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INTRODUCTION TO RISK ASSESSMENT CNC CHARLESTON SC
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ENSAFE/ ALLEN AND HOSHALL

INTRODUCTION TO RISK ASSESSMENT

Presented to:

Restoration Advisory Board for the

Naval Base Charleston

Presented by:

EnSafe/Allen & Hoshall

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INTRODUCTION

- Purpose: Provide an introductory discussion of risk assessment concepts, assumptions, and acronyms

- Intended Outcome: Assist the RAB in understanding subsequent technical discussions of risk assessment results and how they are used to determine appropriate remedial measures

BASIC CONCEPTS

- There is no such thing as Zero Risk.
- There are voluntary and involuntary risks, chronic (long-term) and catastrophic (acute) risks

  - Voluntary Risks: Tobacco use, skydiving
  - Involuntary Risks: Radon gas, solar radiation

BASIC CONCEPTS

- How is it determined that detectable levels of hazardous substances can be left in environmental media at the site without causing health concerns?

- To **estimate** the potential risk to human health and the environment at a hazardous waste site, procedures known as **Risk Assessment** are used

BASIC CONCEPTS (cont'd)

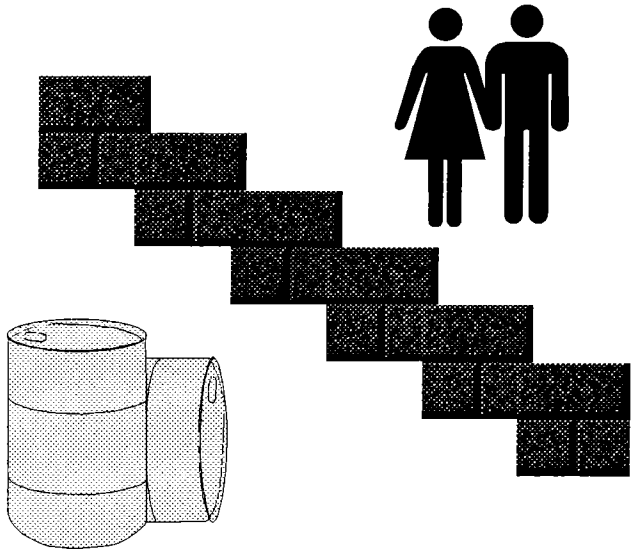
- **Environmental Health Risk:** The likelihood of chemical substances at a site to cause health effects in people on or near the site

- **Risk reduction** is the principle focus of hazardous waste site evaluation

BASIC CONCEPTS (cont'd)

- Risk assessment protocols have been designed to <u>overestimate</u> predictions of risk
  - The rate or incidence of health problems will generally be <u>lower</u> than predicted.

- For risk to exist
  - A ***Hazard*** must exist <u>**AND**</u> ***Exposure*** must take place



RISK ASSESSMENT ELEMENTS

- Four basic elements
  1. Hazard Identification
     (what is there?)
  2. Exposure Assessment
     (can anyone come in contact with it?)
  3. Toxicity Assessment
     (how, and when, is it harmful?)
  4. Risk Characterization
     (how does all this information combine?)

HAZARD IDENTIFICATION

- What chemicals are present and at what concentrations?

- The RCRA Facility Investigation (RFI) at Naval Base Charleston was designed to identify <u>potential</u> hazards

HAZARD IDENTIFICATION (cont'd)

- Selection of *Chemicals of Potential Concern*
  - "hit list", chemicals detected
  - comparison to background
    (naturally-occurring levels)
  - comparison to screening values
    (risk-based concentrations - "RBCs")

HAZARD IDENTIFICATION (cont'd)

- Potentially Hazardous Substances occur in the Environment - How?
  - Naturally throughout the environment at varying concentrations (e.g. lead, arsenic)
  - From human activities that are widespread and common (e.g. auto emissions, wood burning stoves, mining)
  - From human activities that are location-specific and create considerable waste material (e.g. wood preserving, battery recycling)

EXPOSURE ASSESSMENT

Do people come into contact with the hazard?

- how much?
- how often?
- who?
- how many?
- when?
- for how long?
- and to what degree?

Estimates are made for typical individuals at a site, as well as high-risk groups

EXPOSURE ASSESSMENT (cont'd)

- Potential exposure is estimated based on exposed populations, exposure routes, and exposure media. Examples:

Exposed Populations

- Residents (Child and Adult)
- Onsite Workers
- Trespassers
- Fishermen

Exposure Medium

- Soil
- Groundwater
- Surface Water
- Sediment
- Garden Crops (Lettuce)
- Fish/Shellfish (Flounder)

Exposure Route

- Skin Contact
- Inhalation
- Direct Ingestion
- Ingestion of Produce and Fish/Shellfish

EXPOSURE ASSESSMENT

- Dose or Intake
- General Equation For Intake (mg/kg-day) $= \frac{C \times IR \times CF \times FI \times EF \times ED}{BW \times AT}$

- Where:

C = concentration in exposure medium (mg/kg or mg/liter)
IR = intake rate (liters/day, mg/day, cubic meters/day)
CF = conversion factor (kg/mg)
FI = fraction ingested from contaminated source (unitless)
EF = exposure frequency (days/year)
ED = exposure duration (years)
BW = body weight (kg)
AT = averaging time (days)

EXPOSURE ASSESSMENT

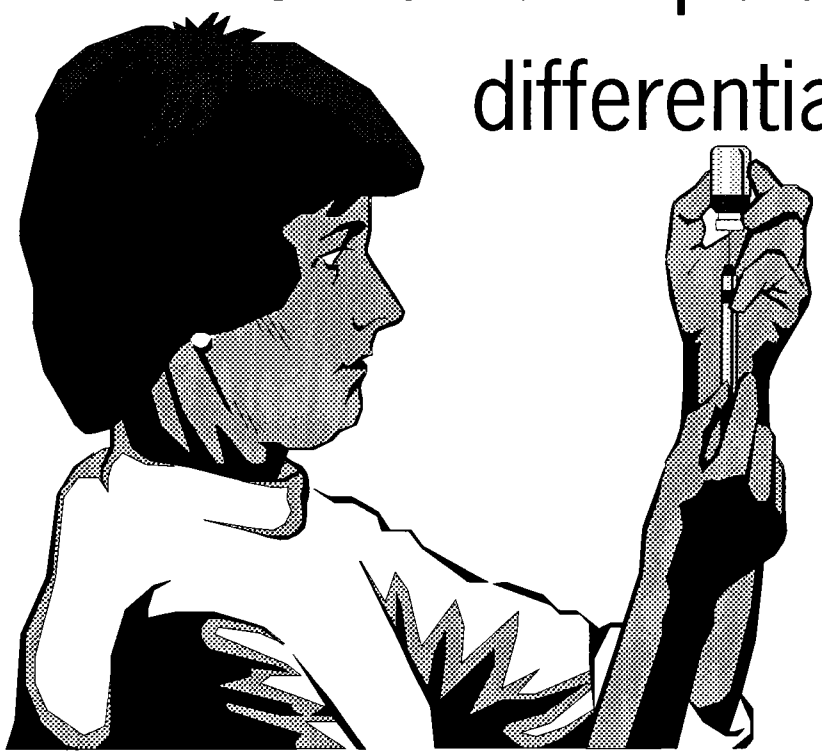
- Major Assumption Differences

PARAMETER	INDUSTRIAL (Adult)	RESIDENTIAL (Child)
Soil Ingestion (mg/day)	50	200
Body Weight (kg)	70 (154 lbs)	15 (33 lbs)
Exposure Frequency (days/year)	250 5 days/wk, 50 wks	350 7 days/wk, 50 wks

TOXICITY ASSESSMENT

- Determine the harmful nature of the hazard
  - Cancer causing or non-cancer causing
    - how does it act?
    - what is the relationship between the exposure (dose) the likelihood and/or severity of the adverse effect?

"All substances are poisons; there is none which is not a poison. The right dose differentiates a poison from a remedy."

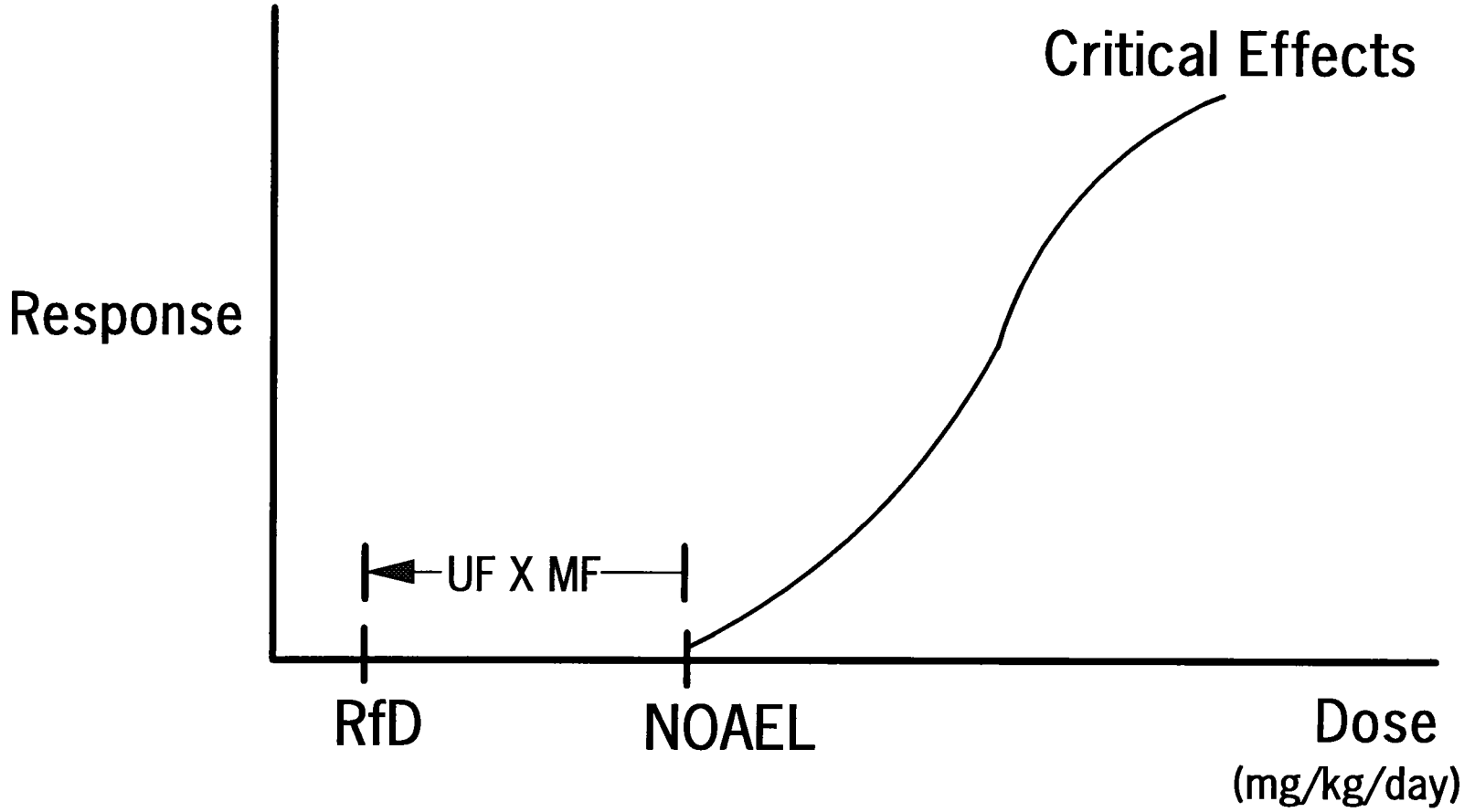


Parcelsus (1493-1541)

REFERENCE DOSE (RfD)

"An estimate (with an uncertainty of one order of magnitude or more) of a lifetime dose which is likely to be without significant risk to human populations."

REFERENCE DOSE



REFERENCE DOSE

- No observed adverse effect level (NOAEL)
- Critical effect and critical study
- Uncertainty factor (UF)
- Modifying factor (MF)
- Reference dose (RfD) = $\frac{\text{NOAEL}}{\text{UF x MF}}$

CARCINOGENIC TOXICITY

- Effects in laboratory animals, when qualified, are applicable to humans

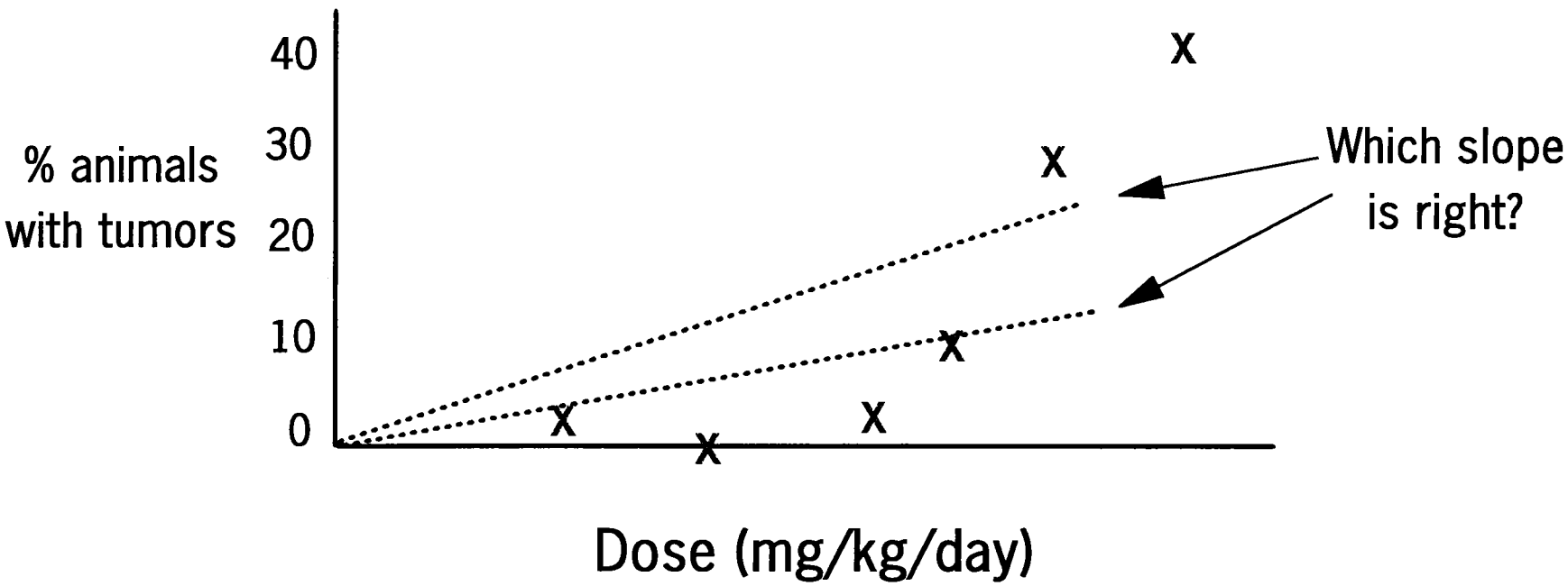
- Exposure to high doses is a valid basis for extrapolation to low doses

  Statistically, to discover a cancer risk of 0.01% or 1×10^{-4}, a study would require 30,000 animals.

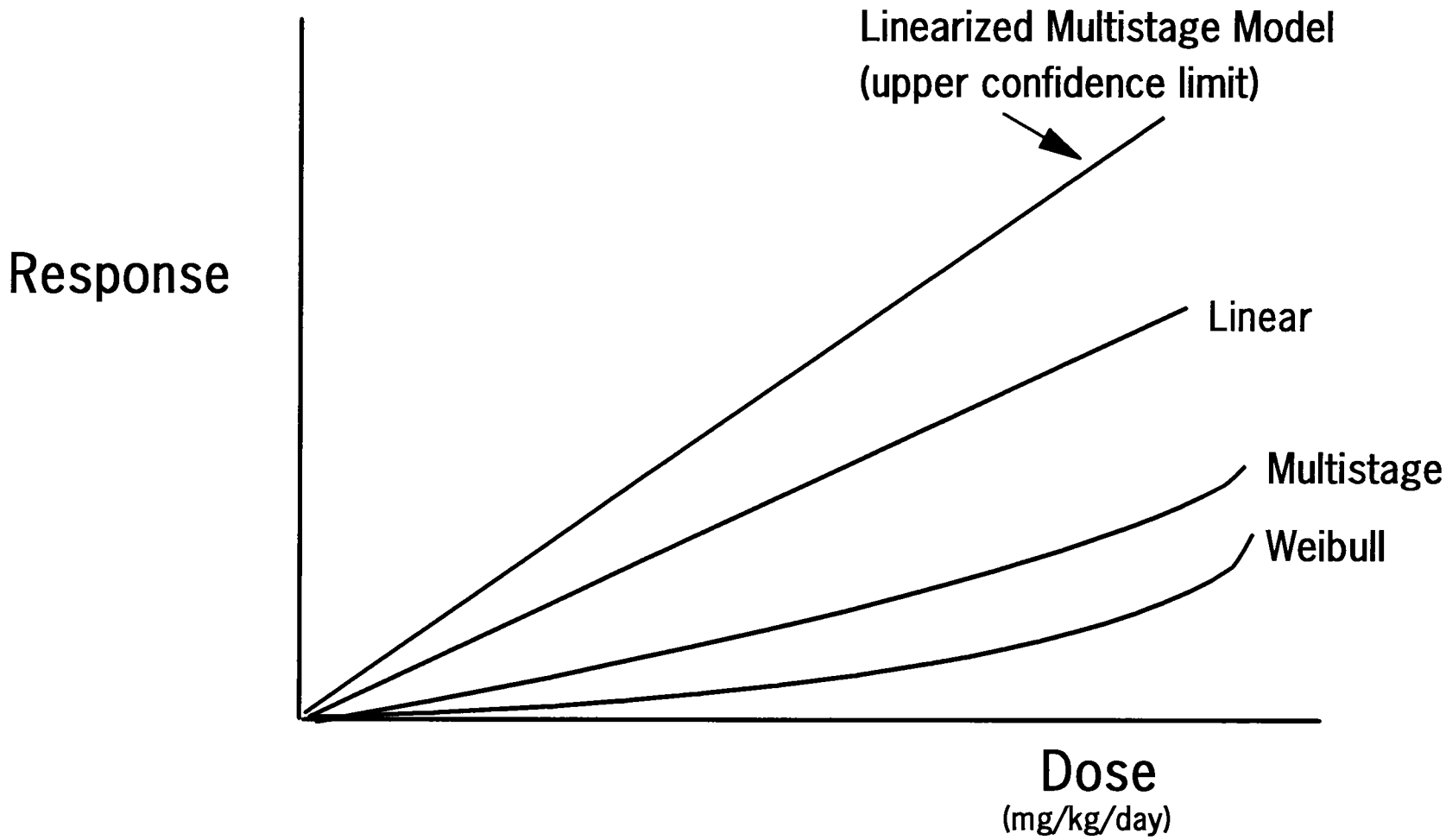
  Staffa and Mehlman "Megamouse Study" - examined effects of aminofluorene on bladder cancer in 24,000 mice.
  Results: INCONCLUSIVE

CARCINOGENIC TOXICITY

- Most studies use 40 animals/dose - 2.5% cancer risk is the minimum detectable



HIGH-TO-LOW DOSE PROBLEM



SOURCES OF TOXICITY DATA

- IRIS - Integrated Risk Information System
- HEAST - Health Effects Assessment Summary Table
- Provisional Values from NCEA - National Center for Environmental Assessment
- Surrogate values
- Other sources

SOURCES OF TOXICITY DATA

HUMAN STUDIES

Case Reports

Epidemiologic studies

- Geographical
- Temporal

ANIMAL STUDIES

General toxicity studies

- Acute
- Chronic

Specialized toxicity studies

- Teratology
- Mutagenicity

TEST TUBE STUDIES

- Microbiological
- Mammalian

RISK CHARACTERIZATION

- Combines results of the exposure and toxicity assessments

- Judges whether the risks could cause human health problems

AFTER THE RISK ASSESSMENT...

- Remedial Goals
  - The results of the risk assessments performed at Naval Base Charleston will help EPA and DHEC decide cleanup (or remedial) levels.
  - Generally, EPA does not require cleanup if cancer risks are lower than one in ten thousand
  - Generally, EPA does not require cleanup if the exposure levels of non-cancer-causing agents are less than the reference dose.

AFTER THE RISK ASSESSMENT... (cont'd)

- Factors Used When Determining Cleanup Requirements - *The Corrective Measures Study* (CMS)
  - Protect Human Health and the Environment
  - Attain Media Cleanup Standards set by the Implementing Agency
  - Control the Sources of Releases
  - Comply with any Applicable Standards for Management of Wastes
  - Other Factors
    a. Long-term reliability and effectiveness
    b. Reduction in the toxicity, mobility, or volume of wastes
    c. Short-term effectiveness
    d. Implementability
    e. Cost

AFTER THE RISK ASSESSMENT... (cont'd)

- Risk Management
  - Considerations for remedy:
    - Technical feasibility
    - Community/State acceptance
    - Cost
  - Questions:
    - Should cleanup be done/What are other alternatives?
    - What should the cleanup levels be?
    - What should the cleanup method be?

FACTORS IMPORTANT IN DERIVING RISK-BASED CLEAN-UP GOALS

- Future land use
- Receptor behavior and activities, i.e., pathways or exposure
- Toxic interaction of contaminants
- Acceptable risk level
  - for carcinogens
  - for non-carcinogens

BASIC QUESTIONS ANSWERED WITH RISK INFORMATION

- How bad is the site?
- How bad could it become if nothing is done?
- Does the site warrant remedial action?
- How much should be cleaned up?
- What will be the result of remedial action?