option
  - RBCA requires careful evaluation of data and solutions
- RBCA is to “risk away” sites
  - This happens when RBCA is not implemented correctly. It is a misuse of a well though out tool
- RBCA cannot be done until LNAPL has been removed
  - The requirement to protect human health and the environment is the overriding criteria even at sites with LNAPL not withstanding CFR 280.64
- RBCA is too complicated
  - It is atool that does require some training and specialized knowledge

Final Thoughts...

- The RBCA process has been invented, it's being widely used, and it is for us to use it prudently, misuse it, or ignore it.

- Prudent application presents tremendous opportunities for working smart to protect current and future public health, water quality and the Environment.

- The successful application of RBCA largely depends on the leadership at each States and clear technical/policy directions available to the practitioners

- Use risk assessment as an honest decision-making tool and not a site-closure only tool.