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RESTORATION ADVISORY BOARD MEETING AGENDA AND SLIDES 17 AUGUST 1995 NS  
MAYPORT FL  
8/17/1995  
RESTORATION ADVISORY BOARD

**AGENDA**  
**RAB Orientation Meeting**  
**August 17, 1995, 6:30 p.m.**

- ▶ Welcome Cheryl Mitchell
  
- ▶ Overhead Presentation Dr. Marland Dulaney  
*INTRODUCTION TO RISK ASSESSMENT*
  
- ▶ Questions about the *GENERAL INFORMATION REPORT (GIR)* Frank Lesesne  
and *RCRA FACILITY ASSESSMENT (RFA)*
  
- ▶ RFA Fact Sheet Cheryl Mitchell  
Overview and Distribution
  
- ▶ NAVSTA Mayport RAB Charter NAVSTA Mayport RAB Members
  
- ▶ Questions & Answers NAVSTA Mayport RAB Members
  
- ▶ General Discussion NAVSTA Mayport RAB Members
  - Availability Session
  - Soon to be released documents
  - Other Topics

*Parking Pass*

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**HUMAN HEALTH  
RISK ASSESSMENT**

**Marland Dulaney, Jr., Ph.D., DABT**

**ABB Environmental Services Inc.  
Tallahassee, Florida**

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**ABB Environmental Services, Inc.**

# Is This Chemical Exposure Safe?

## **4 Basic Steps of Risk Assessment**

- Identify the Chemicals of Concern**
  - Characterize the Extent of Chemical Exposure**
  - Evaluate the Toxicity of the Chemicals of Concern**
  - Estimate the Risk Associated with Chemical Exposure**
-

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## **Identify the Chemicals of Concern**

- Based upon Chemical Analysis**
  - Identify the Contaminated Media  
(e.g., Soil, Water, or Air)**
  - Quantitate the Level of Contamination**
  - Data Usability and Uncertainty Analysis**
  - Background Chemicals**
-

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## **Characterize the Extent of Chemical Exposure**

- Characterize the Physical Setting**
  - Identify Potentially Exposed Populations**
  - Identify Potential Exposure Pathways**
  - Estimate Exposure Concentrations**
  - Estimate Chemical Intakes**
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## Duration of the Chemical Exposure

- Acute - 1 Day to 13 Days
  - Subchronic - 14 Days to 7 Years
  - Chronic - 7 years to a Lifetime
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## **4 Basic Steps of Risk Assessment**

- Identify the Chemicals of Concern**
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  - Evaluate the Toxicity of the Chemicals  
of Concern**
  - Estimate the Risk Associated with Chemical  
Exposure**
-

## **Evaluate the Toxicity of the Chemicals of Concern**

- Gather Qualitative and Quantitative Toxicity Information For Chemicals Being Evaluated**
  - Identify Exposure Periods Required for Toxicity to Occur**
  - Dose Response Assessment**
    - Determine Toxicity Values for Noncarcinogenic Effects**
    - Determine Toxicity Values for Carcinogenic Effects**
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## Toxic Endpoint of Interest

- Systemic Toxicity** - *does it make you sick*
- Carcinogenicity** - *causes cancer*
- Developmental Toxicity** - *learning disabilities*
- Mutagenicity/Teratogenicity/Fetotoxicity**  
*DNA changes*

## EPA Cancer Slope Factor

- A Plausible Upper-Bound Estimate of the Probability of a Response (Carcinogenic) per Unit Intake of a Chemical over a Lifetime

*only 10 known human carcinogens*

## **The Reference Dose (RfD)**

**The RfD is an Estimate (With Uncertainty Spanning Perhaps an Order of Magnitude or Greater) of the Daily Exposure to the Human Population (Including Sensitive Subgroups) That is Likely to be Without Appreciable Risk of Deleterious Effects During a Portion of the Lifetime, in the Case of a Subchronic RfD, or During the Lifetime, in the Case of a Chronic RfD (USEPA, 1989a).**

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## Types of Reference Doses (RfDs)

- Chronic - Exposure From 7 Years to a Lifetime
  - Subchronic - Exposure Between 2 Weeks and 7 Years
  - Developmental
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## Linear Low-Dose Cancer Risk Equation

$$\text{Risk} = \text{CDI} \times \text{SF}$$

Where:

**Risk = A Unitless Probability (e.g.,  $2 \times 10^{-5}$ ) of an Individual Developing Cancer;**

**CDI = Chronic Daily Intake Averaged Over 70 Years (mg/kg-day); and**

**SF = Slope Factor, Expressed in  $(\text{mg}/\text{kg}\cdot\text{day})^{-1}$**

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## Cancer Risk Equation for Multiple Chemicals

$$\text{Risk}_{(\text{Total})} = \text{Risk}_{(1)} + \text{Risk}_{(2)} + \dots + \text{Risk}_{(n)}$$

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## **Non-Cancer Hazard Quotient (HQ)**

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$$\text{HQ} = \frac{\text{Exposure Dose (ED)}}{\text{Reference Dose (RfD)}}$$

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ED and RfD are Expressed in the Same Units (mg/kg/Day) and Represent the Same Exposure Period (Chronic, Sub-Chronic, Short-Term).

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**Non-Cancer Total Hazard Index  
for Multiple Chemicals**

$$\mathbf{HI}_{\text{(Total)}} = \mathbf{HI}_{\text{Pathway}_1} + \mathbf{HI}_{\text{Pathway}_2} + \dots + \mathbf{HI}_{\text{Pathway}_n}$$

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**Non-Cancer Pathway Hazard Index  
for Multiple Chemicals**

$$\mathbf{HI}_{\text{(Pathway)}} = \mathbf{HQ}_1 + \mathbf{HQ}_2 + \dots + \mathbf{HQ}_n$$

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## **Areas of Uncertainty Analysis**

- Physical Setting (Future Land Use, Chemicals not Included in Risk Assessment, etc.)**
  - Exposure Pathway (Why Selected or not Selected)**
  - Models (Assumptions and Limitation of Each Model Used)**
  - Derivation of Toxicity Values**
  - Data Gaps**
-

## **Relevancy of Animal Studies to Humans**

- ❑ **The Fact that Almost All Human Carcinogens are Animal Carcinogens does not Prove that the Converse Relation Holds; i.e., It has not been Proven that All Animal Carcinogens are Human Carcinogens.**
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# **Risks that Increase Probability of Death by One Chance in a Million**

<b>Activity</b>	<b>Cause of Death</b>
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<b>One Chest X-ray Taken in a Good Hospital</b>	<b>Cancer Caused by Radiation</b>
<b>Living 2 Months with a Cigarette Smoker</b>	<b>Cancer, Heart Disease</b>
<b>Eating 40 Tablespoons of Peanut Butter</b>	<b>Liver Cancer Caused by Aflatoxin B</b>
<b>Eating 100 Charcoal-Broiled Steaks</b>	<b>Cancer from Benzopyrene</b>
<b>Drinking Thirty 12-oz Cans Diet Soda</b>	<b>Cancer Caused by Saccharin</b>

**Source:** Adapted from R. Wilson, Analyzing the Risks of Daily Life, *Technology Review*, 81 (1979). See also R. Wilson and E.A.C. Crouch, Risk Assessment and Comparison: an Introduction, *Science*, 236, 267-270 (1987).

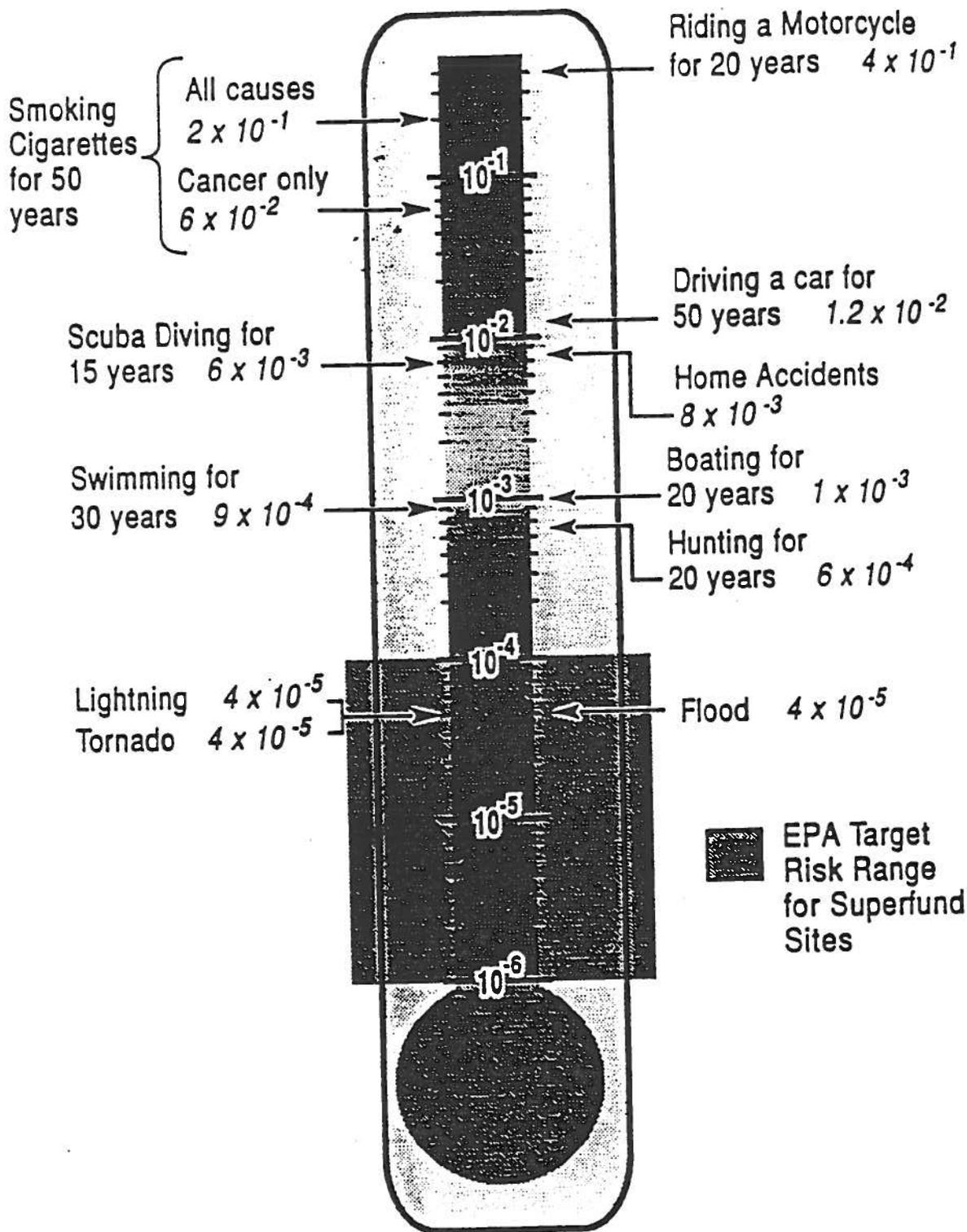


Fig. 1. A representation of excess risk involved with various activities in which the risk has been confirmed by direct observation.

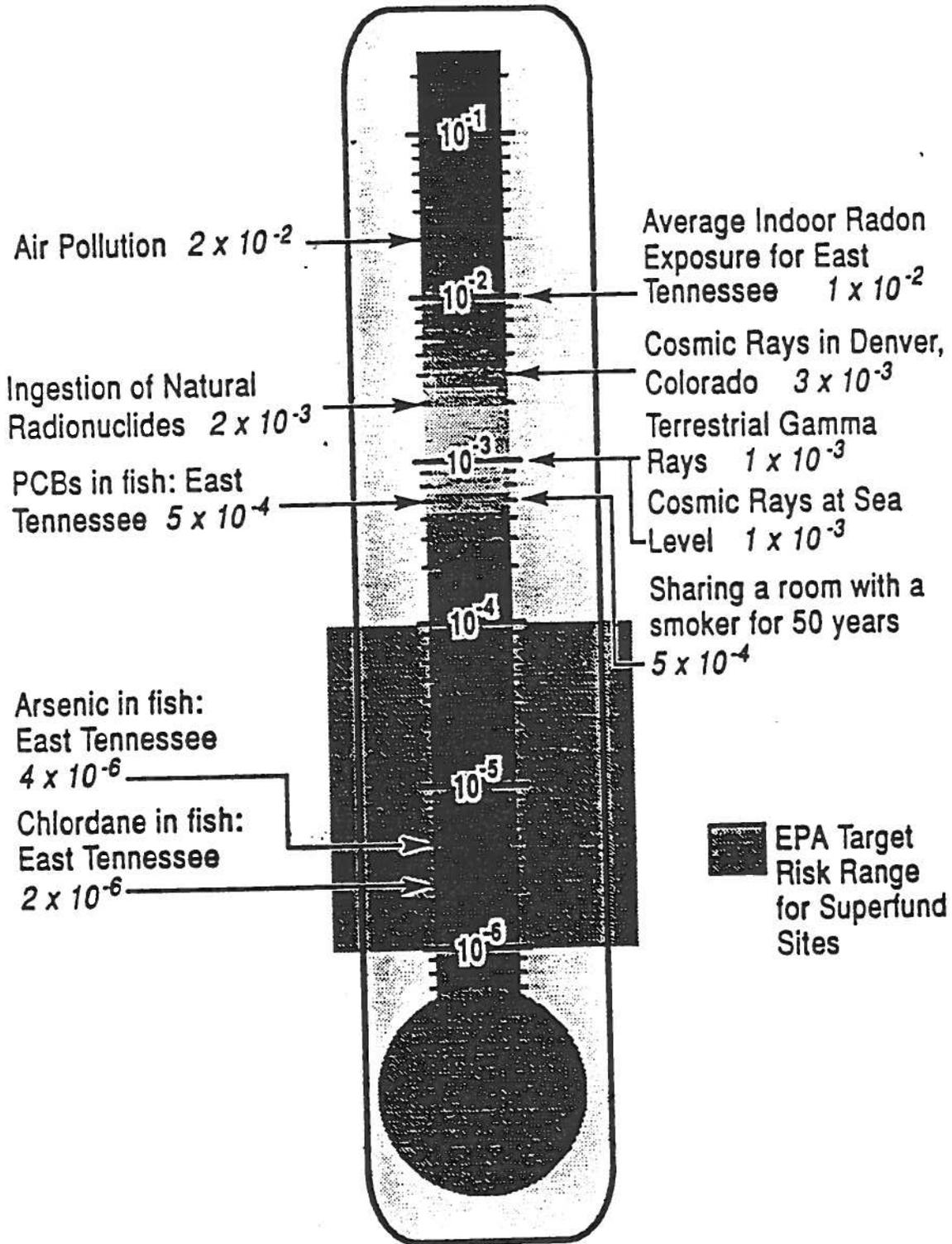


Fig. 2. Nonverifiable risks determined by mathematical extrapolation to low doses that are received from interaction with the environment.

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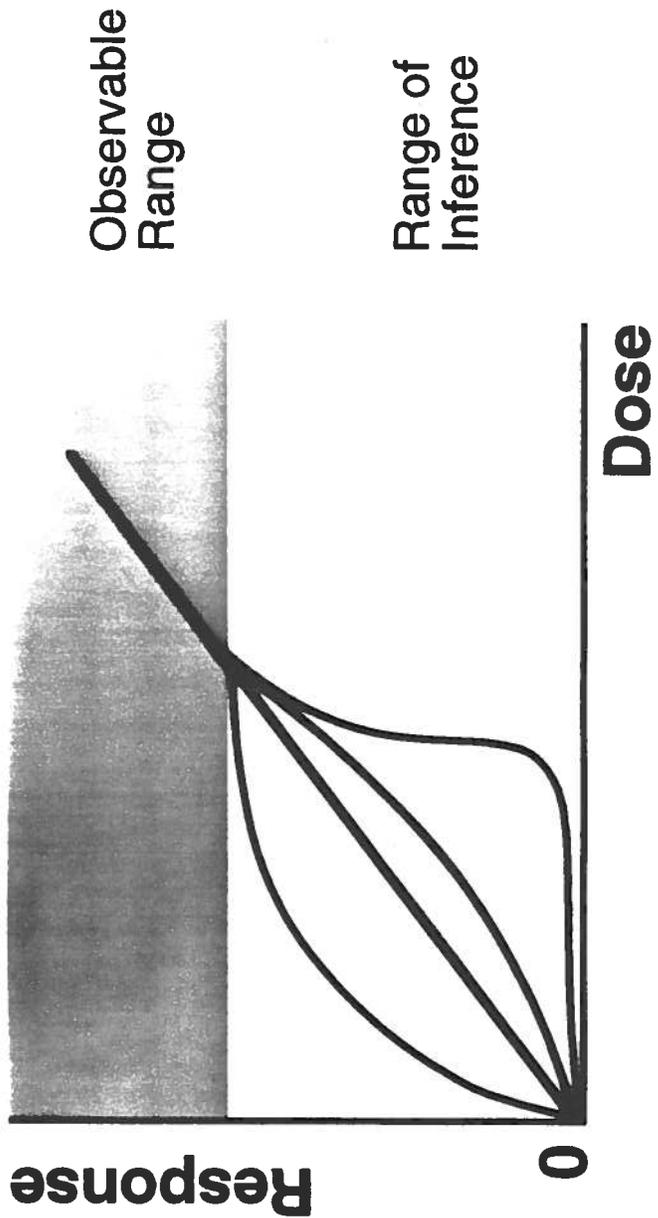
# Are These Estimates Real?

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## **Factors Used in Risk Estimates**

- Contaminant Concentrations**
  - Exposure Pathways**
  - Toxicity Data**
  - Toxicity Analysis**
  - Exposure Factors**
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# Variability in Estimated Low-Dose Risks



# Target Risk Ranges for Risk Management

- $10^{-4}$  to  $10^{-7}$  - The Cleanup Policy Under the USEPA Superfund Cleanup Program.
- $10^{-4}$  to  $10^{-7}$  - USEPA Drinking Water Standards (Maximum Contaminant Levels, or MCLs) Under the Safe Drinking Water Act.
- $10^{-4}$  to  $10^{-7}$  - Alternate Concentration Limits (ACLs, a Form of Groundwater Regulation) Under the Resource Conservation and Recovery Act.
- $10^{-2}$  to  $10^{-6}$  - National Emission Standards for Hazardous Air Pollutants (NESHAPs) Under the Clean Air Act.
- $10^{-5}$  - "No Significant Risk Level" Under California's Proposition 65 (Safe Drinking Water and Enforcement Act of 1986).