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### Slide 11: General Risk Assessment Objectives

#### Do . . .

- Estimate cancer and non-cancer risks
- Identify (sometimes) current ecological impacts
- Identify contaminants that need to be addressed
- Indicate the human populations and ecological resources we are concerned about and how they are exposed
- Identify data gaps for further study

#### Do not . . .

- Determine if human health effects occurred in the past or will occur in the future
- Determine if an observed condition in an individual or population is the result of exposure to site contaminants
- Identify technologies for addressing contamination

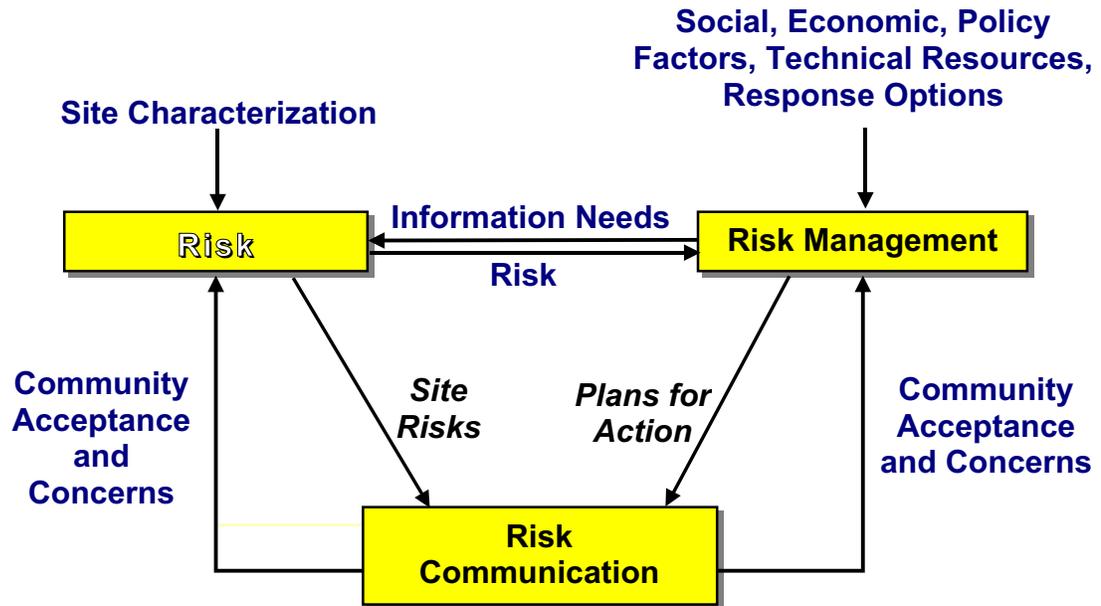


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Department of the Navy RAB/TRC Training Workshop

Slide 12: Risk Assessment is Just One Part of Risk Analysis





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### Slide 13: Four Steps of Risk Assessment

Risk Assessments are Location-Specific but Follow a Standard Process

Each place will have unique characteristics

- history of different things that happened there
- types & distributions of hazards (chemicals)
- available data (from old reports to today's monitoring)
- physical nature of the surface, soil, water
- ecological resources and human populations
- specific ways exposures can occur
- certain ways the area is likely to be used in the future

Same underlying framework used to assess risks



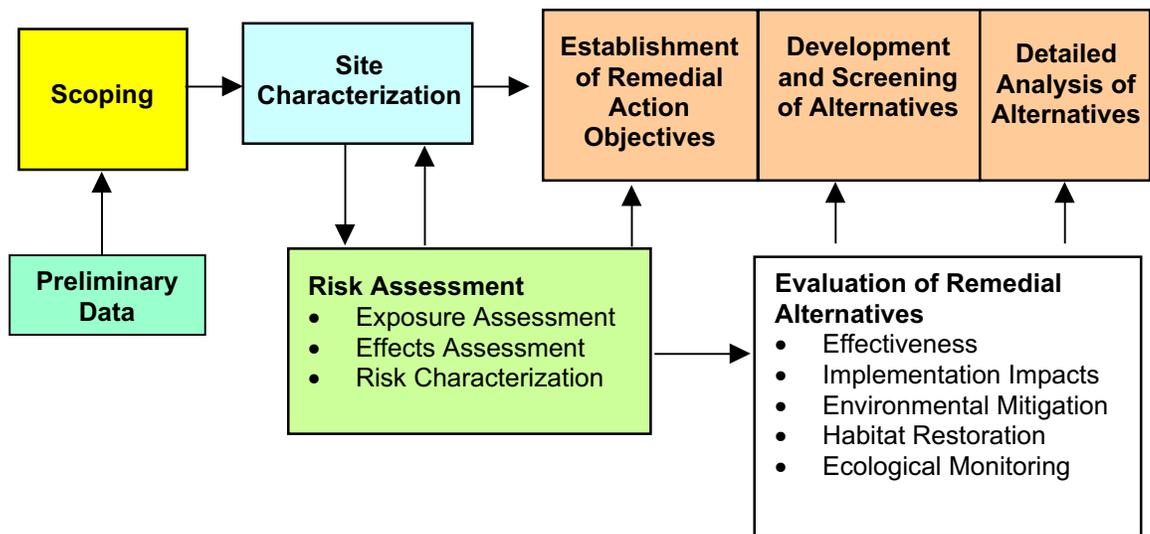
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### Slide 14: The Navy Tiered Approach to Risk Assessment

Where do risk assessments fit under CERCLA and the Navy cleanup program?





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### Slide 15: Navy Approach for Ecological Risk Assessment

Focuses on problem areas:

- avoids “shotgun” approach
- funding and effort expended only on activities that will address your risk management needs

Cost- and effort-effective:

- begin with conservative assumptions
- begin with existing/available data
- only move to greater level of complexity if warranted by the earlier tier results

The tiered approach is a process and not a specific risk assessment method:

- incorporates numerous decision criteria for exiting the process.
- provides for a logical, sequential process for conducting ecological risk assessments and reaching defensible risk management decisions.
- stresses early and frequent interaction between the RPM, the risk assessors, and the regulators in order to avoid unnecessary costs, effort, and surprises
- Serve as decision criteria for continuing or exiting the process
- Agreement points among the risk manager, risk assessor, and regulator
- Aid in tracking contractor activities and specifying contractor deliverables
- Aid in evaluating status of the assessment
- Aid in evaluating appropriateness of the assessment methods and approach



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### Slide 21: Tier 1 - Screening Risk Assessment

#### Ecological Risk Assessment Tier 1

Two steps:

- Step 1 Pathway Evaluation
- Step 2 Exposure Assessment and Risk Characterization
- Each step has exit criteria

#### Human Health Risk Assessment Tier 1

Two parts:

- Tier 1A Risk Based Screening - required
- Tier 1B Site-Specific Risk Based Evaluation- optional



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### Slide 22: Role of the Tier 1 Screening Risk Assessment

- Why not look at all contaminants?
- Risks associated with naturally occurring constituents could drive the assessment (e.g., arsenic)
  - natural and anthropogenic background may obscure evaluation of site-related risks
- Level of effort and costs increase with the number of COPCs
- Public (and regulator) perception of the severity of site contamination tends to increase with the number of contaminants

#### COPC - contaminants of potential concern

- These are site contaminants that may be hazardous to human health and/or ecological resources under current or future site conditions
- Identified through initial risk assessment results (from the screening risk assessment)
- Don't know if a contaminant is "of concern" until the risk assessment is completed



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### Slide 23: Tier 1 Decision Criteria

Results of Tier 1 screening

Best possible outcome

- all COPCs eliminated, site passes the screen, and no further risk assessment required, and remediation is unnecessary (from eco perspective)  
*unlikely*

More typically

- some COPCs completely eliminated through the screening assessment
- other COPCs eliminated for some pathways but kept for others  
*proceed to Tier 2 or remediate*



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### Slide 30: What is an Exposure Scenario?

Specific factors considered in developing exposure scenarios include:

- Route of exposure (ingestion, inhalation, dermal absorption?)
- Exposure time (1, 8, or 24 hours per day?)
- Exposure frequency (every day, once per week?)
- Exposure duration (1 year, 10 years, a lifetime?)



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### Slide 32: Ecological Assessment Endpoints

While it is the entity that influences that scale and character of a risk assessment, it is the attributes of an assessment endpoint that determine what to measure. For practical reasons, it may be helpful to use assessment endpoints that have well-developed test methods, field measurement techniques, and predictive models associated with them. However, do not select assessment endpoints that do not address management goals or that do not fit the needs for the risk assessment solely on the basis of available protocols.

Assessment endpoints must also be:

- ecologically relevant
- susceptible to known or suspected stressor
- linked to the site by exposure
  - if not susceptible and linked, then may be appropriate
  - can't tell if contaminant or other factor responsible

Endpoint selection also includes considerations of the evaluation itself:

- availability of biota to evaluate
- availability of methods



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### Slide 34: How Do We Evaluate Assessment Endpoints?

Potentially tens to hundreds of species for each endpoint

- Develop a manageable subset of species
  - Serve as surrogates for the assessment endpoints
- Typically begin with generic functional categories
  - Small mammal primary consumer, fish-eating bird
- Select individual species to represent the broader receptor group
  - These are the biota evaluated in detail in the Tier 2 BERA

Receptors can be distributed across several categories of species. These will vary from location to location. The timber wolf is listed as endangered in the lower 48 states except Minnesota; it is not listed as endangered in Alaska.



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### Slide 36: Some Basic Toxicological Concepts

Because of the presumed differences in the underlying mechanism of action, carcinogenic and noncarcinogenic COPCs are addressed separately throughout the risk assessment. As will be shown in the session on risk characterization, different measures are used for determining the significance to human health of exposure to these two classes of agents.



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### Slide 37: What is a Toxicity Value?

The toxicity values translate a dose into a risk or hazard index. The slope factors (carcinogens) and RfDs (noncarcinogens) are combined with information on dose (from the exposure assessment) to determine the potential for carcinogenic or noncarcinogenic health effects. This process is described under Step 4, Risk Characterization.

Toxicity values are derived using conservative models:

- RfDs are conservative because order-of-magnitude safety factors are applied to address uncertainty.
- Slope factors are conservative because (1) they represent the upper 95% confidence limit of the slope of the dose response curve, and (2) the slope of the dose-response curve is determined using very conservative models.
  - This means that the risks and hazards tend to be upper bound estimates of the "true" risks/hazards.

Toxicity values are not constants:

- EPA continues to review and revise human values.
- Values not available for all contaminants
  - probably not be available for all site contaminants and routes of exposure.
- Values not available for all biota
  - when available not always widely accepted.
- Toxicity values are a major source of uncertainty in risk assessments.



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### Slide 39: Toxic Potency Varies Over Several Orders of Magnitude

The oral LD50 is the dose that is lethal to 50% of the treated animals.



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### Slide 40: All Risk Assessments Use a Conceptual Model

The CSM is a written description and visual representation (a picture) of:

- what we know about the issues at our site
- what we expect or predict to be going on

The CSM focuses on the relationships among:

- the environment
- the site contaminants
- the human and ecological resources of concern



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### Slide 41: Risk Hypothesis

Represent proposed answers to risk questions regarding your site  
Predictions from the hypotheses can be tested using standard statistical methods, if the studies are appropriately designed.

#### EXAMPLE

##### Issue/Concern

Large mats of algae are clogging the estuary adjacent to our site. Native eelgrass beds disappearing. Brown shrimp fishery has collapsed.

##### HYPOTHESIS

Chemical runoff from the site is eliminating native eelgrass:

- increased algae production reduces light penetration
- chemicals are direct toxic

Shrimp are decreasing due to:

- loss of eelgrass habitat
- periods of low oxygen caused by the algae



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### Slide 45: Exposure Assessment

Remember, without exposure there is no risk. Prior to developing methods for determining the degree of exposure, a site conceptual model will have been developed that will describe likely routes of exposure for ecological receptors. The exposure assessment is geared toward linking COPCs to receptors and toward quantifying the degree of exposure that is occurring or that could occur for those receptors.

Depending on the site, issues, and receptors, a combination of methods may be necessary.

Biomarkers: Physiological or biochemical responses in individual organisms that reflect real-world exposure.



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### Slide 46: Tissue Analysis and Biomarkers

Tissue analyses are used to obtain direct measurements of the concentrations of contaminants in receptors or in food items used by those receptors. This is accomplished by collecting samples from the organisms to be analyzed. In some cases this will be relatively straightforward while in other cases it may be more complicated.

Example: to obtain information about the concentration of heavy metals that a deer might obtain by eating leaves from a site, samples of leaves could be collected, sent to the laboratory and analyzed for the contaminants of concern.

Some considerations include:

- How much tissue is required and how many individuals will need to be collected to have an adequate sample? [Need many grasshoppers to get 30g of tissue, but only a few mice]
- How, when, and where will the organisms be collected?
- How many samples are needed?
- Which tissues should be obtained? [Depends on question being addressed!]
- Are there special handling requirements?
- What detection limits are needed and what special laboratory protocols will be required?



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### Slide 47: Modeling: Estimating Contaminant Doses

Ecological modeling more complicated than it sounds:

- Must consider exposures to multiple media
- Multiple food pathways usually the norm
- Temporal variability, life-stage difference, and sexual differences complicate dose estimates
- Multiple receptors, each with a unique set of uptake parameters



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### Slide 53: Ecological Dose Modeling

$$ADD_{\text{food}} = \sum C_{\text{food}} \times NIR \times FR_{\text{food}} \times SU \times AE$$

where:

$ADD_{\text{food}}$  = Applied daily dose from food item (mg/kg/day)

$C$  = Food item contaminant concentration (mg/kg)

$NIR$  = Normalized ingestion rate (kg food/kg body wt/day)

$FR$  = Fraction of food item in diet (between 0 and 1)

$SU$  = Site use factor (area contamination/home range)

$AE$  = Assimilation efficiency (%)

Similar models can be developed for all critical pathways and food webs. Depending on the receptor, the complete model may require submodels for:

- Vegetation
  - Root uptake - root zone soil solution to roots
  - Root uptake - root zone soil to roots
  - Root uptake - root zone soil solution to aboveground foliage
  - Root uptake - root zone soil to aboveground foliage
  - Rainsplash deposition to foliage
  - Direct deposition to foliage
- Terrestrial Wildlife
  - Dermal contact
  - Inhalation - vapor
  - Inhalation - particulates
  - Ingestion - direct and incidental/food and media
- Aquatic Species
  - Osmotic equilibrium - aquatic plants
  - Osmotic equilibrium - free-swimming biota from surface water
  - Osmotic equilibrium - benthic biota from pore water



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### Slide 54: Effects Assessment

The effects assessment represents an analysis of the ecological response to exposure to the stressor.



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### Slide 55: Literature Reviews

HH = human health

Literature data:

- Often laboratory-based studies
- Often laboratory species such as lab rat; very unlikely on the species you need
- Regional differences in receptor ecology/physiology may be significant

Use of literature data only identifies potential for effect, does not identify actual effects at your site.

Sources:

USFWS, *Contaminant Hazard Reviews*, U.S. Fish and Wildlife Service, Patuxent Wildlife Research Center, Laurel, MD, 20708

AQUIRE , PHYTOTOX, and ECOTOX databases available from the EPA National Health and Environmental Effects Laboratory (NHEERL) at <http://www.epa.gov/ecotox/>



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### Slide 56: Toxicity Testing

There are a wide variety of toxicity tests available to risk assessors. Different test organisms, test duration, measurement endpoints, media of concern, and methodologies are available. There are tests that can be conducted *in situ* (in the field) and those that are conducted in the laboratory. Selection among tests should be based upon the types of habitats being evaluated, the assessment endpoints of interest, the receptors selected for the site, and the type of contamination suspected for the site. As with field studies, media from reference sites should also be tested to allow for comparison with the areas of concern.

Although chronic toxicity tests are typically more expensive than acute toxicity tests, it may be more cost-effective in many cases to forgo acute tests and go directly to chronic tests. If there is acute toxicity, the test organisms will die during the chronic test and this information will still be available. If acute tests are conducted and the test organisms don't die, chronic tests would still be necessary to rule out chronic toxicity.

If toxicity is detected, definitive tests coupled with chemical analyses of media should be considered. Definitive tests use clean media to "dilute" the media from the area of concern, thereby allowing effects at a series of media concentrations to be measured. This can allow determination of useful values such as media-specific NOAECs and LOAECs to be estimated. Such information may be useful for determining cleanup criteria if remediation is deemed necessary later.

Information on the use of toxicity testing and types of tests can be found at:  
<http://www.epa.gov/superfund/programs/risk/ecoup/v2no1.pdf>  
<http://www.epa.gov/superfund/programs/risk/ecoup/v2no2.pdf>



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### Slide 57: Field Studies

- Only means to demonstrate actual population and ecosystem-level effects.
- Measure structural and functional characteristics of populations and ecosystems.
- Because of high degree of natural variability, often need seasonal or multi-year sampling.
- Nature of receptor will play major role in develop of study design and methods.

For example: salmon and Exxon Valdez

- Study design sampled adult salmon 1 year after spill and concluded no effect on salmon.
- Did not consider that the adults were spawned in the area 3-4 years earlier and were never exposed to the spill as young.
- Later sampling of adults showed marked decrease in numbers, suggesting spill had adverse effects on young leaving streams and going out to the ocean.



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### Slide 61: Risk Calculation Using the Quotient Method

Contaminant-specific, often species-specific, media or dose concentrations considered "safe." (Typically lab-based NOAELs or LOAELs values)

Some "standardized" values available for Tier 1 screening:

- ambient water quality criteria (AWQC)
- EPA data bases
- NOAA SQuiRT values
- EPA Region 4 Screening Values

*Hazard Index (HI)* provides a single risk estimate value for multiple contaminants:

$$HI = \sum HQ$$

*Although common for human health risk assessments, the use of HIs in ecological risk assessments is generally not recommended*



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### Slide 62: Site-Derived Risk Ranges

Use data generated by site-specific field and laboratory investigations.

Generate dose-response curves:

- identify NOAEL and LOAEL concentrations
- these bound a target risk range to which the exposure concentration can be compared and an HQ calculated
- avoids/minimizes the use of uncertainty factors

Study design *must be* such that generation of dose-response curves is possible

- studies conducted along contaminant gradients

NOAEL = no-observed-adverse-effect-level = highest concentration at which no adverse effects are evident in the exposed organisms.

LOAEL = lowest-observed-adverse-effect-level = lowest concentration at which an adverse effect is evident in the exposed organisms.

In this figure, the risk range is represented as a concentration ranging between the observed NOAEL and LOAEL values.

To the extent possible, the dose-response curves used to identify the NOAEL and LOAEL values should be derived from site-specific studies conducted as part of the ERA. If your ERA study design will not permit the development of such dose-response curves, then it will not be possible to develop site-specific NOAEL-LOAEL risk ranges. In the absence of site-specific data, data from the literature and available data bases may be used, although their use will add uncertainty to the risk assessment because of the lack of site-specificity.

Note the importance of having a well delineated exposure range. How accurately does a NOAEL of 5 mg/kg and a LOAEL of 500 mg/kg reflect the risk range?



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### Slide 63: Lines-of-Evidence Approach

This slide shows an example of a lines-of-evidence approach (sediment quality triad).

Most common approach; integrates the results of all the studies:

- the greater the evidence or suggestion of adverse effects, the greater the risk
- requires considerable professional judgment
- apply to each assessment endpoint

*Does not provide single risk value.*

Source: Modified from Chapman, P.M., 1990, The Sediment Quality Triad Approach to Determining Pollution-Induced Degradation, *Sci. Total Environ.* 97/98: 815-825.



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### Slide 64: Ecological Significance

May estimate high risk, but if ecologically insignificant, then overall risk characterization is low.



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### Slide 67: How Do We Quantify Risks from Carcinogens?

Carcinogenic risks are summed to estimate the total excess cancer risk. They are summed for each carcinogen and across all pathways.



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### Slide 69: What Do the Numbers Mean?

Cancer risk is the probability or likelihood of getting cancer. A  $1 \times E^{-06}$  risk is equivalent to a one-in-a-million excess risk of cancer from a given level of exposure to a chemical. This means that each individual exposed to that chemical at that level over his/her lifetime has a one-in-a-million chance of getting cancer from that particular exposure. This is similar to saying that because of that chemical, we would expect to see one additional case of cancer in a population of one million people who are all exposed under the same circumstances. Note that cancer risk is described as "excess" because it is over and above the existing background risk of cancer. In the same population of one million people, the number of background cancer cases ranges from approximately 250,000 to 333,000.



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### Slide 71: Tier 3: Evaluation of Remedial Alternatives

Need to consider impacts of taking action from both a human health and ecological perspective.

Reduction in health risks may impact ecology

- will excavating a contaminated area with an established ecosystem to reduce human exposure be worth the tradeoff?

Protecting eco resources may impact human health

- might leaving a thriving ecosystem alone result in unacceptable (uncontrollable) health threats in the future? (migrations to groundwater, food ingestion)



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### Slide 74: CERCLA Remedy Selection Criteria

#### Overall protectiveness of human health and the environment

- balance risk reduction between HH and eco
- balance risk reduction with remedy impacts

#### Compliance with ARAR's

- chemical-specific ARAR's such as AWQC
- location-specific ARAR's such as the Clean Water Act for mitigation/protection of wetlands
- ARAR's such as Endangered Species Act

#### Long-term protectiveness and permanence

- long-term risk reduction, or continued COPC input from other sources
- reliability of institutional/engineering controls in reducing risks
- residual risks to the assessment endpoints
- recovery potential of the impacted habitats

#### Reduction of toxicity, mobility, or volume

- toxic effects to the assessment endpoints reduced
- likelihood of contaminant migration to other habitats currently not at risk

#### Short-term effectiveness

- ecological impacts of implementation
- effectiveness and reliability of associated mitigation measures
- short-term recovery potential of impacted habitats

#### Implementability

- technical feasibility of the remedy
- level of risk reduction

#### Costs

- total costs
- level of risk reduction vs. cost

#### State Acceptance

- may not be an issue
- early/continuous negotiations with regulators and appropriate parties throughout ERA process

#### Community Acceptance

- inclusion of citizen groups throughout the ERA process
- enhanced by ecological risk communication



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### Slide 76: Terrestrial Background Levels: Potassium and Uranium

These graphics show the variation of potassium and uranium concentrations in the soil and rock of the United States.

Examples of anthropogenic background:

- Pesticides and fertilizers in agricultural areas
- PAHs and lead in combustion areas



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### Slide 77: Terrestrial Background Radiation

The total gamma background exposure is estimated by combining the aerial gamma-ray data from the potassium, uranium, and thorium data channels.

It is evident in this graphic that terrestrial levels of background radiation are highest in the Rocky Mountain Region of the United States and lowest in coastal areas.

