Integrated Waste Management Board Risk Assessment Training for Landfill Sites

Office of Environmental Health Hazard Assessment (OEHHA) January 19, 2006

Karlyn Black Kaley, PhD, DABT
Ned Butler, PhD, DABT
Jim Carlisle, DVM, MSc

OEHHA

Chemicals are Everywhere…

- **We Are <u>Very Used</u> to Having Chemicals in Our Environment**
- At Home, Yards & Garages
- Medicines, Health & Nutritional Supplements
- Foods & Food Preservatives
- Personal Products, Cosmetics
- We Are **Largely OK** w/This: **Our Choice**
- **But…What if We Aren't Given a Choice?**

Occupational Examples

- Occupational Exposures, First Hints
- Metal Workers & Goldsmithing
  - Hg & Pb Poisoning (Ellenbog, cira 1480)
- Miner's Sickness (Paracelsus, 1567)
- Chimney Sweeps
  - Scrotal Cancer, PAH's (Pott, 1775)
- Chemical Warfare
  - World War I
  - Phosgene & Mustard Gas (1825)

Environmental & Medical Examples

- "Prohibition" & Bootlegging, 1920's
  - TOCP, Lead, & Methanol Contaminants
  - Affected CNS ("Ginger Jake Walk"), Blindness
- Dichlorodiphenyltrichloroethane (DDT)
  - Environmental Ecosystem Impacts
- Diethylstilbestrol (DES), 1940's-70's
  - "Repro" Cancer in 1966-69
- Thalidomide, Amelia & Phocomelia 1960
- Love Canal, Hazardous Waste, 1970

Chemicals are Everywhere…

- Contaminated Site?…**No Longer Our Choice.**
- When people don't have a choice about whether they might be exposed to a chemical they can become concerned, upset, even angry.
- Risk Assessment is Useful in Educating, Informing & Protecting the Public from Exposure to Harmful Chemicals

Training Objectives

- Introduce IWMB Staff to the Basics of Site Risk Assessment for Landfill Applications
- Define What RA Is
- Determine When a RA Should Be Used & When One May Not Be Needed
- ID Types of Data Collected, When & How
- Outline Internal Cal/EPA IWMB & OEHHA RA Development & Review Process
- Introduce OEHHA Staff & What We Can Help With

How Are We Going to Do This?

- As a Team…
- Us?

How Are We Going to Do This?

- As a Team…

- You?

- Ask For & Expect
- Energy
- Enthusiasm
- Ask Questions…

Basic Toxicology Concepts

Chemicals, Health Impacts & Exposure Routes

Karlyn Black Kaley, PhD, DABT

January 17, 2006

OEHHA

Toxic Substance

- Toxic Substances are those that:
  - can produce ***irreversible*** or ***reversible*** bodily injury;
  - **Reversible** = irritation, swelling, mental confusion, liver effects
  - **Irreversible** = scarring, cancer, death

What is Toxic & What Isn't?

- Paracelsus summed it up perfectly.

"All substances are poisons; there are none which is not a poison."

"The right dose differentiates a poison from a remedy."

***Paracelsus* (1493-1541)**

Definitions…

- **Dose**: The amount of substance that enters the organism
- **Response**: The effect on the organism It can be good…medical therapy…or bad…toxic effects.
- **Exposure**: How Much for How Long?
- Some compounds are obviously more toxic than others, but all substances can be toxic, or non-toxic. It depends on the **dose**, your body's **response** and your **exposure**.

Toxic Nomenclature

non-toxic:	>5,000 mg/kg	1 qt
slightly toxic:	500-5,000 mg/kg	1 pt
mod toxic:	50-500 mg/kg	1 oz
highly toxic:	1-50 mg/kg	1 tsp
extreme toxic:	< 1 mg/kg	taste

Some Examples

Chemical	LD_{50} (µg/kg)
Botulinum Toxin-a	0.00001
Cobra Toxin	20
Strychnine	500
Cyanide	10,000
Alcohol (ethanol)	5,000,000

Health Effects

- May develop from Acute or Chronic exposures to chemicals
- **Cancer**: Uncontrolled malignant cells
- **Mutations**: Damage to genetic materials which control cell division = Cancer ??
- **Teratogens**: Damage to unborn child
  - Most damage occurs in first trimester
- **Reproductive Damage**: ↓ Fertility

Health Effects—Cont'd

- May develop from Acute or Chronic exposures to chemicals
- **Cell** or **Tissue Damage**
- **Organ Damage**
- **System Damage**
- **Permanent Dysfunction**
- **Scarring and/or Disfigurement**
- **Organism Death**

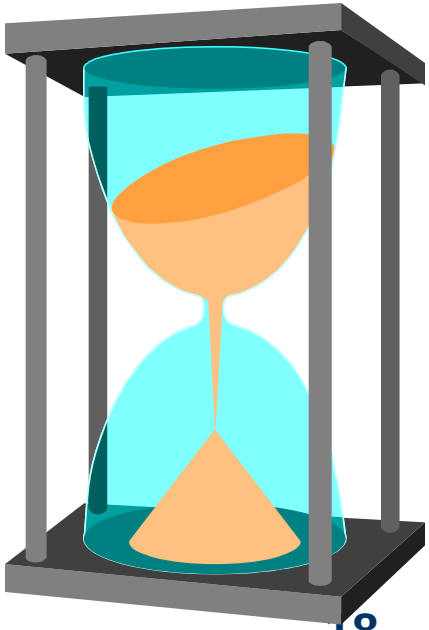
Target Organ Concept

Tendency to Affect One Organ First or More Severely

- **Liver:** solvents, drugs, alcohol
- **Kidney:** metals such as lead, chromium
- **CNS/PNS:** solvents, drugs, pesticides
- **Lungs:** irritant gases, particles
- **Skin:** alkalis (bases), acids
- **Blood:** benzene, carbon monoxide

Exposure: Time & Toxicity

- Time is an important factor when were dealing with toxic substances
- Acute toxicity
  - short-term, high-level exposure
- Chronic toxicity
  - long-term, low level exposure



Acute Toxicity

- Usually one-time, often high exposure
  - spills or uncontrolled releases
  - can happen at home too
- Some acute effects are immediate
  - H_2S, Ammonia, Hydrogen Chloride, Methane
- Some effects may be delayed to 72 hrs
  - Phosphine & Phosgene
  - Paraquat (pesticide & lung damage)

Acute Toxicity Examples

Short Term….

- Sun Burn
- Pesticide Exposures
- Allergic Reaction: Drugs, Insects, Animals
- Chemical Burns
-
-
-

Photo Example

Photo Examples

Chronic Toxicity

- Repeated exposure at often low levels
- May result in accumulation in tissues (Lead, PCBs, Hg - Mercury)
- Repeated damage over time
- Can be more of a problem because
  - Effects may be less obvious
  - Effects may be delayed for years
  - Example: Pb & Children

Chronic Toxicity

- Long-Term…
- **Alcohol**: Liver Disease
- **Smoking**: Tobacco or Other
- **Heavy Metals**:
  - Mercury (CNS & PNS Damage)
  - Lead (Reproduction & Mental Problems)
- **Organic Solvents**: CNS, Cancer, Liver, Kidney, Reproductive Effects

Photo Example

Toxicity: Exposure & You

Concentration	Duration

Exposure Concepts

A Poison or Toxic Substance

Does Not Constitute a Hazard or Risk

Unless Contact is Made with the Organism in a

Quantity & Form

That Can Cause Harm.

Risk / Hazard Triangle

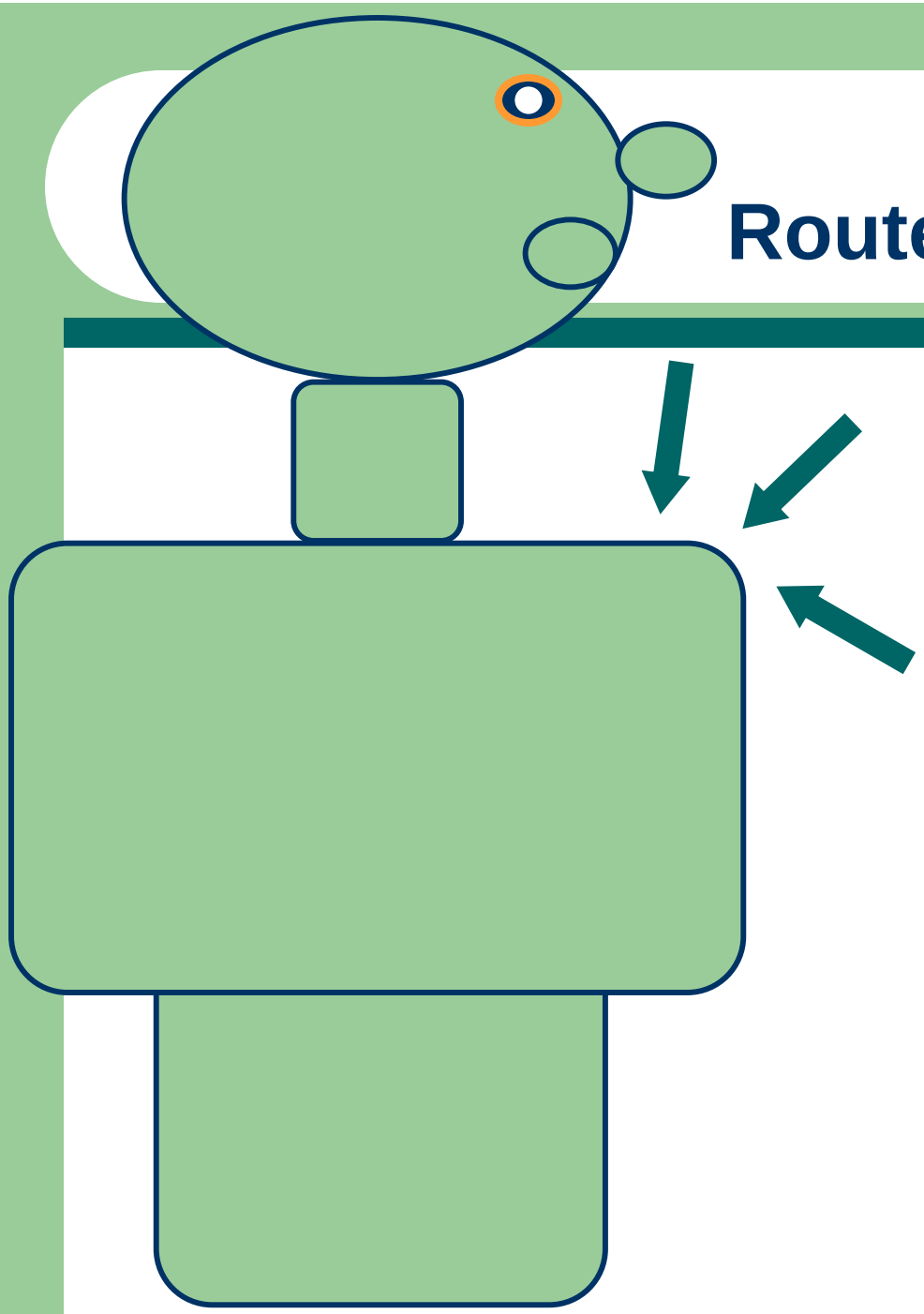
Exposure Concepts

- Entire Environmental & Occupational Regulatory Structure is Defined:
  - 1st by Toxicity Potential;
  - and then, by Exposure Route;
  - and then, by Exposure Occurrence.
- Environmental Exposures More Subtle & Lower Concentration than Occupational/Industrial Exposures
- Different Types of Standards in Place

How Do Chemicals Enter Our Bodies?

- Absorption
- Diffusion
- Facilitated Diffusion
- Active Transport
- Endocytosis

Routes of Exposure

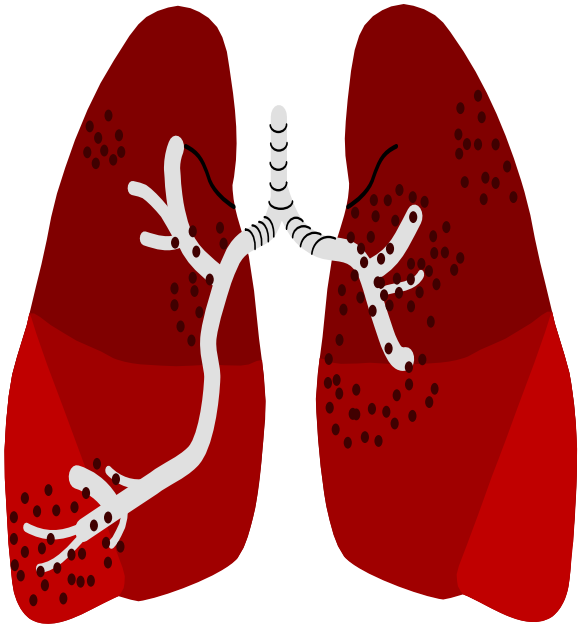


- Skin Contact (Dermal)
- Inhalation
- Ingestion

Photo Example

Routes of Exp: Inhalation

- Direct Contact with Blood Stream
- Tissue is One Cell Thick
- Can Be Easily Damaged
- **IMPORTANT ROUTE TO PROTECT!!!!!**



Exposure & Children

- Children Often At Greater Risk for Exposure
- Don’t Understand or Recognize Risk Settings
- Lots of Hand to Mouth Contact
- Smaller Bodies
- Busy, Active, Higher Respiratory Rates
- Bodies & Systems Still Developing

Facts of Life

- Physical, Chemical, & Toxicological Properties of Substances Determine What **Hazard** or **Risk** They Pose;
- When & Where **We Find Chemicals** & in What Environmental Media;
- How & When We May be **Exposed**;
- And, What Steps We Should Take to Protect **Ourselves** from Exposure

Physical Properties: Phase

- Physical Phase Most Important
  - **Solid, Liquid or Gas**
- Chemicals Can Dissolve in Water
- Can be Transported by Water
- Chemicals Can Shift from One Phase to Another
  - **Vaporize or Evaporate**
  - **Like from a Liquid to a Gas**
  - **Become Airborne, Aerosolized (solid or liquid)**

Phase Determines Chemical Location in Environment

- **Gases**: Found in the Air
  - Present a Risk for Inhalation Exposure
  - Transport Other Gases
- **Solids**: In Soil, On Surfaces as Particles, Or in Air as Dust or Aerosols
  - Contact Exposure to Skin or Eyes, Ingestion via Contaminated Hands (Children), Inhalation if in Particle Form
- **Liquids**: In Soil "Air" Spaces, In Drinking Water
  - Contact Exposure to Skin & Eyes, Ingestion, Contaminated Hands & Clothing
  - Can Transport other Liquids
- May Need **Samples** from **Air**, **Soil** & **Water**

Office of Environmental Health Hazard Assessment: Cal/EPA

Toxicity & Exposure Assessments in Regulatory Risk Assessment

Ned Butler, PhD, DABT

January 17, 2006

OEHHA

First Hour Talk Objective

- Background for landfill risk assessments
  - Toxicity assessment
  - Exposure assessment
- Show how risk assessment evolved through regulatory history

Risk Assessment

- Toxicity Assessment –risk of adverse health effect at a given dose of a chemical
- Exposure Assessment –likely dose of chemical given a regulated source of the chemical

Acute Poisonings and FDA

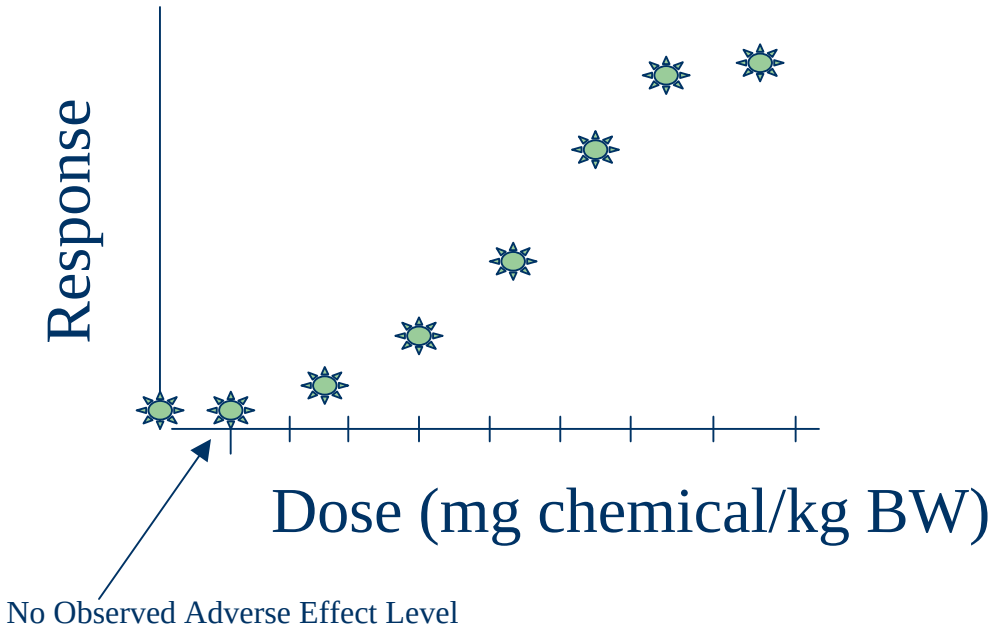
- **Elixir of Sulfanilamide**, contains diethylene glycol that kills 107 persons in 1937
- Congress passes law expanding FDA jurisdiction in 1938

FDA Defined Toxicity Assessment

- No Exposure Assessment Needed
  - Dose = amount in pill
- FDA decades ahead of other regulatory agencies
- FDA set the standards for much of toxicity testing

Dose Response Curves

Dose Response Curve

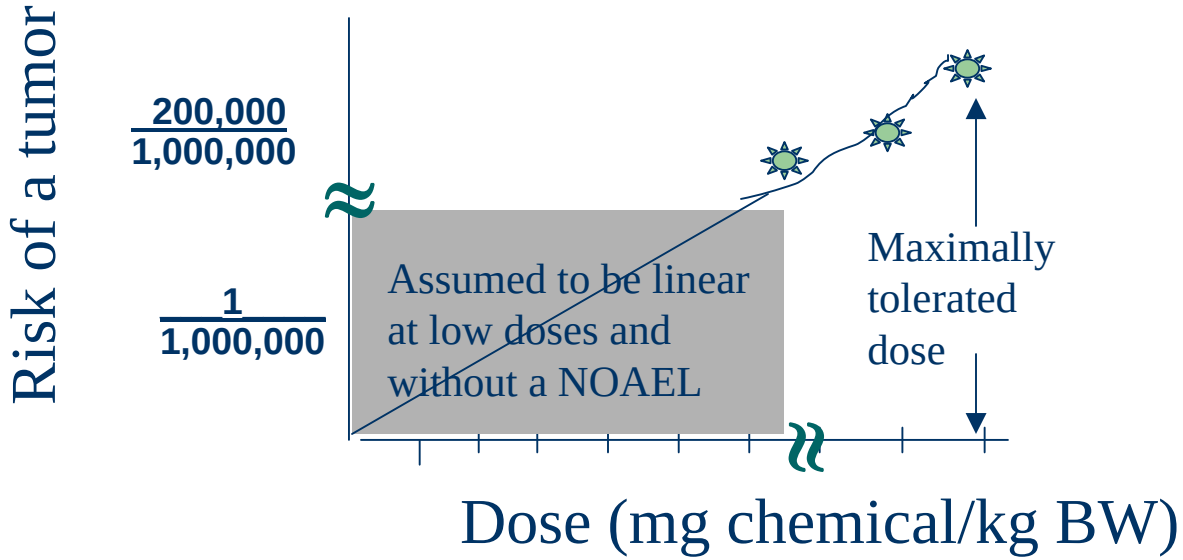


Cancer Risk Assessment

- Two year studies in rats and mice
- Usually 50 animals in each of 2 or 3 high dose groups
- Examine animals for tumors

Toxicity Assessment for Cancer

Cancer Bioassay Data



Establish a Health-Based Maximum Daily Dose

- Cancer-Causing Chemicals
  - Set acceptable risk level (1 in a million)
  - Determine based on slope compute maximum daily dose
- Non-Cancer Endpoint
  - Estimate a NOAEL in animal studies
  - Divide by a safety factor to compute maximum daily dose

Safe Drinking Water

- Protect Public from Drinking Water Contamination
- Set Maximum Concentration Levels (MCLs)
  - Use FDA style Toxicity Assessment to set a health-based maximum daily dose

Safe Drinking Water

- Drinking Water Exposure Assessment

$$\text{MCL} = \frac{\text{Health-based Max Daily Dose}^{1}\ \text{(mg/d)}}{\text{Water Consumption}^{2}\ \text{(liters/d)}}$$

[1] Max Daily Dose is chemical specific

[2] Water Consumption is 2 liter per day

Safe Drinking Water

- SDWA enforcement
- Purveyors of drinking water are required to chemically analyze drinking water. If concentrations exceed MCL, regulatory action follows

Occupational Safety and Health Administration

- Protect Workers from Unhealthy Workplace Air
- Set Permissible Exposure Levels (PELs)
  - Use FDA style Toxicity Assessment to set a health-based maximum daily dose

Occupational Safety and Health Administration

- Workplace Air Exposure Assessment

$$\text{PEL (mg/m}^3\text{)} = \frac{\text{Health-based Max Daily Dose}^1\text{ (mg/d)}}{\text{Inhalation Rate (m}^3\text{/d)}}$$

[1] Max Daily Dose is chemical specific

Occupational Safety and Health Administration

- OSHA enforcement
- Workplace air concentrations are measured and if they exceed the PEL regulatory action is taken

Superfund Cleanup

- When do chemicals at a site pose a health risk?
  - Based on previous regulatory standards
  - Must address multiple chemicals at the same time
  - Source is chemicals in soil so multiple pathways

Landfill Risk Assessment

- Builds on Superfund Cleanup Risk Assessment
- Adds a new pathway – methane carrying volatile chemicals

Office of Environmental Health Hazard Assessment: Cal/EPA

Introduction to Risk Assessment

Jim Carlisle, DVM, MSc

January 19, 2006

OEHHA

What is Risk Assessment?

- **Chemical risk assessment** is an evaluation of the likelihood that a potentially toxic chemical will cause an adverse effect in a given exposure situation or scenario.
- The likelihood of an adverse effect depends on the **kinds of contaminants**, the **concentration** of those contaminants in exposure media, the **populations** that will contact those media, and **how much** and for **how long**.

Two kinds of Risk Assessment

- **<u>Human</u>** and **<u>Ecological</u>**
- We will spend most of the day talking about human health risk assessment.
- The major components of ecological risk assessment are similar, but there is one major additional step: deciding what species will be assessed, serving as surrogates for all ecological communities at the site.

Why Do I Need Risk Assessment?

- While imperfect, it is the best way we have to decide whether contamination is a human health (or ecological) threat
- It is a decision-support tool, but it does not give "the answer".
- It gives **information** to **support a decision**, but there is often other information to consider.
  - E.g. other laws and regulations, community acceptance, economics, feasibility

When Do I Need Risk Assessment?

- Generally when contamination has been documented and a decision needs to be made as to what to do about it
- It is the oversight agency's call as to when risk assessment is required

Major Risk Assessment Components

- Data collection and evaluation
  - Physical characteristics of the site
  - Contamination at the site
  - Past, present, and future site use
- Toxicity and dose-response assessment
- Exposure assessment
- Risk characterization: human health impacts assessment

Major Risk Assessment Components

Data collection & evaluation

- Site history
- Chemicals present or suspected to be present in site soil, water, or air.
- Concentrations of chemicals in site media
  - Usually by sampling and analysis.
  - May model movement between media
- This aspect may be overseen by site managers and/or OEHHA

Major Risk Assessment Components

Toxicity & Dose-response Assessment

- Determining the toxic effects of chemicals and at what dosages those effects may occur.
  - This is done by OEHHA and U.S. EPA
  - Not site specific – there are published lists

Major Risk Assessment Components

Exposure assessment

- Scenario-specific estimates of exposure to toxic chemicals
  - Who is exposed?
  - How often?
  - For how long?
  - By what pathways?
  - To what concentration?

Major Risk Assessment Components

Exposure assessment

- There are several possible exposure scenarios
- Residential is the most common, the most standardized, and usually the most conservative
- Other scenarios: occupational, recreational, school.
- There is an equation for each pathway for each scenario.

Major Risk Assessment Components

Risk Characterization

- Comparing Estimated Exposure to Toxicity Thresholds
- Forward and Backward calculation

Forward Calculation

- Comparing an exposure estimate with a toxicity threshold and expressing the result as a risk of contracting cancer or as a hazard index.
- Toxicity + Exposure = Risk or hazard

Forward Calculation

- Cancer
  - The toxicity portion is called “potency”
  - Multiply estimated exposure by cancer potency to estimate risk
  - Potency * exposure = risk
  - Risk is expressed as a probability
  - Typically upper bound potency and risk

Forward Calculation

- Non-cancer Toxicity
  - The toxicity portion is expressed as the "reference dose (RfD)" or "reference concentration (RfC)"
  - Exposure / RfD = Hazard Quotient
  - Not a probability
  - Hazard Index is the combined hazard quotients from multiple pathways and multiple chemicals

Backward Calculation

- Re-arrange the risk equation and solve for the concentration
- Potency * Exposure = Risk
- Risk / Potency = exposure

Levels or Tiers of Risk Assessment

- Screening or level 1
  - Usually 2 scenarios, Industrial and residential.
  - All exposure factors are standardized for each of the 2 scenarios.
  - Preliminary Endangerment Assessment (DTSC)
    - Does not include vapor intrusion
  - Only appropriate for screening or when all aspects of the on-site exposure scenario match the assumed exposure scenario.
  - Obviously, using a standard exposure equation with standardized input parameters gives a generic or fixed result.
  - Thus we can use backwards calculation to generate lists of screening values corresponding to the assumed exposure scenarios.

Levels or Tiers of Risk Assessment

- Level 2 Site-specific
  - Same route-specific exposure equations
  - Site specificity may be manifested as:
    - Different or additional exposure scenarios, and/or
    - Different exposure parameters for the exposure pathways.
  - Usually done as a forward calculation.
  - Occasionally, people will use site-specific information to modify an existing screening level or to create their own screening concentrations.
  - Must consider additivity

Levels or Tiers of Risk Assessment

- Level 3 Site-specific
  - More detailed and more site specific:
  - Unusual exposure scenarios, and/or
  - Different exposure parameters for the exposure pathways.
  - Extensive site-specific fate and transport

When Does OEHHA Get Involved?

- Work plan
- Site characterization
- Risk assessment

Office of Environmental Health Hazard Assessment: Cal/EPA

Risk Assessment Methodology

Jim Carlisle, DVM, MSc

January 19, 2006

OEHHA

Data collection & evaluation

- Site history
- Chemicals present or suspected to be present in site soil, water, or air.
- Concentrations of chemicals in site media
  - Usually by sampling and analysis.
  - May model movement from one medium to another.
- May be overseen by site managers and/or OEHHA

Media Sampling

- Appropriate media
- Soil matrix,
  - Surface
  - Down to 10 feet
- Air
  - Measured or modeled
- Soil vapor
- Ground water

Media Sampling

- Random
- Targeted or deterministic

Sampling and Analysis

- Analytical methods appropriate for suspected contaminants
  - Adequate sensitivity
- Spatial and Temporal aspects
  - Future concentrations may require modeling
- Conceptual Site Model

Data Validation

- Qualifiers
- Methodology
- Quantitation limits

Chemicals of Potential Concern

- Preferred approach:
  All contaminants identified at the site
  - Chemicals that are not naturally occurring
  - I.e. above background
  - Follow DTSC guidance on background

  www.dtsc.ca.gov/AssessingRisk/upload/backgrnd.pdf

Chemicals of Potential Concern

- Omission of minor contributors (<1% of hazard & risk) m<u>ay</u> be approved
  - But, elimination of contaminants as COPCs is contentious and one of the major causes of delay and/or do-overs.
  - Therefore not recommended

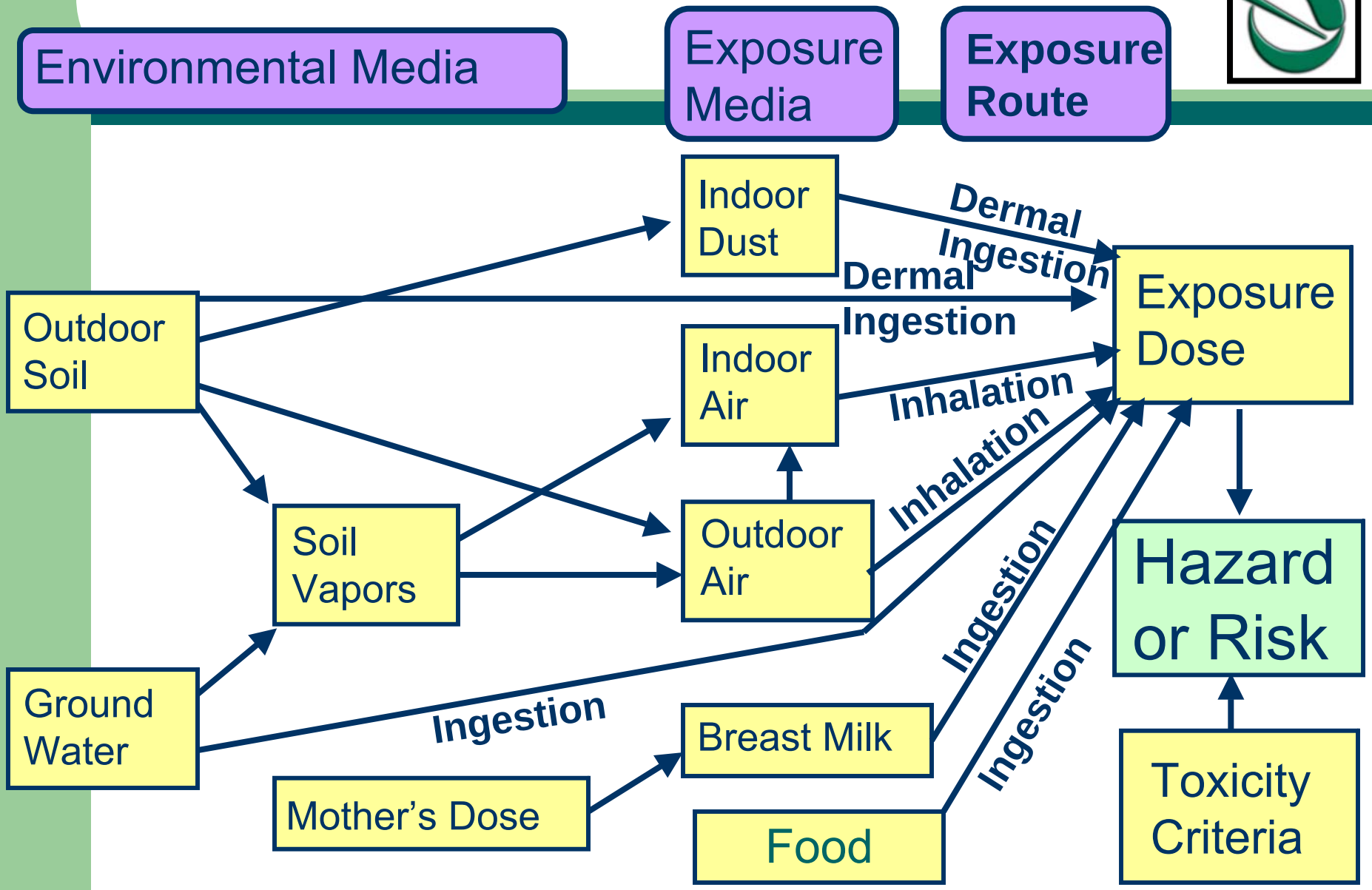
Concentrations in Exposure Media

- 95% UCL
- Maximum
- Area for averaging
  - Scenario dependent

Conceptual Site Model

- How contaminants move between environmental media
- Which exposure media become contaminated
- To what level they become contaminated?
- Who is exposed?
- How often and for how long?
- By what pathways are they exposed?
- Important component for prior review

Conceptual Site Model



Toxicity & Dose-response Assessment

- Not site specific – i.e. there are published lists
- Primary sources of this information: OEHHA & USEPA
- OEHHA criteria are preferred when available (http://www.oehha.ca.gov/risk/ChemicalDB/index.asp)
- 2nd choice: IRIS (Integrated Risk Information Service) (http://www.epa.gov/iris/index.html)
- 3rd choice: Values used to support Region IX PRGs (http://www.epa.gov/Region9/waste/sfund/prg/index.html)
- 4th choice: HEAST values

Exposure Assessment

- Typical Exposure Scenarios
  - Residential is the most common & the most standardized
  - Occupational
  - Recreational
  - School or day care
  - Other

Exposure Assessment

- Exposure Scenarios
  - Generally tied to current or future land use
  - May wish to assess a residential scenario to avoid deed restriction

Exposure Assessment

- Exposure Pathways
  - Inhalation of vapors indoors
    - From soil, ground water, or drinking water
  - Inhalation of vapors outdoors
  - Inhalation of particles
  - Dermal contact with soil
  - Ingestion of soil
  - Ingestion of drinking water

Exposure Assessment

- Exposure Pathways
- Equation for each pathway for each scenario
- Daily dose = concentration * daily contact rate * absorption

Exposure Assessment

- Daily dose = concentration * contact rate * absorption
- Concentration in exposure medium
  - Breathing zone air
  - Ingested soil
  - Drinking water
- Contact rate: amount of exposure medium that is breathed, ingested, or contaminates the skin.
- Absorption:
  - Ingestion and inhalation usually assumed 100%
  - Dermal absorption is chemical-specific

Exposure Assessment

- Dose Duration and Averaging Periods
- Chronic dose = Daily dose * exposure frequency (EF) / 365
  - Applies to chronic toxicity (non-cancer)
- Lifetime average dose = chronic dose * exposure duration (ED) / 70
  - Applies to carcinogenic effects

Risk Characterization

- Forward calculation
  - Comparing an exposure estimate with a toxicity threshold and expressing the result as a risk of contracting cancer or as a hazard index
- Cancer risk (Lifetime Incremental Cancer Risk)
- Non-cancer toxicity (Hazard Index)

Cancer Risk

- LICR is the upper bound on the increased probability of contracting cancer due to exposure to this source
- 25% + 1/million = 25.0001%
- Multiply lifetime average daily exposure by cancer potency to estimate risk (LICR)
- LICR = potency * lifetime average exposure
- LICR = potency * concentration * contact rate * absorption * EF/365 * ED/70

Non-cancer Toxicity

- Hazard Quotient (HQ)
- HQ is the ratio of the estimated exposure to the reference dose (RfD) or reference concentration (RfC).
- HQ = Exposure dose / RfD
- HQ = (Concentration * daily contact rate * absorption * EF / 365) / RfD
- Hazard Index (HI) = $\Sigma(HQ)_{(1.- N)}$
- Not a probability

Backward or Reverse Calculation

- Re-arrange the risk equation and solve for the dose
- Potency * Exposure = Risk
- Risk / Potency = exposure
- In order to solve the equation, one must assume a value for hazard index or risk

“Acceptable” or “Target” Risk or Hazard

- How much risk is “acceptable” a risk management decision
- OEHHA does not decide how much risk is acceptable
- We can advise on past decisions

“Acceptable” or “Target” Risk or Hazard

- Default HI is 1
  - Because there is no way to evaluate HI >1 or <1
- Default Risk is 10^{-6}
  - Higher levels (up to 10^{-4}) may be approved on a case-by case basis.

Screening Levels

- The concentration that gives HQ = 1 or Risk = 10^{-6}
- Appropriate when all aspects of the exposure scenario match the assumed exposure scenario.
- Industrial and residential are the usual scenarios.
- Each scenario uses standardized exposure factors.

Screening Levels

- Do not inherently consider additivity
- Σ(concentration/screening level) $\leq$ 1
- Agencies may take action based on tier 1 analysis or move to tier 2.

Screening Levels

- Sources of screening concentrations
  - OEHHA soil and soil gas screening levels (http://www.oehha.ca.gov/risk/pdf/screenreport010405.pdf)
  - RWQCB ESLs
    - http://www.swrcb.ca.gov/rwqcb2/esl.htm
  - EPA PRGs
    - http://www.epa.gov/Region9/waste/sfund/prg/index.html
  - EPA SSLs
    - http://www.epa.gov/superfund/resources/soil/introtbd.htm)

Level 2 Site-specific Risk Assessment

- Same route-specific exposure equations, but using:
  - Different or additional exposure scenarios, and/or
  - Different exposure parameters for the exposure pathways.
- May be done as a forward or backward calculation.

Level 2 Site-specific Risk Assessment

- Forward calculation
  - Cancer is always additive
  - Add risks from all pathways & chemicals
- Non-cancer effects may or may not be additive, depending on target organ system
  - Add hazard quotients from all pathways & chemicals unless non-additivity is justified

Backward calculation

- Use site-specific information to modify an existing screening level
- Create risk-based site-specific screening concentrations for single chemicals
- Again, additivity must be considered

Confirmation Sampling

- Following removal or remedial action
- What media?
- What analytes?
- For how long?
  - Considerations: Ongoing sources

What Will OEHHA look for in a Risk Assessment?

- Data collection and evaluation (if requested)
- Toxicity and dose-response assessment
- Exposure assessment
- Risk characterization

Data collection and evaluation

- Is the site history and description complete?
- Is the suite of chemicals analyzed for reasonable in light of the site history?
- Are the analytical methods and detection limits appropriate?
- Are background concentrations established (if required)?

Chemicals of Potential Concern

- Are all contaminants retained as COPCs?
  - If not, are excluded contaminants justified?

Toxicity and dose-response assessment

- Were the correct toxicity values used?
- Are the toxic effects of the major contaminants described?

Exposure assessment

- Are appropriate exposure media considered?
- Are concentrations in exposure media calculated correctly?
  - UCL? Maximum? Area-wide averaging?

Exposure assessment

- Are the exposure scenarios consistent with the actual or proposed land use?
- Are the exposure factors appropriate for the scenario?
- Are the equations for each exposure pathway correct?
- Are the exposure calculations correct?

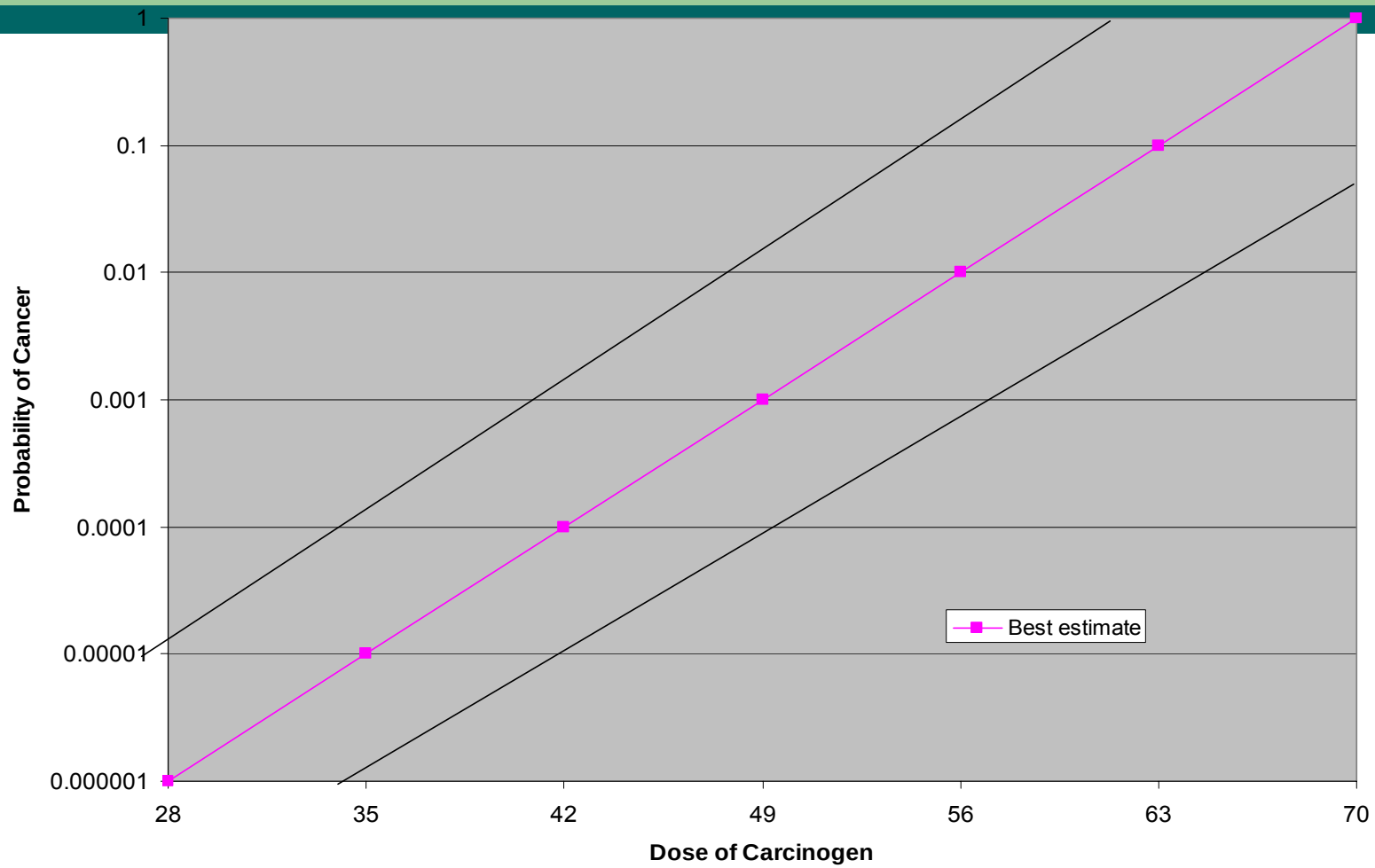
Risk characterization

- Screening (backward)
  - Were appropriate screening values used?
  - Were the screening values compared to appropriate site concentrations?
  - Are additive effects appropriately considered?

Risk characterization

- Site specific
  - Are the cancer risks and hazard indices calculated correctly for each exposure scenario?
  - Are additive effects appropriately considered?
- Are the hazards and risks appropriately interpreted and communicated?

Cancer Dose/response



Workplan Principles

- Specific enough to allow reviewers to spot problem areas early and avoid costly “do-overs”
- Ideally there will be no surprises when the assessment is completed
- Flexible enough to allow project team to respond to new information

Workplan Elements

- Need to know something about the site
- Site history and chemicals, handled, used, or stored on site (or suspected, based on operations)
- Sampling strategy for various media
- Analyses proposed, methods, and detection limits
- Methods for determining chemicals of potential concern

Workplan Elements

- Methods for determining concentrations in exposure media
- Conceptual site model
- Exposure scenarios and exposed populations
- Sources of toxicity criteria
- Screening criteria (if any)

Cal/EPA IWMB & OEHHA Internal Process

OEHHA

OEHHA Interagency Agreement

- Check with Brad Penick to see if the project fits within the scope of the CIWMB/OEHHA IA
- Brad or the project manager/LEA contacts Jim Carlisle in OEHHA
- Jim assigns staff to the project

OEHHA Interagency Agreement

- Project manager/LEA meets with OEHHA staff to explain project & determine if OEHHA can help.
- OEHHA questionnaire may further this discussion
- Brad may attend this meeting to help introduce the parties and get a feel for the timeframes.

OEHHA Interagency Agreement

- Brad or the project manager writes work order describing the project, the work required of OEHHA, & the requested time frame.
- An electronic copy is forwarded to the OEHHA staff assigned to the project, along with project documents for review
- OEHHA staff estimates the cost and time to complete the work

OEHHA Interagency Agreement

- Brad finalizes & signs work order with an amount not to exceed the cost estimate.
- It is also signed by Abel Martinez-Centeno or Glenn Young
- A copy is forwarded to the OEHHA staff
- Any changes in the scope of work or cost overruns must be addressed with an amendment to the original work order.

Follow-up

- OEHHA will issue a draft memorandum reporting their findings
- The project manager should critically read the memo and report back to OEHHA, approving the draft or suggesting changes.
- The memo will then be finalized
- OEHHA requests a customer satisfaction survey to help us serve you better

Limitations and Caveats

- OEHHA;s comments are only suggestions. The final decision on whether to adopt them is yours
- The contractor who prepared the report may disagree with OEHHA
- We will defend our position but will not make the final decision in such cases

Practical Exercise

OEHHA