

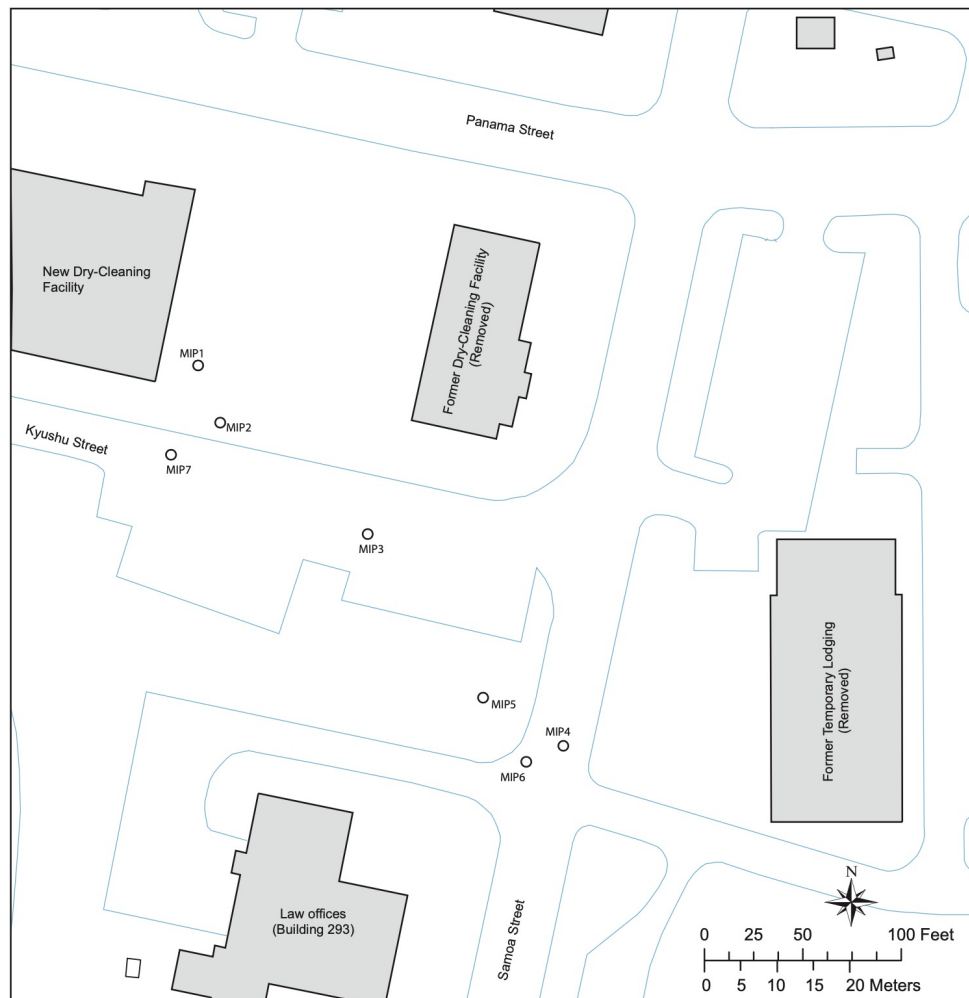
RISK ASSESSMENT



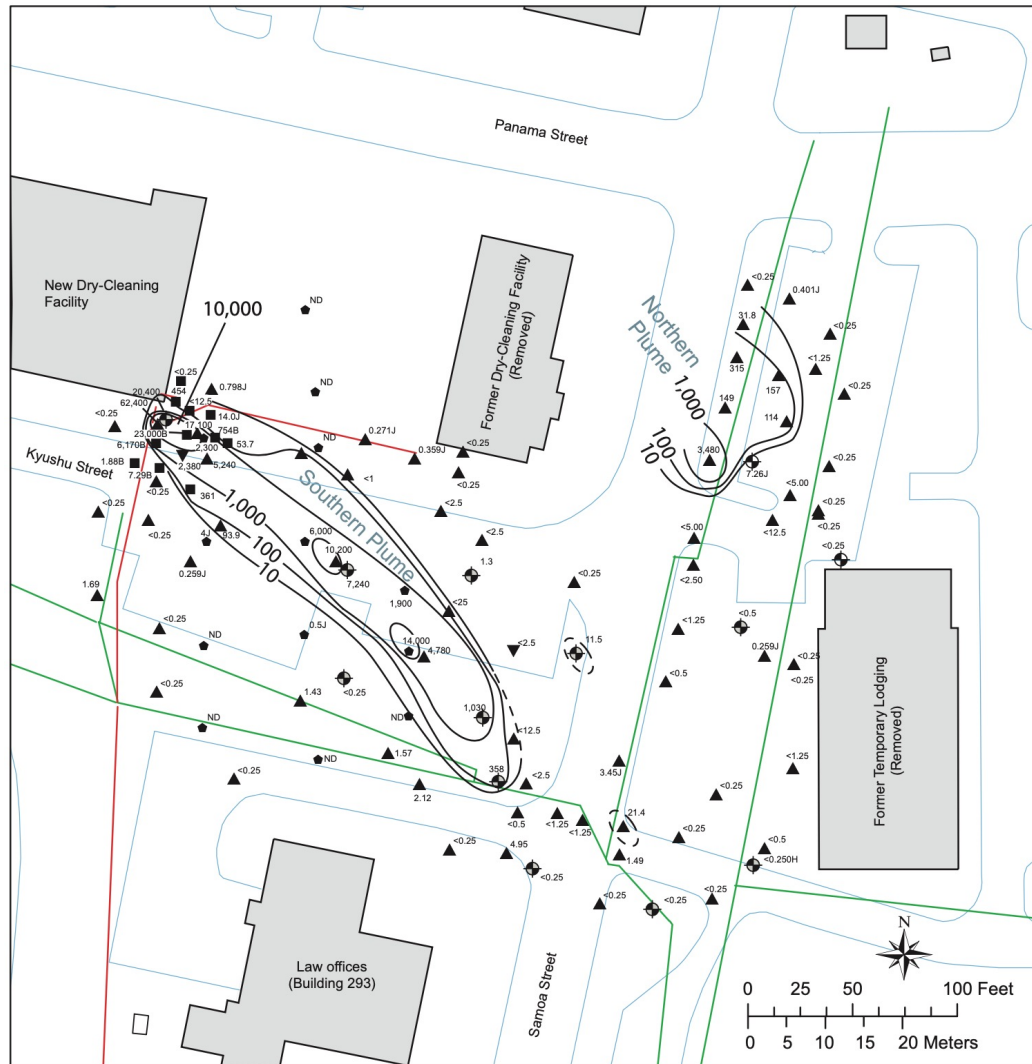
What Is Risk?

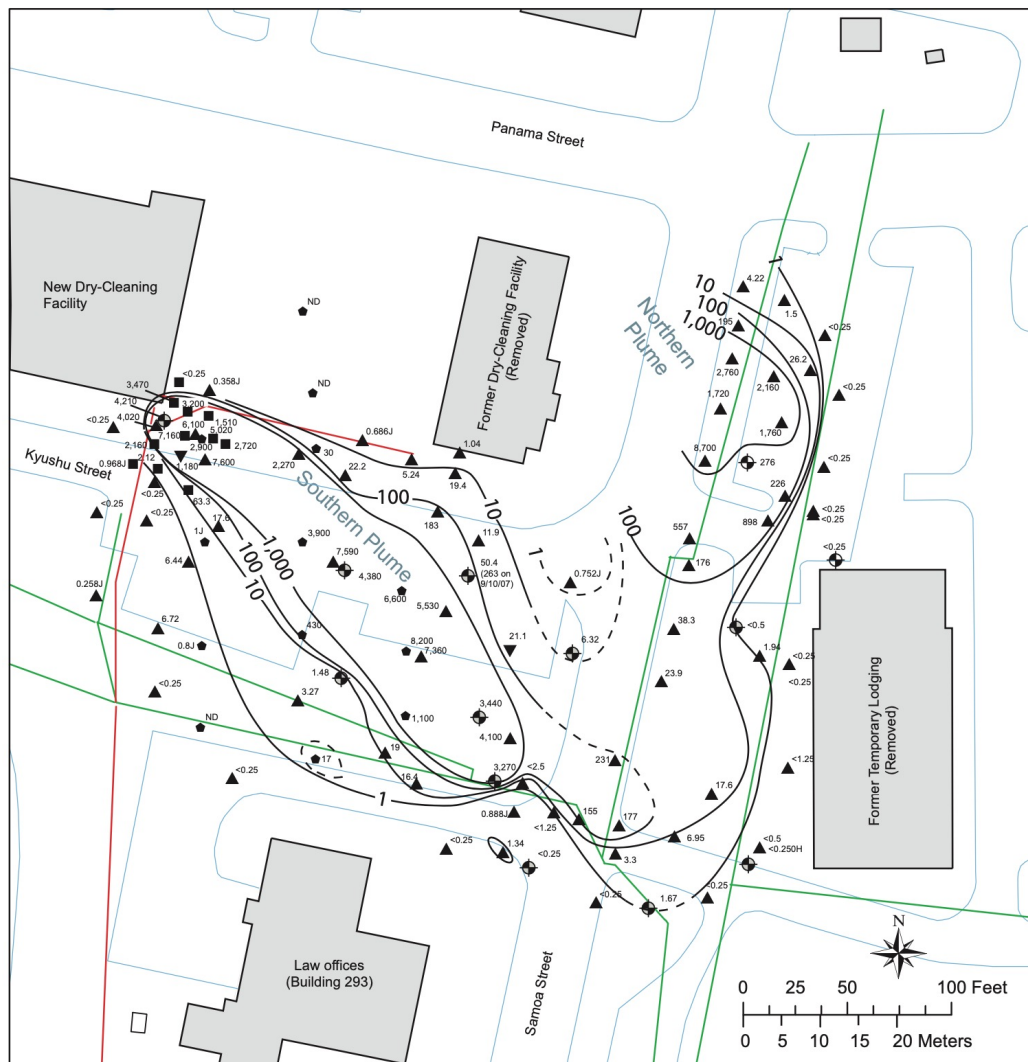
- Probability of an adverse outcome
- What do you understand when someone mentions that a particular activity is safe?
 - ▣ There is usually no such thing as zero risk

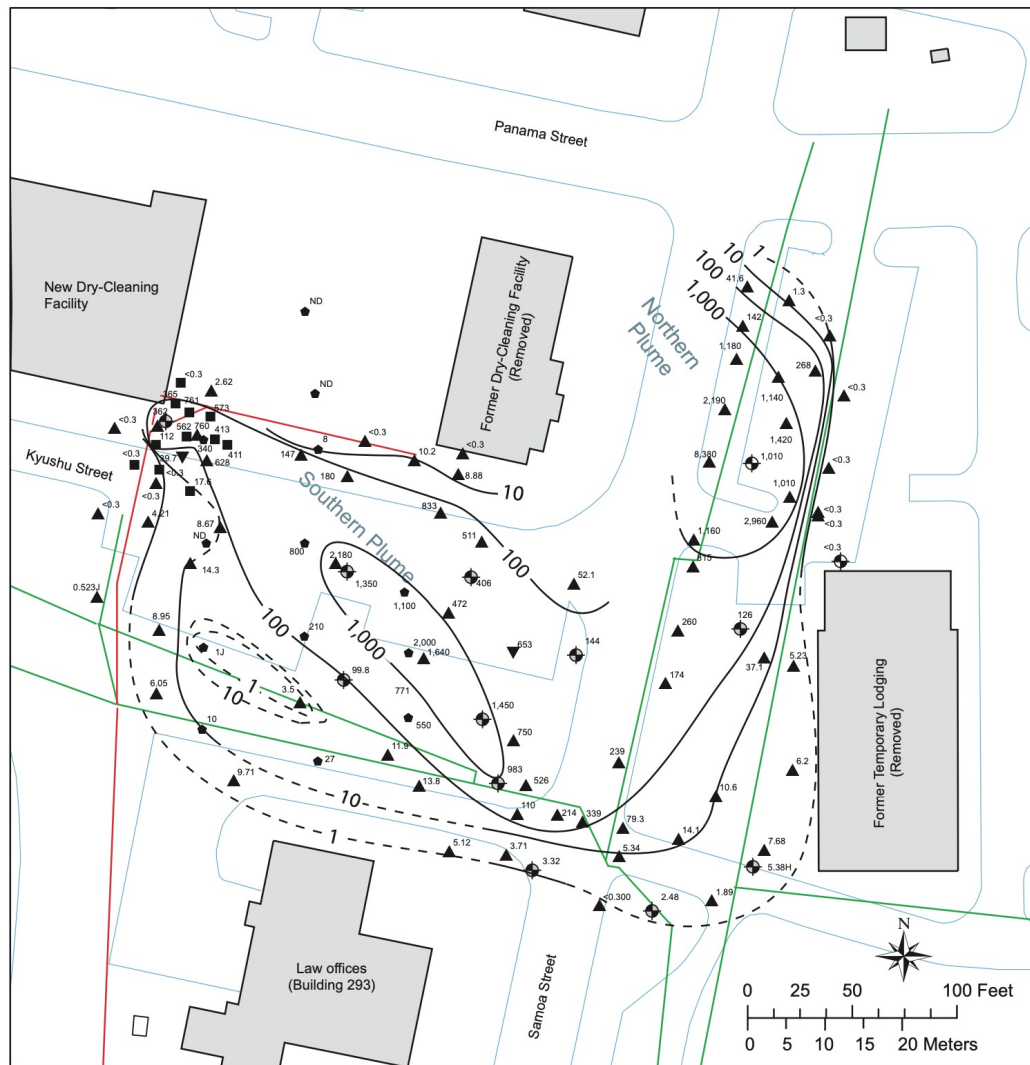
Why Do I care?

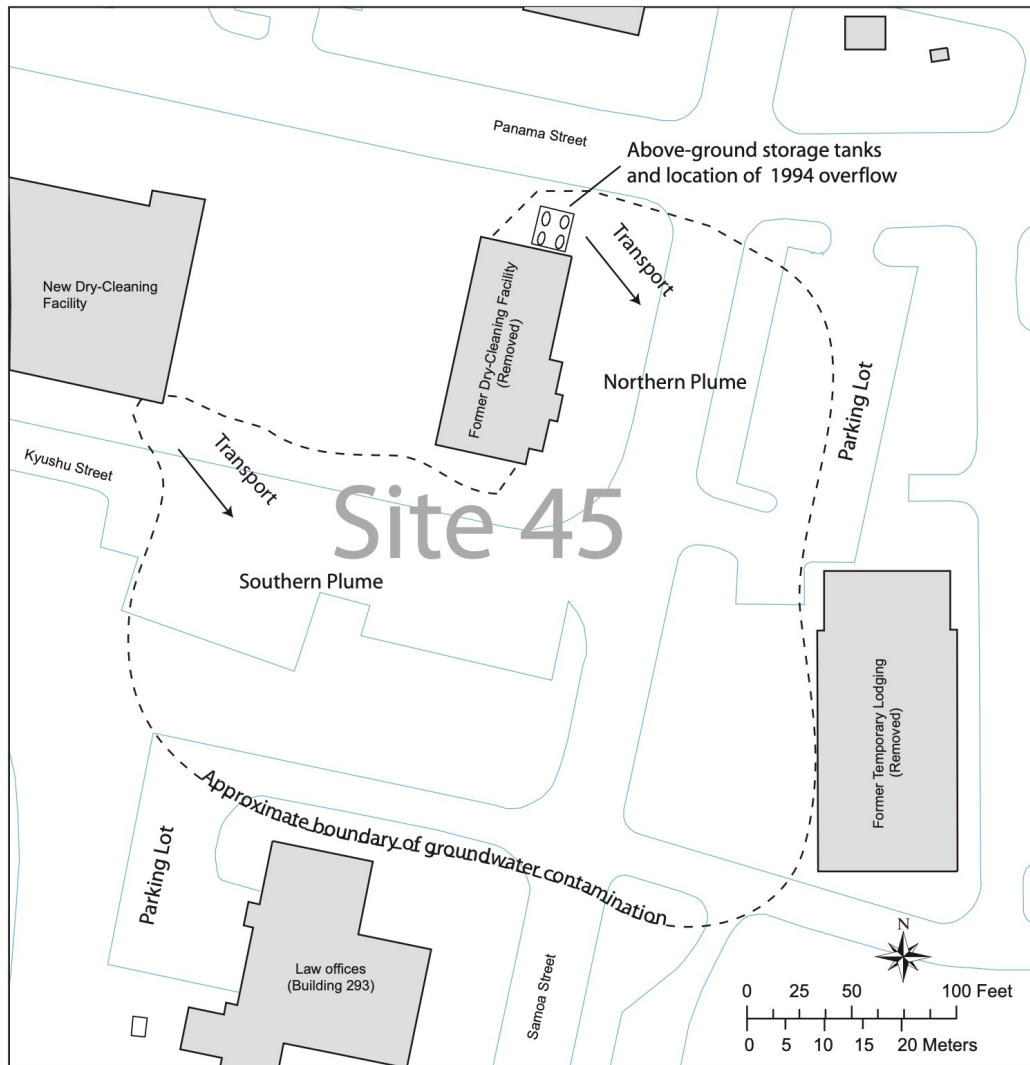


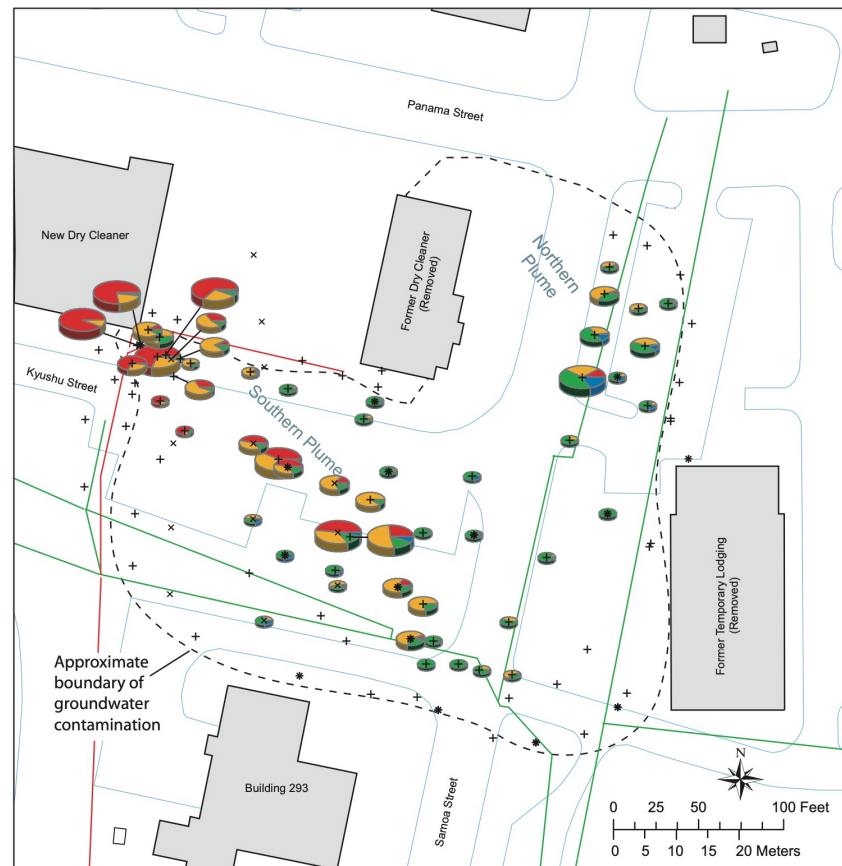
Source, Transport, and Fate of Groundwater Contamination at Site 45, Marine Corps Recruit Depot, Parris Island, South Carolina











- * Monitoring well sampled July 2007 to June 2008
- + USGS temporary well sampled June 2007 to March 2008
- x Tetra Tech NUS, Inc., temporary well sampled 2006 (Mark Sladic, Tetra Tech NUS, Inc., written commun., 2007)
- Storm sewer
- Sanitary sewer

EXPLANATION

TCE PCE
cDCE VC

Concentration of total PCE + TCE + cDCE + VC.

- Greater than 100 micromoles per liter
- 31-100 micromoles per liter
- 0.5-30 micromoles per liter
- Symbols without pie diagram: Less than 0.5 micromole per liter

Health-drinking water contaminated by VC

- Cancer Risk= Intake * S.F.
- $10^{-6} = f(C_e) * S.F$
- Vinyl Chloride, 35 year exposure
 - $C_e = 1.8 * 10^{-5} \text{ mg/L}$
- I could not care about my supervisor; Only me: 5 year exposure
 - $C_e = 1.3 * 10^{-4} \text{ mg/L}$

Legal Aspects of Risk

- How would you go about legislation?
 - ▣ E.g.: A new drug with possible side effects is up for your approval

- In some cases, the computed risk is so small that it does not justify regulation
 - ▣ Designed to protect down to a level of one in a million
- Essentially zero, virtually a “safe dose”

Legal Aspects of Risk

- Risk assessment

- ▣ To determine what level of an agent will produce an effect in one individual out of one million exposed individuals

One in a Million Risks

- Risks estimated to increase chance of death in any year by 0.000001 (one in a million)

Activity	Type of Risk
Smoking 1.4 cigarettes	Cancer, heart disease
Spending 1 hour in a coal mine	Black lung disease
Living 2 days in New York City	Air pollution
Traveling 300 miles by car	Accident
Traveling 10 miles by bicycle	Accident
One chest X-ray	Cancer (radiation)
Eating 1 tbsp. of peanut butter	Cancer (aflatoxin)
Drinking 30 12-oz. cans of soda	Cancer (saccharine)
Living 20 years within 20 miles of a nuclear power plant	Cancer (radiation)

Source: Data from Wilson, R. (1979). TechnolRev, 81, 41–46.

The Receding Zero

- If you came to know that trichloroethylene is in your drinking water, would
- The mere presence of a chemical is insufficient to warrant alarm
- Better analytical techniques:
 - ▣ Lower MDLs
- Purity: Past and Present?

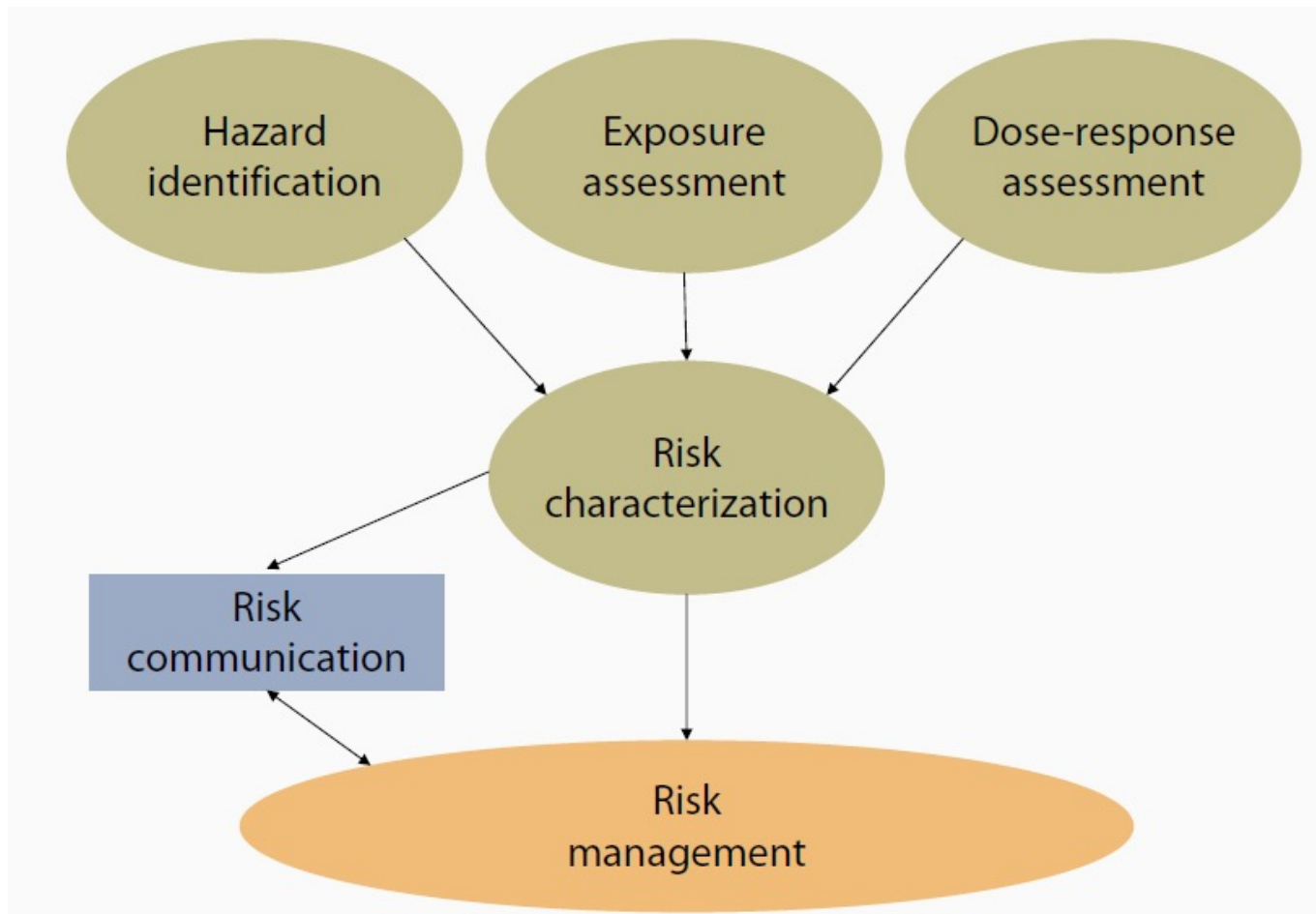
Cost per Life Saved

Activity/process	Dollar amount
Child restraints in cars	1.3 million
Dual master brake cylinders	7.8 million
Asbestos banned in brake linings	230,000
Asbestos banned in automatic transmissions	1.2 billion
Radiation safety standards for X-ray equipment	400,000
Radiation standards for uranium mine tailings	190 million

Risk Analysis Activities: Risk Assessment

- Risk assessment
 - ▣ The systematic characterization of potential adverse health effects resulting from human exposure to hazardous agents

Four Steps of Risk Assessment



Dose-Response/Toxicity Assessment



- How is the identified adverse effect influenced by the level of exposure or dose?

Sources of Toxicity Data

□ Human studies

- ▣ Case reports
- ▣ Cluster analyses
- ▣ Epidemiologic studies

□ Animal studies

- ▣ Specialized toxicity studies
- ▣ Generalized toxicity studies
- ▣ In vitro studies

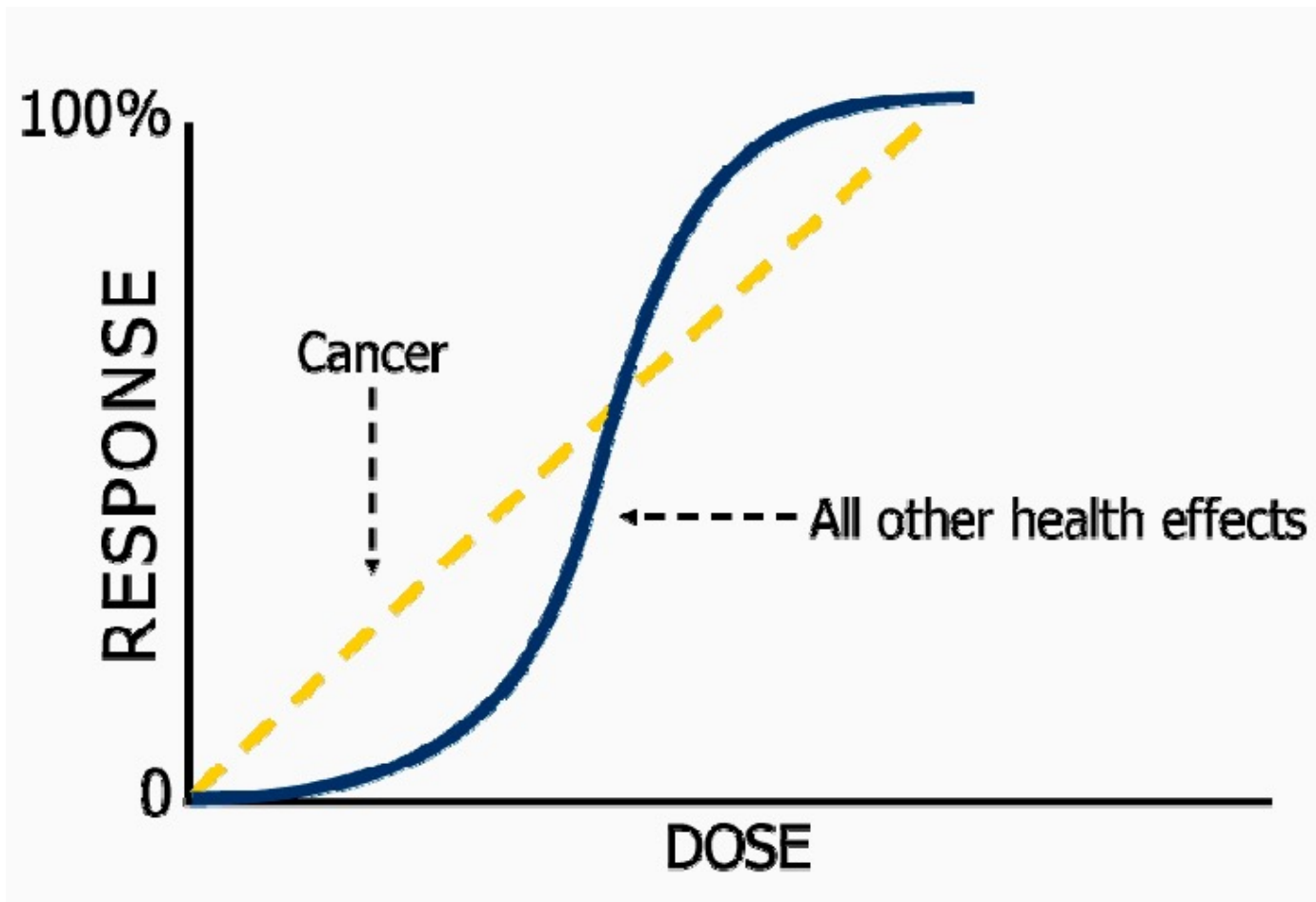
Why Animal Studies?

- Good correlation with human disease
 - ▣ Human carcinogens cause cancer in animals
- Acute toxic doses are similar in humans and a variety of animals
- Anatomical, physiological, and biochemical patterns are similar among mammals
- Accepted by the scientific community

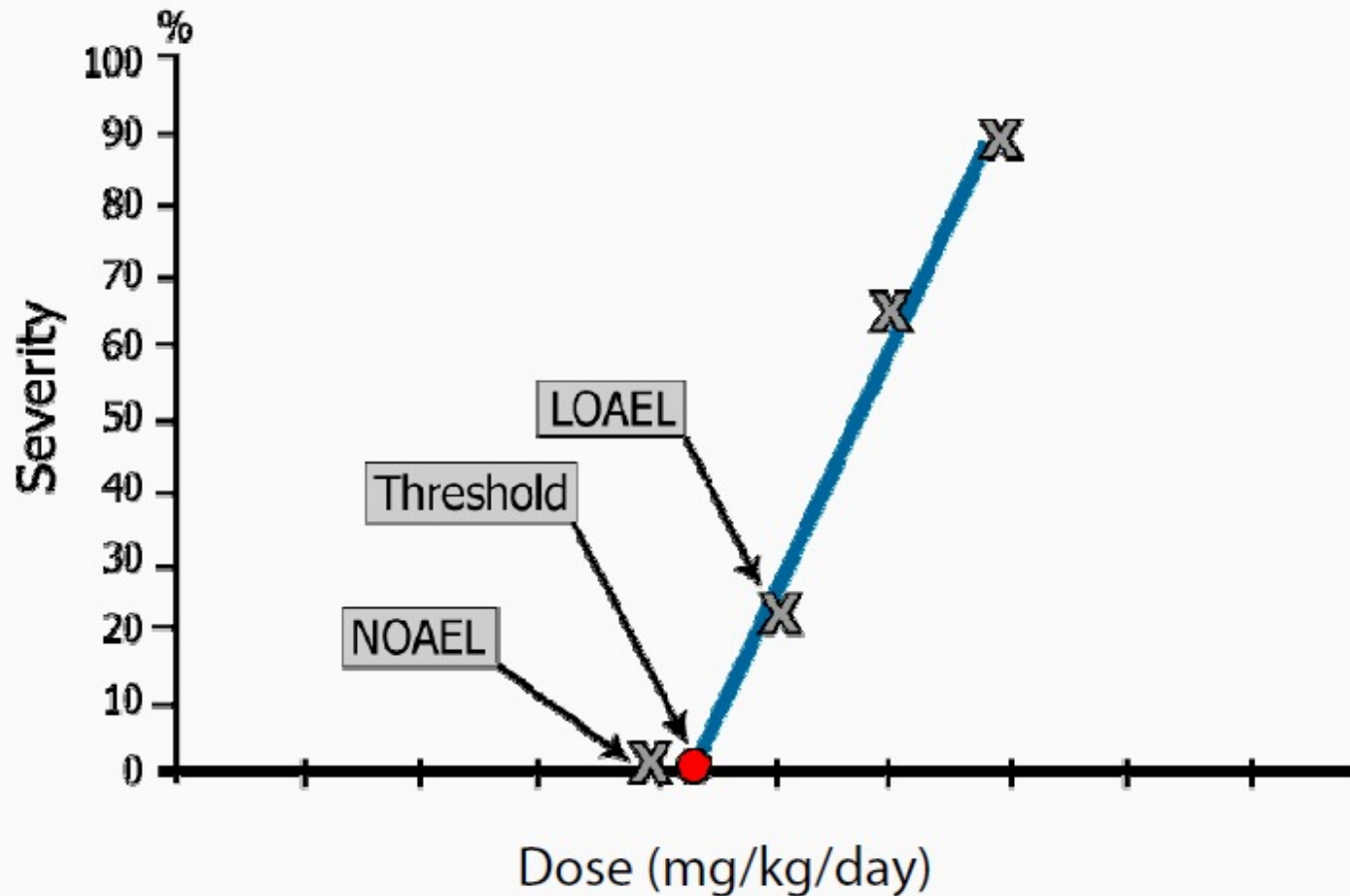
Potential Endpoints

- Respiratory
- Blood and lymph
- Liver
- Kidney
- Nervous system
- Skin
- Reproductive toxicity
- Teratogenicity (embryo development)

Dose-Response Curve

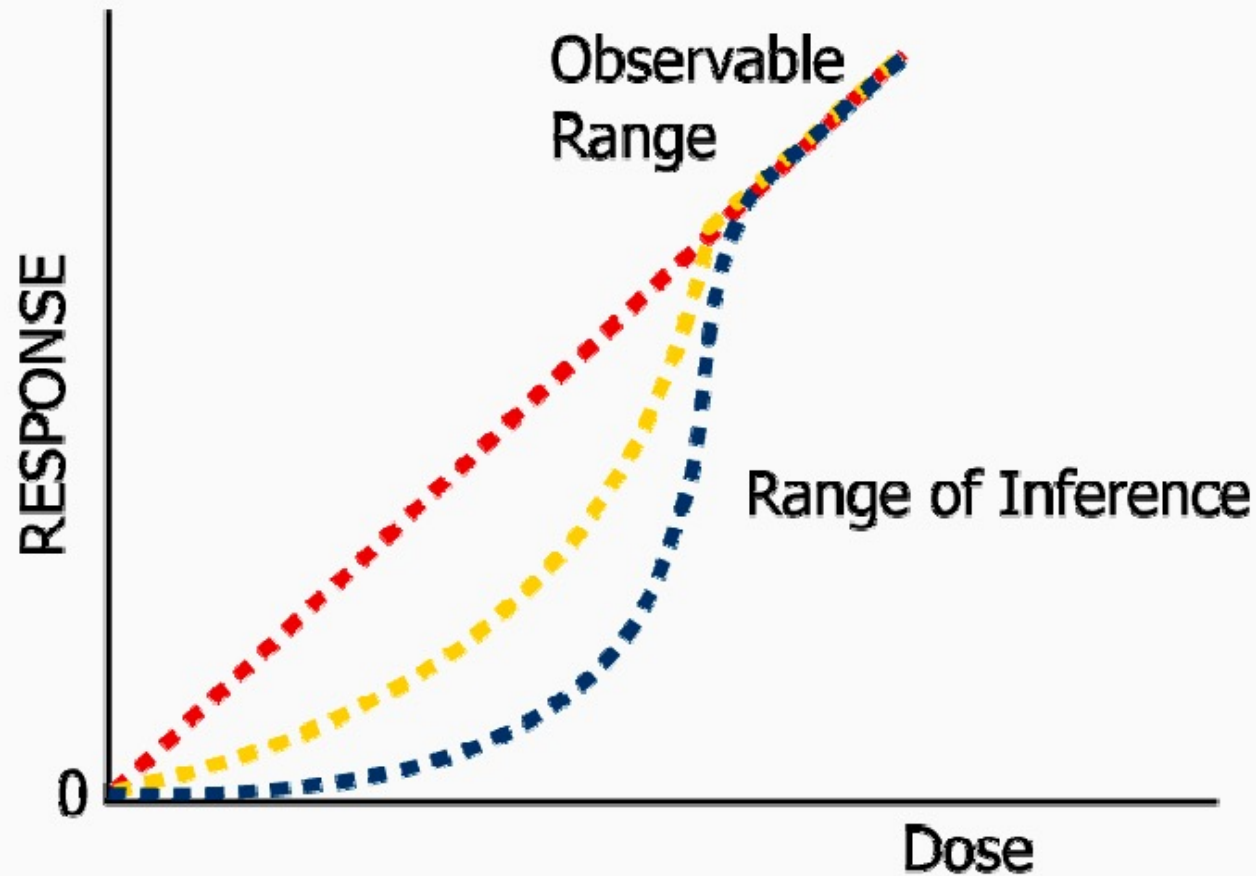


Dose-Response Relationship: Non-Carcinogen

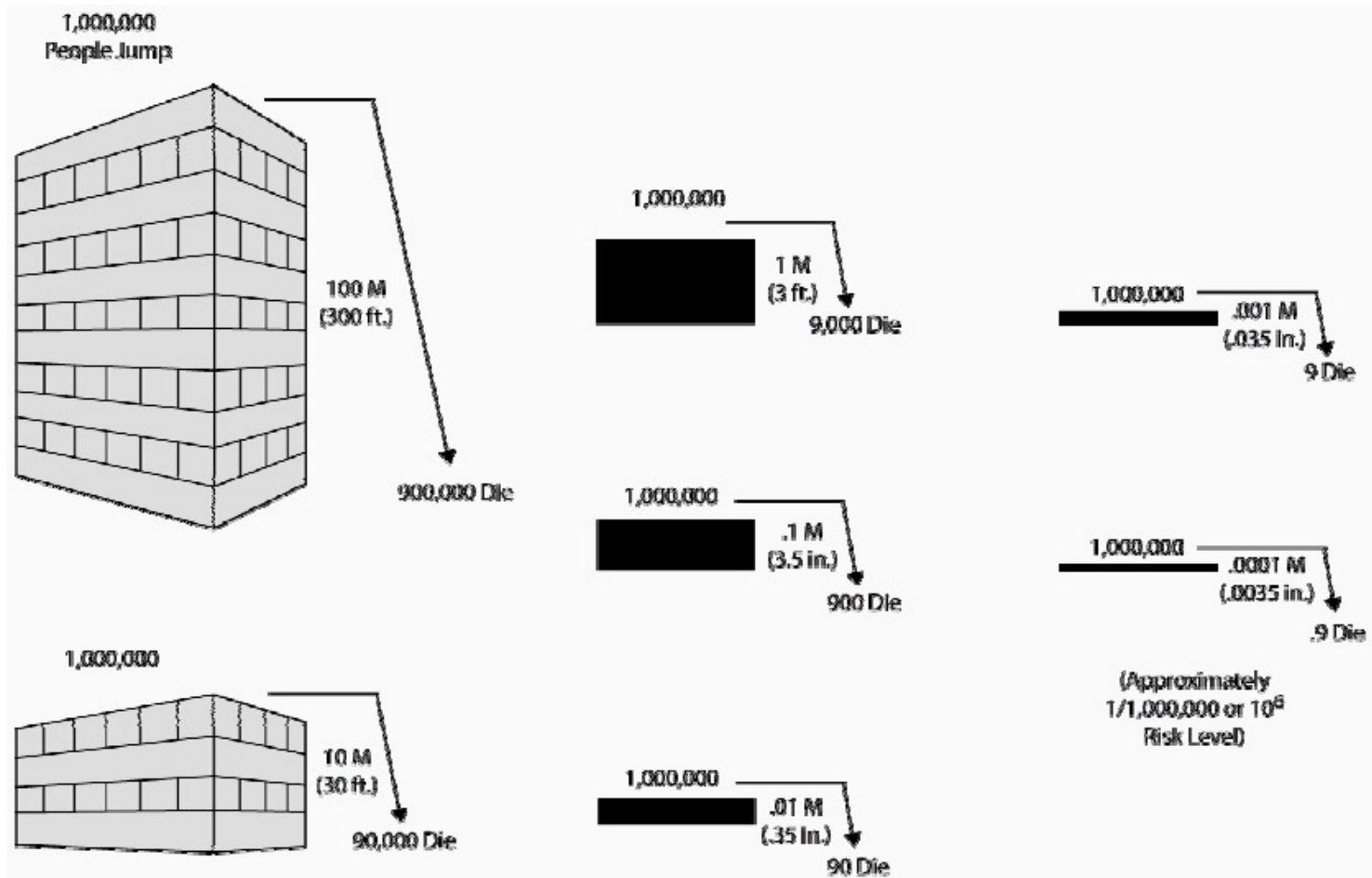


Source: Adapted from Cockersham, L. G. and Shane, B. S.

Dose-Response Relationship: Carcinogen



Linear Extrapolation in Quantitative Risk Assessment



Carcinogens: Weight of evidence classification

<u>US EPA Group</u>	<u>Reference Category</u>
A	Human carcinogen (i.e., known human carcinogen)
B	Probable human carcinogen: B1 indicates limited human evidence B2 indicates sufficient evidence in animals and inadequate or no evidence in humans
C	Possible human carcinogen
D	Not classifiable as to human carcinogenicity
E	No Evidence of carcinogenicity in humans (or, Evidence of non-carcinogenicity for humans)

Uncertainty Factors

$$\frac{\text{(Toxicity Study)} \\ \text{LOAEL or NOAEL}}{\text{Uncertainty Factor}} = \text{"Safe Level"}$$

- LOAEL = Lowest observable adverse effects level; the lowest dose tested that produced an effect
- NOAEL = No observable adverse effects level; the highest dose tested that did not produce an effect

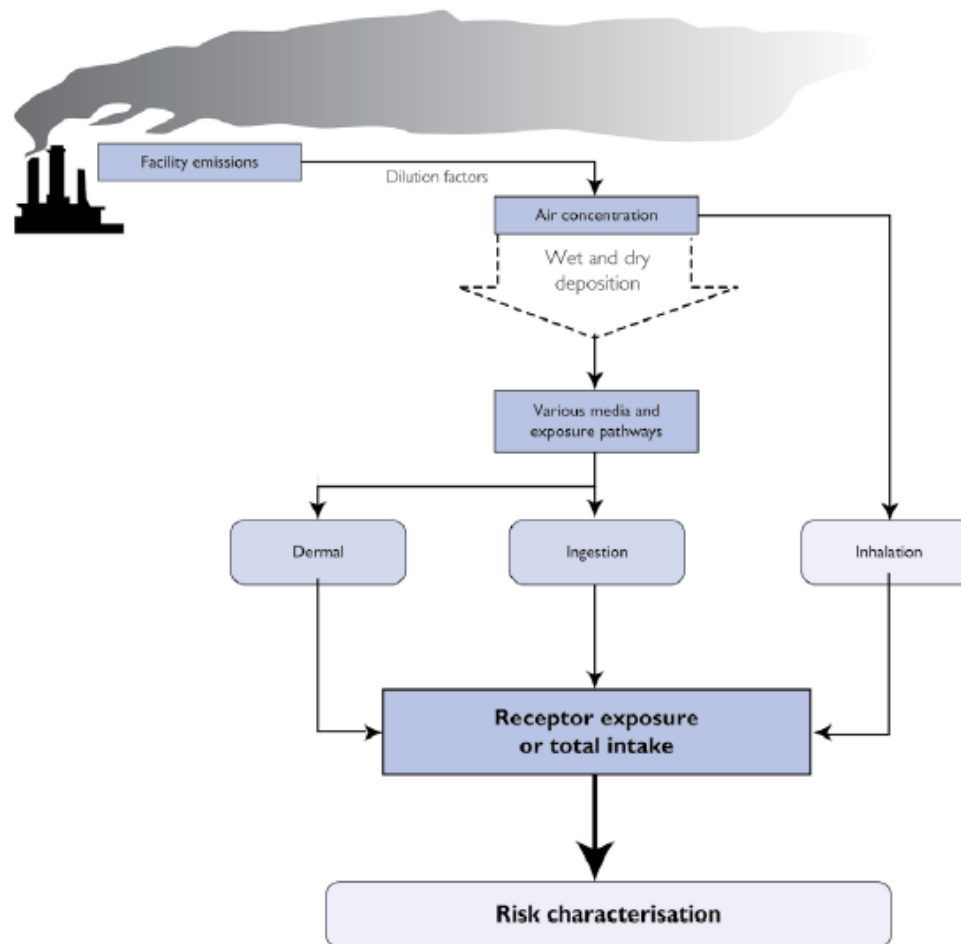
Uncertainty (Safety) Factors

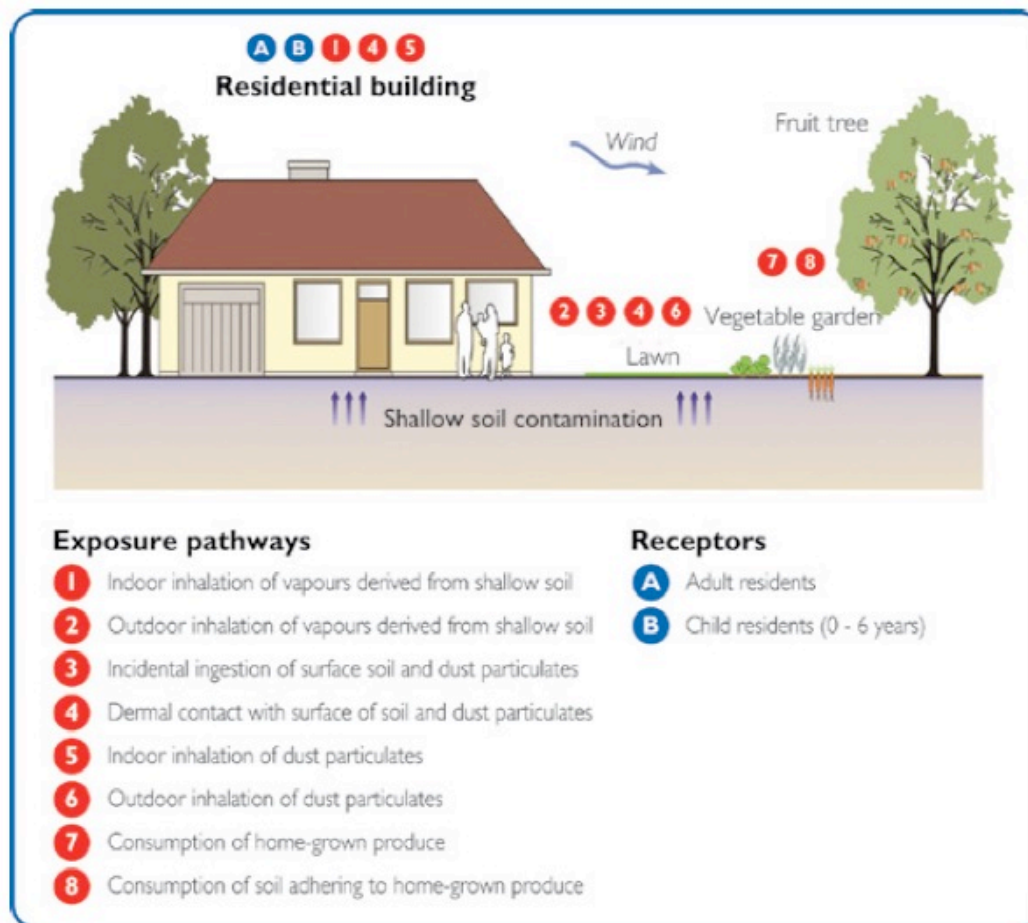
- Uncertainty (safety) factors for risk assessment of non-cancer effects
 - ▣ 10 for human variability
 - ▣ 10 for extrapolation from animals to humans
 - ▣ 10 for use of less than chronic data
 - ▣ 10 for using LOAEL instead of NOAEL

Exposure Assessment



What exposures are experienced or anticipated under different conditions?





Exposure Assessment

- Characterization of the exposure setting
- Identification of the exposure pathway
- Quantification of exposure

Exposure = intensity x frequency x duration

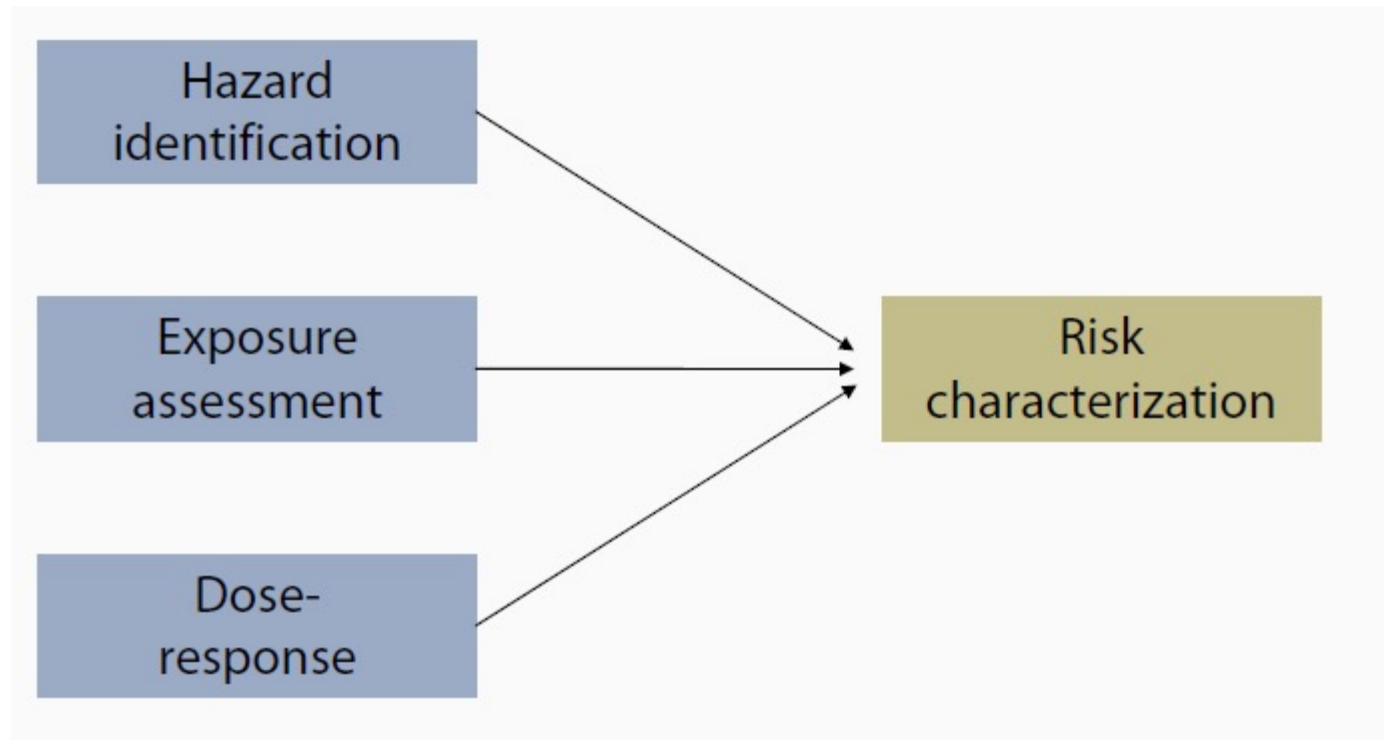
Exposure = how much x how often x how long

Exposure Assessment

□ **Generic $I = C_e * R_i * E_f * E_d / (B_w * A_t)$**

- I = intake (mg/kg-d)
- C_e = exposure concentration (e.g. mg/L)
- R_i = intake rate (e.g. L/d)
- E_f = exposure frequency (e.g. d/yr)
- E_d = exposure duration (e.g. yr)
- B_w = body mass (e.g. kg)
- A_t = averaging time (e.g. day)

4. Risk Characterization



What is the estimated likelihood of the adverse effect occurring in a given population?

Risk

- Carcinogenic Risk = Intake * Slope factor
 - ▣ Risk greater than 10^{-6} for residential settings is unacceptable
- Non Carcinogenic Risk = Intake / Rfd
 - ▣ $HI = \sum HQ$
 - ▣ $HI > 1$ is unacceptable.



HAZARDOUS WASTE MANAGEMENT

- The collection trip by the TSDF is scheduled on quarterly basis.



Collection by TSDF



Safety Office

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- vishwanandan.so@iitr.ac.in
- <https://www.iitr.ac.in/safety/>
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