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**Medical University of South Carolina**
**Environmental Hazards Assessment Program**
**Annual Report**
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## 5.4.4 DEHS- Education and Training Initiative

71. Abstract submitted and accepted, slides from the presentation were used in the upcoming pilot test of the first Professional Development Seminar "Concepts of Risk Analysis"
72. Slides from the presentation were used in the upcoming pilot test of the second Professional Development Seminar "Decision Making in Environmental Risk Management"
73. Slides from the presentation were used in the upcoming pilot test of the second Professional Development Seminar "Decision Making in the Environmental Risk Management"
74. List of members serving on Advisory Committee
75. Advisory Committee Meeting Minutes from November 3, 1993
76. Advisory Committee Meeting Minutes from May 17, 1994
77. Handbook Revised November 1993
78. Revised survey instrument, developed in August, 1993
79. Concepts of Risk Analysis /textbook
80. Decision Making in Environmental Risk Management Textbook
81. Course agenda

Reprints + Preprints removed

ATTACHMENT ~~10~~ /

# "The Role of Risk in Environmental Health Issues"

Presented by Dr. Robert Kennedy, Nancy Kierstead, Dr. Janet Temple

NC/SC Environmental Information Association Annual Meeting, September 23, 1993

EHAP - Education and Training Initiative

Department of Environmental Health Sciences

Medical University of South Carolina

# RISK COMMUNICATION

- College of Health Professions
- Department of Environmental Health Sciences
- Medical University of South Carolina

# Seven Cardinal Rules of Risk Communication

- Accept and involve the public as a legitimate partner
- Plan carefully and evaluate your efforts
- Listen to the public's specific concerns
- Be honest, frank, and open
- Coordinate and collaborate with other credible sources
- Meet the needs of the media
- Speak clearly and with compassion

# RISK COMMUNICATION

College of Health Professions
Department of Environmental Health Sciences
Medical University of South Carolina

# Factors Affecting Risk Acceptability

**Understanding the distinction between risk and risk acceptability is critical to overcoming mistrust and communicating effectively**

# Two Factors Affect the Way People Assess Risk and Evaluate Acceptability

a) The level or risk is only one among several variables that determines acceptability (other variables that matter are fairness, benefits, alternatives, control, and voluntariness.)

b) Deciding what level of risk ought to be acceptable is NOT a technical question but a value question. (People vary in how they assess risk acceptability - they weigh factors according to their own values, sense of risk, and stake in the outcome.)

# Risk

## Voluntary

## vs

## Involuntary

# Goals of Risk Communication

**Should Produce an Involved, Informed, Interested, and Fair-Minded Public, so That Public Opinions and Concerns will be (or Remain) Reasonable, Thoughtful, Calm, Solution-Oriented and Collaborative.**

# Accept and involve the public as a legitimate partner

# Plan carefully and evaluate your efforts

# Listen to the public's specific concerns

# Be honest, frank, and open

# Coordinate and collaborate with other credible sources

# Meet the needs of the media

# Speak clearly and with compassion

# Risk Communication Components

1. Alerting People
2. Reassuring People

# Experts Define Risk

## Magnitude X Probability = Hazard

**Magnitude:** How bad it is when it happens

**Probability:** How likely is it to happen

# Public Define Risk

Strong emotion (outrage)
that is justified

# The Solution

- Take public outrage as seriously as hazard

- Keep them separate.

# Outrage Factors

- Is it Voluntary or Coerced?
- Is it Natural or Industrial?
- Is it Familiar or Exotic?
- Is it Not Memorable or Memorable?
- Is it Not Dreaded or Dreaded?
- Is it Chronic or Catastrophic?

# Outrage Factors

- Is it Knowable or Not Knowable?
- Is it Controlled by Me or by Others?
- Is it Fair or Unfair?
- Is it Morally Irrelevant or Morally Relevant?
- Can I Trust You or Not?
- Is the Process Responsive or Unresponsive?

# Outrage Factors

- Effect on Vulnerable Populations
- Delayed vs. Immediate Effects
- Effect on Future Generations
- Identifiability of the Victim
- Elimination vs Reduction
- Risk-Benefit Ration
- Media Attention
- Opportunity for Collective Action

# Definition of Risk Communication

**The Process by Which Information is Exchanged Among Interested Parties Regarding:**

- Levels of Health or Environmental Risks
- The Significance or Meaning of Such Risks
- Actions and Policies Aimed at Managing or Controlling Risks

# Principles of Risk Communication

- Trust & Credibility
- Understand Audience
- Communication Skills

# Interested Parties

- Industry
- Regulators
- Elected Officials
- Activists
- Employees and & Retirees
- Neighbors
- Concerned Citizens
- Experts
- The Media
- Others

**If We Think [the People] are not Enlightened Enough to Exercise Their Control with a Wholesome Discretion, the Remedy is not to take it From Them, but to Inform Their Discretion.**

**Thomas Jefferson**

# No Risk Comparison Will be Successful if it Appears to be Trying to Settle the Question of Whether a Risk is Acceptable

# Your Job as a Consultant is NOT to Tell the Public About What They Should Accept, but Instead to Tell Them About the Size of the Risk Your Operation Entails.

**Always Aim Your Risk Communication at the Concerns and Information Needs of a Specific Target Audience.**

# Risks that Kill People (or Hurt them or Damage Ecosystem) and the Risks that upset them are Completely Different

# Experts Perception

# vs

# Public Perception

**The Public Often Misperceives the hazard. The Experts often Misperceive the Outrage. But the Overarching Problem is that the Public Cares too little about the Hazard, and Experts care too little about the Outrage.**

**Risk = Hazard + Outrage**

**R = f(H,0)**

# Definition of Risk

## Scientific

**Probability of Adverse Effect Occurring**

## Lay Person's

**Probability of Adverse Effect + Perception**

# Occupational Mortality Rates (Lifetime)

| | |
|---|---|
| Mining | 19/1000 |
| Construction | 8/1000 |
| Manufacturing | 2/1000 |
| Wholesale/Retail Trade | 1/1000 |

# Perception-Affected Decisions

Choice of Dog -- Perception of Crime

Choice of Car -- Larger, More Safe

Moral -- Risk of Eternal Fire in Afterlife

# Salem, Massachusetts

## May - October 1692

## 19 Hanged

# Perception-Influenced Environmental Decisions

- Asbestos Removal in Schools

- Hazardous Waste Sites

# Need for Risk Assessment

Provides

- Objective
- Scientific

Risk Information

# Risk Assessment

## Definition

An Evaluation of the Potential Adverse Impact of a Given Event Upon the Well-Being of a Person or a Population

# RA Use: Risk Management

- Is There a Problem?
- Prioritizing Risks
- Who Is At Risk?

# RA Use: Risk Communication

**Helpful in Explaining**

- Hazards (Harmful Conditions)
- Sources
- Health Effects

# Steps For Risk Assessment

1. Hazard Identification
2. Dose-Response
3. Exposure Assessment
4. Risk Characterization

# 1. Hazard Identification

1. If Chemical Can Impair Human Health
2. Magnitude of Impairment
3. Chemical's
   - Metabolites
   - Contaminants
   - Decomposition Products

# 1. Hazard Identification

## Information to Obtain

1. Physical-Chemical Properties
2. Structure-Activity Relationships
3. Metabolic and Pharmacokinetic Properties
4. Short-Term Tests
5. Long-Term Animal Studies
6. Clinical Studies
7. Epidemiological Studies

# Choosing Studies

- Control Groups
- Timing
- Exposure Characteristics
- Biokinetics
- QA/QC

# 2. Dose - Response

**The Magnitude of Response Associated with a Specific Level of Exposure**

# Extrapolation

## Animal to Human

Chronic Diseases

Low Doses

Ethics

Uncertainty Factors/Dose Conversions

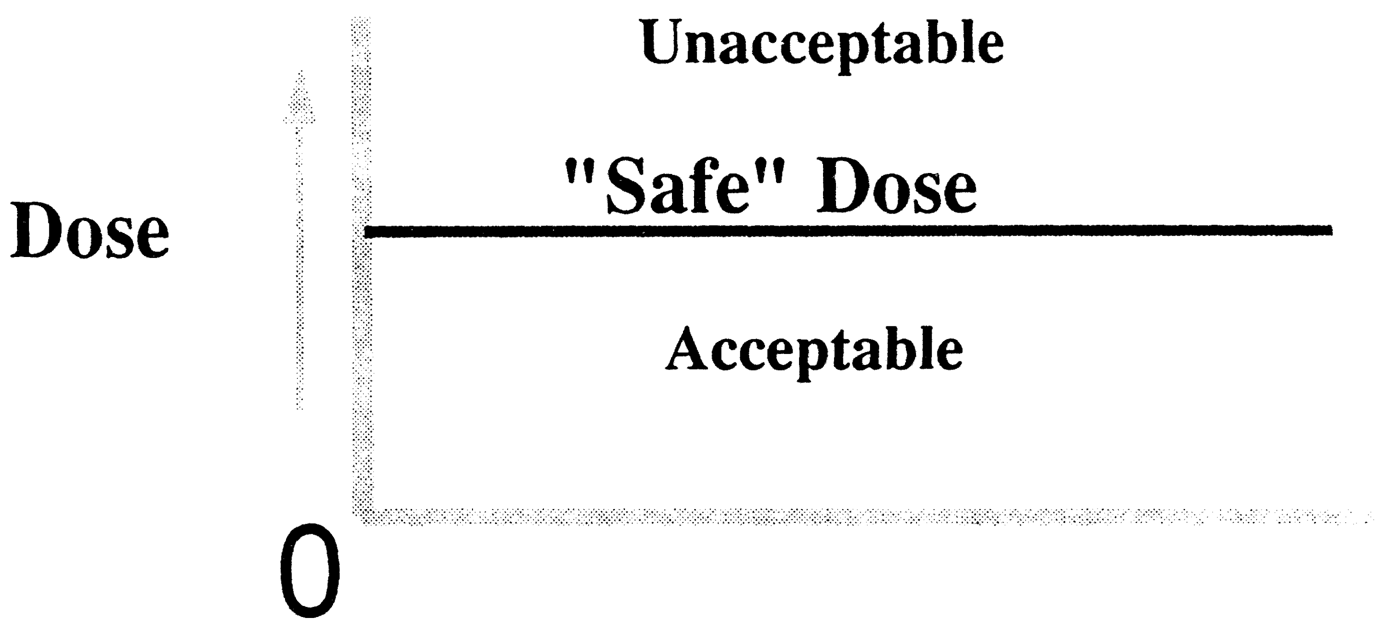
## High to Low Doses

Number of Animals for Low Dose Experiments Not Feasible

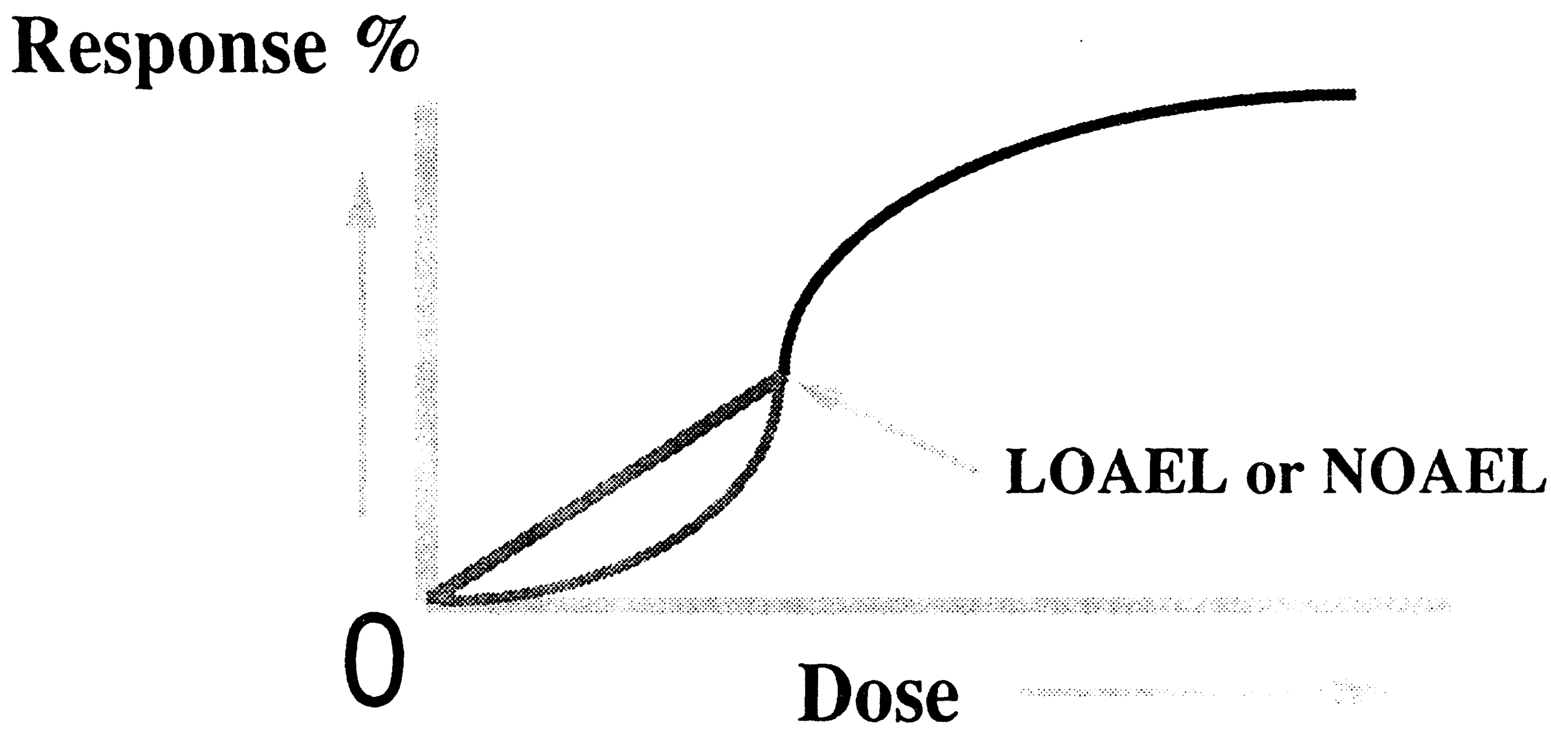
# Types of Dose - Response Relationships

- Threshold
- Nonthreshold

# Dose - Response Threshold



# Dose - Response Non Threshold



# Uncertainties of Dose - Response

- **Animal to Human Extrapolation**
- **High-to-Low Dose Extrapolation**
- **Exposure Characteristics**

# 3. Exposure Assessment

## Magnitude of Actual and/or Potential Human Exposure

# Considerations

1. Source
2. Magnitude
3. Frequency
4. Pathway -- Transport, Fate
5. Duration -- Short-Term, Long-Term

# Complete Pathway

- Source of Contaminant
- Environmental Media and
  Transport Mechanisms
- Point of Exposure
- Route of Exposure
- Receptor Population

# Susceptible Populations

- Age
- Gender
- Nutritional Status
- Predisposing Factors

# Sampling Procedures

Considerations

- Number
- Locations
- Trained Personnel
- Transport and Storage
- Analytical Methods
- QA/QC

# Modeling

## Estimate Concentrations Taking into Account:

- Decay
- Transformations
- Climatic Conditions

# 4. Risk Characterization

**Results of Hazard Identification, Dose-Response, and Exposure Assessments**

1. **Types and Magnitude of Adverse Effects**
2. **Probability of Each Effect Occurring**
3. **Uncertainties**

# Sources of Uncertainty

- Toxic Effects/Dose - Response Values
- Sampling Procedures and Measuring Techniques
- Population Information
- Natural Variation Over Time
- Use of Inappropriate Models

# Expressing Uncertainties

Example:

| Mean Wt. (Lb) | STD (Lb) | 95% CI (Lb) |
|---|---|---|
| 10 | 3 | 4,16 |

# Summary of Risk Assessment

## 1. Not Perfect

- Assumptions and Uncertainties
- Lack of Information

  Over 6,000,000 Chemicals Produced

  EPA's IRIS - Approximately 400 Chemicals

## 2. Multi-Discipline

## 3. Does Not Tell What To Do

## 4. Scientific & Objective Approach to Quantify Risks

# Risk Management - Definition

- The decision making process that uses the results of risk assessment to produce a decision regarding environmental action. Risk management includes consideration of technical, scientific, social, economic, and political information.
- (EPA 1989)

# Decision Making Process

- Human Health Risk Assessment information
- Ecological Risk Assessment information
- Economics (costs and benefits)
- Technological feasibility
  (available control technology)
- Social and political factors
- Regulations/Laws/Guidance
- Liability

# Risk Management

- Federal Government
- Local / Private Sector
- Personal Decision-Making
- Interrelationship

# Risk Management in the Federal Government

- Manage risks via legislation and rule-making
  - Weigh Policy Alternatives
  - Select the most appropriate regulatory action to a potential chronic health hazard
  - Carried out by regulatory agencies
  - Requires the use of value judgements

# RA Information Necessary for Informed Regulatory Decisions

- Regarding:
  - Worker Exposures
  - Industrial Emissions and Effluents
  - Ambient Air and Water Contaminants
  - Chemical Residues in Food
  - Cleanup of Hazardous Waste Sites
  - Naturally Occurring Contaminants

# How do different agencies in the Federal Government address risk?

- What level of risk is acceptable?
- Is there a point at which risks are "de minimis"?
- What is the level of uncertainty associated with the risk assessment?
- Answers are subjective. Rely on "expert opinion".

# Result - Different Levels of Acceptable Risk

- Keep in mind - Different types of risks
- Examine FDA, EPA, OSHA's definition of "acceptable risk"

# FDA

- 1973 - First to use risk assessment for regulatory decisions
- Regulation of carcinogenic drugs in food-producing animals
- Acceptable Lifetime Risk of $10^{-8}$, later $10^{-6}$
- 1 in 100,000,000 later to 1 in 1,000,000

# EPA - Lifetime Acceptable Risk

- Carcinogenic air pollutants - $10^{-5}$ to 0.001
- Active ingredients in pesticides - $10^{-7}$ to 0.02
- SWDA - goal for carcinogens = zero exposure
- Hazardous Waste Sites - $< 10^{-6}$

# OSHA - Setting PEL's

- 1980 Supreme Court definition of "significant risk"
- Risk of 1/1000 is significant occupational risk
- Neither OSHA nor Supreme Court say what risk is "insignificant" (acceptable)

# Risk Management in the Federal Government

- Nature of risks somewhat different
- Do not take into account the additive or interactive effects from exposure to multiple toxicants

# Local Risk Management/Private Sector

- Manage specific risks pertinent to particular situation
  - Community
  - Corporation/Industry
  - School
  - Hazardous Waste Site

# Make Management Decisions Regarding:

- Preventive Actions
- Prioritize Risks
- Remediation Alternatives
- Control Measures

# Industry Perspective

- Reduce and Prevent Occupational and Environmental Health Risks
- Difficult/Impossible to eliminate ALL risks
- Instead, Identify and Prioritize risks
- Reduce/Eliminate those with greatest potential for harm first
- Examine available resources, appropriate technologies, etc.

# Pro-Active Management Plan

- Inventory Risks
- Perform Periodic Audits
- Train Workers
- Allow for External Audits
- Identify Risk Evaluation Methods
- Identify Response Actions
- Effective Risk Communication with Workers and the Public

# Making Management Decisions - Hazardous Waste Site

- Factors which go into the decision
  - Identification of chemicals/radionuclides
  - Quantity/Concentration
  - Primary Exposure Pathways
  - Potential exposure population - demographics
  - Geology/Hydrogeology
  - Current and Future Land Use

# Hazardous Waste Site

- Regulations and Guidance of concern
- Public Health risks prior to, during and after remediation
- Worker Risks prior to, during, and after remediation
- Ecological Risks prior to, during, and after remediation

# Hazardous Waste Site

- What are your remediation goals? - PRGs
- Identify Remediation Alternatives, costs, risks, feasibility, efficiency.
- Identify institutional controls as necessary

# Analyzing Remedial Alternatives

- NCP nine-step criteria
  - Overall protection of human health and the environment
  - Compliance with ARARs
  - Long - term effectiveness and permanence (residual risks)
  - Reduction of toxicity, mobility, or volume via treatment

# NCP nine step criteria (continued)

- Short-term effectiveness - human health and environment
- Implementability
- Costs
- State Acceptance
- Community Acceptance

# NCP Criteria

- First two must be met
- 3-7 are considered balancing criteria
- 8-9 are considered modifying criteria

# Hazardous Waste Site

- Who will pay to clean up the site?
- What government officials will be involved?
- How will the public be involved in the decision making process?
- Public Participation/Risk Communication
- Media attention
- Political Climate, Public Interest Groups, Labor Unions

# Decision Making

- Are the choices you  are making both ethical and equitable?
- Quite often - very qualitative, subjective decisions
- Value Judgements
- Ideally, would like a systematic decision making tool

# Quantitative Tools for Making Decisions

- Cost - Benefit Analysis
  - Convert costs and benefits into dollar values
  - Evaluate options on net benefit($)
  - Human Capital Principle
  - "What is an efficient policy?"

# Decision Making Tools

- Cost - Effectiveness Analysis
  - "What is the most effective way to spend a fixed budget?"
  - Compares Cost Effectiveness Ratios...$/life saved
- Cost - Utility Analysis
  - Special form of CEA
  - costs/QUALY
- Subjective judgement is included here

# Decision Analysis

- Model Decisions with
  - Numerous Alternatives
  - Uncertain consequences
  - Multiple dimensions of value (cost, happiness, risk reduction)

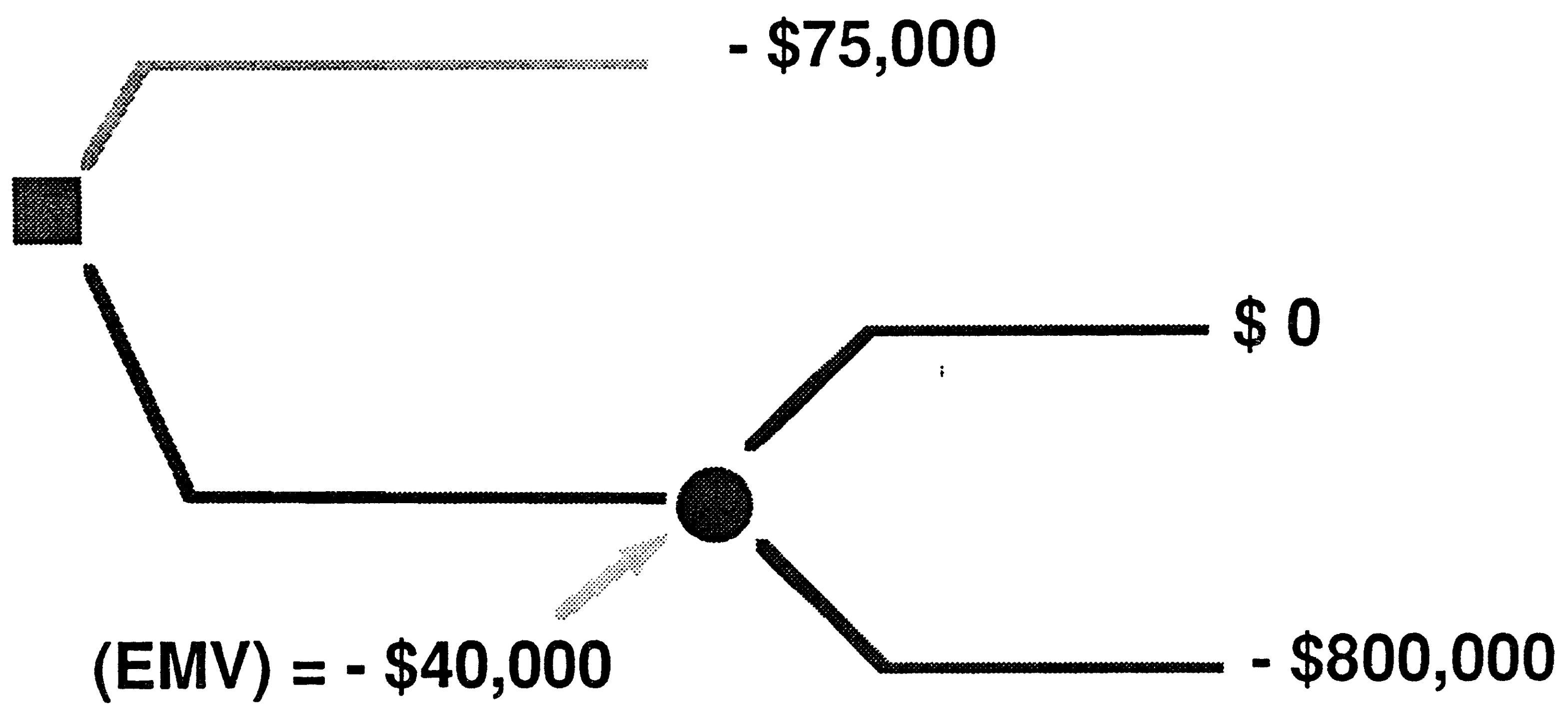
# Decision Analysis

- Decision making under uncertainty
  - Model the problem
  - Ascertain Preferences - Risk Averse, Neutral, Prone
  - Define uncertainty associated with outcome
  - Calculate Expected Value
  - Perform Sensitivity Analysis

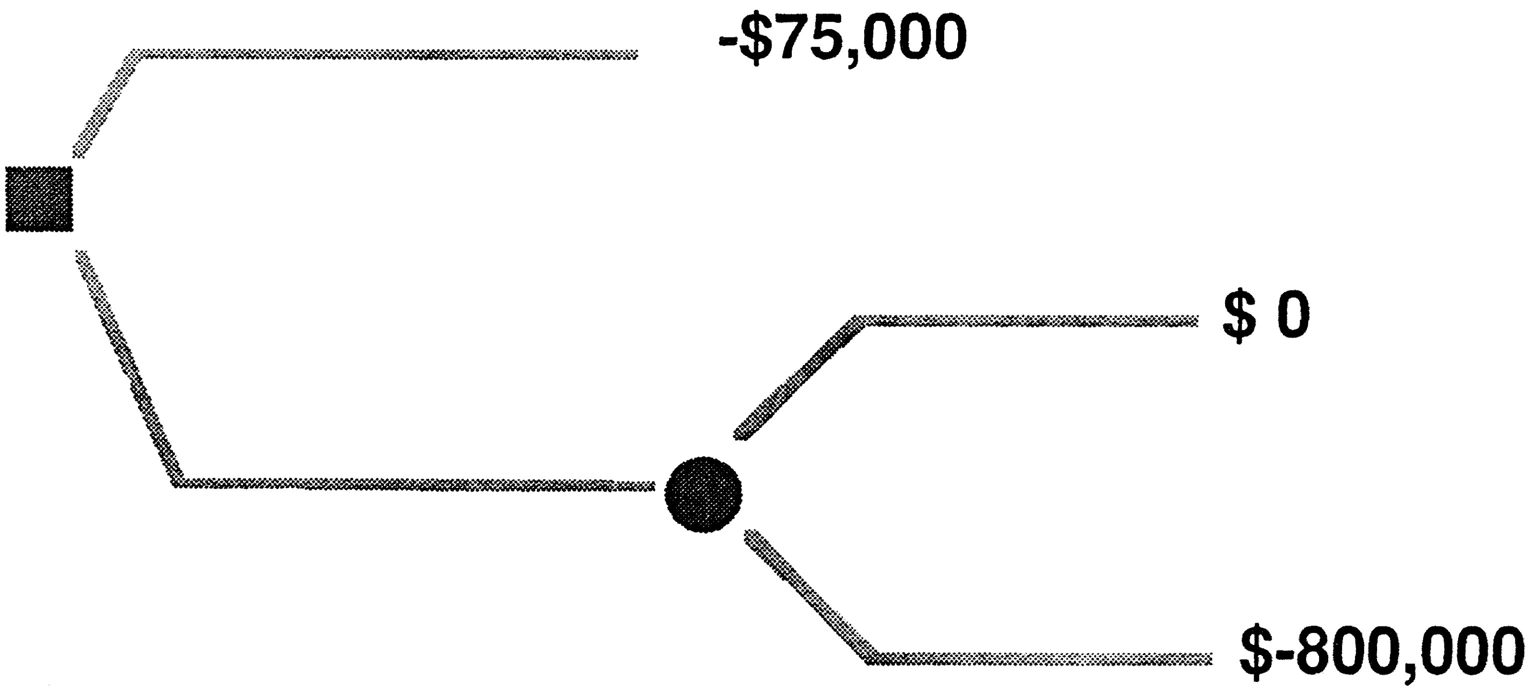
# Decision Analysis

- Uses systematic decision trees
- Decision Nodes (squares)
- Chance Nodes (circles)

# Decision Analysis



# Decision Analysis



# Expected Utility Analysis

- Instead of $ value obtain personal preferences/utility
- Use as a measure of outcome, incorporates risk tendencies
- Multi-attribute Utility Analysis

# Linear Programming

- Problems have definable objective with constraints
- Uncertainty not a large factor
- Optimize the objective function to maximize benefits and/or minimize costs

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# Decision Making tools

- Can be used to systematically model segments of the overall problem
- Should be used in conjunction with subjective, intuitive judgement

# Total Quality Environmental Management

- Leadership
- Information and Analysis
- Strategic Planning
- Human Resource Development
- QA of Environmental Performance
- Environmental Results
- Customer/Stakeholder Satisfaction

# Risk Management Goals

- Eliminate, Reduce, and Manage Risks from occupational and environmental hazards
- Be Pro-active and try to prevent risks from environmental and occupational hazards
- Recognize the importance of effective risk communication/public participation

# RISK COMMUNICATION

# Seven Cardinal Rules of Risk Communication

- Accept and involve the public as a legitimate partner
- Plan carefully and evaluate your efforts
- Listen to the public's specific concerns
- Be honest, frank, and open
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- Meet the needs of the media
- Speak clearly and with compassion

ATTACHMENT 9-2

# THE RISK ANALYSIS PROCESS IN ENVIRONMENTAL DECISION MAKING

**For**

**The Fourth National Symposium And Trade Exhibition**

**On**

**Health Care Safety And The Environment**

Orlando, Florida

Presented by:

Jan Z. Temple, Ph.D.
Medical University of South Carolina
Department of Environmental Health Sciences
171 Ashley Avenue
Charleston, SC 29425-2701

February 14, 1994

Environmental professionals are faced with complex challenges as they contend with human health effects associated with exposures to toxic substances. These challenges include the many potential toxic sources, the severity of and/or the paucity of information regarding the health effects of many agents, the many sources of uncertainty, and the emotional and financial issues related to such exposures. Often the environmental professional has not been trained or is not familiar enough with these issues regarding risk to deal with them in a confident and competent manner.

The Medical University of South Carolina's (MUSC's) Environmental Hazard Assessment Program is involved in numerous research, education, and public outreach in risk. Emphasis is to (1) stress the impacts of human health as environmental risk decisions are made and (2) bring health care professionals to the environmental field. Emphasis for this presentation will be placed on the professional development series designed to provide the environmental professional with background information to enhance their competency in handling environmental risk problems. The objectives of this program are to improve the environmental professional's understanding of risk principles, risk in decision-making, and risk communication. Improvement in these areas should lead to more efficient and acceptable risk management decisions. As environmental regulations increase, the health care community not only needs to abide by such laws, they often can serve in vital roles to society.

An important piece of information needed for valid risk management decisions is an indication of the amount of risk a particular site poses to the public. The degree to which a waste site threatens human health will vary from different sites for many reasons. For example, risks will vary according to the types of substances present and their concentrations; the degree of contaminant containment and the condition of containment vessels; the potential for substance release off-site; the physical, soil, and hydrologic characteristics of the site; and proximity of human populations to a site. A great deal of information is needed to determine the amount of risk a particular site poses to humans. The collecting and interpreting of this information is called risk assessment.

Risks assessments are an integral part of **risk analysis.** Risk analysis is a discipline used to determine environmental and human health problems associated with various activities and substances, compare the effectiveness of remediation technologies, select sites for potential hazardous facilities, and set management priorities (Cohrssen and

Covello, 1981). Along with risk assessment, risk analysis is comprised of risk management and risk communication.

Risk assessments are important because they provide a perspective of the size of the risk a site presents to human health. This information can be used along with other input to determine what should be done about a waste site -- e.g., no action, emergency action, remedial action. Such decisions should not be made lightly as cleanup of hazardous waste sites are expensive and not cost-effective if the site poses little-to-no threat to humans or the environment. Conversely, the site may adversely affect human health and/or the environment if cleanup is required, but not implemented.

The risk assessment process can also be applied to help choose remediation alternatives. The amount of risk a site poses on humans after the application of a particular remediation method can be evaluated. This evaluation will allow a technology's effectiveness to be assessed on a health risk basis.

Furthermore, the extensive information gathered in risk assessment is beneficial in helping environmental professionals communicate health risks related to a site. For example, the risk assessment process gathers information about the identities of chemicals present, their concentrations, and their health effects. Information is also gathered about the pathways that people can become exposed to chemicals, information which may be used to describe how a person may lower their risks for chemical exposures. There also may be specific subpopulations at greater risk for contaminant exposures, subgroups which will be identified in the risk assessment.

Therefore, environmental professionals involved with hazardous waste site remediation and/or environmental restoration need to understand the role of risk analysis and particularly risk assessment for several reasons. First, such an understanding will provide a rationale for their actions related to hazardous waste remediation/environmental restoration. Second, health risks are becoming an important factor in choosing control methods for environmental hazards. Thirdly, environmental professionals increasingly must interact and explain environmental issues to a keenly aware public.

## RISK MANAGEMENT

Risk is the probability of an adverse event occurring as a result of a hazard. A hazard is a potential cause of an adverse effect. For example, an icy road may be a hazard, while a risk is the chance of a car accident occurring as a result of the icy road. Objectively evaluating the magnitude of a risk is the goal of risk assessment. As previously mentioned, risk assessment is a valuable tool for estimating the magnitude of risks to people and the environment at a hazardous waste site. It is, however, just one important piece of information which is incorporated into risk management decisions at hazardous waste sites. Where risk assessment allows us to understand the *size* of the risk, risk management is the process of making decisions to *control* those risks.

A more formal definition of Risk Management follows:

Environmental Protection Agency (EPA) defines Risk Management as....

*"the decision making process that uses the results of risk assessment to produce a decision regarding environmental action. Risk Management includes consideration of technical, scientific, social, economic, and political information" (EPA, 1989a).*

As important environmental risks are identified they must then be controlled or managed so as to reduce significant risks to human health or the environment. Setting goals for risk reduction and determining options for control and remediation of risks are important decisions managers must make. Environmental Risk Management is the process by which those decisions are made.

There are many different types of decisions that are made by risk managers regarding cleanup of a hazardous waste site.

Risks

- Public
  What are the public health risks prior to site remediation, during remediation, after remediation?
- Workers
  What are the risks to workers employed to clean up a site during and after remediation? What about risks to workers who transport the waste?

- Ecosystems/Environment
  What are the ecological risks prior to, during, and after site remediation? To what extent will the ecological welfare be considered in remediation decisions?

Laws & Regulations

- What are the laws, regulations, and guidance that govern the cleanup of a site? What will the involvement be of Federal, State and Local agencies as well as potentially responsible parties?

Remediation Goals and Alternatives

- What are the remediation goals? How "clean" should the site be? How will goals be set for cleanup? Will they be based on technological standards, health standards, or risk information?
- How will remedial alternatives be selected and what are the criteria for choosing one remedial alternative over another?
- What type of remediation alternatives are available? What are the costs associated with different remediation alternatives and what health risks are associated with each alternative? What is the feasibility of the alternatives? The efficiency? Should state-of-the-art technologies be considered? How can different technologies be combined for an optimal solution?
- Should institutional controls be implemented? If yes, what type?

Public/Stakeholder Participation and Social/Political concerns

- Who are the stakeholders who will become involved with the decisions?
- What will be the involvement of stakeholders in the decisions to be made surrounding cleanup?
- How will the public be enjoined to participate in the decisions? How will their input affect the decisions?
- Who will meet with the public to discuss the decisions? Are they effective communicators?
- What type of media attention will there be?
- What is the political culture? Are there any strong public interest groups?

Other concerns

- What will the site be used for in the future? Who will be involved in making this decision?
- Who will pay to clean up the site?
- Are your decisions ethical and equitable?
- Are your decisions defensible?

These questions have no simple answers. Making a risk management decision involves incorporating the input from a number of different factors. These factors are depicted diagrammatically in Figure 1.

**Figure 1**

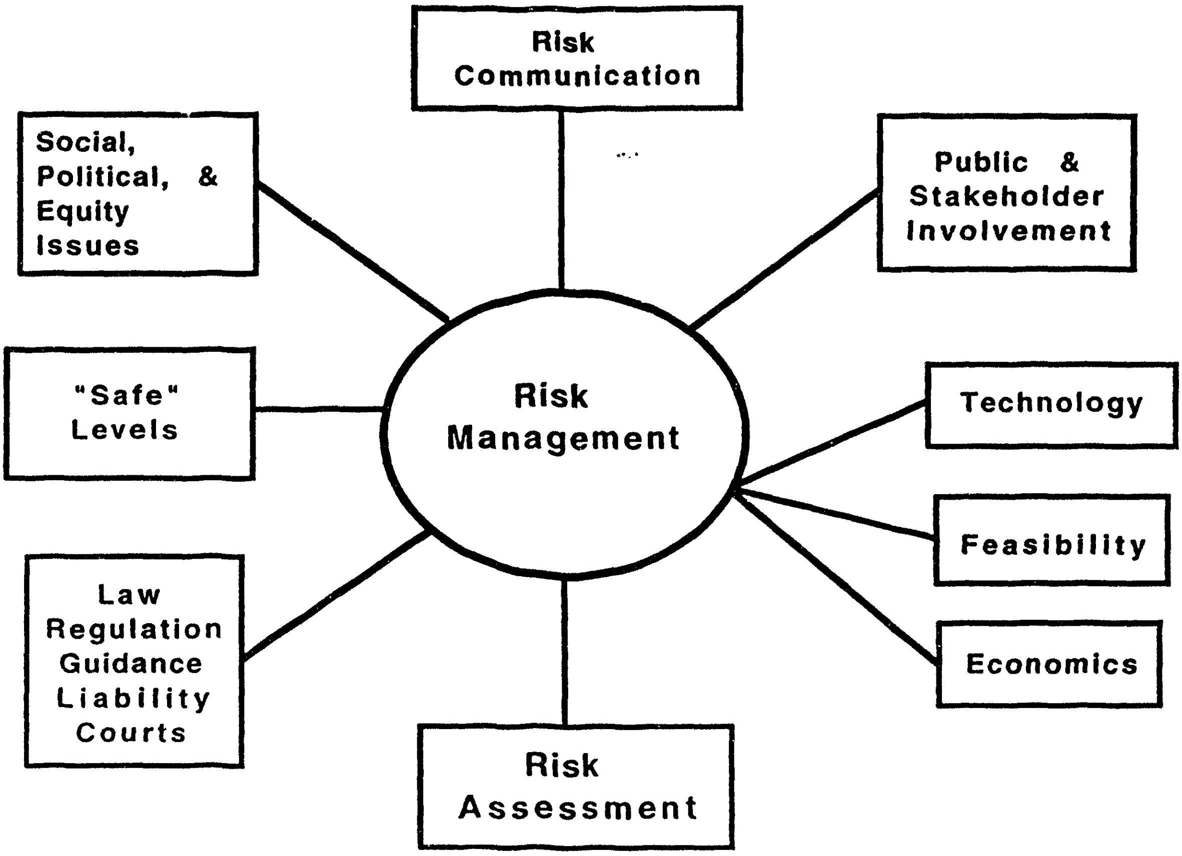



Figure 1 is a simplified diagram showing the inputs which are typically considered as part of a risk management decision. The factors which should be considered in the management decisions involved in selecting remedial alternatives include: the feasibility (both economic and technological), economics (evaluating costs and benefits), and available control technology; protection goals ("safe" levels); social and political factors; public interests, public concerns, and public and stakeholder involvement; laws, regulations, guidance, liability issues and court decisions; risk communication; and human health and ecological risk assessment information. Keep in mind, these inputs are not mutually exclusive as depicted, instead, they are strongly inter-related. One input may have a great impact on another, or many others. For example, the social and political culture of a society can greatly affect public

involvement. Consider the opportunity for public involvement in a dictatorship vs. a democratic political system.

In some instances, one of these factors may out-weigh all others and the decision will be obvious. In many instances, however, the decision will be much more difficult. The factors will need to be weighed and assigned importance by all those involved in making the decision, as well as those affected by the decision.

## RISK COMMUNICATION

> ***"IF WE THINK (THE PEOPLE) ARE NOT ENLIGHTENED ENOUGH TO EXERCISE THEIR CONTROL WITH A WHOLESOME DISCRETION, THE REMEDY IS NOT TO TAKE IT FROM THEM, BUT TO INFORM THEIR DISCRETION."***
>
> **THOMAS JEFFERSON**

In response to increased public concerns about health and environmental risks, business, industry, and government are recognizing the need to improve the means and methods for communicating risk information to stakeholders and enjoin them in the decision making process. Knowledge and skills in risk communication are no less important for effective performance and results, than knowledge and skills in risk assessment. Facts do no speak for themselves. Facts must be presented and communicated effectively if they are to be understood and acted upon in an appropriate manner. Audiences must be understood, concerns validated, mores valued, and trust and credibility established.

Risk communication is an important part of risk analysis that until recently has received little scientific attention (Covello et al., 1989). Risk assessors have believed that if scientific information was provided to the public, that the public would make the appropriate decision. Evidence proves otherwise, as there is ample evidence that communication of risk is considerably more involved than the simple statement of scientific facts (Pavlova and Liftig, 1988: McNeil et al., 1989). Numerous studies have indicated that the public perceives certain human activities as considerably more hazardous than the actual risk indicated and overestimates the incidence of some risks (Slovic et al,1980: Von Winterfeldt et al., 1981).

Three mile island, Agent Orange, Bhopal, Chernoble and AIDS are issues that received strong public and media reaction to different health "crisis". The psychological, economic, and sociopolitical impacts of such crisis have brought to light inadequacies in communication that demand the serious attention of all concerned (Covello et al., 1983). One must recall that there are in excess of six million chemicals in existence, with EPA having compiled in the Integrated Risk Information System (IRIS) toxicological information for only approximately 400 substances. This causes uncertainty as a prevalent factor to contend with in most environmental health risks. Such new and/or unfamiliar types of hazards coupled with public confusion and apprehension, demands attention be given to risk communication.

**Definitions Germane to Risk Communication:**

Risk Communication:

The process by which information is exchanged among interested parties regarding:

- Levels of health or environmental risks
- The significance or meaning of such risks
- Actions and policies aimed at managing or controlling risks

**Goal of Risk Communication:** To produce an involved, informed, interested, and fair-minded public, so that public opinions and concerns will be (or remain) reasonable, thoughtful, calm, solution-oriented and collaborative.

Risk communication occurs when trying to alert individuals or reassure them. Objectives or intended effects of communication concentrate on:

- Information and education
- Behavior change and protective action
- Disaster warnings and emergency information
- Joint problem solving and conflict resolution

**Principles of Risk Communication**

1. Trust and Credibility:

    - Credibility--able to be believed, worthy of reliance or confidence as to truth and correctness.
    - Trust--assured reliance on the character, ability, strength or truth of someone; to place confidence; integrity, veracity, justice, etc. of another.

Factors that influence the perceptions of trust and credibility: caring and empathy, competence and expertise, honesty and openness, dedication and commitment.

2. Understand your audience:
   Always aim your risk communications at the concerns and information needs of a specific target audience. Their perception of the risk may be very different than yours. Your understanding of their values and mores will enhance your ability to communicate. Your ability to read an audience will assist you in focusing on direct and indirect leaders, special interest groups, and the underrepresented. Concentrate on factors that will enhance your credibility to them.

3. Communication skills
   Three equations are often associated with risk communication:

   a) P = R
      The first equation indicates that perceptions <u>are</u> realities. What is perceived as real <u>is</u> real in its consequences. Taking time to understand ones audience must be planned.
   b) C = S
      Communication is a skill that is a product of knowledge, preparation, training and practice.
   c) G = T + C
      The goal of risk communication must be to establish trust and credibility. Dissemination of facts, receptivity to information, and education occur <u>after</u> trust is in place.

**Problems in Addressing Risk Concerns are as Follows:**

1) The cause-effect relationship is not clear for many of today's risks. Exposure to a toxic agent may have no side effects until years or decades later. In any exposed individual, there may be other contributing factors to disease onset, a situation which confounds disease occurrence and toxicant exposure analyses.

2) The subject of scientific debate often leads to public confusion. With uncertainty being a given in many situations, scientific controversy is usually inevitable if not desirable, however, the public is often not able to interpret or justify the merits of opposing views. Extreme views tend to capture attention, particularly those that magnify projected risks. When such views, irrespective of their scientific

merit, challenge those of responsible authorities, the credibility of the latter suffers.

3) No risk is acceptable if it is readily avoidable or if no benefit is to be gained by taking the risk. To interpret and judge a risk properly, the risk must be considered in the context of relevant risk-benefit relationships, taking into account not only the risk in itself and the presumed benefits to be gained by taking the risk, but also the risks and benefits of alternative courses of action. This is further complicated by social, philosophical, ethical, and economic questions, since the risks and benefits may not be distributed equitably and since individuals often differ in their attitudes toward both risks and benefits.

4) Acceptability of a given risk is affected by the extent to which it is perceived to be involuntary, unfamiliar, catastrophic, uncontrollable, and scientifically uncertain.

5) Too often risk communication occurs in a reactionary mode with involved parties already on the defensive. Learned skills in effective risk communication are needed by environmental professionals, administrators, health care professionals, regulators, and other involved individuals to integrate a communication process in their work environment.

## Seven Cardinal Rules of Risk Communication

- Accept and Involve the Public as a Legitimate Partner
- Plan Carefully and Evaluate Your Efforts
- Listen to the Public's Specific Concerns
- Be Honest, Frank, and Open
- Coordinate and Collaborate with Other Credible Sources
- Meet the Needs of the Media
- Speak Clearly and with Compassion

## Conclusion

Effective risk communication is a complex art and skill that requires training and practice to attain the knowledge, attitude, and skills necessary to successfully and genuinely address stakeholder's concerns in environmental health risks and related risk management decisions.

EPA's recent Risk Management Program Rule (RMP) under the Clean Air Act (CAA) of 1990 is aimed at protecting workers and communities from accidental releases of pollutants from industrial facilities. OSHA's process Safety Rule promulgated in February 1992 requires facility managers to share hazard and risk information with workers; the RMP rule will require managers to disclose information and plans to the public. These two regulatory actions reinforce the need for enhanced competencies in understanding and applying Risk Assessments, Risk Management, and effective Risk Communication.

## REFERENCES


Cohrssen, J.J., and Covello, V.T. (1989). Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks. Executive Office of the President of the United States, Washington, DC, National Technical Information Service.

Covello, V., and Allen, F. (1988). Seven Cardinal Rules of Risk Communication. Washington D.C.: US Environmental Protection Agency, Office of Policy Analysis.

Covello, V.D., Von Winterfeldt, and Slovic, P. (1987). Communicating Risk Information to the Public. In J.C. Davies, V. Covello, and F. Allen. (Eds). Risk Communication. Washington D.C.: The Conservation Foundation.

Covello, V.T., McCallum, D.B., & Pavlova, M.T. (Eds.). (1989). Effective Risk Communication: The Role and Responsibility of Government. New York: Plenum Press.

Davies, J.C., Covello, V.T., and Allen, F.M. (1987). Risk Communication. Washington D.C.: The Conservation Foundation.

Environmental Protection Agency. (1988). Environmental Progress and Challenges: EPA's Update. U.S. EPA-230-07-88-033.

Environmental Protection Agency (EPA) (1989a). Glossary of Terms Related to Health, Exposure, and Risk Assessment. Air Risk Information Support Center Research Triangle Park, North Carolina. EPA/450/3-88/016

Environmental Protection Agency (EPA). (1989). The Toxics Release Inventory: A National Perspective. (Health Risk Communication). Washington D.C: U.S. Environmental Protection Agency, Office of the Toxic Substances, Economics and Technology Division: For sale by the Supt. of Docs., U.S. G.P.O.

Environmental Protection Agency (EPA). (1990). Hazardous Substances in our Environment: A Citizen's Guide to Understanding Health Risks and Reducing Exposure. EPA 230/09/90/081.

Environmental Protection Agency. (1989). Risk Communication About Chemicals in Your Community: Facilitator's Manual and Guide. EPA/230/09-89-067.

EPA(1989b). Risk Assessment Guidance for Superfund VOL 1: Human Health Evaluation Manual (Part A) US Dept of Commerce.

EPA (December, 1991a) Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (Part B Development of Risk-based Preliminary Remediation Goals) Interim Office of Emergency and Remedial Response, USEPA

EPA (December, 1991b) Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (Part C Risk Evaluation of Remedial Alternatives) Interim Office of Emergency and Remedial Response, USEPA

Ferguson, M.A., & Valenti, J.M. (1991). Communicating with Environmental and Health Risk Takers: An Individual Differences Perspective. *Health Education Quarterly*. 18 (3), p303-18.

Hadden, S.G. (1989). A Citizen's Right to Know: Risk Communication and Public Policy Boulder: Westview Press.

Hance, B.J., Chess, C., & Sandman, P.M. (1988). Improving Dialogue with Communities: A Risk Communication Manual for Government. New Burnswick, NJ. Environmental Communication Research Program, Cook College, Rutgers University.

Jonsen, A.R. (1991). Ethical Considerations and Responsibilities when Communicating Health Risk Information. *J. clin. Epidermiol*. 44 (suppl. I), p69S-72S.

Krimsky, S., & Plough, A. (1988). Environmental Hazards: Communicating Risks as a Social Process. Dover, Mass.: Auburn House.

Ruckelshus, W.D. (1987). Communicating About Risk. In J.C. Davies, V.T. Covello, and F.W. Allen (Eds.). Risk Communication. p3-9. Washington DC: The Conservation Foundation.

Sandman, P.M. (1986). Explaining Environmental Risk: Some Notes on Environmental Risk Communication. Washington, DC: TSCA Assistance Office, U.S. Environmental Protection Agency.

Sandman, P.M. (1993). Responding to Community Outrages: Strategies for Effective Risk Communication. Fairfax, VA: American Industrial Hygiene Association.

Upton, A.C. (1986). Communicating with the Public on Health Risks. In, National Institute of Environmental Health Sciences Report, Human Health and the Environment: Some Research Needs. Report of the Third Task Force for Research Planning in Environmental Health Sciences. (p335-43). NIH Publication No. 86-1277. Washington, D.C.: U.S. Government Printing Office.

## COMPETENCIES NEEDED BY ENVIRONMENTAL MANAGERS

1. Understand the risk Analysis Process and role in environmental decision making.

2. Understand the role of risk assessment and its function in the Risk Analysis process.

3. Implement Risk Management decisions that place emphasis on human health risks while reviewing engineering solutions.

4. Acknowledge values and implement public participation in environmental decision making.

5. Effective Risk Communication skills.

6. Be familiar with tools used in the decision making process to include Cost Benefit Analysis, Cost Effective Analysis and Decision Analysis.

# The Risk Analysis Process
# Environmental Decision Making

**Fourth National Symposium and Trade Exhibition on**
**Health Care Safety & The Environment**
**February 14, 1994**


**Jan Z. Temple, PhD**
Chairman Department of Environmental Health Sciences
College of Health Professions
Medical University of South Carolina
803-792-5315

# The Environmental Hazards Assessment Program Is An Initiative To Engage Health Care Professionals In Helping Solve The Environmental Problems Our Nation Faces

# Through Education, Research, and Service

# The Medical University of South Carolina (MUSC)

- First Medical School in the South (1824)
- University Status in 1969
- ~2,300 Students - 700 Degrees Each Year
- Over 7,000 Employees
  - 845 Full
  - 1,600 Part-Time Teaching Faculty
  - 2nd Largest Employer in the Charleston Area
- 6 Colleges:
  - Medicine, Pharmacy, Nursing, Graduate Studies, Health Professions, Dental Medicine
- MUSC Medical Center
  - 585 Beds in 4 Hospitals
  - 2 Outpatient Facilities

# EHAP Functions and Goals

- Establish Info Center for Toxicology and Risk Data
- Research Initiative in Risk Assessment and Health Impacts
- Assessment Team to Evaluate Specific Sites
- Graduate and Post-Doctoral Education
- Mid and Upper-Level Managers Training in Environmental Risk Management
- Public Outreach Program

# The Major Thrust of EHAP is Education Information, and Interaction.

- Finding Ways to Engage the Institution, Faculty, Staff, Students, and Practicing Health Care Professionals
- In Environmental Hazards Assessment
- Focused on Integrated, Risk-Based Decision-Making

(The Common Ground)

# The Program Efforts

## Planning & Administration

## Education Initiatives

- Ph.D. and M.S. Programs
- Health Care Professionals - Outreach
- Management/Worker Training

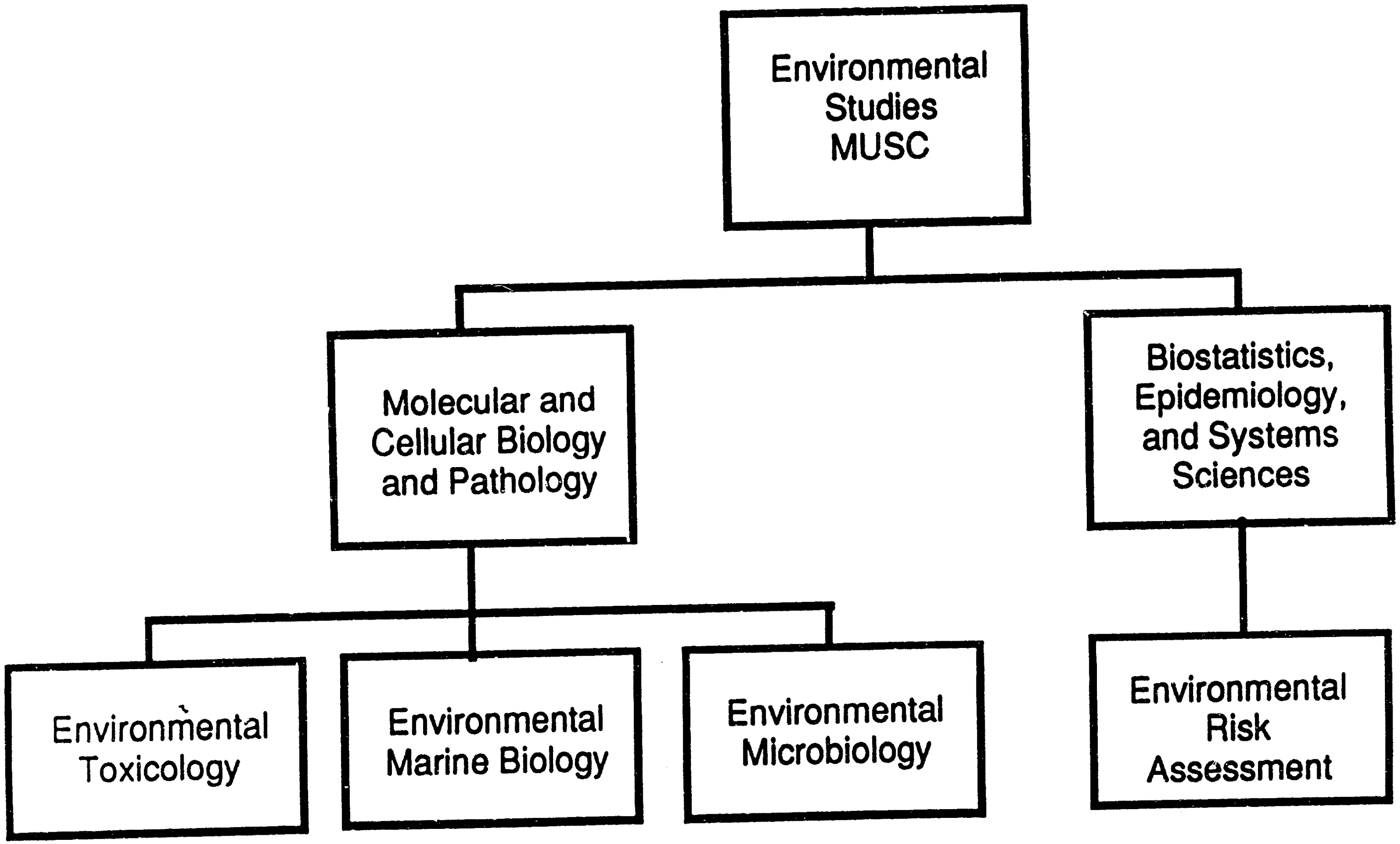
## Information System

- Linking/Accessing Data Bases Worldwide
- Developing New Data Bases

## Targeted Research Program

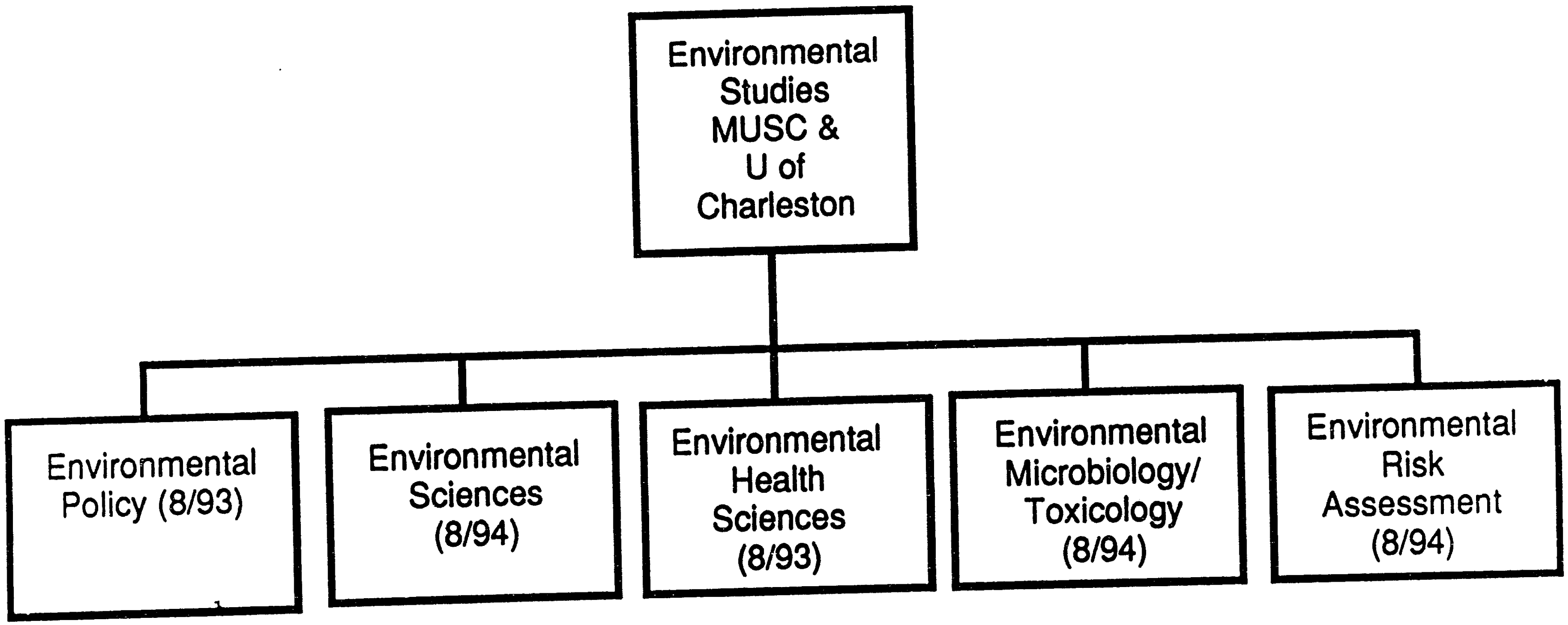
- Integrated Risk Assessment
  - Toxicology
  - Microbiology

# Doctoral Programs



MUSC Environmental Hazards Assessment Program

# Masters Programs



# Task V Goals

Comprehensive Education and Training Program in Environmental Risk Management

# Task V

- Literature Search
- Needs Assessment
- Surveys
- Professional Development S

# Environmental Health Science Professionals (Applied)*

## I. Public Service

- Air Pollution, Water Pollution, and Waste Management
- Regulatory Compliance
- Technology Integration

## II. Academic

- Environmental Management

## III. Consulting

- Business, Industry, and Government Client
- Department of Energy

*Emphasis on impact to human health

## Professional Development Series

- Concepts of Risk Analysis
- Environmental Risk Management
- Risk Communication

# Professional Development Series

- **Executive Risk Overview**
- **Occupational Risks**
- **Chemical and Ecological Risk**
- **Radiological Risk**

# Advisory Committee - Task V

## Representatives From:

- Regulatory Community
- Unions
- Public
- Business and Industry
- Department of Defense
- Department of Energy
- Medical Profession
- Education

# OUTREACH

## "Crossroads of Humanity" Series

- Integrated Risk-Based Decision-Making:
  Health, Economics, and the Environment
- Opinion Makers' Roundtable
  June 12th Taping
  To Be Aired on Educational/Public TV
- Focus Group Workshops To Study Major Issues
  Published Results
  Back to Opinion Makers

# Risk Analysis

Discipline used to determine environmental and human health problems associated with various activities and substances compare the effectiveness of remediation technologies, select sites for potential hazardous facilities, and set management priorities.

# Risk Analysis Components

- Risk Assessment
- Risk Management
- Risk Communication

# Definition of Risk

## Scientific

Probability of Adverse Effect Occurring

## Lay Person's

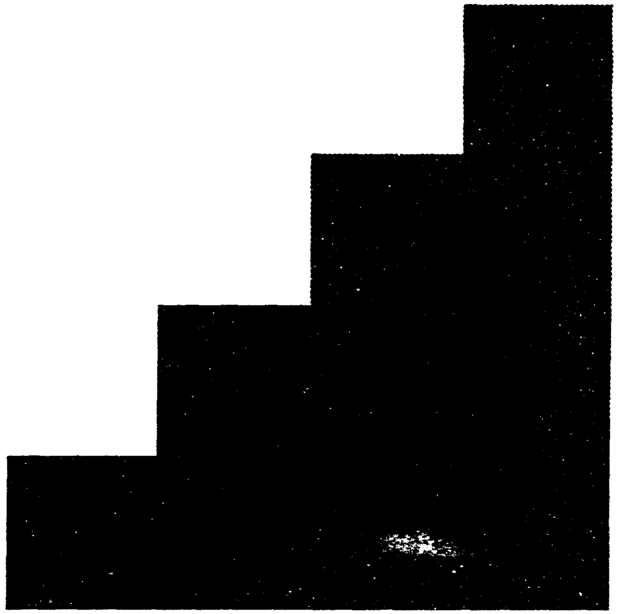
Probability of Adverse Effect + Perception

# Need for Risk Assessment

## Provides

- Objective
- Scientific

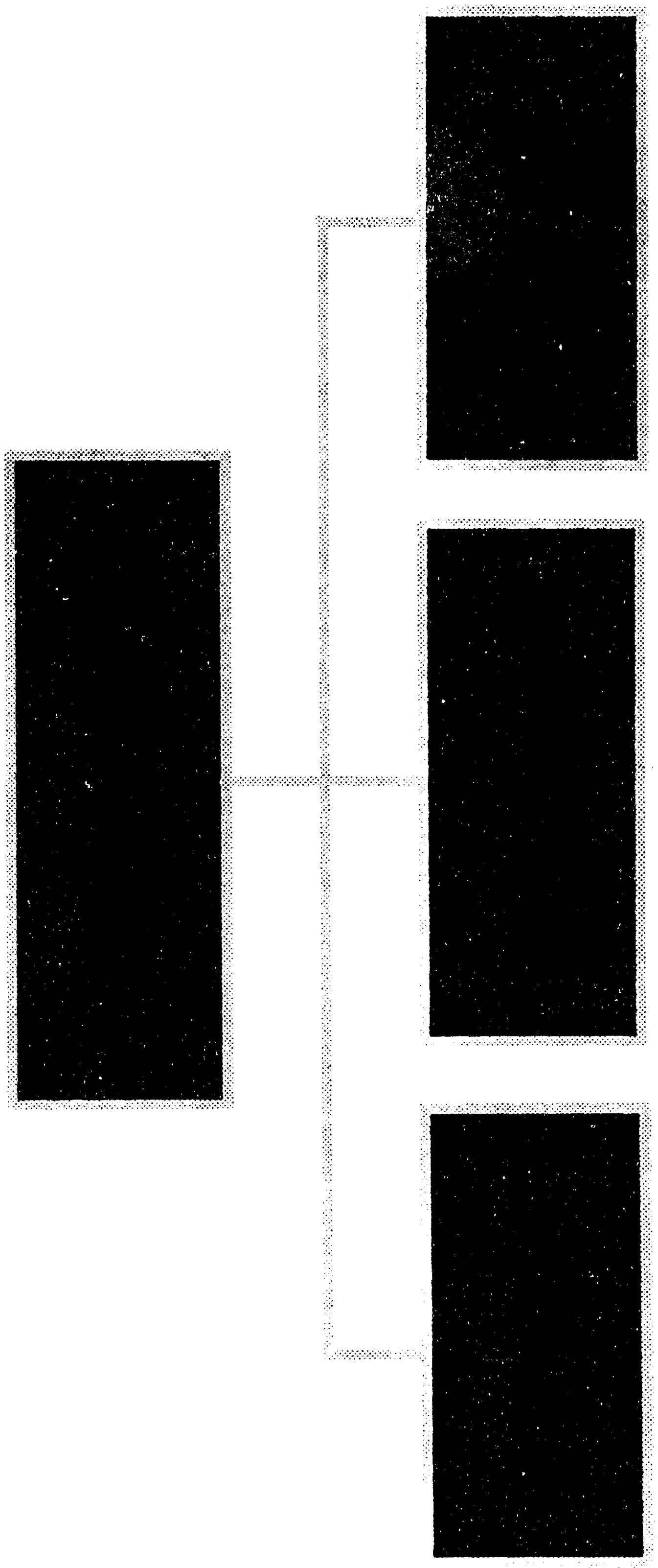
## Risk Information



# Risk Assessment

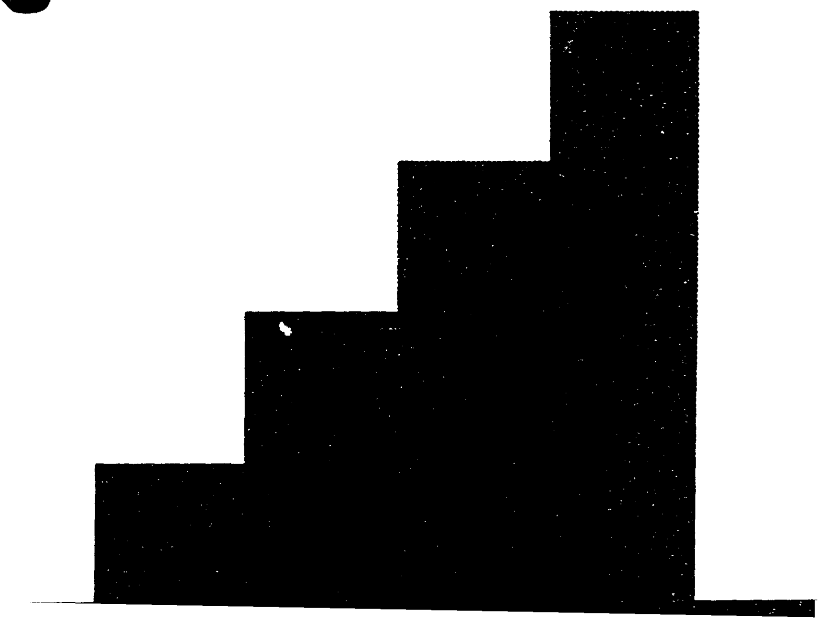
## Definition

**An Evaluation of the Potential Adverse Impact of a Given Event Upon the Well-Being of a Person or a Populatio**



# RA Use: Risk Management

- Is There a Problem?
- Prioritizing Risks
- Who Is At Risk?



# RA Use: Risk Communication

## Helpful in Explaining

- Hazards (Harmful Conditions)
- Sources
- Health Effects

# Steps for Risk Assessment

1. Hazard Identification
2. Dose-Response
3. Exposure Assessment
4. Risk Characterization

# Summary of Risk Assessment

1. Not Perfect
   - Assumptions and Uncertainties
   - Lack of Information

     Over 6,000,000 Chemicals Produced

     EPA's IRIS - Approximately 400 Chemicals

2. Multi-Discipline
3. Does Not Tell What To Do
4. Scientific & Objective Appr
   Quantify Risks

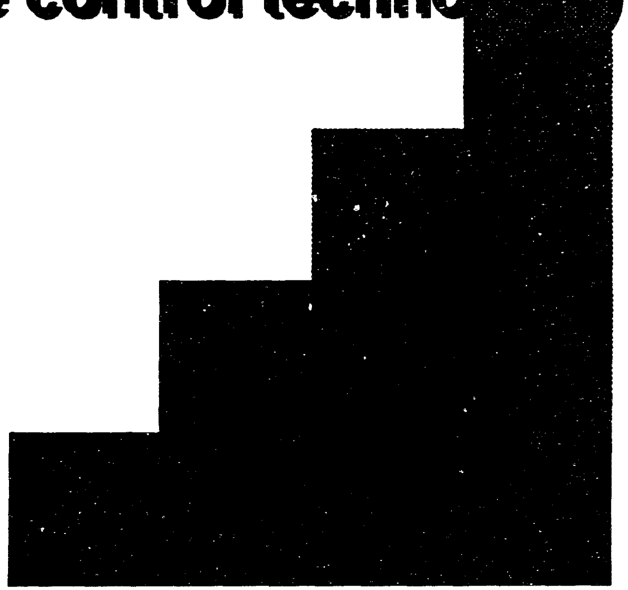
# Risk Management - Definition

The decision making process that uses the results of risk assessment to produce a decision regarding environmental action. Risk management includes consideration of technical, scientific, social, economic, and political information.

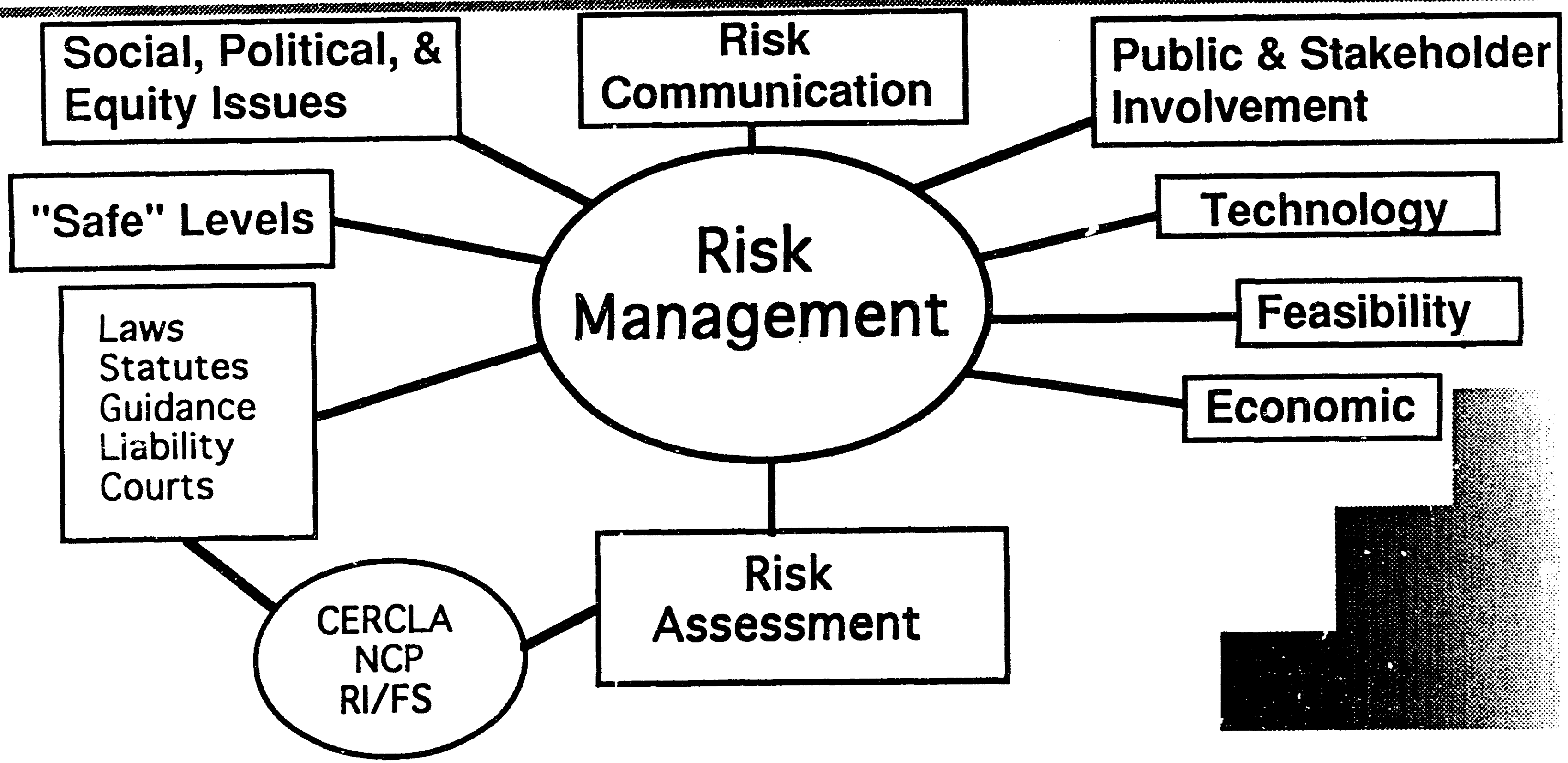
(EPA 1989)

# Decision Making Process

- Human Health Risk Assessment Information
- Ecological Risk Assessment Information
- Economics (costs and benefits)
- Technological Feasibility (available control techno[illegible])
- Social and Political Factors
- Regulations/Laws/Guidance
- Liability



# Risk Management Decisions



# Risk Management in the Federal Government

Manage risks via legislation and rule-making

- Weigh Policy Alternatives
- Select the most appropriate regulatory action to a potential chronic health hazard
- Carried out by regulatory agencies
- Requires the use of value judgements

# RA Information Necessary for Informed Regulatory Decisions

Regarding:

- Worker Exposures
- Industrial Emissions and Effluents
- Ambient Air and Water Contaminants
- Chemical Residues in Food
- Cleanup of Hazardous Waste Sites
- Naturally Occurring Contaminants

# How do different agencies in the Federal Government address risk?

What level of risk is acceptable?

Is there a point at which risks are "de minimis"?

What is the level of uncertainty associated with the risk assessment?

Answers are subjective. Rely on "expert opinion".

# Result -
# Different Levels of Acceptable Risk

Keep in mind - Different types of risks

Examine FDA, EPA, OSHA's definition of "acceptable risk"

# FDA

1973 - First to use risk assessment for regulatory decisions

Regulation of carcinogenic drugs in food-producing animals

Acceptable Lifetime Risk of $10^{-8}$, later $10^{-6}$

1 in 100,000,000 later to 1 in 1,000,000

# EPA - Lifetime Acceptable Risk

Carcinogenic air pollutants - $10^{-5}$ to 0.001

Active ingredients in pesticides - $10^{-7}$ to 0.02

SWDA - goal for carcinogens = zero exposure

Hazardous Waste Sites - $< 10^{-6}$

# OSHA - Setting PEL's

1980 Supreme Court definition of "significant risk"

Risk of 1/1000 is significant occupational risk

Neither OSHA nor Supreme Court say what risk is "insignificant" (acceptable)

# Risk Management in the Federal Government

Nature of risks somewhat different

Do not take into account the additive or interactive effects from exposure to multiple toxicants

# Industry Perspective

Reduce and Prevent Occupational and Environmental Health Risks

Difficult/Impossible to eliminate ALL risks

Instead, Identify and Prioritize risks

Reduce/Eliminate those with greatest potential for harm first

Examine available resources, appropriate technologies, etc.

# Make Management Decisions Regarding:

Preventive Actions

Prioritize Risks

Remediation Alternatives

Control Measures

# Pro-Active Management Plan

Inventory Risks

Perform Periodic Audits

Train Workers

Allow for External Audits

Identify Risk Evaluation Methods

Identify Response Actions

Effective Risk Communication with Workers and the Public

# Hazardous Waste Site

Who will pay to clean up the site?

What government officials will be involved?

How will the public be involved in the decision making process?

Public Participation/Risk Communication

Media attention

Political Climate, Public Interest Groups, Labor Unions

# Decision Making

Are the choices you are making both ethical and equitable?

Quite often - very qualitative, subjective decisions

Value Judgements

Ideally, would like a systematic decision making tool

# Quantitative Tools for Making Decisions

Cost - Benefit Analysis

- Convert costs and benefits into dollar values
- Evaluate options on net benefit($)
- Human Capital Principle
- "What is an efficient policy?"

# Decision Making Tools

Cost - Effectiveness Analysis

"What is the most effective way to spend a fixed budget?"

Compares Cost Effectiveness Ratios...$/life saved

Cost - Utility Analysis

Special form of CEA

costs/QUALY

Subjective judgement is included here

# Decision Analysis

Model Decisions with

- Numerous Alternatives
- Uncertain consequences
- Multiple dimensions of value (cost, happiness, risk reduction)

# Total Quality Environmental Management

Leadership

Information and Analysis

Strategic Planning

Human Resource Development

QA of Environmental Performance

Environmental Results

Customer/Stakeholder Satisfaction

# Risk Management Goals

Eliminate, Reduce, and Manage Risks from occupational and environmental hazards

Be Pro-active and try to prevent risks from environmental and occupational hazards

Recognize the importance of effective risk communication/public participation

**If We Think [the People] are not Enlightened Enough to Exercise Their Control with a Wholesome Discretion, the Remedy is not to take it From Them, but to Inform Their Discretion.**

**Thomas Jefferson**

# Definition of Risk Communication

The Process by Which Information is Exchanged Among Interested Parties Regarding:

- Levels of Health or Environmental Risks
- The Significance or Meaning of Such Risks
- Actions and Policies Aimed at Managing or Controlling Risks

# Goals of Risk Communication

Should Produce an Involved, Informed, Interested, and Fair-Minded Public, so That Public Opinions and Concerns will be (or Remain) Reasonable, Thoughtful, Calm, Solution-Oriented and Collaborative.

# Principles of Risk Communication

- Trust & Credibility
- Understand Audience
- Communication Skills

# Risk Communication Components

1. Alerting People
2. Reassuring People

# Interested Parties

- Industry
- Regulators
- Elected Officials
- Activists
- Employees and & Retirees
- Neighbors
- Concerned Citizens
- Experts
- The Media
- Others

# Two Factors Affect the Way People Assess Risk and Evaluate Acceptability

a) The level or risk is only one among several variables that determines acceptability (other variables that matter are fairness, benefits, alternatives, control, and voluntariness.)

b) Deciding what level of risk ought to be acceptable is NOT a technical question but a value question. (People vary in how they assess risk acceptability - they weigh factors according to their own values, sense of risk, and stake in the outcome.)

# Factors Affecting Risk Acceptability

**Understanding the distinction between risk and risk acceptability is critical to overcoming mistrust and communicating effectively**

# Experts Perception

# vs

# Public Perception

# Experts Define Risk

## Magnitude X Probability = Hazard

**Magnitude:** How bad it is when it happens

**Probability:** How likely is it to happen

# Public Define Risk

Strong emotion (outrage) that is justified

# Outrage Factors

- Is it Voluntary or Coerced?
- Is it Natural or Industrial?
- Is it Familiar or Exotic?
- Is it Not Memorable or Memorable?
- Is it Not Dreaded or Dreaded?
- Is it Chronic or Catastrophic?

# Outrage Factors

- Is it Knowable or Not Knowable?
- Is it Controlled by Me or by Others?
- Is it Fair or Unfair?
- Is it Morally Irrelevant or Morally Relevant?
- Can I Trust You or Not?
- Is the Process Responsive or Unresponsive?

# Outrage Factors

- Effect on Vulnerable Populations
- Delayed vs. Immediate Effects
- Effect on Future Generations
- Identifiability of the Victim
- Elimination vs Reduction
- Risk-Benefit Ratio
- Media Attention
- Opportunity for Collective Action

**The Public Often Misperceives the hazard. The Experts often Misperceive the Outrage. But the Overarching Problem is that the Public Cares too little about the Hazard, and Experts care too little about the Outrage.**

# The Solution

- Take public outrage as seriously as hazard
- Keep them separate.

# No Risk Comparison Will be Successful if it Appears to be Trying to Settle the Question of Whether a Risk is Acceptable

**Your Job as a Consultant is NOT to Tell the Public About What They Should Accept, but Instead to Tell Them About the Size of the Risk Your Operation Entails.**

# Seven Cardinal Rules of Risk Communication

- Accept and involve the public as a legitimate partner
- Plan carefully and evaluate your efforts
- Listen to the public's specific concerns
- Be honest, frank, and open
- Coordinate and collaborate with other credible sources
- Meet the needs of the media
- Speak clearly and with compassion

ATTACHMENT ~~8~~ 3

# RISK ANALYSIS
# IN
# ENVIRONMENTAL HEALTH ISSUES

**For**

**The Eleventh Annual Conference & Exposition**

**Of**

**The Environmental Information Association**

**San Diego, California**

Presented by:

Jan Z. Temple, Ph.D.
Medical University of South Carolina
Department of Environmental Health Sciences
171 Ashley Avenue
Charleston, SC 29425-2701

March 15, 1994

Environmental professionals are faced with complex challenges as they contend with human health effects associated with exposures to toxic substances. These challenges include the many potential toxic sources, the severity of and/or the paucity of information regarding the health effects of many agents, the many sources of uncertainty, and the emotional and financial issues related to such exposures. Often the environmental professional has not been trained or is not familiar enough with these issues regarding risk to deal with them in a confident and competent manner.

The Medical University of South Carolina's (MUSC's) Environmental Hazard Assessment Program is involved in numerous research, education, and public outreach in risk. Emphasis is to (1) stress the impacts of human health as environmental risk decisions are made and (2) bring health care professionals to the environmental field. Emphasis for this presentation will be placed on the professional development series designed to provide the environmental professional with background information to enhance their competency in handling environmental risk problems. The objectives of this program are to improve the environmental professional's understanding of risk principles, risk in decision-making, and risk communication. Improvement in these areas should lead to more efficient and acceptable risk management decisions. As environmental regulations increase, the health care community not only needs to abide by such laws, they often can serve in vital roles to society.

An important piece of information needed for valid risk management decisions is an indication of the amount of risk a particular site poses to the public. The degree to which a waste site threatens human health will vary from different sites for many reasons. For example, risks will vary according to the types of substances present and their concentrations; the degree of contaminant containment and the condition of containment vessels; the potential for substance release off-site; the physical, soil, and hydrologic characteristics of the site; and proximity of human populations to a site. A great deal of information is needed to determine the amount of risk a particular site poses to humans. The collecting and interpreting of this information is called risk assessment.

Risks assessments are an integral part of **risk analysis.** Risk analysis is a discipline used to determine environmental and human health problems associated with various activities and substances, compare the effectiveness of remediation technologies, select sites for potential hazardous facilities, and set management priorities (Cohrssen and

Covello, 1981). Along with risk assessment, risk analysis is comprised of risk management and risk communication.

Risk assessments are important because they provide a perspective of the size of the risk a site presents to human health. This information can be used along with other input to determine what should be done about a waste site -- e.g., no action, emergency action, remedial action. Such decisions should not be made lightly as cleanup of hazardous waste sites are expensive and not cost-effective if the site poses little-to-no threat to humans or the environment. Conversely, the site may adversely affect human health and/or the environment if cleanup is required, but not implemented.

The risk assessment process can also be applied to help choose remediation alternatives. The amount of risk a site poses on humans after the application of a particular remediation method can be evaluated. This evaluation will allow a technology's effectiveness to be assessed on a health risk basis.

Furthermore, the extensive information gathered in risk assessment is beneficial in helping environmental professionals communicate health risks related to a site. For example, the risk assessment process gathers information about the identities of chemicals present, their concentrations, and their health effects. Information is also gathered about the pathways that people can become exposed to chemicals, information which may be used to describe how a person may lower their risks for chemical exposures. There also may be specific subpopulations at greater risk for contaminant exposures, subgroups which will be identified in the risk assessment.

Therefore, environmental professionals involved with hazardous waste site remediation and/or environmental restoration need to understand the role of risk analysis and particularly risk assessment for several reasons. First, such an understanding will provide a rationale for their actions related to hazardous waste remediation/environmental restoration. Second, health risks are becoming an important factor in choosing control methods for environmental hazards. Thirdly, environmental professionals increasingly must interact and explain environmental issues to a keenly aware public.

## RISK MANAGEMENT

Risk is the probability of an adverse event occurring as a result of a hazard. A hazard is a potential cause of an adverse effect. For example, an icy road may be a hazard, while a risk is the chance of a car accident occurring as a result of the icy road. Objectively evaluating the magnitude of a risk is the goal of risk assessment. As previously mentioned, risk assessment is a valuable tool for estimating the magnitude of risks to people and the environment at a hazardous waste site. It is, however, just one important piece of information which is incorporated into risk management decisions at hazardous waste sites. Where risk assessment allows us to understand the *size* of the risk, risk management is the process of making decisions to *control* those risks.

A more formal definition of Risk Management follows:

> Environmental Protection Agency (EPA) defines Risk Management as....
>
> *"the decision making process that uses the results of risk assessment to produce a decision regarding environmental action. Risk Management includes consideration of technical, scientific, social, economic, and political information" (EPA, 1989a).*

As important environmental risks are identified they must then be controlled or managed so as to reduce significant risks to human health or the environment. Setting goals for risk reduction and determining options for control and remediation of risks are important decisions managers must make. Environmental Risk Management is the process by which those decisions are made.

There are many different types of decisions that are made by risk managers regarding cleanup of a hazardous waste site.

Risks

- Public
  What are the public health risks prior to site remediation, during remediation, after remediation?
- Workers
  What are the risks to workers employed to clean up a site during and after remediation? What about risks to workers who transport the waste?

- Ecosystems/Environment
  What are the ecological risks prior to, during, and after site remediation? To what extent will the ecological welfare be considered in remediation decisions?

Laws & Regulations

- What are the laws, regulations, and guidance that govern the cleanup of a site? What will the involvement be of Federal, State and Local agencies as well as potentially responsible parties?

Remediation Goals and Alternatives

- What are the remediation goals? How "clean" should the site be? How will goals be set for cleanup? Will they be based on technological standards, health standards, or risk information?
- How will remedial alternatives be selected and what are the criteria for choosing one remedial alternative over another?
- What type of remediation alternatives are available? What are the costs associated with different remediation alternatives and what health risks are associated with each alternative? What is the feasibility of the alternatives? The efficiency? Should state-of-the-art technologies be considered? How can different technologies be combined for an optimal solution?
- Should institutional controls be implemented? If yes, what type?

Public/Stakeholder Participation and Social/Political concerns

- Who are the stakeholders who will become involved with the decisions?
- What will be the involvement of stakeholders in the decisions to be made surrounding cleanup?
- How will the public be enjoined to participate in the decisions? How will their input affect the decisions?
- Who will meet with the public to discuss the decisions? Are they effective communicators?
- What type of media attention will there be?
- What is the political culture? Are there any strong public interest groups?

Other concerns

- What will the site be used for in the future? Who will be involved in making this decision?
- Who will pay to clean up the site?
- Are your decisions ethical and equitable?
- Are your decisions defensible?

These questions have no simple answers. Making a risk management decision involves incorporating the input from a number of different factors. These factors are depicted diagrammatically in Figure 1.

**Figure 1**

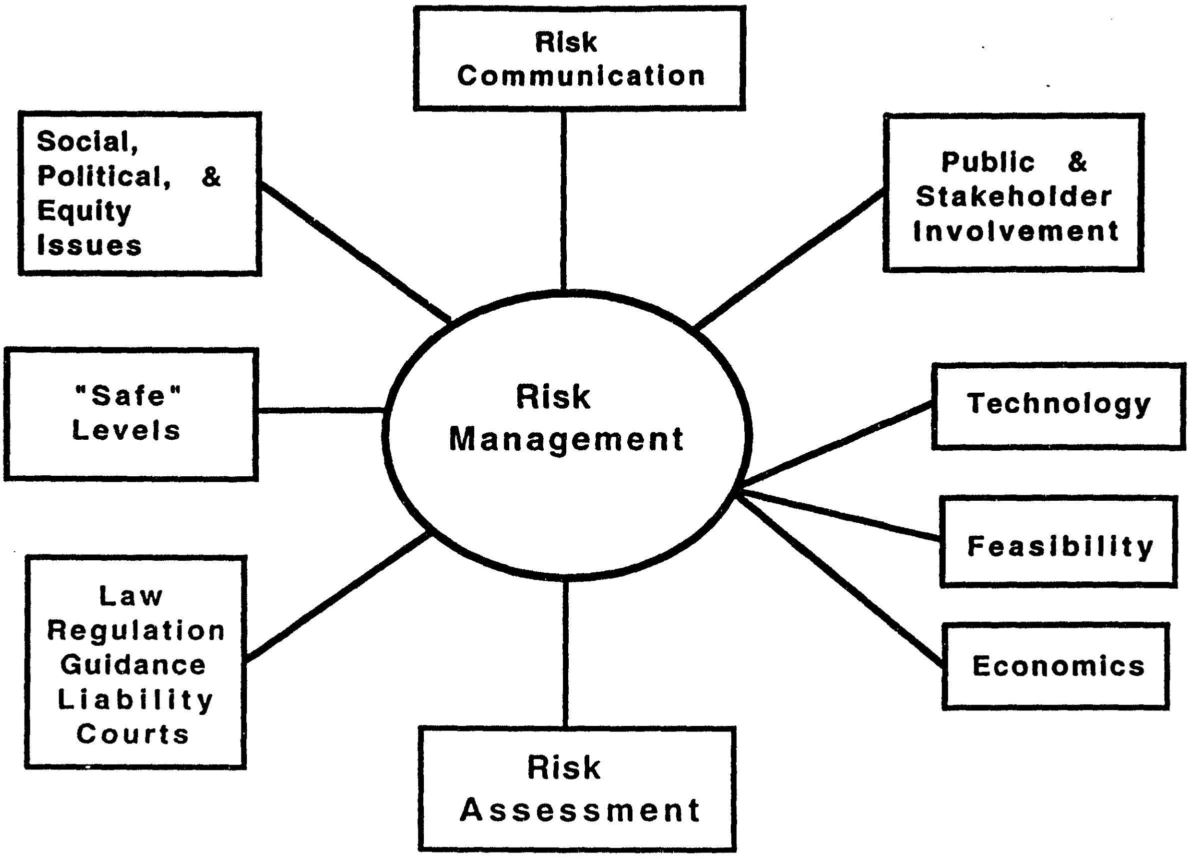



Figure 1 is a simplified diagram showing the inputs which are typically considered as part of a risk management decision. The factors which should be considered in the management decisions involved in selecting remedial alternatives include: the feasibility (both economic and technological), economics (evaluating costs and benefits), and available control technology; protection goals ("safe" levels); social and political factors; public interests, public concerns, and public and stakeholder involvement; laws, regulations, guidance, liability issues and court decisions; risk communication; and human health and ecological risk assessment information. Keep in mind, these inputs are not mutually exclusive as depicted, instead, they are strongly inter-related. One input may have a great impact on another, or many others. For example, the social and political culture of a society can greatly affect public

involvement. Consider the opportunity for public involvement in a dictatorship vs. a democratic political system.

In some instances, one of these factors may out-weigh all others and the decision will be obvious. In many instances, however, the decision will be much more difficult. The factors will need to be weighed and assigned importance by all those involved in making the decision, as well as those affected by the decision.

**RISK COMMUNICATION**

> ***"IF WE THINK (THE PEOPLE) ARE NOT ENLIGHTENED ENOUGH TO EXERCISE THEIR CONTROL WITH A WHOLESOME DISCRETION, THE REMEDY IS NOT TO TAKE IT FROM THEM, BUT TO INFORM THEIR DISCRETION."***
>
> **THOMAS JEFFERSON**

In response to increased public concerns about health and environmental risks, business, industry, and government are recognizing the need to improve the means and methods for communicating risk information to stakeholders and enjoin them in the decision making process. Knowledge and skills in risk communication are no less important for effective performance and results, than knowledge and skills in risk assessment. Facts do no speak for themselves. Facts must be presented and communicated effectively if they are to be understood and acted upon in an appropriate manner. Audiences must be understood, concerns validated, mores valued, and trust and credibility established.

Risk communication is an important part of risk analysis that until recently has received little scientific attention (Covello et al., 1989). Risk assessors have believed that if scientific information was provided to the public, that the public would make the appropriate decision. Evidence proves otherwise, as there is ample evidence that communication of risk is considerably more involved than the simple statement of scientific facts (Pavlova and Liftig, 1988: McNeil et al., 1989). Numerous studies have indicated that the public perceives certain human activities as considerably more hazardous than the actual risk indicated and overestimates the incidence of some risks (Slovic et al,1980: Von Winterfeldt et al., 1981).

Three mile island, Agent Orange, Bhopal, Chernoble and AIDS are issues that received strong public and media reaction to different health "crisis". The psychological, economic, and sociopolitical impacts of such crisis have brought to light inadequacies in communication that demand the serious attention of all concerned (Covello et al., 1983). One must recall that there are in excess of six million chemicals in existence, with EPA having compiled in the Integrated Risk Information System (IRIS) toxicological information for only approximately 400 substances. This causes uncertainty as a prevalent factor to contend with in most environmental health risks. Such new and/or unfamiliar types of hazards coupled with public confusion and apprehension, demands attention be given to risk communication.

**Definitions Germane to Risk Communication:**

Risk Communication:

The process by which information is exchanged among interested parties regarding:

- Levels of health or environmental risks
- The significance or meaning of such risks
- Actions and policies aimed at managing or controlling risks

**Goal of Risk Communication:** To produce an involved, informed, interested, and fair-minded public, so that public opinions and concerns will be (or remain) reasonable, thoughtful, calm, solution-oriented and collaborative.

Risk communication occurs when trying to alert individuals or reassure them. Objectives or intended effects of communication concentrate on:

- Information and education
- Behavior change and protective action
- Disaster warnings and emergency information
- Joint problem solving and conflict resolution

**Principles of Risk Communication**

1. Trust and Credibility:

   - Credibility--able to be believed, worthy of reliance or confidence as to truth and correctness.
   - Trust--assured reliance on the character, ability, strength or truth of someone; to place confidence; integrity, veracity, justice, etc. of another.

Factors that influence the perceptions of trust and credibility: caring and empathy, competence and expertise, honesty and openness, dedication and commitment.

2. Understand your audience:
Always aim your risk communications at the concerns and information needs of a specific target audience. Their perception of the risk may be very different than yours. Your understanding of their values and mores will enhance your ability to communicate. Your ability to read an audience will assist you in focusing on direct and indirect leaders, special interest groups, and the underrepresented. Concentrate on factors that will enhance your credibility to them.

3. Communication skills
Three equations are often associated with risk communication:

a) P = R
The first equation indicates that perceptions are realities. What is perceived as real is real in its consequences. Taking time to understand ones audience must be planned.

b) C = S
Communication is a skill that is a product of knowledge, preparation, training and practice.

c) G = T + C
The goal of risk communication must be to establish trust and credibility. Dissemination of facts, receptivity to information, and education occur after trust is in place.

**Problems in Addressing Risk Concerns are as Follows:**

1) The cause-effect relationship is not clear for many of today's risks. Exposure to a toxic agent may have no side effects until years or decades later. In any exposed individual, there may be other contributing factors to disease onset, a situation which confounds disease occurrence and toxicant exposure analyses.

2) The subject of scientific debate often leads to public confusion. With uncertainty being a given in many situations, scientific controversy is usually inevitable if not desirable, however, the public is often not able to interpret or justify the merits of opposing views. Extreme views tend to capture attention, particularly those that magnify projected risks. When such views, irrespective of their scientific

merit, challenge those of responsible authorities, the credibility of the latter suffers.

3) No risk is acceptable if it is readily avoidable or if no benefit is to be gained by taking the risk. To interpret and judge a risk properly, the risk must be considered in the context of relevant risk-benefit relationships, taking into account not only the risk in itself and the presumed benefits to be gained by taking the risk, but also the risks and benefits of alternative courses of action. This is further complicated by social, philosophical, ethical, and economic questions, since the risks and benefits may not be distributed equitably and since individuals often differ in their attitudes toward both risks and benefits.

4) Acceptability of a given risk is affected by the extent to which it is perceived to be involuntary, unfamiliar, catastrophic, uncontrollable, and scientifically uncertain.

5) Too often risk communication occurs in a reactionary mode with involved parties already on the defensive. Learned skills in effective risk communication are needed by environmental professionals, administrators, health care professionals, regulators, and other involved individuals to integrate a communication process in their work environment.

## Seven Cardinal Rules of Risk Communication

- Accept and Involve the Public as a Legitimate Partner
- Plan Carefully and Evaluate Your Efforts
- Listen to the Public's Specific Concerns
- Be Honest, Frank, and Open
- Coordinate and Collaborate with Other Credible Sources
- Meet the Needs of the Media
- Speak Clearly and with Compassion

## Conclusion

Effective risk communication is a complex art and skill that requires training and practice to attain the knowledge, attitude, and skills necessary to successfully and genuinely address stakeholder's concerns in environmental health risks and related risk management decisions.

EPA's recent Risk Management Program Rule (RMP) under the Clean Air Act (CAA) of 1990 is aimed at protecting workers and communities from accidental releases of pollutants from industrial facilities. OSHA's process Safety Rule promulgated in February 1992 requires facility managers to share hazard and risk information with workers; the RMP rule will require managers to disclose information and plans to the public. These two regulatory actions reinforce the need for enhanced competencies in understanding and applying Risk Assessments, Risk Management, and effective Risk Communication.

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## REFERENCES


Cohrssen, J.J., and Covello, V.T. (1989). Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks. Executive Office of the President of the United States, Washington, DC, National Technical Information Service.

Covello, V., and Allen, F. (1988). Seven Cardinal Rules of Risk Communication. Washington D.C.: US Environmental Protection Agency, Office of Policy Analysis.

Covello, V.D., Von Winterfeldt, and Slovic, P. (1987). Communicating Risk Information to the Public. In J.C. Davies, V. Covello, and F. Allen. (Eds). Risk Communication. Washington D.C.: The Conservation Foundation.

Covello, V.T., McCallum, D.B., & Pavlova, M.T. (Eds.). (1989). Effective Risk Communication: The Role and Responsibility of Government. New York: Plenum Press.

Davies, J.C., Covello, V.T., and Allen, F.M. (1987). Risk Communication. Washington D.C.: The Conservation Foundation.

Environmental Protection Agency. (1988). Environmental Progress and Challenges: EPA's Update. U.S. EPA-230-07-88-033.

Environmental Protection Agency (EPA) (1989a). Glossary of Terms Related to Health, Exposure, and Risk Assessment. Air Risk Information Support Center Research Triangle Park, North Carolina. EPA/450/3-88/016

Environmental Protection Agency (EPA). (1989). The Toxics Release Inventory: A National Perspective. (Health Risk Communication). Washington D.C: U.S. Environmental Protection Agency, Office of the Toxic Substances, Economics and Technology Division: For sale by the Supt. of Docs., U.S. G.P.O.

Environmental Protection Agency (EPA). (1990). Hazardous Substances in our Environment: A Citizen's Guide to Understanding Health Risks and Reducing Exposure. EPA 230/09/90/081.

Environmental Protection Agency. (1989). Risk Communication About Chemicals in Your Community: Facilitator's Manual and Guide. EPA/230/09-89-067.

EPA(1989b). Risk Assessment Guidance for Superfund VOL 1: Human Health Evaluation Manual (Part A) US Dept of Commerce.

EPA (December, 1991a) Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (Part B Development of Risk-based Preliminary Remediation Goals) Interim Office of Emergency and Remedial Response, USEPA

EPA (December, 1991b) Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (Part C Risk Evaluation of Remedial Alternatives) Interim Office of Emergency and Remedial Response, USEPA

Ferguson, M.A., & Valenti, J.M. (1991). Communicating with Environmental and Health Risk Takers: An Individual Differences Perspective. *Health Education Quarterly*. 18 (3), p303-18.

Hadden, S.G. (1989). A Citizen's Right to Know: Risk Communication and Public Policy Boulder: Westview Press.

Hance, B.J., Chess, C., & Sandman, P.M. (1988). Improving Dialogue with Communities: A Risk Communication Manual for Government. New Burnswick, NJ. Environmental Communication Research Program, Cook College, Rutgers University.

Jonsen, A.R. (1991). Ethical Considerations and Responsibilities when Communicating Health Risk Information. *J. clin. Epidermiol*. 44 (suppl. I), p69S-72S.

Krimsky, S., & Plough, A. (1988). Environmental Hazards: Communicating Risks as a Social Process. Dover, Mass.: Auburn House.

Ruckelshus, W.D. (1987). Communicating About Risk. In J.C. Davies, V.T. Covello, and F.W. Allen (Eds.). Risk Communication. p3-9. Washington DC: The Conservation Foundation.

Sandman, P.M. (1986). Explaining Environmental Risk: Some Notes on Environmental Risk Communication. Washington, DC: TSCA Assistance Office, U.S. Environmental Protection Agency.

Sandman, P.M. (1993). Responding to Community Outrages: Strategies for Effective Risk Communication. Fairfax, VA: American Industrial Hygiene Association.

Upton, A.C. (1986). Communicating with the Public on Health Risks. In, National Institute of Environmental Health Sciences Report, Human Health and the Environment: Some Research Needs. Report of the Third Task Force for Research Planning in Environmental Health Sciences. (p335-43). NIH Publication No. 86-1277. Washington, D.C.: U.S. Government Printing Office.

# The Risk Analysis Process
# Environment Decision Making

## 11th Annual Conference and Exposition of the Environmental Information Association
## March 15, 1994


**Jan Z. Temple, PhD**
Chairman Department of Environmental Health Scie
College of Health Professions
Medical University of South Carol
803-792-5315

# The Environmental Hazards Assessment Program Is An Initiative To Engage Health Care Professionals In Helping Solve The Environmental Problems Our Nation Faces

## Through Education, Research, and Service

# The Medical University of South Carolina (MUSC)

First Medical School in the South (1824)

University Status in 1969

~2,300 Students - 700 Degrees Each Year

Over 7,000 Employees

- 845 Full
- 1,600 Part-Time Teaching Faculty
- 2nd Largest Employer in the Charleston Area

6 Colleges:

- Medicine, Pharmacy, Nursing, Graduate Studies, Health Professions, Dental Medicine

MUSC Medical Center

- 585 Beds in 4 Hospitals
- 2 Outpatient Facilities

# EHAP Functions and Goals

- Establish Info Center for Toxicology and Risk Data
- Research Initiative in Risk Assessment and Health Impacts
- Assessment Team to Evaluate Specific Sites
- Graduate and Post-Doctoral Education
- Mid and Upper-Level Managers Training in Environmental Risk Management
- Public Outreach Program

# The Major Thrust of EHAP is Education Information, and Interaction.

- Finding Ways to Engage the Institution, Faculty, Staff, Students, and Practicing Health Care Professionals
- In Environmental Hazards Assessment
- Focused on Integrated, Risk-Based Decision-Making

(The Common Ground)

# The Program Efforts

## Planning & Administration

## Education Initiatives

- Ph.D. and M.S. Programs
- Health Care Professionals - Outreach
- Management/Worker Training

## Information System

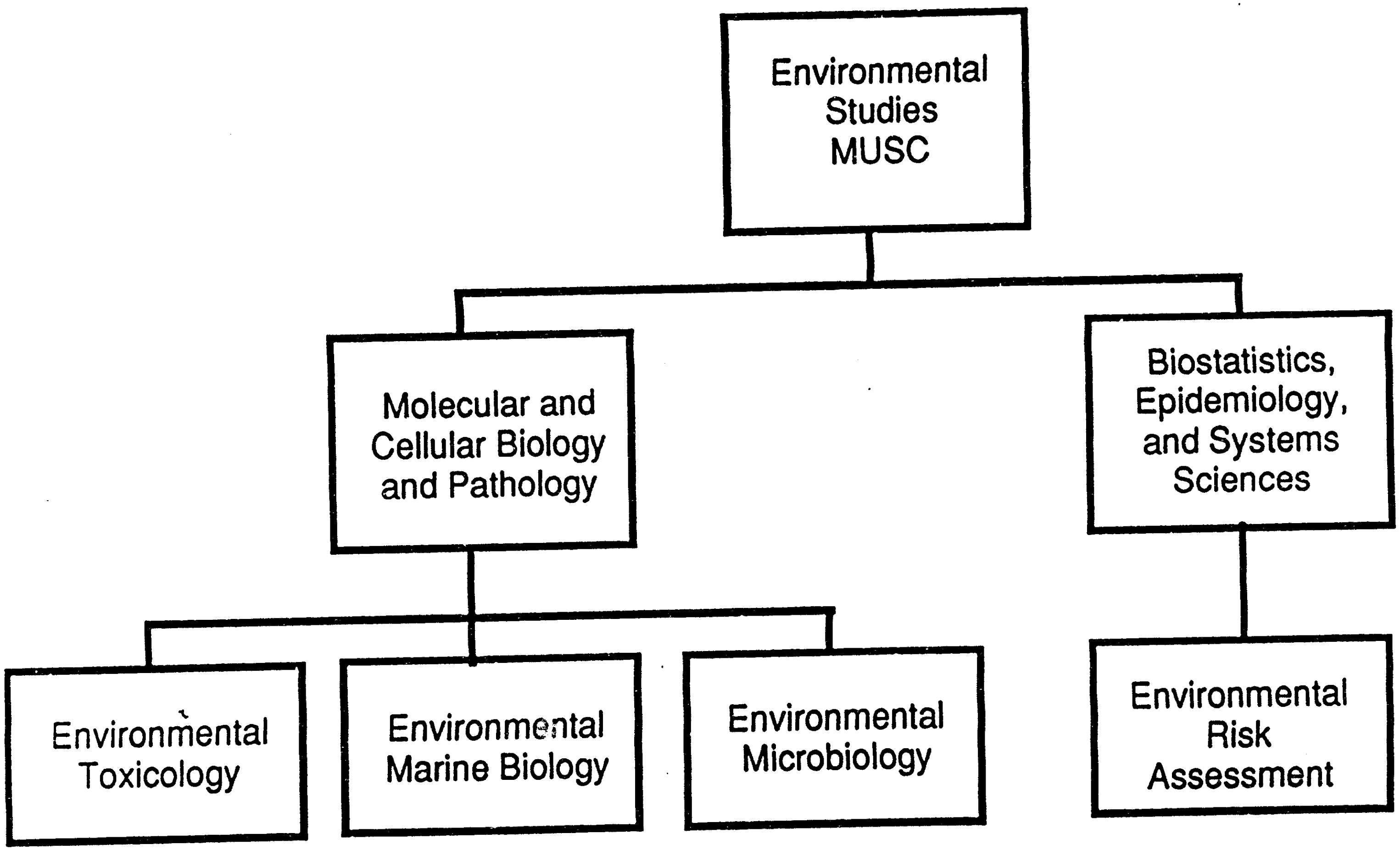
- Linking/Accessing Data Bases Worldwide
- Developing New Data Bases

## Targeted Research Program

- Integrated Risk Assessment
  - Toxicology
  - Microbiology

MUSC Environmental Hazards Assessment Program

# Doctoral Programs



MUSC Environmental Hazards Assessment Program

# Masters Programs

- Environmental Studies MUSC & U of Charleston
  - Environmental Policy (8/93)
  - Environmental Sciences (8/94)
  - Environmental Health Sciences (8/93)
  - Environmental Microbiology/ Toxicology (8/94)
  - Environmental Risk Assessment (8/94)

# Task V Goals

## Comprehensive Education and Training Program in Environmental Risk Management

# Task V

- Literature Search
- Needs Assessment
- Surveys
- Professional Development [redacted]

# Environmental Health Science Professionals (Applied)*

## I. Public Service

- Air Pollution, Water Pollution, and Waste Management
- Regulatory Compliance
- Technology Integration

## II. Academic

- Environmental Management

## III. Consulting

- Business, Industry, and Government Clients
- Department of Energy

*Emphasis on impact to human health

# Professional Development Series

- Concepts of Risk Analysis
- Environmental Risk Management
- Risk Communication

# Professional Development Series

- Executive Risk Overview
- Occupational Risks
- Chemical and Ecological Risk
- Radiological Risk

# Advisory Committee - Task V

## Representatives From:

- Regulatory Community
- Unions
- Public
- Business and Industry
- Department of Defense
- Department of Energy
- Medical Profession
- Education

# OUTREACH

## "Crossroads of Humanity" Series

- Integrated Risk-Based Decision-Making:
  Health, Economics, and the Environment
- Opinion Makers' Roundtable
  June 12th Taping
  To Be Aired on Educational/Public TV
- Focus Group Workshops To Study Major Issues
  Published Results
  Back to Opinion Makers

# Risk Analysis

Discipline used to determine environmental and human health problems associated with various activities and substances compare the effectiveness of remediation technologies, select sites for potential hazardous facilities, and set management priorities.

# Risk Analysis Components

- Risk Assessment
- Risk Management
- Risk Communication

# Definition of Risk

## Scientific

Probability of Adverse Effect Occurring

## Lay Person's

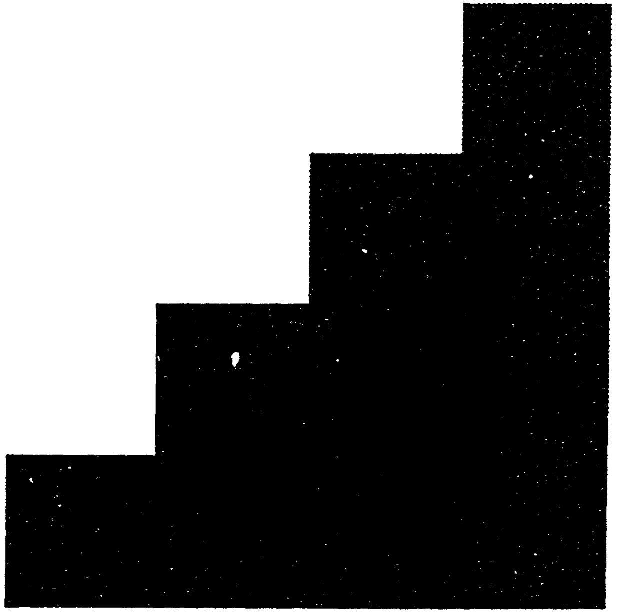
Probability of Adverse Effect + Perception

# Need for Risk Assessment

## Provides

- Objective
- Scientific

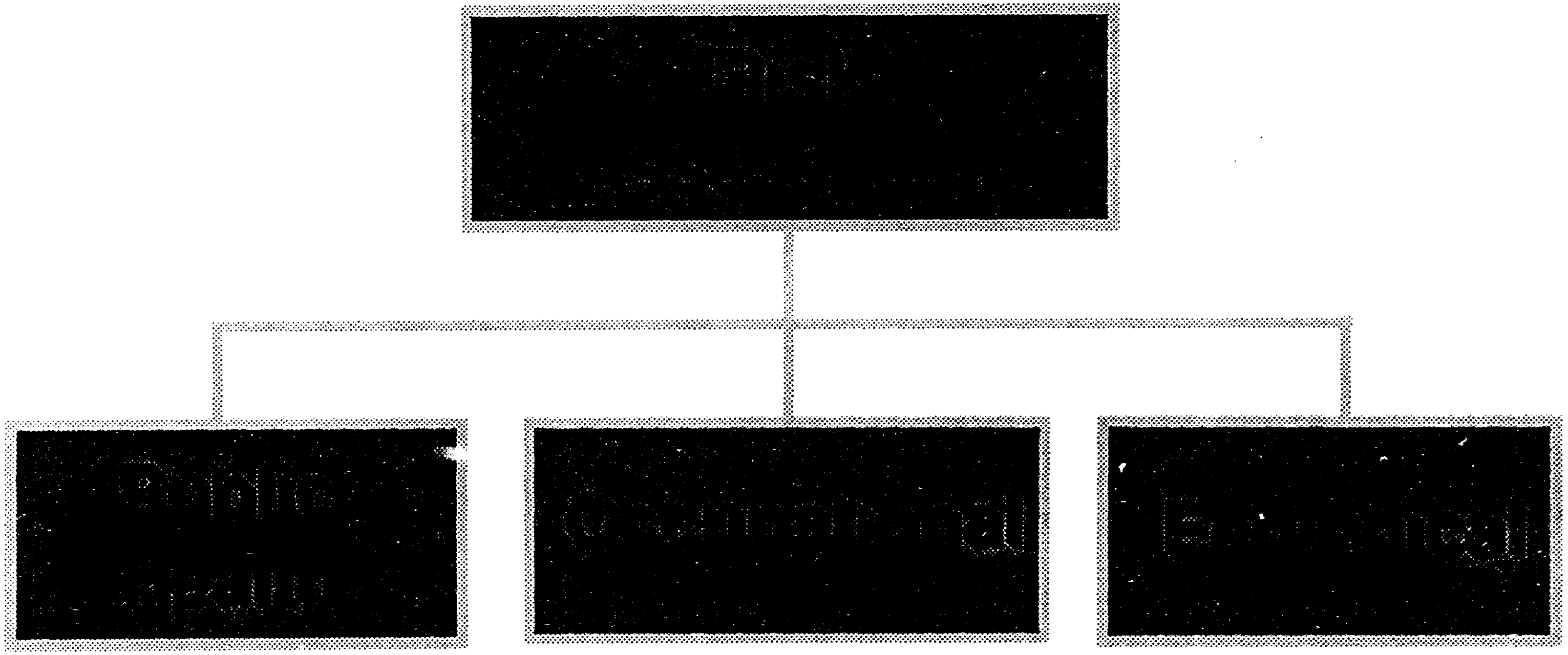
## Risk Information



# Risk Assessment

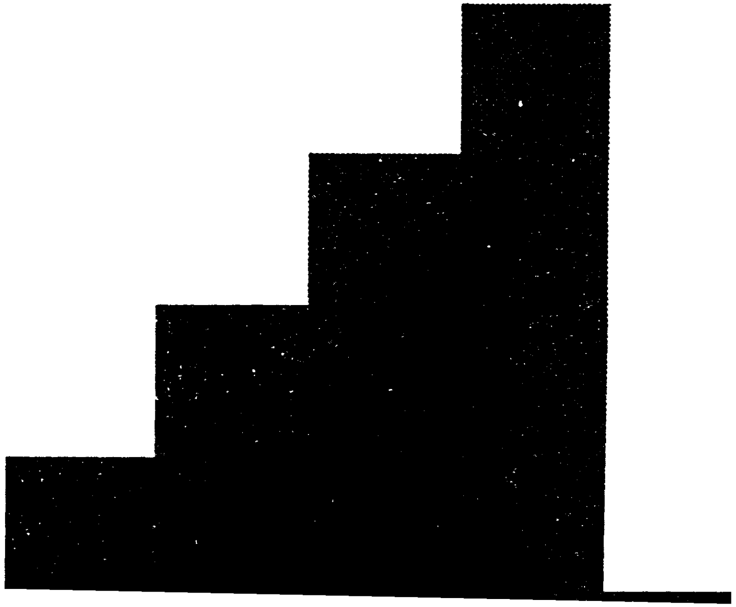
## Definition

**An Evaluation of the Potential Adverse Impact of a Given Event Upon the Well-Being of a Person or a Populatio**



# RA Use: Risk Management

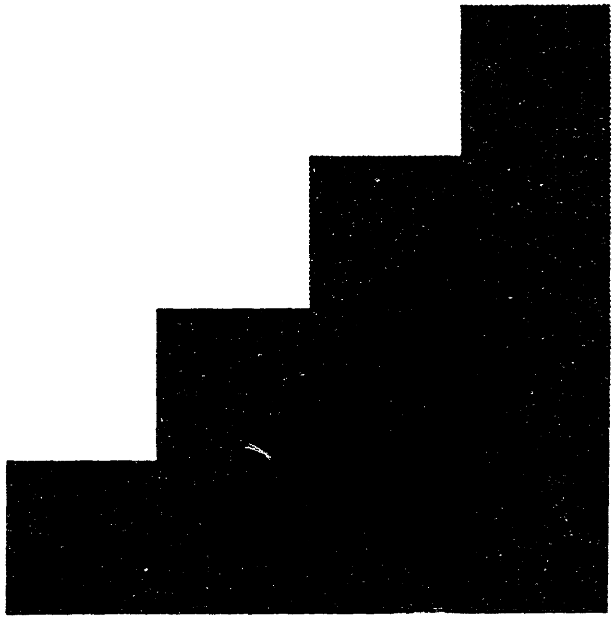
- Is There a Problem?
- Prioritizing Risks
- Who Is At Risk?



# RA Use: Risk Communication

**Helpful in Explaining**

- Hazards (Harmful Conditions)
- Sources
- Health Effects



# Steps for Risk Assessment

1. Hazard Identification
2. Dose-Response
3. Exposure Assessment
4. Risk Characterization

# Summary of Risk Assessment

1. Not Perfect
   - Assumptions and Uncertainties
   - Lack of Information

     Over 6,000,000 Chemicals Produced

     EPA's IRIS - Approximately 400 Chemicals

2. Multi-Discipline
3. Does Not Tell What To Do
4. Scientific & Objective Appr
   Quantify Risks

# Risk Management - Definition

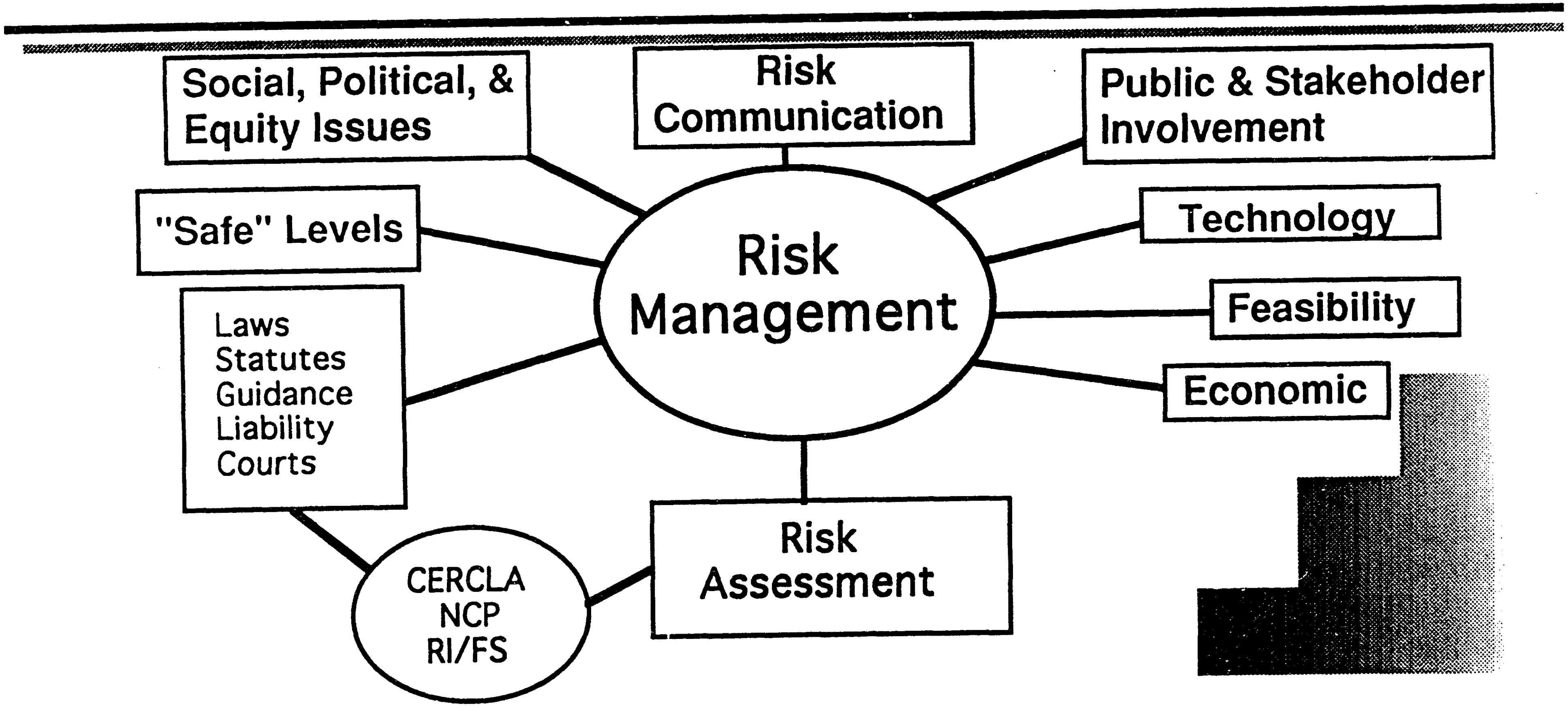
The decision making process that uses the results of risk assessment to produce a decision regarding environmental action. Risk management includes consideration of technical, scientific, social, economic, and political information.

(EPA 1989)

# Decision Making Process

- Human Health Risk Assessment Information
- Ecological Risk Assessment Information
- Economics (costs and benefits)
- Technological Feasibility (available control techno[illegible])
- Social and Political Factors
- Regulations/Laws/Guidance
- Liability

# Risk Management Decisions



# Risk Management in the Federal Government

Manage risks via legislation and rule-making

- Weigh Policy Alternatives
- Select the most appropriate regulatory action to a potential chronic health hazard
- Carried out by regulatory agencies
- Requires the use of value judgements

# RA Information Necessary for Informed Regulatory Decisions

Regarding:

- Worker Exposures
- Industrial Emissions and Effluents
- Ambient Air and Water Contaminants
- Chemical Residues in Food
- Cleanup of Hazardous Waste Sites
- Naturally Occurring Contaminants

# How do different agencies in the Federal Government address risk?

What level of risk is acceptable?

Is there a point at which risks are "de minimis"?

What is the level of uncertainty associated with the risk assessment?

Answers are subjective. Rely on "expert opinion".

# Result - Different Levels of Acceptable Risk

Keep in mind - Different types of risks

Examine FDA, EPA, OSHA's definition of "acceptable risk"

# FDA

1973 - First to use risk assessment for regulatory decisions

Regulation of carcinogenic drugs in food-producing animals

Acceptable Lifetime Risk of $10^{-8}$, later $10^{-6}$

1 in 100,000,000 later to 1 in 1,000,000

# EPA - Lifetime Acceptable Risk

Carcinogenic air pollutants - $10^{-5}$ to 0.001

Active ingredients in pesticides - $10^{-7}$ to 0.02

SWDA - goal for carcinogens = zero exposure

Hazardous Waste Sites - $< 10^{-6}$

# OSHA - Setting PEL's

1980 Supreme Court definition of "significant risk"

Risk of 1/1000 is significant occupational risk

Neither OSHA nor Supreme Court say what risk is "insignificant" (acceptable)

# Risk Management in the Federal Government

Nature of risks somewhat different

Do not take into account the additive or interactive effects from exposure to multiple toxicants

# Industry Perspective

Reduce and Prevent Occupational and Environmental Health Risks

Difficult/Impossible to eliminate ALL risks

Instead, Identify and Prioritize risks

Reduce/Eliminate those with greatest potential for harm first

Examine available resources, appropriate technologies, etc.

# Make Management Decisions Regarding:

Preventive Actions

Prioritize Risks

Remediation Alternatives

Control Measures

# Pro-Active Management Plan

Inventory Risks

Perform Periodic Audits

Train Workers

Allow for External Audits

Identify Risk Evaluation Methods

Identify Response Actions

Effective Risk Communication with Workers and the Public

# Hazardous Waste Site

Who will pay to clean up the site?

What government officials will be involved?

How will the public be involved in the decision making process?

Public Participation/Risk Communication

Media attention

Political Climate, Public Interest Groups, Labor Unions

# Decision Making

Are the choices you are making both ethical and equitable?

Quite often - very qualitative, subjective decisions

Value Judgements

Ideally, would like a systematic decision making tool

# Quantitative Tools for Making Decisions

Cost - Benefit Analysis

- Convert costs and benefits into dollar values
- Evaluate options on net benefit($)
- Human Capital Principle
- "What is an efficient policy?"

# Decision Making Tools

Cost - Effectiveness Analysis

"What is the most effective way to spend a fixed budget?"

Compares Cost Effectiveness Ratios...$/life saved

Cost - Utility Analysis

Special form of CEA

costs/QUALY

Subjective judgement is included here

# Decision Analysis

Model Decisions with

- Numerous Alternatives
- Uncertain consequences
- Multiple dimensions of value (cost, happiness, risk reduction)

# Total Quality Environmental Management

Leadership

Information and Analysis

Strategic Planning

Human Resource Development

QA of Environmental Performance

Environmental Results

Customer/Stakeholder Satisfaction

# Risk Management Goals

Eliminate, Reduce, and Manage Risks from occupational and environmental hazards

Be Pro-active and try to prevent risks from environmental and occupational hazards

Recognize the importance of effective risk communication/public participation

**If We Think [the People] are not Enlightened Enough to Exercise Their Control with a Wholesome Discretion, the Remedy is not to take it From Them, but to Inform Their Discretion.**

**Thomas Jefferson**

# Definition of Risk Communication

The Process by Which Information is Exchanged Among Interested Parties Regarding:

- Levels of Health or Environmental Risks
- The Significance or Meaning of Such Risks
- Actions and Policies Aimed at Managing or Controlling Risks

# Goals of Risk Communication

Should Produce an Involved, Informed, Interested, and Fair-Minded Public, so That Public Opinions and Concerns will be (or Remain) Reasonable, Thoughtful, Calm, Solution-Oriented and Collaborative.

# Principles of Risk Communication

- Trust & Credibility
- Understand Audience
- Communication Skills

# Risk Communication Components

1. Alerting People
2. Reassuring People

# Interested Parties

- Industry
- Regulators
- Elected Officials
- Activists
- Employees and & Retirees
- Neighbors
- Concerned Citizens
- Experts
- The Media
- Others

# Two Factors Affect the Way People Assess Risk and Evaluate Acceptability

a) The level or risk is only one among several variables that determines acceptability (other variables that matter are fairness, benefits, alternatives, control, and voluntariness.)

b) Deciding what level of risk ought to be acceptable is NOT a technical question but a value question. (People vary in how they assess risk acceptability - they weigh factors according to their own values, sense of risk, and stake in the outcome.)

# Factors Affecting Risk Acceptability

Understanding the distinction between risk and risk acceptability is critical to overcoming mistrust and communicating effectively

# Experts Perception

# vs

# Public Perception

# Experts Define Risk

## Magnitude X Probability = Hazard

**Magnitude:** How bad it is when it happens

**Probability:** How likely is it to happen

# Public Define Risk

**Strong emotion (outrage) that is justified**

# Outrage Factors

- Is it Voluntary or Coerced?
- Is it Natural or Industrial?
- Is it Familiar or Exotic?
- Is it Not Memorable or Memorable?
- Is it Not Dreaded or Dreaded?
- Is it Chronic or Catastrophic?

# Outrage Factors

- Is it Knowable or Not Knowable?
- Is it Controlled by Me or by Others?
- Is it Fair or Unfair?
- Is it Morally Irrelevant or Morally Relevant?
- Can I Trust You or Not?
- Is the Process Responsive or Unresponsive?

# Outrage Factors

- Effect on Vulnerable Populations
- Delayed vs. Immediate Effects
- Effect on Future Generations
- Identifiability of the Victim
- Elimination vs Reduction
- Risk-Benefit Ratio
- Media Attention
- Opportunity for Collective Action

**The Public Often Misperceives the hazard. The Experts often Misperceive the Outrage. But the Overarching Problem is that the Public Cares too little about the Hazard, and Experts care too little about the Outrage.**

# The Solution

- Take public outrage as seriously as hazard

- Keep them separate.

# No Risk Comparison Will be Successful if it Appears to be Trying to Settle the Question of Whether a Risk is Acceptable

**Your Job as a Consultant is NOT to Tell the Public About What They Should Accept, but Instead to Tell Them About the Size of the Risk Your Operation Entails.**

# Seven Cardinal Rules of Risk Communication

- Accept and involve the public as a legitimate partner
- Plan carefully and evaluate your efforts
- Listen to the public's specific concerns
- Be honest, frank, and open
- Coordinate and collaborate with other credible sources
- Meet the needs of the media
- Speak clearly and with compassion

ATTACHMENT 4

# ENVIRONMENTAL HAZARDS ASSESSMENT PROGRAM

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ATTACHMENT ~~2~~ 5

Foreword

On Wednesday, November 3, 1993, The Medical University of South Carolina (MUSC) convened the second meeting of the Environmental Risk Management Advisory Committee in Charleston, South Carolina to provide guidance and recommendations on the development of the Environmental Risk Management training and education programs.

A preliminary session was held at Celia's Porta Via Restaurant on the evening of November 2, 1993.

This summary of meeting includes the minutes from the meeting, agenda and a list of the participants. The Medical University of South Carolina wishes to thank the participants for their candid and insightful observations and suggestions.

The committee meeting and training session was made possible by a United States Department of Energy grant DE-FG01-92EW50625.

## 1. INTRODUCTION

The Advisory Committee comprised of business, union, industry, EPA and OSHA Regulatory, Department of Energy, Department of Defense, public interest, education and medical personnel reconvened on November 3, 1993 to provide guidance to the Medical University of South Carolina Environmental Hazard Assessment Education/training initiatives.

Dr. Jan Temple extended a welcome to all of the attendees and thanked them for their presence and commitment to our task.

<u>Attending the November 3, 1993 Advisory Committee meeting</u>

| | |
|---|---|
| Dr. Hugh W. McKinnon | US Environmental Protection Agency |
| Mr. Dennis Berry | Sandia National Laboratory |
| Mr. Kenneth G. Koller | Idaho National Engineering Laboratory |
| Ms. Susan Eisenberg | National Assoc of Environmental Professionals |
| Mr. Isiah Sewell | US Department of Energy |
| Mr. Jud E. Ellis | Rust International |
| Mr. Randy Foster | Oil, Chemical and Atomic Workers Union |
| Mr. Mike Reed | MUSC |
| Dr. Jan Z. Temple | MUSC |
| Mr. Brian Costner | Energy Research Foundation |
| Mr. Jeffery Immel | Westinghouse Savannah River Company |

<u>Advisory Committee Member Attending Only Preliminary Session</u>

| | |
|---|---|
| Mr. B. G. Beck | Coleman Research Corporation |

<u>Advisory Committee Members Not Attending</u>

| | |
|---|---|
| Dr. Peter F. Infante | OSHA/DOL |
| Ms. Sylvia Kieding | Oil, Chemical and Atomic Workers Union |
| Dr. Curtis C. Travis | Oak Ridge National Laboratory |
| Mr. Rick Lemaire | Department of Defense |
| Ms. June Ollero | US Department of Labor |
| Mr. Brad Brockbank | Colorado Center for Environmental Management |
| Ms. Libby Averill | Workplace Healthfund |

<u>Presentations Made By Faculty in College Health Professions Environmental Health Sciences.</u>

Dr. Bobby Kennedy
Ms. Nancy Kierstead
Mr. Bill Hotle
Mr. Mike Reed
Dr. Jan Z. Temple

New member, Jeffery Immel, was introduced. Also attending for the first time were Brian Costner and Randy Foster. The role and function of the Advisory Committee was reemphasized and an Advisory Committee handbook disseminated. The Advisory Committee's interest will serve in a guiding capacity to support and advise the Department of Environmental Health Sciences in addressing their task of the Medical University's Environmental Hazards Assessment Program. The committee will provide guidance in the design and development of the professional development series for mid and upper level management training in risk assessment and environmental management. Worker training issues will also be addressed to include environmental and occupational risks as they relate to mandated compliance training.

The meeting summary of the June 3, 1993 was addressed with no changes being made.

Program Goals and Deliverables of Environmental Risk Management Education and Training Initiative (Task 5) were outlined. Milestones for 1993-94 are:

1. Activate and utilize advisory committee in guiding capacity.
   - Direction
   - Course Review

2. Established off-site library and automated access to Federal Registers.

3. Develop needs assessment instrument to secure profiles of Environmental Professionals.

4. Development of Professional Development Seminars in Risk.
   - Concepts of Risk Analysis
   - Risk Management (Decision Making)
   - Risk Communication

5. Network on local, regional and national level.

6. Reports
   - Quarterly Reports
   - Networking and Meetings

Dr. Jan Temple gave a recap of the Department's risk related activities.

1. Dr. Jan Temple, Dr. Bobby Kennedy and Nancy Kierstead gave a presentation to the North Carolina/South Carolina Environmental Information Association in September 1993. Their presentation topic was entitled, "The Role of Risk in Environmental Health Issues."

2. The Department submitted an abstract to Society for Risk Analysis for presentation of Environmental professionals perception of risk education. The paper was accepted for presentation.

3. Dr. Jan Temple was invitied by the Governor of Washington State to participate in the Hanford Summit meeting in Pasco, Washington (Hanford Site). The national summit, focusing on environment, technology and the economy was sponsored by the Hanford Nuclear Reservation in conjunction with the US Department of Energy (DOE). The meeting attracted more than 600 representatives from both the public and private sectors, including senior government officials, field experts and community leaders. Temple was selected as the spokesperson representing education and training.

Mike Reed explained the professional development series in risk. The intent is to introduce participants to the concept of risk analysis.....not make them risk assessors. Clarification was made as to the target audiences being middle and upper management.

Jud Ellis concurred that his firm's need was for mid-level environmental managers who are supervising programs. Ken Koller added that public awareness/public participation needs to be an essential element in programs offered.

Mike Reed explained that our initial objective was to develop a professional development series in Risk. Dr. Bobby Kennedy gave an Overview of our first course, "Concepts in Risk Analysis." It will focus on receiving input from each of the Advisory Committee members. The method of delivery is slides, lectures, etc. Assessments on individual topic presentations and overall program evaluations will be conducted.

Dennis Berry stated the public's understanding of "Risk" was thought to be one thing and "Risk Assessments" often were not trusted. Trainers and Educators need to work with Intervener's Groups in the hopes that trust will begin. This task initiative should help with this problem.

Susan Eisenberg stated disclosure of risk will give the public better knowledge of risk in the environment. It was a perception that the general public wants zero risk and that this is often difficult to attain.

Mike Reed stated that the programs we are developing are general and can be modified for site specific needs. It was also stated that target audiences will change and that programs will be modified accordingly.

Nancy Kierstead then gave a short overview regarding Course II: Risk Based Decision Making for Environmental Managers. This course will introduce the student to the decision making process as it affects the environmental manager. Several management tools to enhance decision making will be introduced including decision analysis, cost benefit analysis, cost-effectiveness analysis, and linear programming. Numerous case studies will be introduced to illustrate the varied approaches to managing environmental risks.

The Committee endorsed this direction and rendered the following comments:
Jud Ellis said the general comment from the public is, "Those guys are trying to figure out a way not to have to clean up what they dirtied up!"

Brian Costner commented that confrontation is never easy. Trust must be established if Communication is to be effective. Risk assessments are presumed to be a way of avoiding cleanup. Profit agenda all too often is the driver of distrust in Environmental Restoration.

Dennis Berry stated that identifying, acknowledging and accepting risk is necessary for credibility in risk analysis.

Jeffery Immel talked about Risk minded people. He stated risk is serious but is often the result of bad data.

Dr. Hugh McKinnon noted MUSC is charged with using their knowledge to create credibility.

Bill Hotle presented a survey instrument designed to conduct needs assessment and develop a profile of environmental managers. The instrument can be modified for site specific needs. Predicated on funding, the survey can be delivered to Environmental Professional Organizations serving as an indicator of existing levels of expertise in risk and recommendations for education and training on a national basis.

Dennis Berry emphasized that the survey must be pilot tested and considerations of federal system restraints be kept in mind.

Susan Eisenberg suggested holding focus meetings around state and national meetings as an option to conducting surveys which often get low returns.

Ike Sewell stated the need to understand risk is more important then the need to know risk. Surveys can be used or modified to fit a special groups need.

Ken Koller said the survey should have a "needs statement" on what the results of survey will be used for.

Dr. Jan Temple Spoke on Course III: Risk Communication. This professional development seminar in risk communication introduces the student to the seven cardinal rules of effectively communicating risk concepts. The students learn how to involve the community early, to plan carefully and to evaluate performance, to listen carefully to the audience, to be honest and sincere, to establish credibility through the scientific community, to meet the needs of the media, and to speak clearly with compassion. Perceived risks can only be addressed with compassion and concern. This presentation explains the difficulties that may be encountered and how to learn from previous mistakes. Upon completion of this program, the student will be able to understand the concerns of the stakeholders and will be able to respond to the difficult issues that may be present. Approaches to delivery were presented. The following were committee member comments:

Jeffery Immel discussed video conferences. It is his consensus that they are not interactive and WSRC is not satisfied with this type of training. MUSC and WSRC are making plans for pilot risk courses to be presented at Westinghouse Savannah River Company in Aiken, SC.

Jud Ellis endorsed that course testing be conducted. Members agreed.

Dennis Berry suggested training be provided to employees and perhaps modified and offered to local concerned public.

Randy Foster noted in these types of presentations ground rules must be identified.

Brian Costner stated there is a national organization of environmental reporters which might be a possible method of informing the public about our Risk Initiatives. He suggested that perhaps contact should be made with Keith Schneider of *The New York Times*.

A working lunch ensued.

Mike Reed spoke on Directives for 1993-94. Future development series would be 1) occupational risk, 2) ecological risk and 3) radiological risk. The driver for occupational risk is health effects. In-house training programs to identify these risk and ability to distinguish the difference between hazard assessment and risk assessment are needed. Supervisors and employees must clearly understand why they must 1) follow work practices, 2) know emergency procedures and 3) have equipment suitable for the task at hand. OSHA is also considering workplace identification of risks being communicated to workers prior to exposure.

Discussion on terminology and topics ensured. It was clear that occupational health risk was vital to daily business operations. Ecological risk brought much discussion.

Ken Koller stated human and ecological risk go hand in hand

.
The Advisory Committee was given a short break after which the pilot class was begun. This was a two day class reviewed by the committee with discussions and evaluations after each topic section. At the conclusion of the course an overall evaluation was administered. The Committee was thanked for its time and dismissed. All comments will be complied and disseminated to committee members and taken under advisement by MUSC.

ATTACHMENT 3-6

Foreword

n Tuesday, May 17, 1994, The Medical University of South Carolina (MUSC) convened the third neeting of the Environmental Risk Management Advisory Committee in Charleston, South Carolina to rovide guidance and recommendations on the development of the Environmental Risk Management raining and education programs.

preliminary session was held at Charleston Crab House Restaurant on the evening of Monday, May 16, 994.

his summary of meeting includes the minutes from the meeting, agenda and a list of the participants. The ledical University of South Carolina wishes to thank the participants for their candid and insightful bservations and suggestions.

he committee meeting and training session was made possible by a United States Department of Energy rant DE-FG01-92EW50625.

1. INTRODUCTION

The Advisory Committee comprised of business and industry leaders, members of unions, EPA and OSHA Regulatory staff, members of Department of Energy and Department of Defense, public interest, educators and medical personnel reconvened on May 17, 1994 to provide guidance to the Medical University of South Carolina's Environmental Hazard Assessment Program Education/Professional Training initiatives.

Dr. Jan Temple extended a welcome to all of the attendees and thanked them for their presence and commitment to our task.

Attending the May 17, 1994 Advisory Committee meeting

| | |
|---|---|
| Dr. Hugh W. McKinnon | US Environmental Protection Agency |
| Mr. Dennis Berry | Sandia National Laboratory |
| Mr. Kenneth G. Koller | MAC Technical Service Company |
| Ms. Susan Eisenberg | National Assoc of Environmental Professionals |
| Mr. Mike Reed | MUSC |
| Dr. Jan Z. Temple | MUSC |
| Dr. Todd D. Stong | Coleman Research Corporation |
| Dr. David Hoel | MUSC Dept. of Biostatistics Epidemology and Systems Science (DBESS) |

Advisory Committee Members Not Attending

| | |
|---|---|
| Mr. Jud E. Ellis | Rust International |
| Mr. Brian Costner | Energy Research Foundation |
| Mr. Randy Foster | Oil, Chemical and Atomic Workers Union |
| Mr. Jeffery W. Immel | Westinghouse Savannah River Company |
| Dr. Peter F. Infante | OSHA/DOL |
| Ms. June Ollero | US Department of Labor |
| Dr. Don Scrimgeour | Colorado Center for Environmental Management |
| Mr. Isiah Sewell | US Department of Energy |
| Dr. Curtis C. Travis | Oak Ridge National Laboratory |

Presentations Made By Faculty
College Health Professions Environmental Health Sciences.
Dr. Jan Z. Temple
Dr. Bobby Kennedy
Mr. Bill Hotle
Mr. Mike Reed
Ms. Nancy Kierstead

Environmental Hazards Assessment Program (EHAP)
Dr. Glen Fleming

New member, Dr. Todd Stong was introduced. The Advisory Committee's interest serves in a guiding capacity to support and advise the Department of Environmental Health Sciences in addressing their task of the Medical University's Environmental Hazards Assessment Program. The committee provides guidance in the design and development of the professional development series for mid and upper level management training in risk assessment and environmental management. The revised meeting summary of the November 3, 1994 meeting was distributed with modifications noted and no further changes being made.

Dr. Bobby Kennedy recapped the previous risk analysis classes held in November and January. Comments/evaluations from the previous risk class were distributed along with a revised course book. Members highlighted/scanned the publication with discussion among the group regarding suggestions about the publication.

Summary of Comments:

Numerous comments were made to modify the Regulation Section of the Concepts of Risk Course. DOE requirements address Environmental Law, Regulations and Guidelines and have internal policy orders adding requirements for contractors.

Dennis Berry commented that DOE external regulations have been expanded. He has an expanded copy of regulations from DOE regarding Federal, State and Local guidelines which will be sent to us.

After much discussion and suggestions regarding enhancements to course book, Dr. McKinnon suggested that in the future texts be mailed to members before the meeting so they could be reviewed more thoroughly. He suggested that a specified timeframe be set aside to address this task.

The group then took a lunch break.

Dr. Bobby Kennedy gave a short overview of the second course developed entitled, "Decision Making in Environmental Risk Management."

Directives for fiscal year 1994-95 were discussed. Dr. Jan Temple announced plans for Dr. Max Lum to present a "Risk Communications" course to Department of Environmental Health Sciences on June 2, 1994. She further discussed creating a certificate program in risk. The concept was well received.

Mike Reed gave an overview of the professional development series which the Department of Environmental Health Sciences is undertaking. Additional courses will include Risk Communication, Occupational Risk and an Executive Overview of Risk Analysis. He explained that an OSHA reform package will drive the need for a fundamental understanding of occupational risk. Mr. Reed also mentioned proposed series development plans for Chemical/Ecological and Radiological/Ecological courses for future years based on funding. Dr. Hugh McKinnon inquired about funds available for course development. An indepth discussion followed Dr. McKinnon's question.

Dr. Glen Fleming gave an overview of his directives/achievements in the DOE Environmental Hazard Assessment Program (EHAP). Work has lead to :

(a) Family Medicine workshop for 3rd year students
(b) Proposed handbook for mayors
(c) Education, training & outreach program
(s) Purity Video concept - His department is now available to go out for the "Town of Purity" where they will help conduct town meetings.

Discussion followed with questions by members as to whether a short version of the Risk Analysis course might be beneficial to mayors and other public officials. It was agreed that it would be very beneficial.

Dr. Jan Temple informed Advisory Committee:

1. Availability of Survey Instrument.
2. Contract has been signed to provide Risk Analysis Training to Charleston Naval Shipyard. The first course entitled, "Concepts of Risk Analysis" will be presented to 30 engineers being transitioned into the environmental field.
3. Risk Training for Westinghouse Savannah River Company is still in the negotiating stage.

Ken Koller suggested Mr. John Steele, WSRC, be contacted regarding training at Aiken.

Questions were asked regarding EHAP funds available for academic programs. Dr. Temple and Mike Reed expressed their disappointment that an academic program had not been funded. Discussion followed with all members asking questions and offering suggestions.

1. Rationale for not funding an Academic Director's position, once a national search was underway, puzzled committee members.
2. Ken Koller inquired about plan submitted to EHAP.
3. Questions asked were:
   (a) Had we considered partnering with another University?
   (b) Amount of time needed to get program underway if funded?
   (c) Could our public service offerings fund the seed money to get the academic program started?
4. Dennis Berry asked if Risk Analysis, Risk Management and Risk Communication courses could be academic course offerings? Dr. Temple responded affirmative, however, funding remained a concern.
5. Ken Koller suggested interfacing with University of Nevada as they are beginning to develop a Masters program in Environmental Health Sciences.

Dr. Hugh McKinnon stated EHAP was started because of need. He suggested we meet with Carol Henry and ask for comments and enlist the help of Carol Henry and Clyde Frank to go to EM30 and EM40. Ken Koller stated odds good if request being presented to Carol Henry. He felt endorsements would be received before leaving room of meeting.

Dr. Stong suggested we work through Dr. Martin Jones with a request from DOE headquarters to secure additional support as the program is definitely needed.

Dennis Berry noted there is a need for education in Occupational Risk . He commented perhaps there could be a trade off associated with risk/cleanup.

Ken Koller suggested the use of Graduate Students from a business school be considered to draft a marketing plan for courses now developed so department could generate funds.

Next meeting will be planned for November 7-9, 1994. The pilot course, "Risk Communication" will be offered at that time.

Committee adjourned for the beginning presentations of the pilot course, "Decision Making in Environmental Risk Management."

The second pilot of the course, "Decision Making in Environmental Risk Management" is scheduled August 2-3, 1994.

/gh

ATTACHMENT 4-7

# Medical University of South Carolina

## Environmental Hazards Assessment Program

# Environmental Risk Management Advisory Committee Handbook

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## Table of Contents



The Environmental Risk Management Advisory Committee Handbook (Rev 1) has been developed and is subject to review and revision as required by the judgement of the Advisory Committee and the Environmental Risk Management Training and Education Initiative Program Director.

The research for the Environmental Risk Management Advisory Committee Handbook was supported either in full or in part from funds provided by the US Department of Energy Grant DE-FG01-92EW50625. Such support does not constitute an endorsement by DOE of the views expressed in this Handbook.

# ABOUT THE ADVISORY COMMITTEE

The Advisory Committee consisting of government, industry, labor unions, public interest organizations, regulatory agencies, education, and medical profession representatives will serve in a guiding capacity to support and advise the Department of Environmental Health Sciences in addressing the Medical University's Environmental Hazards Assessment Program. The committee will provide guidance in the design and development of mid- and upper-level management training surrounding risk assessment and environmental management. Worker training issues will also be addressed to include environmental and occupational risks as they relate to mandated compliance training.

**About the Environmental Hazards Assessment Program (EHAP)**

The Medical University of South Carolina has established the "Environmental Hazards Assessment Program." This program was created to initiate a major radioactive and hazardous waste risk assessment and management program focusing upon the environment and health. Government organizations along with Business and Industry have realized that engineering alone cannot solve the issues which will arise in the future in regards to the handling, disposal, and remediation of hazardous or regulated wastes. Corrective actions at hazardous waste remediation sites and operational facilities must be based upon potential health risks, and EHAP as part of MUSC, brings leadership, responsiveness, and credibility toward meeting these goals.

As a national center of excellence, EHAP will assemble an interdisciplinary team to study, interpret, and disseminate health and risk-related information for the purposes of advice to industry, government, and the public. Key to this effort will be unique educational programs designed to produce the technical, scientific and health care professionals required to carry out effectively such an ambitious restoration and management initiative. The program is based upon a number of closely interacting and interrelated functions which include:

- EHAP is developing an information system to provide base-level capabilities to access and develop databases world-wide.

- A Ph.D. program in Environmental Risk Assessment and a Masters Degree in Environmental Sciences are being initiated.

- The Department of Environmental Health Sciences is working to design, develop, and deliver Environmental Risk Management Seminars to address management and worker issues.

- MUSC hosts nationally-televised broadcasts of panelists engaging in "round table" socratic dialogues on environmental risk.

- The Statewide Family Practice System will develop programs for all Family Medicine residents on the effects of environmental exposure on human health.

- EHAP is recruiting stakeholders to examine the environmental health issues in light of the existing science, and to make rational decisions vis-a-vis the basic science needed to progress towards understanding the health impacts.

# Advisory Committee Procedures

## Appointment to Committees

The Environmental Risk Management Training and Education Initiative Program Director in consultation with the Director of the Environmental Hazards Assessment Program will select committee members. Once the prospective member has been approved, the Training and Education Program Director will contact the individual to determine if he or she will serve. The Environmental Risk Management Training and Education Initiative Program Director will then send a letter, appointing the person to the Environmental Risk Management Advisory Committee. Appointments will begin initially in June of 1993.

## Organization

1) The membership of the Advisory committee shall consist of at least twelve (12) and no more than eighteen (18) members, appointed by the Environmental Risk Management Training and Education Initiative Program Director. Potential appointees are to be evaluated for membership on the criteria of expertise and/or experience, enthusiasm, character and available time for committee activities.

2) The Advisory Committee shall meet not less than two times per year but may meet more often if needed.

3) The Environmental Risk Management Training and Education Initiative Program Director will assure minutes of meetings are recorded and distributed.

## Committee Roles

1) It shall be the charge of the Advisory Committees to provide knowledgeable counsel and advisement of the Medical University of South Carolina's Environmental Risk Management Training and Education Initiative concerning the development and progress of the Environmental Risk Management programs of study.

2) The Environmental Risk Management Advisory Committee members will represent viewpoints of their respective industries as they relate to Environmental Risk Management now and in the future.

## Functions of the Advisory Committee (continued)

11) **Plan Future Equipment and Facilities**
The committee can be invaluable in recommending equipment and facilities.

12) **Identify Public and Industrial Resources**
The advisory committee will assist in identify resources which would support the instructional program.

13) **Review Programs**
The committee will review the results of students and industry studies that will suggest when program changes are necessary.

### Meetings

The Advisory Committee will convene two times per year or more, if necessary. The Environmental Risk Management Training and Education Program Director will be responsible for notifying members of meeting, compiling and distributing the agenda and material at least two weeks in advance of meeting. In addition to the members of the committee, the EHAP Environmental Risk Management Training and Education Program Director will distribute meeting information to other interested parties and individuals as necessary.

### Minutes of Meetings

The EHAP Environmental Risk Management Training and Education Program Director will ensure the minutes of all meetings will be recorded and distributed to all member of the committee. The official copy of the minutes will be kept on file in the EHAP Environmental Risk Management Training and Education Initiative Program Director's office.

Whatever their form, minutes should include the following information:

1. Date, time, and place of meeting
2. Names of those in attendance
3. Date of significant correspondence or other documents considered at the meeting
4. Important decisions and recommendations

Survey Rational:

On a daily basis environmental professionals make decisions regarding handling, disposing, or cleaning-up of hazardous substances. These substances may include hazardous chemicals, radioactive materials, or mixed wastes. Environmental professionals must make decisions on the most appropriate method to deal with these substances. In recent years a concerned public has begun to scrutinize these decisions more and more. Training to deal with these situations may not have been in an environmental professionals formal education. This lack of training may give rise to undue tension between environmental professionals and the public.

As public awareness has grown there is less tolerance of contamination in the environment. Even the perception of a possible hazard requires environmental professionals to justify their actions. Public outcry has also influenced government. New laws or regulations are continuously being implemented that affect the actions of environmental professionals Environmental professionals must be able to justify and provide information as to why their decisions are not only safe but the most cost effective for all involved. The justification often requires an evaluation of risks associated with decisions and actions.

The evaluation of *(environmental and occupational)* risks and the methods and manner in which risk assessment is done is a relatively new science that emerged during the 1980's. As it applies to environmental professionals, risk assessment can be defined as:

> "A way of examining risks so that they may be better avoided, reduced, or otherwise managed. Risk implies uncertainty, so that risk assessment is largely concerned with uncertainty and with a concept of probability that is often difficult to grasp." (RIHRA).

The majority of environmental professionals have worked in their field for many years and may not have formal education or training in risk assessment, management, or communication. As public concern for health and hazardous materials increases, environmental professionals will need to use these new risk approaches to explain and substantiate their decisions.

The Medical University of South Carolina has established an Environmental Hazards Assessment Program (EHAP). The purpose of EHAP is to serve as a source of information on environmental risk assessment. As part of this effort, the needs of mid- and upper-level managers that deal with environmental issues are being addressed. A continuing education series is being developed that will address the needs of mid- and upper-level managers in the areas of risk assessment, management, and communication. The primary recipient of such training will be environmental professionals that are involved in the management of hazardous chemicals, radioactive materials, and mixed waste. To ensure the specific areas of risk education needed by environmental professional are covered in the education programs, the Medical University of South

Carolina is conducting this needs assessment. To fully understand the existing level of knowledge in risk education the survey will examine the extent of risk education environmental professionals currently possess as well as their opinion on areas of particular need for continuing risk education.

Target Population

The target population for the research will be members of environmental professional societies across the United States. Environmental Professionals are the primary individuals that deal with hazardous, radioactive, or mixed wastes on a day to day basis. Members of different environmental associations will be randomly selected. The sample population and method was chosen because:

1) it provides a cross-section of various social institutions; i.e., government, industry, advocate groups;
2) it provides a manageable and feasible means to assess training on a national level;
3) the results will be statistically meaningful and capable of being extrapolated to the target populations, those with a special interest in the environment;
4) and the results obtained would be indicative of those most likely to utilize risk training courses.

The focus of this study is to identify and clarify areas of continuing education that will allow environmental professionals to do their work more effectively in regard to risk assessment, management, and communication. The study is not to determine if environmental professionals are qualified to do their work, but to aid in developing education that will benefit environmental professionals. To meet these goals we must identify the existing level of risk knowledge and education that environmental professionals currently hold. This will require questions on their general education and continuing education as well as specific questions on their training in risk assessment, communication, and management.

This research instrument is supported from funds by the U.S. Department of Energy grant DE-FG01-92EW50625.
Such support does not constitute an endorsement by DOE of the views expressed in this survey.

Please complete the following information:

Name: (optional) ______________________________

Occupation (Title): ______________________________

Years in Current Position: ________

Employer: ______________________________

Years with Current Employer: ________

Work Location: (City/State) ______________________________

Work Mailing Address (optional): ______________________________

______________________________

______________________________

______________________________

______________________________

How many years of education have you completed? (please circle appropriate answer)

1 High School Education or Less
2 Associate Degree or Technical School
3 Some College
4 Undergraduate Degree
5 Masters Degree
6 Doctorate or Professional Degree
7 Other (please elaborate) ______________________________

For your education, what was your primary area of study ? ______________________________

How long have you worked in the environmental field? __________ Years

What is your area of specialty? (please be specific as possible)

______________________________

______________________________

______________________________

______________________________

6 Concerning your work, does your employment / duties / responsibilities involve?

| | Work Involves (please check appropriate answer) | |
|---|---|---|
| | Yes (1) | No (2) |
| Disposal of hazardous, radioactive, or mixed waste? | _____ | _____ |
| Management of hazardous, radioactive, or mixed waste? | _____ | _____ |
| Selecting the disposal methods for hazardous materials? | _____ | _____ |
| Cleaning up hazardous, radioactive, or mixed waste sites? | _____ | _____ |
| Ensuring safe work practices are utilized by your company? | _____ | _____ |
| Selecting engineering methods to use in the clean-up process? | _____ | _____ |
| Conducting Remediation Investigations / Feasibility Studies? | _____ | _____ |
| Specifying personal protective equipment to be used by personnel performing their normal daily operations? | _____ | _____ |
| Specifying personal protective equipment to be used by personnel cleaning-up hazardous material? | _____ | _____ |
| Justification of what personal protective equipment is used for a specific an environmental problem? | _____ | _____ |
| Justification of why a specified engineering practice was chosen related to an environmental problem? | _____ | _____ |
| Performing quantitative risk analysis? | _____ | _____ |
| Informally assessing the risks associated with certain hazards or working conditions? | _____ | _____ |
| Interacting with the community concerning public safety? | _____ | _____ |
| Interacting with the media (newspaper, radio, TV)? | _____ | _____ |
| Predicting exposure using a probability distribution? | _____ | _____ |
| Interacting with the public concerning safety and hazardous materials? | _____ | _____ |

Please feel free to expand any of the above areas as you feel necessary.

A Concerning your formal education (high school, college, graduate or professional school), did you receive courses or lectures concerning? (please check appropriate answer)

B In your current position or occupation would additional training or education in the previously listed subject areas be beneficial? (please check appropriate answer)

| | 7 A Education Included | | 7 B Training in Subject Matter Beneficial (please check appropriate answer) | | | | |
|---|---|---|---|---|---|---|---|
| | Yes | No | Strongly Agree | Agree | Indifferent | Disagree | Strongly Disagree |
| Poisons or chemicals and their effect on the human body, i.e. toxicology ? | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Conducting Remediation Investigations / Feasibility Studies? | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Methods used to calculate incidence of disease in populations? | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Pathways of exposure and methods that chemicals enter the human body? | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Incidence, distribution, and control of disease? | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Risk values and how they are determined? | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Cost Benefit / Effectiveness Analysis | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Decision Analysis | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Ecological Risk Assessment | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Economics | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Environmental Engineering | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Environmental Fate & Transport | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Environmental Law | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Federal Environmental Regulations | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Industrial Hygiene | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Linear Programming | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Optimization | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Pollution Prevention | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Radiation Safety | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Risk Analysis | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Risk Assessment | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Risk Communication | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Risk Management | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Risk Perception | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Risk Prioritization / Hazard Ranking | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| State and Local Regulations | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Statistics | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Waste Minimization | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |
| Worker Safety | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] | [ ] |

8 Are there any areas of study not listed in question 7, that continuing education would benefit you in your work? (please list and describe)

a ______________________________

b ______________________________

c ______________________________

d ______________________________

| | Please check appropriate answer Yes (1) | No (2) | Unsure |
|---|---|---|---|
| 9 Would a continuing education program that led to a nationally recognized certification in risk analysis be beneficial to you? ................. | [ ] | [ ] | [ ] |
| 10 Does your facility / organization have required levels of training (certifications, degree, training courses, etc.) for Environmental Mangers? ........... | [ ] | [ ] | [ ] |

→ If you answered YES, please provide additional information on the required training.

a ______________________________

b ______________________________

c ______________________________

d ______________________________

Risk Analysis consists of Risk Assessment, Risk Management, and Risk Communication.

| | Please check appropriate answer Yes (1) | No (2) | Unsure |
|---|---|---|---|
| 11 Have you received any education / training in risk analysis? ........................................ | [ ] | [ ] | [ ] |

→ If you answered YES, please provide additional information on the training.

| Course Description or Title | Training Provider |
|---|---|
| | |
| | |
| | |
| | |

| | Please check appropriate answer | | |
|---|---|---|---|
| | Yes (1) | No (2) | Unsure |
| 2 Does your company presently offer any risk analysis training on site or through outside organizations? .................................. | [ ] | [ ] | [ ] |

If you answered YES, please provide additional information on the training.

| Course Description/Title | Training Provider |
|---|---|
| | |
| | |
| | |
| | |

Risk Analysis consists of Risk Assessment, Risk Management, and Risk Communication.

Risk Assessment is the use of information to evaluate and estimate the risk of exposure to a chemical or substance.

Risk Management is the process of interpreting risk-assessment findings and integrating results with engineering information, public concerns, and economic factors to determine the most appropriate action to reduce the risk and control future problems.

Risk Communication is the exchange of information about health or environmental risks among risk assessors and managers, the general public, news media, interest groups, etc.

| | Training in Subject Matter Beneficial (please check appropriate answer) | | | | |
|---|---|---|---|---|---|
| | Strongly Agree | Agree | Indifferent | Disagree | Strongly Disagree |
| Do you believe there is a need for Risk Assessment training at your company / facility?......... | [ ] | [ ] | [ ] | [ ] | [ ] |
| Do you presently foresee a need for Risk Management training at your company / facility? ........... | [ ] | [ ] | [ ] | [ ] | [ ] |
| Do you presently foresee a need for Risk Communication training at your company / facility? ........ | [ ] | [ ] | [ ] | [ ] | [ ] |

16 If you were given reasonable freedom in budget and time for continuing education of Environmental Managers what three (3) areas of experience or training would you seek?

a ______________________________

b ______________________________

c ______________________________

17 Identify three (3) items that are primary factors interfering with your maximum effectiveness as an Environmental Manager / Professional.

a ______________________________

b ______________________________

c ______________________________

18 Do you have any questions or comments?

______________________________

______________________________

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**THANK YOU**

# Concepts Of Risk Analysis

Presented by

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**College of Health Professions**
**Department of Environmental Health Sciences**
**171 Ashley Avenue**
**Charleston, S.C. 29425**
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Revision 1

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# PREFACE

Environmental professionals are faced with complex challenges as they contend with human health effects associated with exposures to toxic substances. These challenges include the many potential toxic sources, the severity of and/or the paucity of information regarding the health effects of many agents, the many sources of uncertainty, and the emotional and financial issues related to such exposures. Often the environmental professional has not been trained or is not familiar enough with these issues regarding risk to deal with them in a confident and competent manner.

This course is designed to provide the environmental professional with background information to enhance their competency in handling environmental risk problems. The objectives of this course are to improve the environmental professional's understanding of risk principles, risk in decision-making, and risk communication. Improvement in these areas should lead to more efficient and acceptable risk management decisions.

**DISCLAIMER:**
*Information provided is based upon current scientific and technical understanding of the issues presented. The course is intended to provide a basic understanding of concepts involved in risk assessment, risk management, and risk communication, and not to serve as a guidance manual to conduct or perform these functions. Following the advice in this manual may not be applicable for a given situation, contacting an expert or regulator in a particular area is recommended. Mention of any trade names or commercial products does not constitute endorsement or recommendation for use.*

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# INTRODUCTION TO THE RISK ANALYSIS PROCESS

American history provides ample evidence to support the hypothesis that we are a nation of risk-takers. Our country was emigrated by people who forfeited their way of life to begin anew in an undeveloped and mysterious land. Our nation took great risks to gain independence by fighting the world's most powerful country. Pioneers blazed across the West, risking their lives in hopes of creating a better life in the new territories beyond the Mississippi River. However, as our society matures, its becoming clear that there are risks the American populace are less willing to accept. In particular, there seems an unwillingness to accept those risks associated with the waste and by-products of industrial and manufacturing processes.

The Industrial Revolution of the late 19th century was spurred by the application of scientific principles and discoveries which improved manufacturing, engineering, chemical, medical, communication, and transportation capabilities. Technologies evolved which forged America forward to become the world's industrial leader. During this time of rapid industrial advancement, little thought was given to controlling the release and buildup of noxious industrial substances. Much of this oversight had to do with the lure of quick profits and the lack of understanding of the ill-effects related to many industrial processes.

As a result of this inattentiveness, the quality of our environment was frequently damaged, and human health was adversely affected as well. Adverse human effects of industrial substances are known to arise from occupational exposures and exposures to contaminated water, food, air, and soil. Occupational exposures to various chemicals or mixtures of chemicals can cause a variety of illness. For example, some substances can cause cancer (e.g., 4-aminodiphenyl -- bladder cancer in rubber and dye employees; benzene -- leukemia in petrochemical workers; asbestos -- lung cancer in shipyard builders; coke oven emissions -- renal cancer in metal foundry employees; vinyl chloride -- liver cancer in polyvinyl resin makers), other substances affect the nervous system (e.g., carbon monoxide -- miners; hydrogen sulfide -- rayon makers; and lead -- battery reclamation workers), and others the reproduction system [e.g., dibromochloropropane (DBCP, a fungicide) reduces sperm count in pesticide workers; anesthetic gases -- spontaneous abortions reported for female operating room personnel] (Amdur M.O., Doull J., and Klaasen C.D., 1991; Key M.M., et al.,1977).

The health effects of drinking water contaminated with raw sewage are well known (e.g., infectious diseases such as cholera, typhoid, and dysentery). Industrial waste products also may be a cause for health concerns. For instance, during the 1950's in a town near Minamata Bay, Japan an industrial plant discharged metallic mercury into the bay. The metallic mercury was converted to a more toxic organomercury -- a potent neurotoxin -- by fish and shellfish found there. Seafood from the bay was a major source of sustenance for the people of this region. As a result, approximately 1,200 cases of organomercurial poisoning occurred, some were fatal (Amdur M.O. et al., 1991).

Industrial waste products have also contaminated other sources of food, resulting in dire consequences. For instance, in 1973 Michigan livestock were contaminated with Firemaster™ BP-6, a flame retardant composed of mixtures of polybrominated biphenyls (PBB). This situation apparently occurred from Firemaster™ BP-6 accidently being substituted for a magnesium oxide food supplement (Dunckel, A.E., 1975). Subsequently, PBB contamination spread through the food chain for several months, and was ingested by consumers of meat and dairy products. Although no gross disease symptoms were reported for humans, several studies on Michigan dairy farm residents showed various immunologic effects (e.g., decrease peripheral T-cell numbers, increased lymphocytes without detectable membrane markers, increased Ig levels) (NIEHS, 1983; Bekesi, J.G., et al.,1987; Bekesi, J.G., 1978). The effect of these abnormalities on current or future health status is not known (Amdur, M.O. et. al., 1991). Regarding nonhuman effects, over 34,000 cattle and millions of chickens had to be destroyed because they were contaminated with PBB.

In contrast to the PBB contamination experienced in Michigan, very serious human health consequences were observed in the epidemics of organomercurial poisoning in Iraq during 1956, 1960, and 1971-1972. Here, peasant farmers used seed grain treated with an organomercurial antifungal agent to make bread (Bakir F, et al., 1973). There were 6,530 cases of organomercurial poisoning admitted to hospitals, 459 of whom died (Amdur, M.O. et. al., 1991).

Waste products of our modern society have also been shown to affect air quality, which in turn affects human health. There have been several major episodes of air pollution causing mortality, e.g.; Donora, Pennsylvania 1948 -- twenty people died as a result of sulfur oxides produced by a zinc smelter; London, England 1952 -- 4,000 deaths occurred during five days of air pollution resulting from smoke produced from coal heating; New York, New York 1960's -- air quality was greatly affected by smog (ReVelle P. and Revelle C., 1992), and Bhopal, India 1984 -- methyl isocyanate was released into the atmosphere as a result of operational and equipment failures. An estimated 2,800 local residents perished (EPA. 1988). Air pollution also has been associated with non-fatal effects such as impaired pulmonary function and bronchial responsiveness in primary school children (Wang JY, Hsiue TR, Chen HI,1992.; Huang JL, Wang SY, Hsieh KH, 1991), decreased mucociliary clearance, nonspecific bronchial reactivity (Gong H Jr, 1992), increased upper respiratory infections in infants (Jaakkola JJ, Paunio M,Virtanen M, Heinonen OP., 1992) and exacerbating asthma attacks (Schawartz J, et al., 1993).

In Japan, an outbreak of the disease called *itai-itai* ("ouch, ouch") was caused by smelter wastes that contaminated the soils of rice paddies. The heavy metal, cadmium, which is readily absorbed by plants, was present in this waste. The cadmium accumulated in rice grown on the contaminated soil, and was later ingested by the local residents. Female residents began to show a variety of symptoms, predominated by aching bones (Amdur, M.O. et. al., 1991). In other instances contaminated soil can be a direct source of toxic exposure. For example, soil and dust contaminated with lead are a major source of lead exposure in children (ATSDR, 1988).

The lack of control of toxic substances associated with industrial production has led to another legacy, a massive amount of hazardous waste and the proliferation of hazardous waste sites. Approximately 230 million tons of hazardous waste is generated each year in the United States (EPA, 1987). The EPA reports that there are over 30,000 hazardous waste sites that have the potential to release hazardous substances into the environment (EPA, 1988). Since the late 1970's the American public has considered hazardous waste sites to be among the nation's major threats to their health. However, in the scientific community there is much uncertainty about the impact these sites have on public health. The following discussion reviews studies exploring the health effects of hazardous waste sites. These studies took place in the states of New York, Pennsylvania, Massachusetts, Tennessee, and California.

The name of the New York community Love Canal is synonymous to many with the term "hazardous waste". Homes and schools in this community were built upon land that previously was used as a burial site for approximately 19,000 metric tons of organic solvents, chlorinated hydrocarbons, acids, and other hazardous waste during the 1940's. Health studies of the Love Canal community have found an adverse impact of growth (Paigen B. et al., 1987) and birth weight (Vianna N. and Polin, A., 1984)) for children living near the waste site. However, there was no statistically significant relationships found between residency near the site and cancer (Janerich D.T. et al., 1981), or genetic aberrations (Heath Jr., C.W., et al., 1984).

A study of 246 people who were at least 25 years old and worked or lived near the Hyde Park Landfill (north of Niagara Falls, N.Y.) was conducted to survey their medical status. Of the 180 variables evaluated (reported health conditions, health risk factors, or laboratory results), nine (9) were statistically significant indicators of adverse health for the Hyde Park group compared to a sample from a national survey. These significant health conditions were: surgery for hiatus hernia, other abdominal surgery, loss of blood from stomach or bowels, hiatus hernia, benign tumor, frequent cough, use of skin medicine, skin moles, and leg pains (Rothenberg, R., 1981).

The Drake Chemical Superfund Site in Lock Haven, Pennsylvania (Clinton County) is an eight-acre area owed by the Drake Chemical Company. Between the years 1962 and 1981, the Drake Company manufactured intermediate chemicals for producers of dyes, pharmaceuticals, cosmetics, textiles, plant additives, and pesticides. Chemicals from these operations were stored and treated on the site, and subsequently contaminated the area. In 1983 a health study of the community near the site was conducted. Its results found increased rates of skin problems and sleepiness for residents living nearer (2-4 blocks) the site than residents living further from the site (Logue J.N. and Fox, J.M., 1986). Another health study of this area had reported an increase in mortality from bladder cancer and all cancer deaths for residents of Clinton County when compared to the U.S. population (Budnick, L.D.et al., 1984).

The association between health effects of hazardous waste sites and nearby residents was also explored in the communities of Woburn and Lowell, Massachusetts. The town of Woburn has been an industrial site for over 130 years. The major manufacturing products have been chemicals, leather goods, arsenic pesticides, textiles, paper, TNT, and glue. Waste products from these industrial processes migrated into two of the towns municipal drinking water wells. A study of the Woburn community reported an elevated rate of childhood leukemia, perinatal deaths, congenital anomalies, and childhood disorders for those with access to this contaminated water when compared to national data (Lagakos, S.W., Wessen, B.J., and Zelen, M., 1986). The Lowell study found those residing near a five acre waste site to have more self-reported complaints of respiratory problems (e.g., wheezing, shortness of breath, persistent colds, coughs), constitutional complaints (fatigue, bowel dysfunction), irregular heartbeat, irritation of eyes and nose than a sample of people living at least one-half mile from the site (Ozonoff, D.et al., 1987).

In Hardeman County, Tennessee, waste from a pesticide manufacturer contaminated the community drinking water supply for about 60 people (Clark, C.S., et al., 1982; Meyer, C.R., 1983). Approximately 300,000 barrels of waste were buried in shallow trenches on the 200-acre site during the years 1962-1972. In 1977, nearby residents complained their water had an unpleasant odor and taste. They also reported a high number of ill-health symptoms (e.g., skin and eye irritation, upper respiratory infection). In 1979, the results of an extensive health study of these residents showed indications of abnormal hepatic function and hepatomegaly. These conditions subsided within a few months after the initial study, an effect thought resulting from the residents' cessation of drinking contaminated water (Meyer, C.R.,1983).

During the 1940's in Fullerton Hills, California, acidic sludge produced from refining aviation fuel was disposed of in a 20 acre waste site known as the McColl site. Between the years 1951 and 1962, mud from oil drilling explorations also was deposited at the site. Most of the site was covered with soil, and during the late 1970's and early 1980's residential development took place here (Lipscomb JA, 1991). In 1981 a health study was conducted on 377 households in the proximity of the site by the California Department of Health Services. This study found McColl residents had reported higher rates of general ill-health symptoms (e.g., loss of appetite, fatigue, headache, skin irritation) than comparison samples taken from communities located further from the site (Satin, KP, 1983). In 1988, a follow-up health survey was conducted on residents in the McColl site area. This survey found McColl respondents again reporting more general ill-health symptoms than a control sample. This latter study is important because it also attempted to address the issue of reporting bias -- proximity to a site influencing responses. The results of this assessment indicated that psychological stress possibly may be a factor in symptom onset (Lipscomb JA, 1991).

Although there seems to be evidence that hazardous waste sites adversely affect human health, there remains a great deal of uncertainty and controversy about this relationship. The limitations of studies completed to date make it impossible to conclude causal or noncausal associations. These limitations include (among others): small sample size, inability to measure exposure, inability to control for effects of extraneous factors, lack of specific outcomes, extended latency for many chronic diseases associated with low levels of exposure, lack of cause and effect temporal association, and biases associated with self-reported illness. Neutra, et al. (1991) present an interesting discussion of the multiple interpretations of elevated symptoms associated with hazardous waste sites.

In light of the limitations of health studies related to hazardous waste sites and the uncertainty of the effects hazardous wastes have on human health, hazardous waste sites should be considered as possible threats to human health. This consideration is due to the potential for extremely toxic substances being placed in some sites (see Appendix A). Decisions must be made in regard to dealing with these potential health threats.

Methodologies of **Risk Analysis** provide approaches that can be used in making decisions related to the managing of environmental problems. Risk analysis is a discipline that can be used to determine environmental and human health problems associated with various activities and substances, compare the effectiveness of remediation technologies, select sites for potential hazardous facilities, and set management priorities (Cohrssen and Covello, 1981). Risk analysis is comprised of risk assessment, risk management, and risk communication. This course will provide an overview of risk management and risk communication principles, and discuss in more detail the process of risk assessment.

The emphasis on risk assessment for this course results from the need for information about the amount of risk a waste site imposes on human health. The degree to which a waste site threatens human health will vary from different sites for many reasons. For example, risks will vary according to the types of substances present and their concentrations; the degree of contaminant containment and the condition of containment vessels; the potential for substance release off-site; the physical, soil, and hydrologic characteristics of the site; and proximity of human populations to a site. A great deal of information is needed to determine the amount of risk a particular site poses to humans.

Risk assessment provides an approach to organize and collect great amounts of environmental and toxicological data that may be used to determine the size of risk a site presents to human health. The resulting information can be used along with other input to determine what should be done about a waste site -- e.g., no action, emergency action, remedial action. Such decisions should not be made lightly as cleanup of hazardous waste sites are expensive and not cost-effective if the site poses little-to-no threat to humans or the environment. Conversely, the site may adversely affect human health and/or the environment if cleanup is required, but not implemented.

The risk assessment process can also be applied to help choose remediation alternatives. The amount of risk a site presents to humans after the application of a particular remediation method can be evaluated. This evaluation will allow a technology's effectiveness to be assessed on a health risk basis.

Furthermore, the extensive information gathered in risk assessment is beneficial in helping environmental professionals communicate health risks related to a site. For example, the risk assessment process gathers information about the identities of chemicals present, their concentrations, and their health effects. Information is also gathered about the pathways that people are exposed to chemicals, information which may be used to describe how to lower risks for chemical exposures. There also may be subpopulations more susceptible to the effects of contaminant exposure and subgroups which will be identified in the risk assessment.

Environmental professionals involved with hazardous waste site remediation and/or environmental restoration need to understand the role of risk analysis and particularly risk assessment for several reasons. First, such an understanding will provide a rationale for their actions related to hazardous waste remediation/environmental restoration. Secondly, health risks are becoming an important factor in choosing control methods for environmental hazards. Thirdly, environmental professionals increasingly must interact and explain environmental issues to a keenly aware public. This professional development course is intended to provide the student with a basic understanding of the various aspects of risk analysis -- risk assessment, risk management, and risk communication.

## Appendix A

## ATSDR AND EPA LIST OF PRIORITY HAZARDOUS SUBSTANCES
(Top 25)

Benzo(a)pyrene
Dibenzo(a,h)anthracene
Benzo(a)antracene
Cyanide
Dieldrin/aldrin
Chloroform
Benzene
Vinyl chloride
Methylene chloride
Heptachlor
Trichlorethylene
N-Nitrosodiphenylamine
1,4-Dichlorobenzene
Bis(2-ethylhexyl)phthalate
Tetrachloroethylene
Benzo(b)fluoranthene
Chrysene
2,3,7,8-Tetrachlorodibenzo-p-dioxin
Lead
Nickel
Arsenic
Beryllium
Cadmium
Chromium
PCBs

Source: DHSS, ATSDR, EPA (1988). Federal Register: Hazardous Substances Priority List, Toxicological Profiles; Notice. Thursday, October 20, 1988, p. 41284.

## REFERENCES


Amdur M.O., Doull J., and Klaasen C.D. (Eds). (1991). Casarett and Doull's Toxicology, The Basic Science of Poisons. (4th ed.). New York: McGraw-Hill, Inc.

Bakir F, Damluji, S.F., Amin-Aki, L., Murtadha, M., Khalidi, A., Al-Rawl, N.Y., Tikriti, S., Dhahir, H.I., Ciarkson, T.W., Smith, J.C., and Doherty, R.A. (1973). Methylmercury Poisoning in Iraq. Science. 181, p230-241.

Bekesi, J.G., r...and, J.F., Anderson, H.A., Fischbein, A.S., Rom, W.I, Wolff, M.S., and Selikoff, I.J. (1978). Lymphocyte function of Michigan dairy farmers exposed to polybrominated biphenyls. Science. 199, p1207-1209.

Budnick, L.D., Sokal, D.C., Falk, H., Logue, J.N., Fox, J.M. (1984) Cancer and Birth Defects Near the Drake Superfund Site, Pennsylvania. Archives of Environmental Health. 39, p409-413.

Clark, C.S., Meyer, C.R., Gartside, P.S. Gartside, Majeti, V.A., Specker, B. Balistreri, W.F, and Elia, V.J. (1982). An environmental health survey of drinking waster contamination by leachate from a pesticide waste dump in Hardeman County, Tennessee.

Dunckel, A.E. (1975). An updating on the polybrominated biphenyl disaster in Michigan. Arch Environ Health. 46, p296-299.

Environmental Protection Agency. (1987). National Biennial RCRA Hazardous Waste Report US.

Environmental Protection Agency. (1988). Environmental Progress and Challenges: EPA's Update. U.S. EPA-230-07-88-033.

Gong H Jr. (1992). Health Effects of Air Pollution. A review of clinical studies. Clin Chest Med (U.S.). 13 (2), p201-214.

Heath Jr., C.W., Nadel M.R., Zack, M.M., Chen, A.T.L., Bender, M.A., Preston, R.J. (1984) Cytogenetic Findings in Persons Living Near the Love Canal. Science. 251, p1437-1440.

Hsieh KH. (1991). Effect of short-term exposure to low levels of $SO_2$ $NO_x$. on pulmonary function and methacholine and allergen bronchial sensitives in asthmatic children. J. Am. Vet. Med. Assoc. 167, p838-843.

Jaakkola J.J., Paunio M., Virtanen M., Heinonen O.P. (1992). Low-level air pollution and upper respiratory infections in children. Am J Public Health. 81, p1060-1063

Janerich D.T., Burnette W.S., Feck, G., Hoff M., Nasca, P, Polednak, A.P., Greenwald, P. and Vianna, N. (1981). Cancer Incidence in the Love Canal Area. Science. 212, p1404-1407

Key M.M., Henschel A.F., Butler J., Ligo R.N., Tabershaw I.R. (Eds). (1977). Occupational Diseases A Guide to Their Recognition. U.S. Department of Health, Education ,and Welfare. Public Health Service. U.S. Government Printing Office, Washington D.C.

Lagakos, S.W., Wessen, B.J., and Zelen, M. (1986). An Analysis of Contaminated Well Water and Health Effects in Woburn, Massachusetts. Journal of the American Statistical Association. 81, p583-598.

Lipscomb, J.A, Goldman, L.R, Kenneth P.S, Smith D.F, Vance W.A, and Neutra R.N (1991). A follow-up study of the community near the McColl waste disposal site. Environmental Health Perspectives. 94, p15-24.

Logue J.N. and Fox, J.M. (1986). Residential Health Study of Families Living Near the Drake Chemical Superfund Site in Lock Haven, Pennsylvania. Archives of Environmental Health. 41, p222-228.

MacMahon, B. (1986). Comment on the study: An Analysis of Contaminated Well Water and Health Effects in Woburn, Massachusetts. Journal of the American Statistical Association. 81, p597-599.

Meyer, C.R. (1983). Liver Dysfunction in Residents Exposed to Leachate From a Toxic Waste Dump. Environmental Health Perspectives. 48, p9-13.

Neutra R, Lipscomb J, Satin, K, Shusterman, D (1991). Hypotheses to explain the higher symptom rates observed around hazardous waste sites. Environmental Health Perspectives. 94, p31-38.

NIEHS (1983). Investigation of the Immunological, Toxicological Effects of PBB in Michigan Farmers and Chemical Workers. Progress Report: Bekesi. Contract NO1-ES90004.

Ozonoff, D. Colten, M.E., Cupples, A., Heeren, T., Schatzkin, A., Mangione, T. Dresner, M. Colton, T. (1987). Health Problems Reported by Residents of a Neighborhood Contaminated by a Hazardous Waste Facility. American Journal of Industrial Medicine. 11, p581-597.

Paigen B., Goldman, L.R., Magnant, M.M., Highland J.H., and Steegmann A.T. (1987). Growth of Children Living Near the Hazardous Waste Site, Love Canal. Human Biology. 59, p489-508

ReVelle P. and Revelle C. (1992). The Global Environment Securing a Sustainable Future. Boston, Mass:Jones and Bartlett Publishers.

Roboz, J.P., Fichbein, A., and Selikoff, I.J. (1987). Clinical Immunology Studies in Individuals Exposed to Environmental Chemicals. In Berlin, A, Dean, J. , Draper, M.H., Smith, E.M.B., and Spreafico, F. (Eds.): Immunotoxicology. Martinus Nijhoff Publishers, Dordrecht. pp. 347-361.

Rothenberg, R. Morbidity Study at a Chemical Dump - New York. Morbidity and Mortality Weekly Report. 30 (24), p293-294.

Satin, K.P, Deane, M, Leonard, A, Neutra, R, Harnly, M, and Green, R.R (1983). The McColl site health survey: an epidemiologic and toxicological assessment of the McColl Site in Fullerton, California. California Department of health Services, Special Epidemiological Studies Program, Berkeley, CA.

Schawartz J., Slater D., Larson T.V., Pierson W.E., Koenig J.Q. (1993). Particulate air pollution and hospital emergency room visits for asthma in Seattle. Am Rev Respir Dis. 147, p826-831.

U.S. Department of Health and Human Services, Agency for the Toxic Substance and Disease Registry (1988). The Nature and Extent of Lead Poisoning in Children in the United States: A Report to Congress. Atlanta, GA: DHSS, CDC.

Vianna N., Polin, A. (1984). Incidence of low birth weight among Love Canal residents. Science. 226, p1217-1219

Wang J.Y., Hsiue T.R., and Chen H.I.(1992). Bronchial responsiveness in an area of air pollution resulting from wire reclamation. Arch Dis Child 67, p488-490

## REVIEW QUESTIONS

## INTRODUCTION TO RISK ANALYSIS PROCESS

1. List all potential sources of environmental contamination that have been shown to adversely effect human health.

2. Is there conclusive evidence which shows that exposure to substances emanating from hazardous waste sites adversely affect human health? Explain.

3. List reasons why risk assessments are important.

4. Describe the major results of the health studies conducted of Love Canal, New York.

# 1 INTRODUCTION TO RISK MANAGEMENT

**Objective:** Provide an introduction to risk management issues at hazardous waste sites

**Learning Tasks:** Information in this chapter should enable students to:

- Be familiar with the definition of risk management
- Identify the factors involved in making environmental risk management decisions
- Increase the awareness of issues encountered by a risk manager during a hazardous waste site remediation

## INTRODUCTION TO RISK MANAGEMENT

Risk is the probability of an adverse event occurring as a result of a hazard. A hazard is a potential cause of an adverse effect. For example, an icy road may be a hazard, while a risk is the chance of a car accident occurring as a result of the icy road. Objectively evaluating the magnitude of a risk is the goal of risk assessment. As previously mentioned, risk assessment is a valuable tool for estimating the magnitude of risks to people and the environment at a hazardous waste site. It is, however, just one important piece of information which is incorporated into risk management decisions at hazardous waste sites. Where risk assessment allows us to understand the *size* of the risk, risk management is the process of making decisions to *control* those risks.

A more formal definition of Risk Management follows:

> Environmental Protection Agency (EPA) defines Risk Management as....
>
> *"the decision making process that uses the results of risk assessment to produce a decision regarding environmental action. Risk Management includes consideration of technical, scientific, social, economic, and political information" (EPA, 1989a).*

As important environmental risks are identified they must then be controlled or managed so as to reduce significant risks to human health or the environment. Setting goals for risk reduction and determining options for control and remediation of risks are important decisions managers must make. Environmental Risk Management is the process by which those decisions are made.

There are many different types of decisions that are made by risk managers regarding cleanup of a hazardous waste site.

Risks

- Public
  What are the public health risks prior to site remediation, during remediation, after remediation?
- Workers
  What are the risks to workers employed to clean up a site during and after remediation? What about risks to workers who transport the waste?

- Ecosystems/Environment
  What are the ecological risks prior to, during, and after site remediation? To what extent will the ecological welfare be considered in remediation decisions?

Laws & Regulations

- What are the laws, regulations, and guidance that govern the cleanup of a site? What will the involvement be of Federal, State and Local agencies as well as potentially responsible parties?

Remediation Goals and Alternatives

- What are the remediation goals? How "clean" should the site be? How will goals be set for cleanup? Will they be based on technological standards, health standards, or risk information?
- How will remedial alternatives be selected and what are the criteria for choosing one remedial alternative over another?
- What type of remediation alternatives are available? What are the costs associated with different remediation alternatives and what health risks are associated with each alternative? What is the feasibility of the alternatives? The efficiency? Should state-of-the-art technologies be considered? How can different technologies be combined for an optimal solution?
- Should institutional controls be implemented? If yes, what type?

Public/Stakeholder Participation & Social/Political concerns

- Who are the stakeholders who will become involved with the decisions?
- What will be the involvement of stakeholders in the decisions to be made surrounding cleanup?
- How will the public be enjoined to participate in the decisions? How will their input affect the decisions?
- Who will meet with the public to discuss the decisions, are they effective communicators?
- What type of media attention will there be?
- What is the political culture? Are there any strong public interest groups?

Other concerns

- What will the site be used for in the future? Who will be involved in making this decision?
- Who will pay to clean up the site?
- Are your decisions ethical and equitable?
- Are your decisions defensible?

These questions have no simple answers. Making a risk management decision involves incorporating the input from a number of different factors. These factors are depicted diagrammatically in Figure 1-1.

**Figure 1-1**

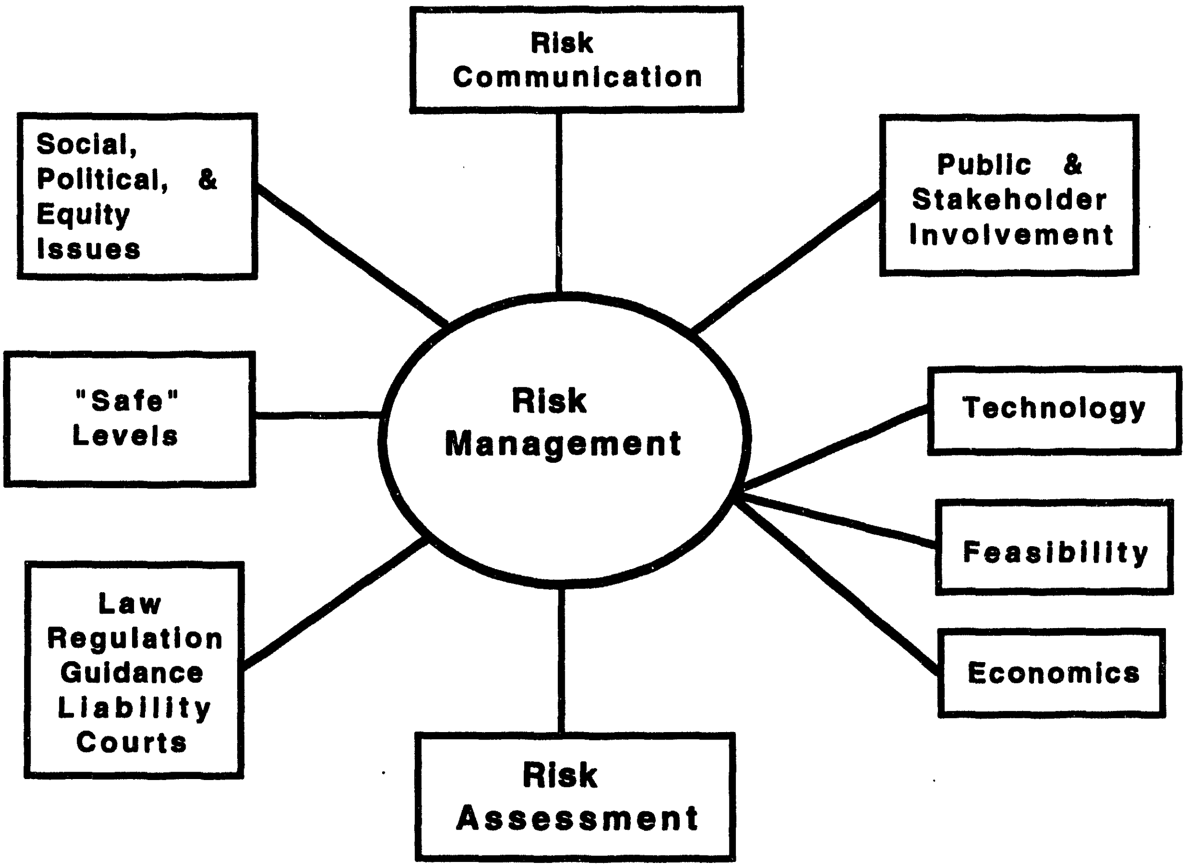



Figure 1-1 is a simplified diagram showing the inputs which are typically considered as part of a risk management decision. The factors which should be considered in the management decisions involved in selecting remedial alternatives include: the feasibility (both economic and technological), economics (evaluating costs and benefits), and available control technology; protection goals ("safe" levels); social and political factors; public interests, public concerns, and public and stakeholder involvement; laws, regulations, guidance, liability issues and court decisions; risk communication; and human health and ecological risk assessment information. Keep in mind, these inputs are not mutually exclusive as depicted, instead, they are strongly inter-related. One input may have a great impact on another, or many others. For example, the social and political culture of a society can greatly affect public

involvement. Consider the opportunity for public involvement in a dictatorship vs. a democratic political system.

In some instances, one of these factors may out-weigh all others and the decision will be obvious. In many instances, however, the decision will be much more difficult. The factors will need to be weighed and assigned importance by all those involved in making the decision, as well as those affected by the decision. A brief discussion of these factors shown in Figure 1-1 follows:

EPA gives guidance for **setting "safe" levels** for cleanup. (EPA 1991a) This guidance asks risk managers to set Preliminary Remediation Goals (PRGs) for cleanup. These goals establish the highest level of contaminant which may remain after cleanup. It is assumed that these levels will be "safe" for human health. PRGs can be based on current available regulations, or they can be calculated based on an assumed level of risk (e.g. one case of disease in a million). Setting PRGs and determining "safe" levels will be discussed in Chapter 11, Risk Management.

In order to make decisions among remediation alternatives there must be a general understanding of the types of remediation **technologies**. Examples of these technologies will be introduced in Chapter 10. Each alternative has an associated **cost** as well as a potential **benefit**. Also, some remediation alternatives may be more **feasible** than others (both technologically and economically) depending on the characteristics related to a site. These issues must be weighed when selecting a final remedial alternative.

The **political climate and societal values** of a community can play a large part in the overall outcome of the decision. Obtaining a socially acceptable and equitable solution ideally should be a goal. These social factors add a large subjective component to the decision.

**Public and stakeholder concerns** are also important inputs into this type of decision making process. Enjoining the public and the stakeholders at an early stage in the process is essential to make a well informed, socially acceptable decision. These factors will be briefly introduced and elaborated in Chapter 11. Once the public and stakeholders have been enjoined in the decision making process, there must also be effective communication among interested parties. The ability to effectively communicate with the public and stakeholders is an important skill, which is the focus of Chapter 12 entitled **Risk Communication.**

Sections II and III of this book discuss **risk assessment**. Section III details the methodology related to EPA's human health evaluation for the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) sites. The goal of this assessment is to determine the types, magnitude, and probability of harmful effects on human health occurring as a result of contamination emanating from a site. The baseline risk assessment which is performed considers predominantly risks to **public health**. Other types of risk assessments which may be performed at a CERCLA site include **occupational** and **ecological** risk assessments. (Figure 1-2). While these are not discussed in detail in this course, they are important in making risk management decisions. Occupational risk assessments are performed to obtain an estimate of health risks for workers who are involved with the hazardous waste site before, during and after remediation. Ecological risk assessments provide an estimate of ecological effects before, during and after the hazardous waste remediation process.

**Figure 1-2**


A risk manager must have a solid understanding of the risk assessment process in order to use the risk estimate information in a management decision. The major components of **Risk Assessment** which will be detailed in this book include: Hazard Identification, Exposure Assessment, Toxicological Dose Response, and Risk Characterization. Uncertainty within risk assessment will also be discussed along with the limitations of risk assessments.

Risks can be imposed on employees in the workplace, for the general public, and on the environment and the ecosystems. An important reason for establishing **laws, regulations, and guidance** is the public's demand for a safe and healthful environment and workplace. Compliance with laws and regulations are a crucial element of risk management decisions. The Federal Government has passed a variety of laws which govern these areas of potential risk and will be briefly discussed in the next chapter of this section. Emphasis in this book, however, will be placed on those laws, regulations, and guidance which pertain to the cleanup of hazardous waste. Specifically, we will discuss the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) whose regulations are enforced by EPA. CERCLA, through the National Contingency Plan, mandates cleanup requirements for abandoned hazardous waste sites. It also requires that risk assessments be performed to assess baseline risks at a site, and the information from the assessments be used in determining remedial alternatives. The process of collecting information for selecting remedial alternatives is called the Remedial Investigation/Feasibility Study (RI/FS). The next chapter in this section will develop further the relationship of risk assessment and the laws, regulation, and guidance which govern abandoned hazardous waste sites. The final chapter in this section will detail the RI/FS and how risk assessment plays a role in the process.

# REFERENCES


Environmental Protection Agency (EPA) (1989a). Glossary of Terms Related to Health, Exposure, and Risk Assessment. Air Risk Information Support Center Research Triangle Park, North Carolina. EPA/450/3-88/016

EPA(1989b). Risk Assessment Guidance for Superfund VOL 1: Human Health Evaluation Manual (Part A) US Dept of Commerce.

EPA (December, 1991a) Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (Part B Development of Risk-based Preliminary Remediation Goals) Interim Office of Emergency and Remedial Response, USEPA

EPA (December, 1991b) Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (Part C Risk Evaluation of Remedial Alternatives) Interim Office of Emergency and Remedial Response, USEPA

## REVIEW QUESTIONS

## INTRODUCTION TO RISK MANAGEMENT

1. What is the difference between a risk and a hazard?

2. List the factors that are used in making a risk management decision.

3. What are the three types of **risk assessments** that are important for making risk management decisions at hazardous waste sites?

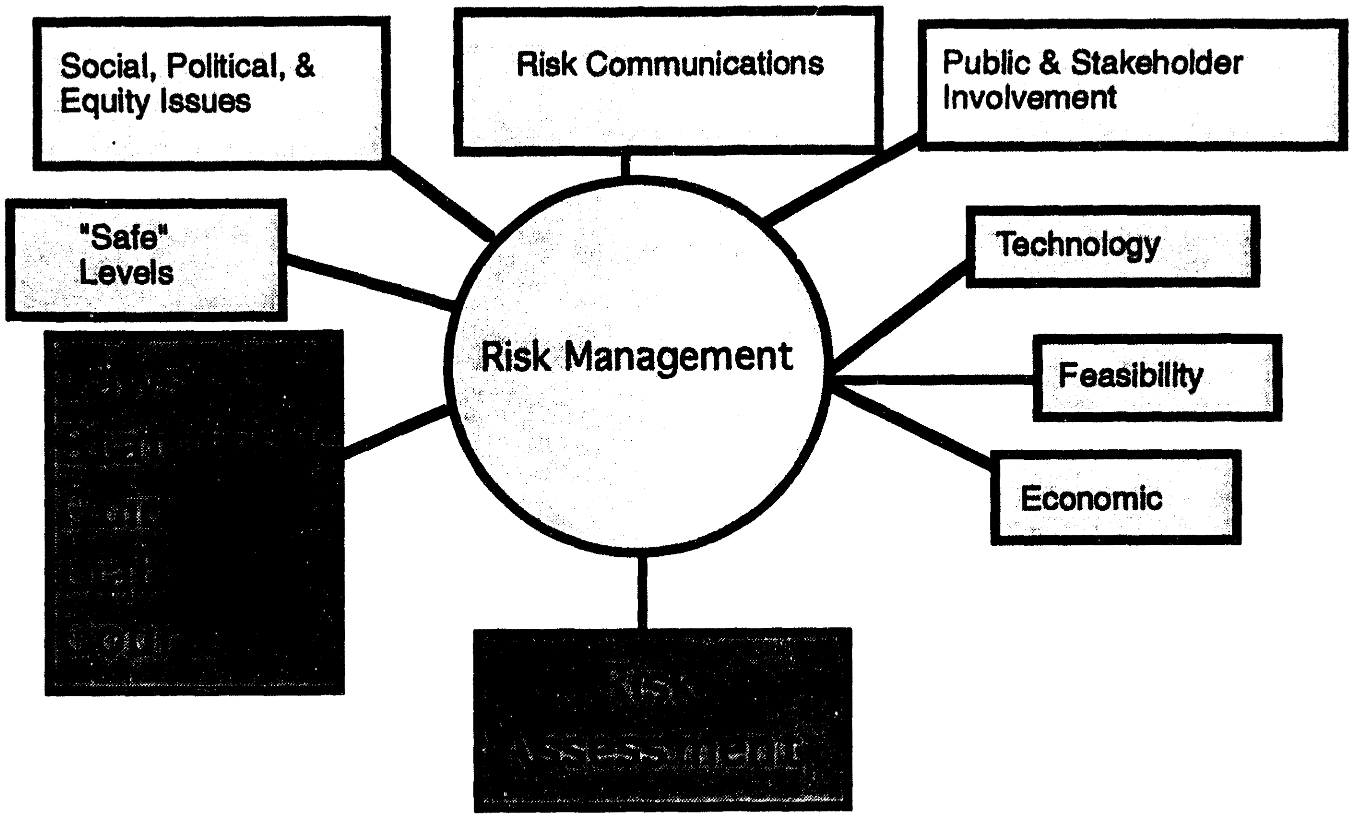
# 2 RISK MANAGEMENT AND ENVIRONMENTAL LAW, REGULATION, & GUIDANCE

**Objective:** Provide an overview concerning the role of environmental laws, regulations, and guidance in risk assessment and risk management decision-making.

**Learning Tasks:** Information in this chapter should enable students to:

- Understand the organization of the Federal Government and their rule-making policies
- Become familiar with the history of hazardous waste legislation
- Be introduced to major federal environmental laws, regulations, and guidance
- Gain an understanding of the role of risk in federal government regulation
- Become familiar with the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) and the National Contingency Plan (NCP)

## INTRODUCTION TO ENVIRONMENTAL LAW, REGULATION, AND GUIDANCE

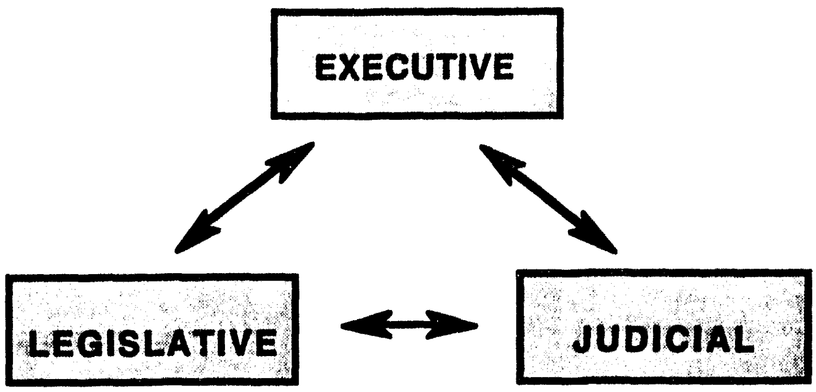



This chapter will provide an understanding of the laws, regulations, and guidance associated with risk assessment. First, an introduction to Federal Government administration and rulemaking will be discussed. A basic overview of important environmental laws and regulations will follow. Emphasis will remain on hazardous waste legislation to include a historical perspective and discussions of pertinent law and regulation. Finally, the Environmental Protection Agency's (EPA's) guidance regarding conducting risk assessments along with Remedial Investigation/ Feasibility Studies (RI/FS) at Superfund sites will be addressed.

### Organization of the Federal Government

In order to gain a broad understanding of how our Federal Government addresses issues of environmental law, it is essential to understand the tripartite model of government embodied in the constitution; the separation of powers among the legislative, executive, and judicial branches of government. Figure 2-1.

**Figure 2-1**




Administrative agencies, such as the Environmental Protection Agency (EPA), Occupational Safety and Health Administration (OSHA), and the Food and Drug Administration (FDA), are created by the **legislative branch**, managed and operated by the **executive branch**, and subjected to periodic review by the **judicial branch**.

The **legislative branch** (Congress) can respond to an area of concern by creating new administrative agencies or by granting new powers and responsibilities to an existing agency. They write and enact enabling legislation which gives the agencies their statutory mandate - the formal directive from Congress with regard to the subject matter in question. This legislation is often in the form of an Act, a statute, or a law. For example, the Occupational Safety and Health Act "..authorizes the Secretary of Labor to set mandatory occupational safety and health standards". An agency often administers more than one originating statute. The EPA has been given the directive to deal with toxic air pollutants under the Clean Air Act, toxic water pollutants under the Clean Water Act, toxic wastes deposited into the ground under the Resource Conservation and Recovery Act (RCRA), and toxic chemicals generally under the Toxic Substances Control Act (TSCA). Further, two or more agencies may have overlapping statutory mandates. For example both OSHA and EPA have the authority to regulate worker exposure to harmful chemicals. (Ashford, 1991).

Federal Administrative Agencies are set within the **executive branch** of the government's organizational structure. The President controls the appointment process to select an agency's upper management, but political appointees are subject to Senate approval. Agencies carry out their statutory mandate by promulgating (making known the terms of law) administrative regulations and standards. EPA and OSHA follow an informal "notice and comment" rule-making process described in the next section.

The ultimate arbiters of the meaning of a particular statute or constitutional provision are the courts...the **judicial branch**. Agencies can be challenged if it is felt that they have promulgated regulations which do not correspond to the "intent" of a statute.

Law and Rule-making

**Legislation** is created when bills are proposed and passed by Congress. The provisions of legislation become **regulation** when the agencies within the executive branch (e.g., EPA, DOT, OSHA) implement the intentions of the law by developing and enforcing regulations. To clarify, Congress (the legislature) writes and passes laws, which we will refer to as legislation in this section. Agencies (eg., OSHA, EPA) develop and enforce regulation to carry out the intent of the legislation.

Agencies can promulgate regulations only after a public notice and an opportunity for public comment occurs. This rulemaking policy is in accordance with the Administrative Procedures Act (APA). The rule-making procedure is as follows:

First, a proposed regulation is developed by an agency and published in the Federal Register. The Federal Register is a compendium of notices, announcements, proposed and final rules (regulations), and descriptions of the activities of the federal government. It is published every business day.

Once the regulation is proposed, a public comment period (usually 60 days) is established, and a public hearing occurs if requested by at least five people. After the public comment period closes, the proposed regulation is revised as appropriate in light of the comments. A final regulation is then promulgated. An agency can later change a final regulation by publishing proposed amendments to a final regulation, interim final amendments, technical amendments, and clarification notices (Wagner, 1992).

The proposed, final, or amended regulation consists of three parts; the heading, the preamble, and the text. The preamble contains a summary of the action being taken, and provides information regarding the purpose and intent of the regulations. It is written in "non-regulatory" language. The text is the actual regulations which are proposed or promulgated. When they are promulgated, they become part of the Code of Federal Regulations (CFR) and carry the full force of the law. Further clarification of regulations is provided through the issuance of guidance documents and policy directives. Guidance documents are issued primarily to elaborate and provide direction on the implementation of regulations. Policy directives specify procedures that must be followed pertaining to a regulation (Wagner, 1992).

<u>Where can Legislation and Regulation be found?</u>

Legislation, consisting of Laws, Statutes, and Acts, are codified in the **United States Code (USC)**. These are often accessible at university libraries.

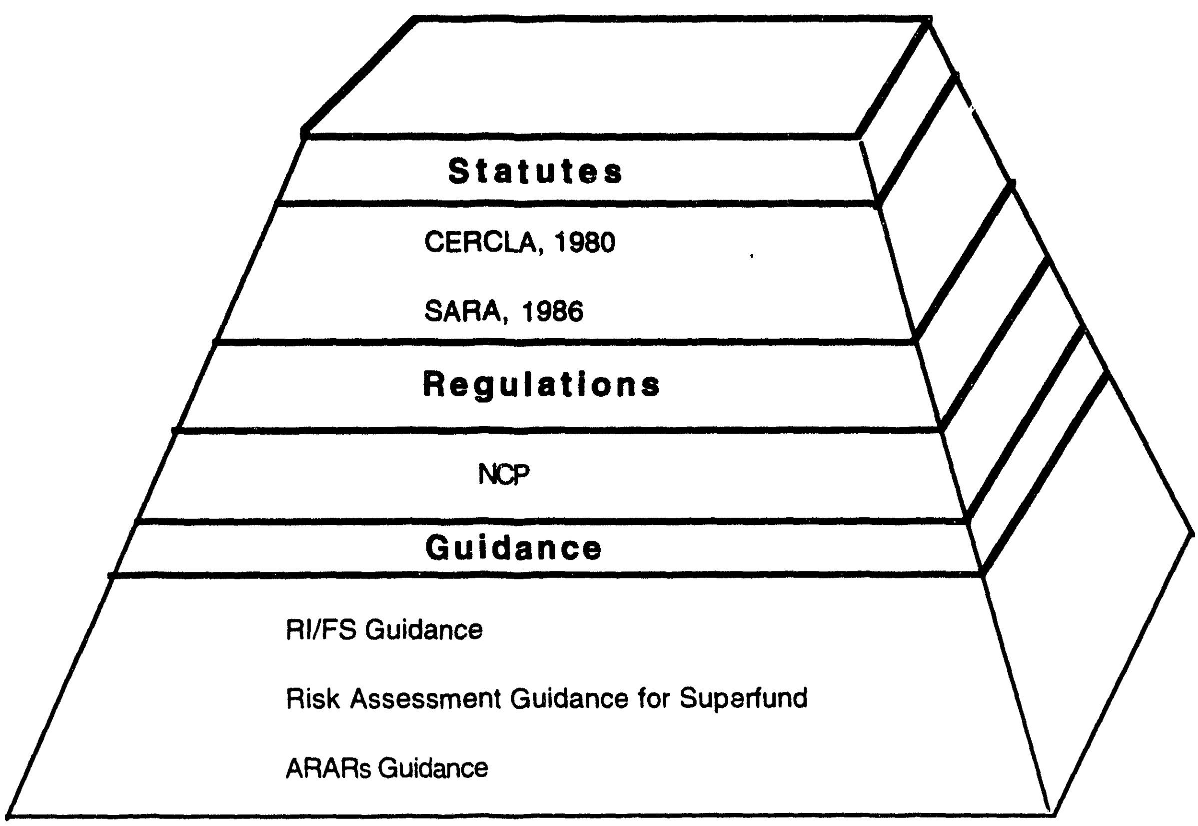
The **Code of Federal Regulations (CFR)** is the compilation of all final Federal regulations in effect in the United States. The full text of all final regulations, not including the preamble, promulgated by all federal government agencies, is included in the CFR. The CFR is divided into 50 titles covering the areas subject to federal regulation. Title 40 of the CFR deals with protection of the environment. This is where EPA regulations are found. Title 29 deals with labor, and is where Occupational Health and Safety Administration (OSHA) regulations are found. Title 49 deals with transportation, including hazardous materials and hazardous waste transportation (Lindgren, 1990).

As discussed above, the **Federal Register (FR)** is published every business day. It serves as a source of information regarding the current activities of all federal agencies. As rules, regulations, and standards are proposed, promulgated, or amended, they are published in this reference.

Federal Laws vs State Laws

Federal laws form the basis for environmental risk regulation, but superimposed on the federal laws may be a layer of state laws and court decisions. In general, state laws, rules and regulations must be at least as stringent or more stringent than federal laws. The Resource Conservation and Recovery Act (RCRA) may be carried and implemented by states in lieu of the Federal Government as long as the state's program is equivalent and consistent with the Federal Program. Some laws, such as Comprehensive Environmental Response Compensation and Liability Act (CERCLA), cannot be delegated to states for implementation, however, states may enter into a "cooperative agreement" with EPA. There may also be another layer of directives, orders, or policies that are specific to the place of employment, in addition to state and federal laws (See Figure 2-2).

**Figure 2-2**
**Relationship of Documents**
**Regarding Superfund Human Health Evaluation**



(EPA, 1989)

Environmental Laws and Regulation

There was much activity in the 1970's and 1980's related to environmental legislation due. to a number of issues surrounding health effects from hazardous waste dumps, pesticides, contamination in drinking water, etc. Congress responded to public demand for protection from these risks by passing, amending and re-authorizing a number of environmental laws regarding the protection of the public, workers, and the environment (See Table 2-1).

Many federal health and safety standards have included a directive to control public health risks. Three agencies involved in identifying and managing risks include:

**EPA** - Environmental Protection Agency
Department of Health and Human Services -- Concerned with public health and the environment. Clean Air Act, Clean Water Act, CERCLA, RCRA, FIFRA, and TSCA etc.

**OSHA** - Occupational Safety and Health Administration
Department of Labor -- Worker Protection Issues; Occupational Safety and Health Act; Safety; Hazard Communication; Hazardous Waste Operations and Emergency Response (HAZWOPER); confined; spaces; lead; asbestos; bloodborne pathogens; lab safety; etc.

**FDA** - Food and Drug Administration -- Food, Drug, and Cosmetic Act - Regulates food additives, food contaminants, naturally occurring parts of food or color additives to food, drugs, or cosmetics, as well as potential carcinogens.

## Table 2-1
## Major Federal Legislation

| Major Federal Legislation | Dates of Enactment |
|---|---|
| Asbestos Hazard Emergency Response Act (AHERA) | 1986 |
| Clean Air Act (CAA) | 1955, 1963, 1965, 1967, 1970, 1974, 1977, 1990 |
| Clean Water Act (CWA) | 1948, 1956, 1961, 1965, 1966, 1970, 1972, 1977, 1987 |
| Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) | 1980 |
| Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) | 1947, 1972, 1975, 1978, 1983, 1988 |
| Food, Drug, and Cosmetic Act (FDCA) | 1906, 1938, 1958, 1960, 1968 |
| Hazardous Materials Transport Act (HMTA) | 1975 |
| National Environmental Policy Act (NEPA) | 1969 |
| Occupational Safety and Health Act (OSHA) | 1970 |
| Resource Conservation and Recovery Act (RCRA); Hazardous and Solid Waste Amendments (HSWA) | 1976, 1984 |
| Safe Drinking Water Act (SDWA); Lead Contamination Control Act (LCCA) | 1974, 1986, 1988 |
| Solid Waste Disposal Act (SWDA) | 1970, 1976, 1980, 1984 |
| Superfund Amendments and Reauthoriztion Act (SARA) Title III - Emergency Planning and Community Right to Know Act (EPCRA) | 1986 |
| Toxic Substances Control Act (TSCA) | 1976, 1986 |

(Zimmerman, 1990)

## HISTORY OF HAZARDOUS WASTE LEGISLATION

Throughout the 1970's and 80's public concerns grew regarding past waste disposal practices and the resulting potential adverse health effects. In response to the public outcry, Congress took action by passing legislation. What follows is a brief chronology of some of the events which led to the environmental hazardous waste legislation which is in place today.

1965 - Solid Waste Disposal Act (SWDA) - Dept. of Health Education and Welfare.
SWDA helped localities turn their dumps into covered sanitary landfills which looked and smelled better as well as cut down on the air pollution from waste burning operations at the dumps. This act was amended in 1970 to produce the first Resource Conservation and Recovery Act (RCRA).

1971 - Times Beach, MO. Sludge wastes contaminated with 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD) were taken from a hexachlorophene production facility in Verona, MO and mixed with waste oil. This mixture was sprayed for dust control on residential, commercial and public areas of Eastern Missouri (Johnson, 1988). The entire community was relocated due to the potential health effects.

1975 - Congress recognized the "...need to encourage technical innovation in the management of the three to four billion tons of discarded materials generated in the US each year". This led to the enactment of what we know as the Resource, Conservation, and Recovery Act (RCRA).

1976 - RCRA enacted by Congress. This legislation was composed of the following basic elements.

1. Identify and list hazardous waste
2. Registering generators, transporters, and disposal facilities so that the ultimate fate of every waste listed as hazardous could be traced.
3. Cradle-to-grave tracking system of hazardous waste from the source to the point of final burial

EPA was to draft regulations to carry out the hazardous waste provisions of the Act. These regulations were not promulgated until 1980.

1978 - Niagara Falls, NY - Love Canal

Love canal was an uncompleted half mile long waterway dug around the turn of the century by William T Love. Beginning in the 1930's its trench (clay lined bottom) was used as an industrial dump for over 200 chemicals. The canal was sold to Hooker Chemical and Plastics Corporation in 1947 and used as a industrial waste depository until 1953. It was then sold to Niagara Falls board of education which built a school on the site and sold the rest to a home contractor. In 1976, heavier than normal rains (over a period of years) raised the water table and sent the chemicals bubbling into basements and playgrounds.

In 1978, the first disaster declaration was made and 37 families were moved from their homes in Love Canal. As of 1980, 1000 families were evacuated, and cleanup and relocation costs were estimated to be in excess of $20 million. The issue of Love Canal forced EPA to begin proposing the long awaited RCRA regulations to deal with hazardous waste.

1979 - Woburn, MA

Hazardous waste was discovered near two of eight municipal wells that supplied water to Woburn, MA. 32 different volatile organics (VOC's) and 22 metals were identified in the drinking water. The VOC's included trichloroethylene, tetrachloroethylene, and chloroform. There was also a cluster of 20 cases of childhood leukemia. The two wells were closed in 1979. At the request of the citizens, the state and federal authorities examined the potential problem and found elevated levels of leukemia in children in Woburn. Studies since then have both supported this finding and been inconclusive as to the cause of the leukemia. It was concluded that a definitive causal link was not established, but there was reason for concern (Johnson, 1988 Upton, 1989).

1980 - RCRA regulations finally unveiled

Spring 1980, EPA issued final hazardous waste regulations to provide "cradle to grave" tracking of hazardous wastes from the point of generation to the point of disposal and for 30 years thereafter. An interesting anecdote: The site at which the unveiling of the RCRA rules was to take place, a New Jersey chemical waste dump, blew up shortly before invited dignitaries and press were scheduled to arrive!

With the RCRA rules in place, there still remained the issue of what to do with those sites which were abandoned. Congress noted that the responsible parties should pay for cleanup of existing sites posing health problems.

The General Accounting Office (GAO) recommended that a self-sustaining national trust fund be established to pay for cleaning up abandoned hazardous waste sites. EPA agreed with GAO, "...thus Superfund was conceived".

1980 - Superfund: (a.k.a. Comprehensive Environmental Response, Compensation, and Liability Act - CERCLA)
Provides for response to cleanup of environmental problems through the following mechanisms: 1) Identify the abandoned hazardous waste sites, 2) Establish a mechanism for response, and 3) Develop liability and determination systems.

1984 - Hazardous and Solid Waste Amendments (HSWA) - RCRA amendments.

1986 - Superfund Amendments and Reauthorization Act (SARA) - CERCLA amendments.

**MAJOR LAWS AND REGULATIONS:**

**Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) 1980 & Superfund Amendments and Reauthorization Act (SARA) 1986**

CERCLA was designed to provide a system to identify and clean up chemical and hazardous substance releases. It established a $1.6 billion fund to pay for cleanup of environmental contamination where no responsible parties can be found, or where those responsible cannot or will not pay for cleanup. The Act also and enables the government to collect costs of cleaning up a release from responsible parties. Furthermore, CERCLA requires industry to report hazardous substance releases that exceed EPA established "reportable quantities" to the National Response Center (1-800-424-8802 or 1-202-267-2675). In 1986, CERCLA was amended by SARA, which clarifies program direction and expedites cleanup activities. SARA established a $8.5 billion fund to finance Superfund response activities. Under SARA, sources of revenues come from taxes on petroleum products, feed stock chemicals, imported chemical derivatives, and a broad-based surtax collected from certain corporations; appropriations from the general fund; costs recovered from responsible parties; and interest earned on trust fund monies. Among a number of other things, SARA incorporates strict cleanup standards strongly favoring permanent remedies at waste sites. It requires that individual health assessments be made on each site, and establishes a schedule for completion of cleanup work. SARA provides for increased state involvement in program decisions and for greater citizen involvement in remedy selection and cleanup. SARA also establishes a $500 million trust fund for cleanup of Underground Storage Tanks (USTs), a program to maximize the safety of workers engaged in hazardous waste operations, an emergency planning and community right to know program (Title III); and a radon gas and indoor air quality research program (Title IV). Federal facilities were not included in the 1980 Act, but were specifically included in SARA 1986 Section 120(a)(1). See Appendix A for an outline of CERCLA as amended by SARA.

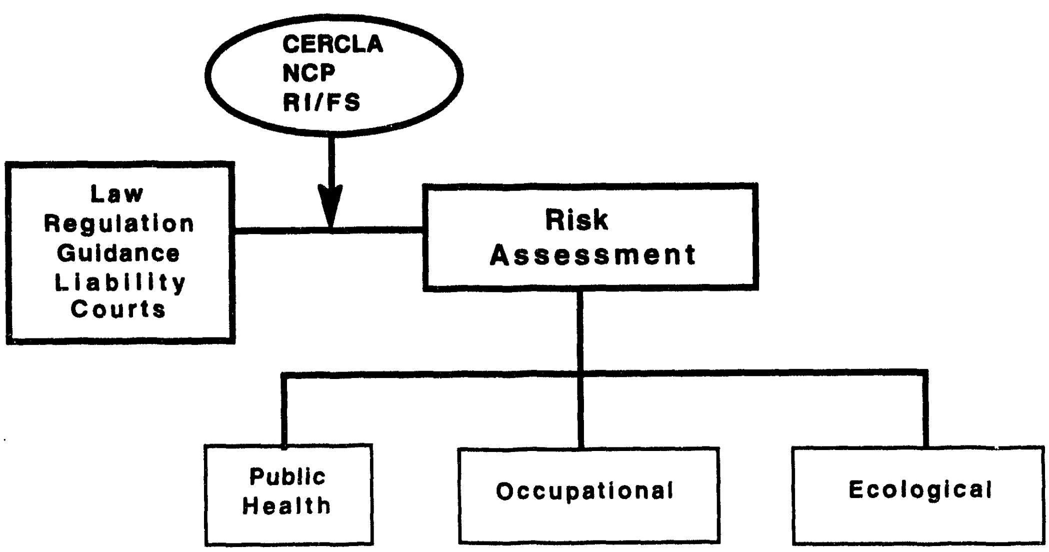
<u>Liability Issues</u>

CERCLA liability extends to all properties (the environment) contaminated by hazardous substances. Parties liable for releases of hazardous substances are known as Potentially Responsible Parties (PRPs) which include: current owners or operators of a site, owners and operators at the time of disposal of a hazardous substance, generators of hazardous substances disposed, and, transporters of such substances to a site. CERCLA imposes both strict, joint and several liability for all costs of site cleanup and damages incurred. Strict liability means without regard to fault or degree of care exercised. Joint and several liability means that any PRP is potentially fully liable (Broetzman, 1993).

**The National Oil and Hazardous Substances Contingency Plan - NCP (40 CFR 300)**

The National Oil and Hazardous Substances Contingency Plan, more commonly known as the National Contingency Plan (NCP), are the regulations which outline how the federal government responds to hazardous substance releases into the environment. The plan was originally part of the Clean Water Act (CWA) and was used to respond to oil spills into navigable waters. The plan was broadened to include releases of hazardous substances into the environment from uncontrolled waste sites when Superfund was enacted in 1980. The plan establishes regional response teams to handle emergency situations, and a national response team for technical advice. Part of the NCP directs the EPA to keep a list (National Priorities List - NPL) of abandoned or hazardous waste sites and update it annually. Sites are rated according to relative risk with the Hazard Ranking System (HRS) (See Appendix D), and by consideration of available information as to the quantity and toxicity of hazardous substances at a facility and their potential effects on the environment if released. The NCP also includes procedures for conducting Preliminary Assessments/Site Inspections (PA/SI), Remedial Investigations/Feasibility Studies (RI/FS), and removal efforts. During the RI/FS baseline risk assessments are required. The EPA methodology for conducting risk assessments will be discussed further in Section III of this book. Figure 2-3 depicts the connection between Law and Risk Assessment at CERCLA hazardous waste sites.

**Figure 2-3**



**Resource Conservation and Recovery Act (RCRA) 1976 & Hazardous Solid Waste Amendments (HSWA) 1984** - RCRA provides "cradle to grave" authority to control and track hazardous wastes from their point of generation to their ultimate disposal. It affects Hazardous Waste generators, transporters, and Treatment, Storage, and Disposal (TSD) facilities. The key provisions of RCRA direct the EPA to develop: criteria to determine which wastes are hazardous, a system to track wastes from point of generation to point of disposal, standards for the construction and operation of disposal facilities, a system for issuing permits to TSD's, and guidelines for developing state hazardous waste management programs. Although enacted in 1976, final regulations were not published until 1980. In 1984, RCRA was amended by HSWA which set further deadlines for regulatory actions. HSWA closed some of the loopholes which allowed vast amounts of hazardous waste to go unregulated. It alleviated small generator exemptions, placed severe restrictions on land disposal, stipulated minimum technological requirements, and enacted a new subtitle dealing with Underground Storage Tanks.

CERCLA vs RCRA Remediation

The interrelationship between CERCLA and RCRA authorities and programs has caused confusion for active sites with past contamination problems. The distinguishing characteristic between RCRA and CERCLA is that RCRA regulates hazardous materials management and cleanup at active and future sites, whereas CERCLA provides companion remedial authority for inactive sites. RCRA requirements are designed for interim status and new facilities seeking to continue or cease operations at active hazardous waste management sites, while CERCLA's emphasis is to remedy inactive (abandoned) waste sites not covered by RCRA.

Federal Facilities

Current EPA policy favors the use of RCRA regulations for remediation where such authority can be exercised. This may vary from state to state. SARA requires, however, that all federal sites with hazardous waste cleanup problems, including those sites that are active, be listed under the NPL and be restored according to the terms and schedules contained in a "federal facility agreement" developed for each site by the federal agency which manages the site, EPA, and the host state. These negotiated agreements often allow remediation activities to proceed under a combination of RCRA and CERCLA (Broetzman, 1993). For a discussion of RCRA corrective action remedial procedures refer to Appendix C.

**Clean Water Act (CWA)**--Formerly the Federal Water Pollution Control Act (FWPCA)
The Clean Water Act regulates the quality of surface water primarily by providing a permit system that governs the amount of contaminants that may be discharged into surface waters. The National Pollutant Discharge Elimination System (NPDES) permits for a facility specify the kinds and amounts of pollutants that may be discharged by a facility over a given period of time.

**Safe Drinking Water Act (SDWA)**
This act protects the drinking water system by setting Maximum Contaminant Levels (MCL's) for public drinking water systems. Because the majority of drinking water (80%) comes from groundwater (underground aquifers), MCLs are used as the basis for ground water cleanup criteria for CERCLA and generally for all environmental cleanup that involves potable water.

**Clean Air Act (CAA) of 1970, Amended in 1977, 1990**
The Clean Air Act regulates both stationary and mobile sources of air pollution. It requires the EPA to enforce National Emissions Standards for Hazardous Air Pollutants (NESHAPS); National Ambient Air Quality Standards (NAAQS); New Source Performance Standards (NSPS); and promote the Prevention of Significant Deterioration (PSD).

**Toxic Substances Control Act (TSCA) of 1976**
TSCA regulates the manufacture and commercial distribution of hazardous chemical products within the United States and mandates that they be evaluated for health and environmental effects. It does not govern the export of these products. Regulations for high risk chemicals include: halogenated chlorofluoroalkanes (a type of CFC), friable Asbestos (AHERA), and TCDD (dioxin). Also, under TSCA, EPA prohibits the manufacture, processing, distribution, and most uses of PCBs.

TSCA has many provisions which regulate hazardous substances. TSCAS legislation required EPA to compile an inventory of existing chemicals in U.S. commerce. Also, manufacturers and importers must notify EPA at least 90 days before manufacturing a new chemical or importing a new chemical in bulk for commercial purposes. This is called pre manufacture notification. Firms must include all exposure information known to them and any test data in their possession on the health and environmental effects of a new chemical. Specifically, a full report or standard literature citation must be submitted to substantiate the following types of data: health effects, ecological effects, physical and chemical properties, environmental fate characteristics, monitoring, and test data related to environmental release of a substance. Also, data must be supplied to show the chemical, if not subject to a test rule, will not present unreasonable risk to health or the environment.

**National Environmental Policy Act (NEPA)** - NEPA is designed to ensure the impacts of proposed major federal actions on the human environment are assessed. It requires Environmental Impact Statements prior to major federal action (or federally sponsored action) which *significantly* affects the human environment.

**Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)**
Under the Federal Insecticide, Fungicide, and Rodenticide Act, all pesticide manufacturers must register their products with the EPA before they can legally distribute and sell them in the United States. Products must not pose unreasonable adverse effects to humans or the environment. In coming to regulatory decisions, the agency must adhere to FIFRA's risk/benefit provision which requires EPA to weigh the social, economic, and environmental costs against a pesticides benefits. Five risk criteria include: Acute toxicity to humans or domestic animals, the potential of adverse chronic effects in humans, hazards to non-target organisms, separate criteria for hazards to threatened or endangered species, and other adverse effects criteria in cases where the pesticide offers benefits that justify its continued use. Pesticide applicators must be certified.

**Hazardous Materials Transport Act (HMTA)**
The Hazardous Materials Transport Act gives the Department of Transportation (DOT) authority to regulate within the US the movement of substances that may pose a hazard to health or the environment when transported by air, highway, rail or water. Exempt are those substances regulated by the U.S. Coast Guard under the Ports and Waterways Safety Act. HMTA regulates shippers, carriers or transporters, and those who manufacture packages or containers used to transport hazardous materials. They must be registered with DOT and are issued registration certificates. Hazardous substances and wastes regulated by RCRA and Superfund come under DOT regulation when they are transported.

## THE ROLE OF RISK IN FEDERAL GOVERNMENT REGULATION

The **federal government** attempts to manage risks to workers, the public, and the environment with legislation, policy and rule-making.

The legislative branch passes laws which empower the agencies to promulgate rules that carry out the intent of the law. They set exposure limits, emission limits, or may require control methods or personal protective equipment in an attempt to reduce the risks of concern. Often times disputes over what level of risk is acceptable are settled in the federal courts.

The National Academy of Sciences characterized governmental risk management as follows:

> Risk management is the process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic, and political concerns to reach a decision.
>
> It is the process of evaluating regulatory actions and selecting among them. Risk management, which is carried out by regulatory agencies by various legislative mandates, is an agency decision-making process that entails consideration of political, social, economic, and engineering information with risk-related information to develop, analyze, and compare regulatory options and to select the appropriate regulatory response to a potential chronic health hazard. The selection process necessarily requires the use of value judgments on such issues as the acceptability of risk and the reasonableness of the costs of control (National Research Council, 1983, 18-19).

Risk assessment and management are an integral part of contemporary regulatory activity. Major federal health and safety statutes described above have included a directive to control public health risks. These statutes, however, did not define what degree of public health risk was acceptable or unacceptable. This stipulation was left to the regulatory agencies to determine

The FDA was the first government agency to use risk assessment to make regulatory decisions. In 1973, the FDA proposed a method for the regulation of carcinogenic drugs used in food-producing animals. An acceptable lifetime cancer risk was initially proposed of $10^{-8}$ or one cancer in one hundred million. Later, another risk assessment methodology was adopted and the acceptable lifetime risk was increased to $10^{-6}$ or one in one million (Hallenbeck, 1993).

The EPA has been somewhat inconsistent in its definition of acceptable lifetime risk. In decisions regarding the regulation of carcinogenic air pollutants risks in the range of one in 100,000 (0.00001) to one in one thousand (0.001) have been considered acceptable (Hallenbeck, 1993). In decisions regarding active ingredients in pesticides, risks ranging from $10^{-7}$ (one in 10 million) to 0.02 (2 of 100) were considered acceptable. Regarding enforcement of the Safe Drinking Water Act (SDWA), the EPA goal for carcinogens is zero exposure...very difficult to achieve. And finally, regarding hazardous waste sites, EPA generally requires cleanup levels for carcinogens which are commensurate with a risk residual of $10^{-5}$-$10^{-6}$ (Hallenbeck, 1993).

OSHA, in setting Permissible Exposure Levels (PEL's) for carcinogens, is guided by a 1980 Supreme Court definition of "significant risk" in *Industrial Union Department v. American Petroleum Institute* case (known to many as the "benzene case") (Ashford, 1991). The Court found a risk of 1/1000 to be significant. Neither the Supreme Court nor OSHA have stated what they consider to be an insignificant (acceptable) occupational risk. To place worker lifetime mortality risk of 1/1000 in perspective, the average lifetime risk of a work-related death in the private sector is 2.9/1000 (mostly accidents). Since 1980, OSHA has revised many of the PEL's, and it appears that OSHA was exceeding the Supreme Court guideline for the definition of significant risk in some cases. (Hallenbeck, 1993) As of 1993 however, all current PEL's were vacated in a court decision, and are now being enforced at the less protective 1970 PEL's.

The International Commission on Radiological Protection (ICRP) recommends limits for radiation dose limits for workers and the general population. These limits are adopted by most nations including the U.S. Nuclear Regulatory Commission (NRC). Assuming 45 years of employment in the nuclear industry, the ICRP recommended worker annual dose limit translates into a lifetime cancer mortality risk of 4/100. The general population annual dose limit translates into a lifetime cancer mortality risk of 4/1000 (assuming 70 years of exposure to the limit) (Hallenbeck, 1993).

Overall, agencies (FDA, EPA, OSHA) usually do not take into account additive or interactive effects from exposure to multiple toxicants. An exception to this is the ICRP dose limits which **do** take into account the additive effect of exposure to all radionuclides.

Many federal environmental laws and regulations explicitly or implicitly recognize that very small levels of risk may not deserve attention, but the determination of how small those levels should be is controversial. The concept of "de minimis" risk refers to a policy decision which establishes a specific level below which risks are so small that they can usually be ignored. Proponents of a "de minimis" risk-management principle contend that regulatory agencies should establish "de minimis" levels and regulate only those hazards that pose a risk greater than these levels. Critics of the "de minimis" criterion, however, argue that the use of "de minimis" risk criterion is problematic because of the difficulties of defining a level of risk that is insignificant. Defining a "de minimis" risk level is extremely difficult due to the additive effects of more than one exposure, synergistic effects and the fact that people perceive risks differently (Cohrssen & Covello, 1989).

**CURRENT GUIDANCE PERTAINING TO RISK ASSESSMENT**


EPA - (1989), Risk Assessment Guidance for Superfund Volume 1 - Human Health Evaluation Manual, Part A, B, C. EPA/540/1-89/002, (December, 1989)

EPA - (1986), Guidelines for Carcinogen Risk Assessment. 51 Federal Register 33992 (September 24, 1986)

EPA - (1986), Guidelines for Exposure Assessment. 51 Federal Register 34042 (September 24, 1986)

EPA - (1986), Guidelines for Mutagenicity Risk Assessment. 51 Federal Register 34006 (September 24, 1986)

EPA - (1986), Guidelines for the Health Assessment of Suspect Developmental Toxicants. 51 Federal Register 34028 (September 24, 1986)

EPA - (1986), Guidelines for Health Risk Assessment of Chemical Mixtures. 51 Federal Register 34014 (September 24, 1986)

EPA - (1988), Guidance for Conducting Remedial Investigations and Feasibility Studies Under CERCLA. Interim Final. Office of Emergency and Remedial Response. (OSWER Directive 9355.3-01).

National Academy of Sciences (NAS) National Research Council (NRC) (1983). Risk Assessment in the Federal Government: Managing the Process. National Academy Press. Washington, DC.

## REFERENCES


Ashford, N.A., and Caldart, C.C. (1991). Technology, Law, and the Working Environment. Van Nostrand Reinhold, New York.

Broetzman, G. (1993). Colorado Environmental Remediation Programs. Colorado Center For Environmental Management, Golden, CO.

Cohrssen, J.J., and Covello, V.T. (1989). Risk Analysis: A Guide to Principles and Methods for Analyzing Health and Environmental Risks. Executive Office of the President of the United States, Washington, DC, National Technical Information Service.

Environmental Protection Agency. (1989). Risk Assessment Guidance for Superfund VOL 1: Human Health Evaluation Manual (Part A) US Dept of Commerce.

Hallenbeck, W.H. (1993). Quantitative Risk Assessment for Environmental and Occupational Health, Second Edition, Lewis Publishers, Inc., Chelsea, Michigan.

Johnson, B.L. (1988). "Public Health Effects of Hazardous Waste in the Environment", In: R.Abbou (Ed.) Hazardous Waste: Detection, Control, Treatment. Elsevier Science Publishers B.V., Amsterdam.

Lindgren, G.F. (1990). Managing Industrial Hazardous Waste: A Practical Handbook, Lewis Publishers Inc., Chelsea, Michigan.

Upton, A.C et al. (1989). "Public Health Aspects of Toxic Chemical Disposal Sites", Annu. Rev. Public Health, 10: 1-25, Annual Reviews Inc.

Wagner, T.P. (1992). The Hazardous Waste Q&A: An In-depth Guide to the Resource Conservation and Recovery Act and the Hazardous Materials Transportation Act. Van Nostrand Reinhold, New York.

Zimmerman, R. (1990). Governmental Management of Chemical Risk: Regulatory Processes for Environmental Health. Lewis Publishers Inc., Chelsea, Michigan.

## REVIEW QUESTIONS

## RISK MANAGEMENT AND ENVIRONMENTAL LAW, REGULATION, & GUIDANCE

1. What are the responsibilities of the legislative, executive, and judicial branches of government?

2. What is the difference between legislation and regulation?

3. What is the primary responsibility of the Environmental Protection Agency (EPA)?

4. Describe the purpose of the Comprehensive Environmental Response Compensation and Liability Act (CERCLA) and the National Contingency Plan (NCP).

# 3 OVERVIEW OF THE REMEDIAL INVESTIGATION/FEASIBILITY STUDY

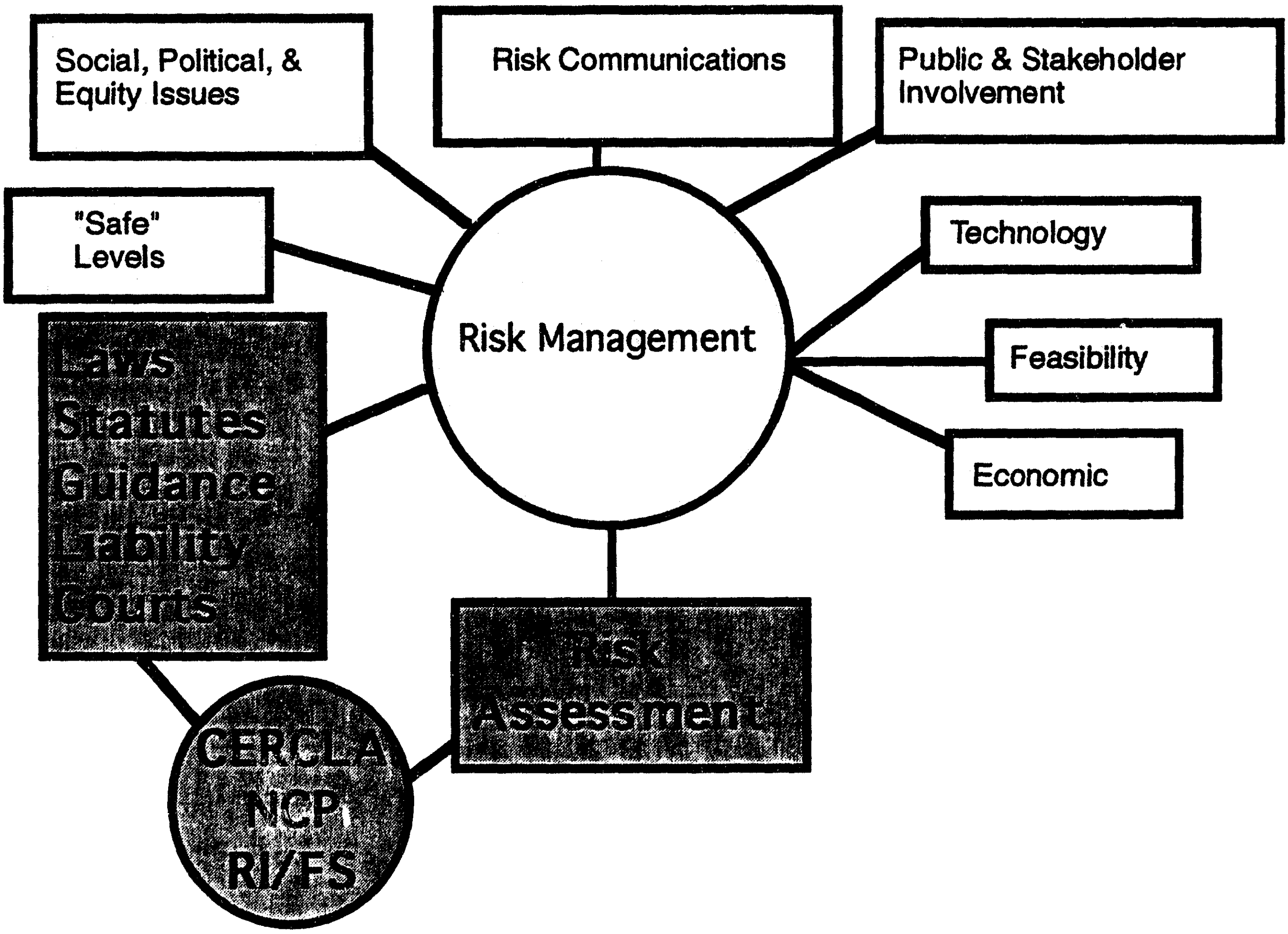
**Objective:** Provide an overview concerning the role of risk assessment in the Remedial Investigation/Feasibility Study

**Learning Tasks:** Information in this chapter should enable students to:

- Understand how waste sites become involved with federal remediation action.
- Become familiar with the role of the National Contingency Plan and its steps of action related to remediation efforts
- Explain the role of Risk Assessment in the Remedial Investigation/Feasibility Study (RI/FS).

## OVERVIEW OF REMEDIAL INVESTIGATION/FEASIBILITY STUDIES (RI/FS)

**Figure 3-1**



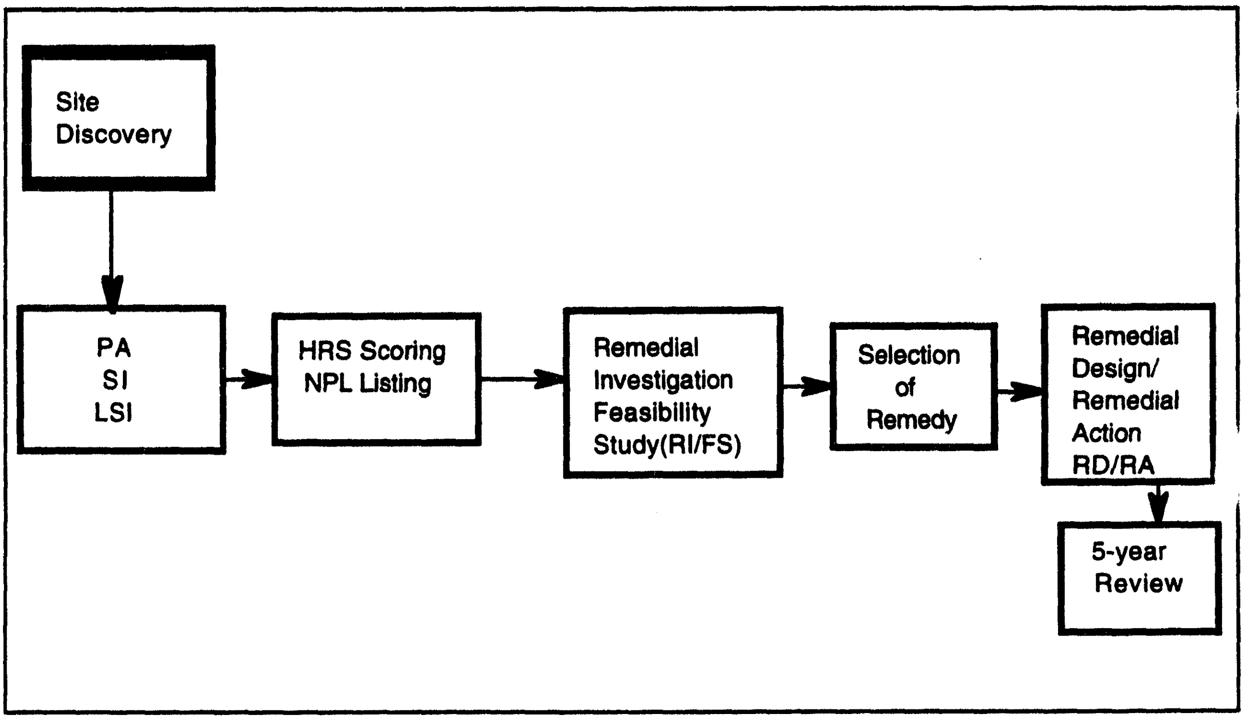

Hazardous waste sites are remediated under a variety of laws and regulations. In Chapter 2, the distinction between RCRA corrective actions and CERCLA remedial actions was clarified. Appendix C further describes RCRA corrective actions. This chapter describes the Remedial Investigation/Feasibility Study outlined in the National Contingency Plan for CERCLA Remedial Actions (Figure 3-1).

How does a waste site become considered for remedial action under CERCLA?

Subpart E, Hazardous Substance Response of the National Contingency Plan (NCP), outlines a plan covering the activities involved in abating and remedying releases or threats of releases of hazardous substances, pollutants, and contaminants. The NCP states action for removal and remedial response.

The remedial response process involves seven steps (See Figure 3-2).

**FIGURE 3-2**
**THE REMEDIAL RESPONSE PROCESS**




(EPA, 1989)

### 1. Site Discovery or Notification

- Releases of hazardous agents are identified by federal, state, or local government agencies or private parties and are reported to the National Response Center or EPA.

- Sites are screened to identify release situations warranting further remedial response consideration.

- Sites warranting response consideration are entered into the CERCLA Information System (CERCLIS -- serves as data base of site information and tracks the change in status of a site through the response process).

2. **Preliminary Assessment and Site Inspection (PA/SI)**

- The major objective of the Preliminary Assessment is to identify the magnitude of the hazards, source, nature of release, and the necessity of action. The Site Investigation examines the nature of the hazards, characterizes the problems, the need for additional actions, site visits and sampling.

- All available information about a site (including off-site reconnaissance) is collected and reviewed to evaluate the source and the nature of hazardous substances present. Responsible parties are identified if possible.

- A determination is made whether further (high or medium priority) or no further action (no future remedial action planned-(NFRAP) is needed.

- Samples to assess contamination are collected as necessary.

- Risk-related information is collected so the site can be scored for Hazard Ranking System (HRS-See Appendix D). The HRS is a major objective of PA/SI.

- If a site is considered for inclusion on National Priorities List (NPL), a listing site inspection (LSI) is conducted. The LSI is more extensive investigation than PA/SI.

- Main objective of LSI is to collect sufficient data about site to support the HRS.

3. **Establishing Priorities for Remedial Action**

- Sites are scored using the HRS (based on data from PA/SI and LSI). This score is a measure of relative risk or potential risk at the site.

- Score on HRS (Appendix D) determines inclusion on NPL. The HRS score must be 28.5 or greater to be placed on the NPL. Sites on the NPL are eligible for Superfund-financed remedial action.

- Listing, however, is not a guarantee of getting Superfund money.

- Federal facilities can be placed on the NPL, but are not eligible for Superfund money.

## 4. Remedial Investigation/Feasibility Study (RI/FS)

A remedial action, as defined by Section 101 (24) and 40 CFR 300.68) is a response to a release that is consistent with a permanent remedy to prevent or minimize the release of hazardous substances, pollutants, or contaminants so that they do not cause substantial danger to the present or future public health or the environment.

The RI/FS is the framework for determining appropriate remedial action at Superfund sites, however, it is not restricted to Superfund sites. During the RI/FS a Human Health Evaluation is required by EPA under guidance given in the Risk Assessment Guidance for Superfund, Human Health Evaluation Manual, Parts A, B, and C. Figure 3-3 shows where these three EPA guidance documents are to be utilized during the remedial response process. The RI/FS is briefly introduced below. The next section of this chapter will discuss further the RI/FS and the role of risk assessment within the RI/FS.

The **Remedial Investigation (RI)** involves characterizing the contamination at the site and obtaining information needed to identify, evaluate, and select cleanup alternatives. It includes planning, site characterization, identification of possible response actions, treatability studies, and the **baseline risk assessment**. This baseline risk assessment will be discussed in detail in the Risk Assessment Section of this book.

The **Feasibility Study (FS)** involves the formal analysis of the remedial alternatives based upon nine evaluation criteria as described in the National Contingency Plan. These criteria require, at a minimum, protection of human health and the environment as well as compliance with all Applicable or Relevant and Appropriate Requirements (ARARs) of other laws and regulations. Other balancing criteria include long term effectiveness and permanence, reduction of toxicity, mobility, or volume through treatment, short term effectiveness, implement-ability, and costs. State and community acceptance are other factors which should also be considered.

Prior to the RI/FS is a **project scoping** stage. This is a very important stage in the overall process for the design of the RI/FS. This stage is described in detail in the next section of this chapter.

5. **Selection of Remedial Action**

- The results of RI/FS are reviewed at this stage to identify a preferred method of remediation action (preferred alternative) which is announced to the public in a Proposed Plan.

- Primary consideration when selecting a remedial action should be protection of human health and environment by eliminating, reducing, or controlling risks posed through each exposure pathway. A risk manager also must consider if the alternative is cost effective; if it utilizes permanent solutions; if there are alternative treatment technologies; and if ARARs have been met

- The risk information obtained during the risk assessments are key inputs into the remedy selection.

- The lead agency reviews any resulting public comments on the Proposed Plan, consults the support agencies to evaluate if the preferred alternative is still the most appropriate action and then makes the final decisions.

- A Record of Decision (ROD) is written to document the rationale for the selected site remedy action.

6. **Remedial Design/Remedial Action**

During this step, the selected remedial action, which has been documented in the ROD, is developed and then implemented.

7. **Five-year Review**

The NCP states that there must be periodic review of remedial actions at least every five years for as long as hazardous agents remain on site. If they are still found to be a threat during these reviews, a remedial action may be changed.

## THE ROLE OF RISK ASSESSMENT IN THE RI/FS

Risk assessment is embodied in the health evaluation process used in the remedial response program. This section will discuss the role of risk assessment in that process.

The goal of human health evaluation process is to provide the framework for developing the risk information necessary to assist decision-making at remedial sites.

Specific objectives of the Human Health Evaluation process as outlined in EPA guidance are to provide:

1. **An analysis of baseline risks to help determine the need for action at sites. (Part A, Baseline Risk Assessment)**

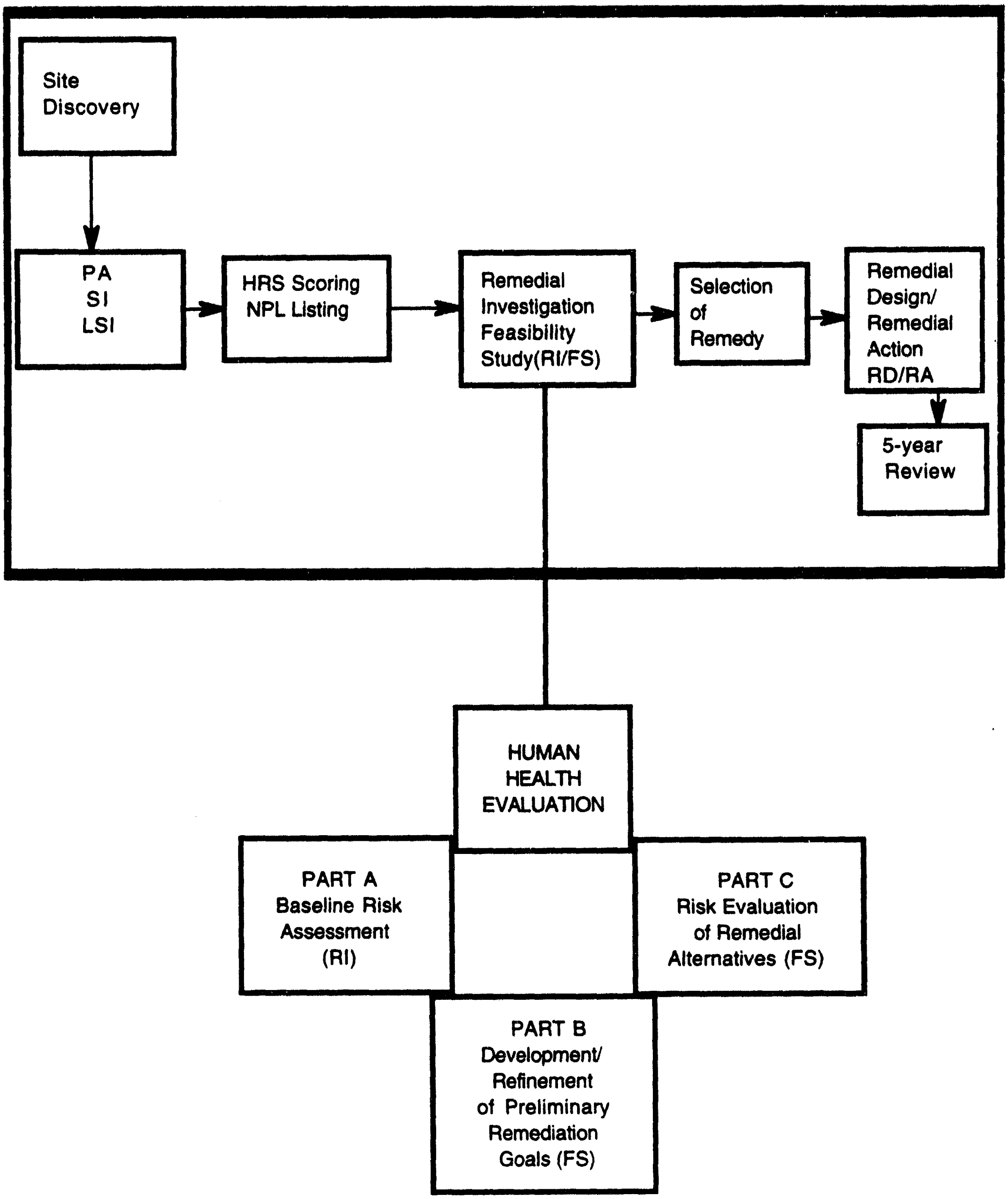
2. **A basis for determining levels of chemicals that can remain on-site and still be adequately protective of public health. (Part B, Setting Preliminary Remediation Goals)**

3. **A basis for comparing potential health impacts of various remedial alternatives. (Part C, Evaluating Remedial Alternatives)**

4. **A consistent process for evaluating and documenting public health threats at sites.**

**See Figure 3-3.**

## FIGURE 3-3
## THE REMEDIAL RESPONSE PROCESS




(EPA, 1989)

Part A of the Human Health Evaluation Guidance from EPA which describes how to conduct a baseline risk assessment will be discussed in Section III of this book. Parts B and C will be discussed in Chapter 10.

**Components of RI/FS:**
Figure 3-4 diagrams the RI/FS process and shows where risk information should be gathered during this process in order to obtain necessary information for the human health evaluation. The major sections of the RI/FS include:

- Project Scoping
- Site Characterization (RI)
- Establishment of Remedial Action Objectives (FS)
- Development and Screening of Alternatives (FS)
- Detailed Analysis of Alternatives (FS)

Project Scoping

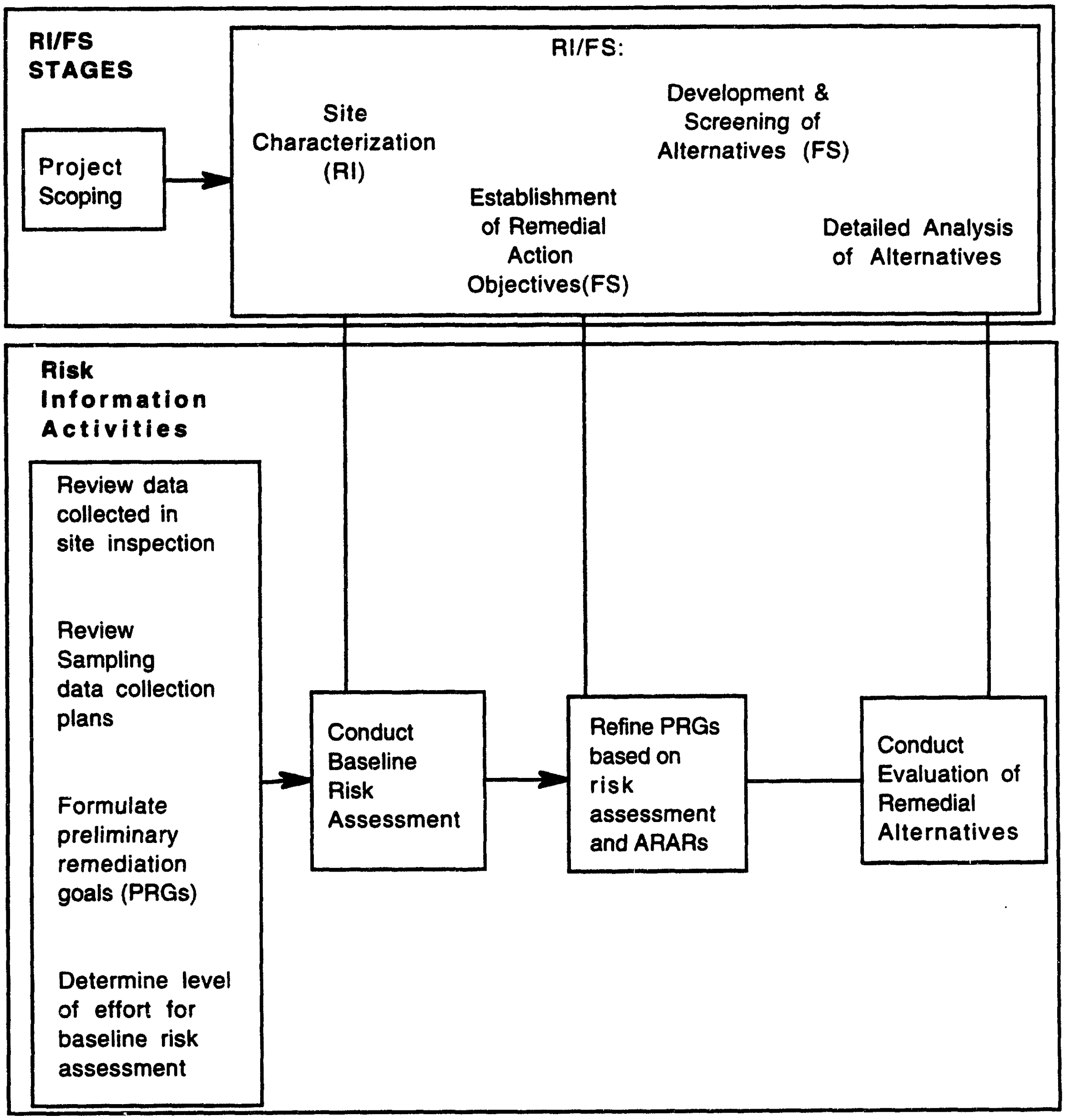
Goal: To specify the appropriate type and extent of investigation and analysis that should be undertaken for a given site.

Objectives:
- Identify types of decisions that need to be made and who will participate in these decisions. It is at this point where public and stakeholder involvement becomes crucial.
- Determine the type, (including quantity and quality) of data needed.
- Design efficient studies to collect data.
- Formulate preliminary remediation goals (PRG's).
- Determine level of effort for baseline risk assessment.

A conceptual model is developed, the model considers:

- The sources of contamination
- Potential pathways of exposure
- Potential receptors
- Identifies potential ARARs

## FIGURE 3-4
## The Role of Risk in the RI/FS Process




(EPA, 1989)

The model is initially developed during scoping with readily available information and is refined as additional information is obtained (See Figure 3-5).

## FIGURE 3-5
## CONCEPTUAL MODEL

| | VARIABLES | HYPOTHESES TO BE TESTED |
|---|---|---|
| SOURCES | •CONTAMINANTS<br>•CONCENTRATIONS<br>•TIME<br>•LOCATIONS | •SOURCE EXISTS<br>•SOURCE CAN BE CONTAINED AND DISPOSED<br>•SOURCE CAN BE TREATED |
| PATHWAYS | •MEDIA<br>•RATES OF MIGRATION<br>•TIME<br>•LOSS AND GAIN OF FUNCTIONS | •PATHWAY EXISTS<br>•PATHWAY CAN BE INTERRUPTED<br>•PATHWAYS CAN BE ELIMINATED |
| RECEPTORS | •TYPES<br>•SENSITIVITIES<br>•TIME<br>•CONCENTRATIONS<br>•NUMBERS | •RECEPTOR IS NOT IMPACTED BY MIGRATION OF CONTAMINANTS<br>•RECEPTOR CAN BE RELOCATED<br>•INSTITUTIONAL CONTROLS CAN BE APPLIED<br>•RECEPTOR CAN BE PROTECTED |

Source: EPA, 1989

## Remedial Investigation (RI)

Site Characterization

The sampling plan developed in the project scoping is implemented and field data are collected and analyzed to determine the nature and extent of threats to human health and environment at the site.

Preliminary site characterization may be used to identify ARARs, cleanup standards, standards of control (maximum contaminant levels), and other substantive environment protection requirements, criteria, or limitations promulgated under federal or state law that specifically address a hazardous substance, pollutant, contaminant, remedial action, location or other circumstance at a CERCLA site.

Major components of site characterization:

- Collect and analyze field data to characterize site
- Develop baseline risk assessment (human and environment)
- Perform treatability studies

Baseline Risk Assessment:

Results are used to:

a. Determine current or future adverse effects to humans in absence of action to mitigate or control releases.

b. Help determine whether additional response action is necessary.

c. Modify preliminary remediation goals (PRG's).

d. Help support selection of the "no action" remedial alternative, if appropriate.

e. Document magnitude of risk, and primary causes of risk.

## Feasibility Study (FS)

Goal: To provide the decision-maker with an assessment of remedial alternatives, including their relative strengths and weaknesses, and the trade-offs in selecting one alternative over another. There is much interaction between the remedial investigation and the feasibility study.

<u>Steps of FS</u>

1. **Establish protective remedial action objectives** related to contaminants and media of concern, potential exposure pathways, and preliminary remediation goals.

   - Preliminary Remediation Goals (PRG's) are usually initially developed during project scoping or prior to the completion of the baseline risk assessment. PRG's are initial clean-up goals that (1) are protective of human health and the environment and (2) comply with ARARs.

   - Preliminary goals are refined or confirmed after baseline risk assessment and are based initially on chemical-specific ARARs. Thus goals are intended to be protective and comply with ARARs.

   - Analytical approach used to develop these refined goals involves:

     a) Identifying chemical specific ARARs.

     b) Identifying protective levels based on risk assessment when chemical-specific ARARs are not available or situations where multiple contaminants or multiple exposure pathways may make the ARAR not protective.

     c) Identifying non-substance-specific goals for exposure pathways (if necessary).

     d) Determining a refined preliminary remediation goal that is protective of human health for all substance/exposure pathway combinations being addressed.

2. **Development and Screening of Alternatives**

   Once remedial action objectives have been developed, general response actions are formulated, (e.g., treatment, containment, excavation, pumping, or other actions).

This involves two activities:

- Determine the volume or area of waste or media that needs to be remediated as determined by ARARs, chemical-specific environmental fate and toxicity data, and engineering analyses.

- Screen remedial action alternatives and associated technologies to identify those that would be effective for contaminants and media of interest at the site.

## 3. Detailed Analysis of Alternatives

Each remedial alternative is assessed against the National Contingency Plan's specific evaluation criteria (nine criteria discussed earlier).

1) Overall protection of human health and environment.

2) Compliance with ARARs (applicable or relevant and appropriate requirements of the Resource Conservation and Recovery Act (RCRA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), Clean Air Act (CWA), and other federal and state environmental laws).

3) Long-term effectiveness and permanence -- involves residual risks after initial remedial objectives met. Also effectiveness of controls, untreated waste and impact on human health and environment should remedy fail.

4) Reduction of toxicity, mobility, or volume through use of treatment.

5) Short-term effectiveness -- Assess impact of method during construction and implementation phase until remedial response objectives met -- consider impact on human health and environment during implementation and length of time until finished.

6) Implementability

7) Costs

8) State acceptance

9) Community acceptance

Under NCP, first two (1-2, i.e., protect and ARARs) must be met. Criteria 3-7 are considered balancing criteria, 8-9 are considered modifying criteria. These will be discussed in further detail in Chapter 11, Risk Management.

## REFERENCES

Environmental Protection Agency. (1989). Risk Assessment Guidance for Superfund VOL 1: Human Health Evaluation Manual (Part A) US Dept of Commerce.

EPA (December, 1991a) Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (Part B Development of Risk-based Preliminary Remediation Goals) Interim Office of Emergency and Remedial Response, USEPA

EPA (December, 1991b) Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (Part C Risk Evaluation of Remedial Alternatives) Interim Office of Emergency and Remedial Response, USEPA

## REVIEW QUESTIONS

## OVERVIEW OF THE REMEDIAL INVESTIGATION/FEASIBILITY STUDY

1. What is the major objective of the Preliminary Assessment/Site Inspection?

2. Explain the purpose of the Hazard Ranking System.

3. What are the specific objectives of the Human Health Evaluation process?

4. List the components of the RI/FS.

5. List the nine NCP evaluation criteria for selective remedial alternatives.

# 4 CONCEPTS OF ENVIRONMENTAL TOXICOLOGY

**Objectives:** To understand the properties which contribute to a chemical's toxicity and factors which enhance the likelihood of a hazardous event occurring. To explore the chemical/physiological interaction between a chemical and human-kind.

**Learning Tasks:** Information in this chapter should enable students to:

- Define toxicology

- Understand important factors of toxic response

  a) Contaminant - key characteristics
  b) Pathway of exposure
     --Types
     --Environmental fate -- transport, transformation
  c) Routes of exposure
     --Routes
     --Defenses
     --Factors that affect toxic response
     --Pharmacokinetics principles
  d) Human involved -- factors that affect response
  e) Modes of action -- types
  f) Effects
     --types
     --carcinogenesis
     --classification
     --combinations
     --dose-response threshold

- Identify sources of toxicologic data

  a) strengths
  b) weaknesses

## INTRODUCTION

### WHAT IS TOXICOLOGY AND TOXICITY?

Toxicology - The study of the harmful effects of substances and other forms of matter.

Toxicity - Degree of harmful effect on a target organism.

### THE TOXIC RESPONSE

The Toxic Response Contains Six Components:

**A. The Contaminant**
**B. Pathways of Exposure**
**C. Route of Exposure**
**D. A Human Exposed**
**E. Mode of Action**
**F. An Effect**

### A. THE CONTAMINANT

1. Type
   - Biological (e.g.,viruses, bacteria, fungus, plants, parasites)
   - Physical (e.g., temperature, pressure, radiation, noise, vibration)
   - Chemical (e.g., gases, vapors, solids, and particulates)

2. Persistency

3. Solubility (hydro-lipophilic)

4. Toxicity

5. Amount

## B. PATHWAYS OF EXPOSURE

1. Water (ingestion, contact)

2. Air (inhalation) - particulate and vapors

3. Biota (uptake, surface contamination)

4. Soil (ingestion, contact)

Environmental Transport/Fate

The environment is a very dynamic system as exemplified by the hydrologic cycle. This cycle shows water being transported through air, water, biota, and soil, and then being transformed into different forms of matter (solid, gas, and liquid).

Because of this dynamic situation, it should be expected that chemicals will move, or be **transported**, within the components of the system. Various events can occur to a chemical during transport, for example in:

1. Air
   - photodegradation
   - oxidation
   - precipitation

2. Soil
   - photodegradation
   - metabolism
   - evaporation

3. Water
   - hydrolysis
   - oxidation
   - metabolism
   - evaporation
   - sedimentation

4. Biota
   - metabolism
   - storage
   - excretion

Factors that affect chemical's transport/fate

1. Water solubility
2. Soil adsorption
3. Vaporization
4. Bioaccumulation
5. Degradation

Pathways are important because they affect the concentration and nature of a chemical and provide a means of human contact regarding exposure.

## C. ROUTES OF EXPOSURE

1. Toxicants contact the body and may exhibit either or both of the following:

   a. Local effect -- occur at the region of contact.
   b. Systemic effect -- toxicant enters bloodstream (absorption) and is transported to organ where effect occurs (target organ).

2. How do toxicants enter the body?

   Three primary routes of entry into body:

   a. Inhalation
   b. Dermal absoorption
   c. Ingestion

   **Inhalation:**

   Humans inhale approximately 20 cubic meters of air per day at normal inspiration. Air travels through nares, trachea, bronchus, bronchioles, and aveoli, the site of gaseous exchange. The respiratory system is divided into three major regions: naso-pharnygeal (upper), tracheo-broncial (middle), and pulmonary or aveolar region (deep). It is important to note that cells in the aveolar region are only one cell layer thick. The lung has a large surface area, approximately 150-180 square meters.

The lungs are a favorable route for chemical absorption because:

- Large volume of air is inhaled, good for air-borne agents
- Large surface area of lungs
- Thin barrier between aveoli and bloodstream

Factors related to a toxicants absorption are:

- Size
- Reactivity with water
- Solubility
- Rate of inspiration
- Concentration
- Form (vapor, particulate)

Defense Mechanisms of Lungs

Several defense mechanisms of the lungs protects against absorption. There are various structural, physical, and physiological means to prevent a toxicant from entering the blood stream via the lungs. These defenses will be discussed accordingly within the three pulmonary regions.

a. Naso-pharyngeal (upper)
   - Nose hairs
   - Bifurcation
   - Mucous

   **Impaction is important

b. Tracheo-bronchial
   - Cilia
   - Bifurcation
   - Mucous

   **Impaction and sedimentation important

c. Aveolar
   - Sedimentation
   - Macrophages

**Dermal Contact:**

The skin is the organ with the largest area available for exposure to toxic substances (approximately two square meters). There are two major layers--epidermis (no blood vessels), dermis (blood vessels). There are four possible toxicant interactions with skin:

a. Skin effectively prevents toxicant penetration
b. Substance reacts with skin causing irritation
c. Substance causes skin sensitization
d. Substance can penetrate skin and be absorbed

There are two major routes of penetration through skin: through epidermal cells (most important) and through hair follicles and sweat glands. In general, absorption of ionic (hydrophilic) substances is negligible, while lipid soluble (lipophilic) substances are more easily absorbed.

Toxicant absorption via the dermal route is affected by: temperature and perspiration, concentration of toxicant, pH of skin, molecular size of toxicant, and condition of skin.

Defense Mechanisms of the Skin

Defenses of the skin include: several layers of cells before there are blood vessels (structure), dead layers of cells on outer layer (strateum corneum), sensory receptors (pain, temperature), and immune response to infections agents.

**Ingestion:**

When a toxicant is consumed, it enters the alimentary tract, a tube that runs from the mouth to the anus. In the occupational setting, toxicity by ingestion generally is lower than inhalation for several reasons. For example fewer substances can be ingested (cannot ingest a gas), eat less frequently, poorer absorption into bloodstream, high acidity of stomach (pH 1-2), alkaline juices of pancreatic juices in small intestine, and pancreatic enzymes that can metabolize foreign agents. However, consumption of contaminated drinking water is considered the primary means of community exposure to a toxicant due to hazardous waste releases.

Defense Mechanisms of the Digestive Tract

Factors not favoring toxicant absorption:

a. Food and liquids ingested along with toxin -- dilutes and interacts
b. Intestines "selective" in their absorption of substances
c. Substances absorbed by intestines are carried to liver which metabolizes toxicants

Other factors affecting absorption:

a. Condition of alimentary tract -- mucous intact
b. Nutritional status
c. Similarity of toxicant to nutrient

4. Pharmacokinetics/Toxicokinetic

What happens when a chemical enters the body?

The effect that a chemical agent has on a living organism generally depends on the level of the substance in the tissue (body burden) and the duration it remains in the body. The time that a toxicant remains in the body is determined by the amount of toxicant that the individual comes into contact with, the duration of exposure, and the metabolic fate of the chemical in the body (Doull, Klaassen, and Amdur, 1980).

Pharmacokinetics --

The qualitative and quantitative study of absorption, distribution, biotransformation, and elimination of an agent over time in an organism (plant or animal) (Ecobichon, 1992).

Information about Pharmacokinetics allows the prediction of the following:

a. Duration of agent's toxic action
b. The persistence of the agent and/or transformation products in target organs
c. The disposition in storage sites of the agent.

5. Factors involved in pharmacokinetics

Absorption

Absorption is the entrance of a toxicant into the bloodstream. Therefore, it is necessary for a toxin to cross cell membranes to be absorbed. Absorption is important for systemic effects -- toxic effects that occur at an organ distant from the point of entry. The chemical is carried to the target organ -- organ at which toxic response is manifested -- via the bloodstream.

The ability of a toxicant to cross cell membranes is a very important property of absorption. Four ways a chemical may pass through a cell membrane are (Lu, 1991):

a. **Passive Diffusion**
Passive diffusion is the predominant means of chemical passage across cell membranes. The rate of chemical passage is directly related to the concentration gradient across the membrane (chemical moves high to low concentrations) and the solubility (fat soluble versus water soluble). Many chemicals are not easily absorbed in their ionized state, but their absorption may be enhanced in their nonionized state. Therefore, the amount of nonionized substance will affect absorption.

b. **Filtration**
The membranes of the capillaries and the glomeruli have relatively large pores (approximately 70 nm) and allow molecules smaller than albumin (molecular weight 60,000) to pass through. The bulk flow of water through these pores results from hydrostatic and/or osmotic pressure and can act as carrier of toxicants. The pores in most cells are relatively small (about 4 nm) and allow chemicals up to a molecular weight of 100-200 to pass through. Chemicals of larger molecules, therefore, can filter into and out of the capillaries. These larger molecules can establish an equilibrium between the concentrations in the plasma and in the extracellular fluid, but they cannot do so by filtration between the extracellular and intracellular fluids.

c. **Carrier-Mediated Transport**
This mode of absorption involves the formation of a complex between a chemical and a macromolecular carrier on one side of a cell membrane. The complex is able to diffuse across the membrane, where the chemical is released. The carrier then returns to the original surface where it is able to repeat this transport function. The carrier can become saturated, in which case the rate of transport is no longer dependent on the concentration of the chemical. Structure, conformation, and charge are important in determining the affinity of a chemical for a carrier site, and competitive inhibition can occur among chemicals with similar characteristics.

Types:

- Active transport:
  A carrier that can move molecules across a membrane against a concentration gradient, or, if the molecule is an ion, against an electrochemical gradient. It requires the expenditure of metabolic energy and can be inhibited by poisons that interfere with cell metabolism.
- Facilitated diffusion:
  Similar to active transport but cannot transport molecules against a concentration gradient. It is not energy-dependent, and metabolic poisons do not inhibit the process.

d. **Endocytosis** -- Engulfing by the Cell
Particles may be engulfed by cells. When the particles are solid, the process is called phagocytosis and when they are liquid, it is called pinocytosis. Endocytosis is important for removal of particulate matter from the alveoli and of certain toxic substances from the blood by the reticuloendothelial system.

6. Biotransformation of Toxicants (Lu, 1991)

Biotransformation involves the metabolic transformation (either building up or breaking down) of a toxicant once it enters the body. The most important site of such reactions is the liver, other sites include the lungs, stomach, intestine, skin, and kidneys.

Biotransformation mechanisms are divided into two major types:

a. Phase I reactions -- oxidation, reduction, and hydrolysis

b. Phase II reactions -- produce a compound (a conjugate) that is biosynthesized from the toxicant, or its metabolites, plus an endogenous metabolite

Biotransformation is a process that, in general, converts the parent compound into metabolites and then forms conjugates. However, for some chemicals only one of these steps may be involved. For example, benzene undergoes a phase one reaction to form phenol, which conjugates with sulfate, a phase II reaction. However, phenol will conjugate with sulfate without a phase I reaction. The result of the biotransformation process are metabolites and conjugates that usually are more water-soluble and more polar than the parent compound. This conversion makes the compound more readily excreted, which is important for detoxication.

However, in certain cases biotransformation may lead to metabolites that are more toxic than the parent compounds. These reactions are known as "bioactivation" (to be discussed in 8b., page 4-15).

7. PHASE I REACTIONS (Lu, 1991)

Degradation Reactions

a. Oxidation - The process of an atom becoming more positive in valence charge, by losing electrons. This process is usually accomplished by combining with oxygen. A variety of chemicals undergo biotransformation by oxidative processes. The most important enzyme systems catalyzing these processes involve cytochrome P-450 and NADPH cytochrome P-450 reductase. In these reactions, one atom of molecular oxygen is reduced to water and the other oxygen is incorporated into the substrate.

   Oxidation may take place in a variety of reactions, and often more than one metabolite is formed.

Examples of oxidation processes include:

- epoxidation: e.g., aldrin to dieldrin
- alcohol dehydrogenase converts alcohol to acetaldehyde to acetic acid

b. Reduction - The process of making an atom more negative in valence charge, by gaining electrons. This process is usually accomplished by adding electrons of hydrogen. Toxicants may undergo reductions through the function of reductases. These reactions are less prevalent in mammalian tissues but occur more in intestinal bacteria.

Examples of reduction reactions include:

- Azo reduction: azobenzene to aniline
- Reverse of alcohol dehydorgenases

c. Hydrolysis - In hydrolysis, water is added across bonds and in turn breaks the bonds. Many toxicants that contain ester-type bonds are subject to hydrolysis, e.g., esters, amides, and compounds of phosphate. Mammalian tissues, including the plasma, contain a large number of nonspecific esterases and amidases, which are involved in hydrolysis.

8. PHASE II REACTIONS (Lu, 1991)

a. **Conjugation Reactions**
Several types of endogenous metabolites may form conjugates with the toxicants or their metabolites to comprise the Phase II reactions. The conjugates formed are generally more water-soluble and more readily excreted than the original toxicant.

Types of Conjugate Reactions:

1) Glucuronide Formation - Glucuronide formation is the most common and most important type of conjugation. The enzyme catalyzing this reaction is UDP-glucuronyl transferase (uridine-5'-diphopho-**a**-D-glucuronic acid). This enzyme is located in the endoplasmic reticulum.

There are four classes of chemical compounds that are capable of forming conjugates with glucuronic acid:

- aliphatic or aromatic alcohols
- carboxylic acids
- sulfhydryl compounds
- amines

2) Sulfate Conjugation - This reaction is catalyzed by the enzymes, sulfotransferases, which are found in the cytosolic fraction of liver, kidney, and intestine. The coenzyme is PAPS (3'-phosphoadenosine-5'-phosphosulfate). The functional groups of the toxic compounds for sulfate transfer are phenols and aliphatic alcohols as well as aromatic amines.

3) Methylation - Methylation is catalyzed by methyl transferases, the coenzyme involved is SAM (S-andenosylmethionine). This reaction does not always increase the water solubility of the methylated products.

4) Acetylation - This reaction involves the transfer of acetyl groups to primary aromatic amines, hydrazines, hydrazides, sulfonamides, and certain primary aliphatic amines. The enzyme and coenzyme involved are N-acetyl transferases and acetyl coenzyme A, respectively.

5) Amino Acid Conjugation - This conjugation is catalyzed by amino acid conjugates and coenzyme A. Aromatic carboxylic acids, arylacetic acids, and aryl-substituted acrylic acids can form conjugates with a-amino acids, mainly glycine, but also glutamine in humans.

6) Glutathione Conjugation - This process is affected by glutathione S-transferases and the cofactor glutathione. Glutathione conjugates subsequently undergo enzymatic cleavage and acetylation, forming N-acetylcysteine (mercapturic acid) derivatives of the toxicants, which are readily excreted.

In the process of biotransformation of toxicants, a number of highly reactive electrophilic metabolites maybe formed. Some of these metabolites can react with cellular constituents and cause cell death or induce tumor formation. The role of glutathione is to react with the electrophilic metabolites and thus prevent their harmful effects on the cells. However, exposure to a very large amount of such reactive substances can deplete the glutathione, thereby resulting in marked toxic effects.

b. **Bioactivation** (Lu, 1991)
Certain chemically stable compounds can be converted to chemically reactive metabolites. The reactions are generally catalyzed by cytochrome P-450-dependent monoxygenase systems, but other enzymes, included those of the intestinal flora, may also be involved. The reactive metabolites, such as epoxides, can become covalently bound to cellular macromolecules and cause necrosis and/or cancer. Others, such as free radicals, can cause lipid peroxidation resulting in tissue damage. Examples of chemicals known to be bioactivated:

- Epoxide Formation--Many aromatic compounds are converted to epoxides by microsomal mixed function oxygenase systems. Ex. bromobenzene to bromobenzene epoxide. The amount of glutathione available for conjugation will affect the toxicity of epoxides formed. Other examples are: aflatoxin $B_1$, benzene, benao[a]pyrene, furosemide, olefines, polychlorinated and polybrominated biphenyls, trichloroethylene, and vinyl chloride. The bioactivation takes place mainly in the liver, and the resulting reactive metabolites induce toxicity through covalent binding with macromolecules in the tissue, resulting in necrosis or cancer formation.

1) N-Hydroxylation -- Microsomal enzymes from many tissues can N-hydroxylate a variety of chemicals. Some of the N-hydroxy metabolites (acetaminophen, 2-AAF, urethane, and certain aminoazo dyes) can cause cancer or tissue necrosis through covalent binding, whereas others (certain aromatic amines) can induce hemolysis or methemoglobinemia.

2) Free Radical and Superoxide Formation -- Certain halogen-containing compounds undergo metabolism to form free radicals. For example, carbon tetrachloride forms tri-chloromethyl radical, which causes peroxidation of polyunsaturated lipid as well as covalently binds to protein and unsaturated lipid. These initial reactions may affect various cellular components. Halothane and bromotrichloro-methane are other examples of chemicals that may form free radicals as does the herbicide paraquat.

3) Activation in the GI Tract -- Nitrites and certain amines can react in the acidic environment of the stomach to form nitrosamines, many of which have been shown to be potent carcinogens, and nitrates, which under certain conditions, can be converted to nitrites that may induce methemoglobinemia.

Toxicants generally undergo several types of biotransformations, resulting in a variety of metabolites and conjugates. The importance of various types of biotransformation of a toxicant depends on many host, environmental, and chemical factors as well as dose of the toxicant. Because the metabolites from different biotransformations are often different in their effects, the toxicity of a chemical can be greatly altered by these factors. A toxicant may be transformed in one organ to a stable metabolite, which is transported to another organ and metabolized to a toxic metabolite.

c. **Distribution** (Lu, 1991)

A chemical is distributed rapidly throughout the body after it enters the blood. The rate of distribution to each organ is related to the blood flow through the organ, the ability of the chemical to cross capillary walls and cell membranes, and the affinity of components of the organ for the chemical.

1) Barriers - The blood-brain barrier is located at the capillary wall. The capillary endothelial cells in the brain are tightly joined, leaving few or no pores between these cells. Thus, a toxicant has to pass through the capillary endothelium to enter brain tissue. A lack of

vesicles in these cells further reduces toxicant transport ability. Finally, the protein concentration of the interstitial fluid in the brain is low, in contrast to that in other organs; protein binding therefore does not serve as a means for the transfer of toxicants from the blood to the brain. Therefore, the penetration of toxicants into the brain is dependent on their lipid solubility. For example: methyl mercury readily crosses the brain-blood barrier and severely affects the central nervous system while inorganic mercury is not lipid-soluble, does not cross the blood-brain barrier, and exerts its effect on the kidneys.

The placental barrier differs anatomically among various animal species. Also, the number of layers may change as the gestation progresses. The relationship between number of layers of the placenta and permeability needs further quantification. However, the placenta barrier does impede the transfer of toxicants to the fetus.

2) Other barriers - Eyes and testicles have barriers. The erythrocyte plays a role in the distribution of some toxicants. For example, its membrane acts as a barrier against the penetration of inorganic mercury compounds but not alkyl mercury. There is an affinity of the erythrocyte cytoplasm for alkyl mercury compounds. Because of these factors, the concentration of inorganic mercury compounds in the erythrocytes is about half that in the plasma, whereas the concentration of methyl mercury in the erythrocyte is about ten times that in the plasma.

3) Binding and Storage - Binding of a chemical in a tissue can result in a higher concentration in that tissue. There are two major types of binding, covalent and noncovalent.

- Covalent- irreversible and is, in general, associated with significant toxic effects.

- Noncovalent - usually accounts for a major portion of the dose and is reversible. This type of binding plays an important role in the distribution of toxicants in various organs and tissues.

4) Storage - Plasma proteins can bind normal physiologic constituents in the body as well as many foreign compounds. Many foreign compounds bind to the albumin and are therefore not immediately available for distribution to the extravascular space. However, since the binding is reversible, the chemical may dissociate from the protein, thereby increasing the level of unbound chemical, which is then free to impact a target organ.

The liver and kidney have a high capacity for binding chemicals. This characteristic may be related to their metabolic and excretory functions. Certain proteins have been identified in these organs for their specific binding property such as metallothionein. This protein is important for the binding of cadmium in the liver and kidney and possibly also for the transfer of the metal from the liver to the kidney.

The adipose tissue is an important storage depot for lipid-soluble substances such as DDT, dieldrin, and polychlorinated biphenyls (PCB). Plasma concentrations may increase as a result of reduce fat depot following starvation.

Bone is a major storage site for such toxicants as fluoride, lead, and strontium. The storage takes place by an exchange between the toxicants in the interstitial fluid and the hydroxyapite crystals of bone mineral. Fluoride ion ($F^-$) may replace the hydoxyl ion (OH-), and calcium may be replaced by lead or strontium. These stored substances can be released by ionic exchange and by dissolution of bone crystals through osteoclastic activity.

d. **Excretion** (Lu, 1991)
After absorption and distribution in an organism, toxicants are excreted. They are excreted as the parent chemicals, as their metabolites, and/or as conjugates of them. The principle route of excretion is the urine, but the liver and lungs are also important for certain types of chemicals. The gastrointestinal tract, mother's milk, and sweat and saliva are minor routes of excretion of toxicants.