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Welcome – Thanks for joining us.
ITRC's Internet-based Training Program

Risk Assessment and Risk Management: Determination and Application of Risk-Based Values

State Screening Values Document: Examination of Risk-Based Screening Values and Approaches of Selected States (RISK-1, 2005)

Electronic Fact Sheet for Risk Assessment (2006)

Sponsored by: Interstate Technology and Regulatory Council (www.itrcweb.org)
Hosted by: US EPA Clean Up Information Network (www.cluin.org)

Assessment of human health risks posed by exposure to hazardous substances is a vital component to the process of remediation of contaminated sites. Risk-based screening values are developed and used in both planning and conducting site remediation. This training course is designed for site managers and others involved in making remedial decisions to help them better understand the risk assessment / risk management process.

This training course describes the development and application of risk-based screening values. The first module provides a review of key risk assessment concepts related to risk management. It also introduces the *Electronic Risk Resource Fact Sheet* developed by the ITRC Risk Assessment Resources team. The second module focuses on the process by which risk-based levels are derived in different states. This module introduces the document, *Examination of Risk-Based Screening Values and Approaches of Selected States* (RISK-1, 2005), developed by the ITRC Risk Assessment Resources team. The third module examines the application of risk assessment to remediation operations in two case studies providing examples of how risk assessment has actually been implemented, based upon research and case studies conducted by the ITRC Risk Assessment Resources team. This training course describes a number of the reasons behind variations in risk-based screening values and their use in risk management. Overall, the training course enhances the transparency and understanding of risk assessment and its use in remediation.

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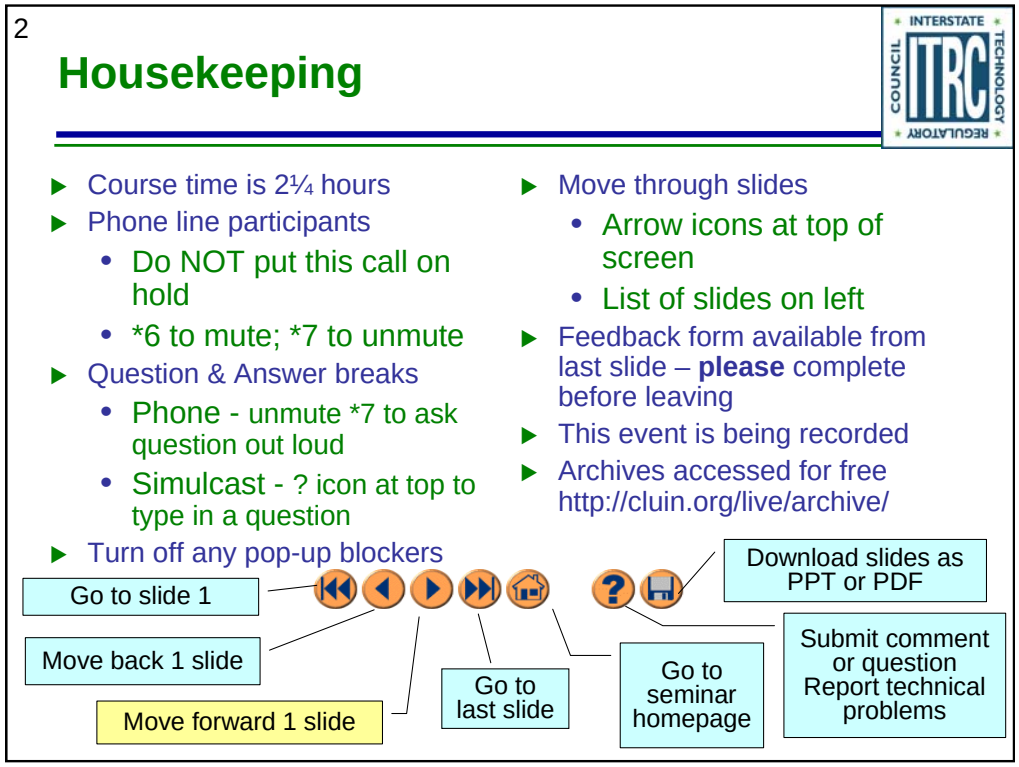

Although I'm sure that some of you are familiar with these rules from previous CLU-IN events, let's run through them quickly for our new participants.

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You should note that throughout the seminar, we will ask for your feedback. You do not need to wait for Q&A breaks to ask questions or provide comments using the ? icon. To submit comments/questions and report technical problems, please use the ? icon at the top of your screen. You can move forward/backward in the slides by using the single arrow buttons (left moves back 1 slide, right moves advances 1 slide). The double arrowed buttons will take you to 1st and last slides respectively. You may also advance to any slide using the numbered links that appear on the left side of your screen. The button with a house icon will take you back to main seminar page which displays our agenda, instructor bios, links to the slides and additional resources. Lastly, the button with a computer disc can be used to download and save today's presentation slides.

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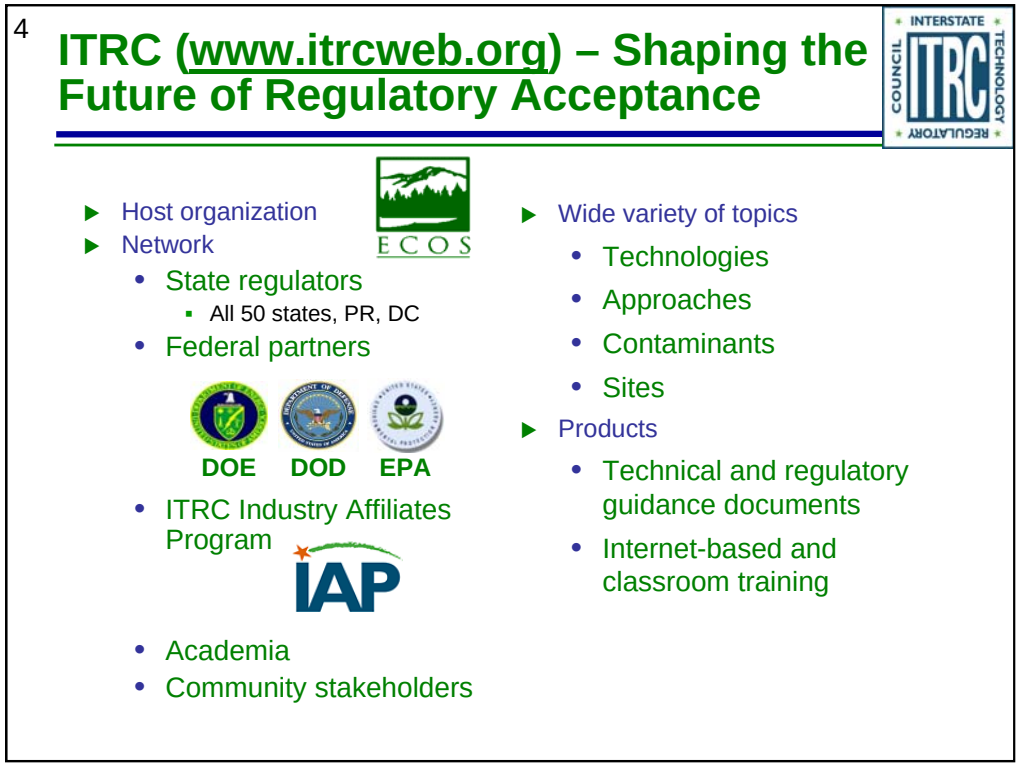

The Interstate Technology and Regulatory Council (ITRC) is a state-led coalition of regulators, industry experts, citizen stakeholders, academia and federal partners that work to achieve regulatory acceptance of environmental technologies and innovative approaches. ITRC consists of all 50 states (and Puerto Rico and the District of Columbia) that work to break down barriers and reduce compliance costs, making it easier to use new technologies and helping states maximize resources. ITRC brings together a diverse mix of environmental experts and stakeholders from both the public and private sectors to broaden and deepen technical knowledge and advance the regulatory acceptance of environmental technologies. Together, we're building the environmental community's ability to expedite quality decision making while protecting human health and the environment. With our network of organizations and individuals throughout the environmental community, ITRC is a unique catalyst for dialogue between regulators and the regulated community.

For a state to be a member of ITRC their environmental agency must designate a State Point of Contact. To find out who your State POC is check out the "contacts" section at www.itrcweb.org. Also, click on "membership" to learn how you can become a member of an ITRC Technical Team.

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ITRC Course Topics Planned for 2010 – More information at www.itrcweb.org

Popular courses from 2009

- Decontamination and Decommissioning of Radiologically-Contaminated Facilities
- Enhanced Attenuation of Chlorinated Organics
- In Situ Bioremediation of Chlorinated Ethene - DNAPL Source Zones
- LNAPL Part 1: An Improved Understanding of LNAPL Behavior in the Subsurface
- LNAPL Part 2: LNAPL Characterization and Recoverability
- Perchlorate Remediation Technologies
- Performance-based Environmental Management
- Phytotechnologies
- Protocol for Use of Five Passive Samplers
- Quality Consideration for Munitions Response
- Determination/Application of Risk-Based Values
- Use of Risk Assessment in Management of Contaminated Sites

New in 2010

- Decision Framework for Applying Attenuation Processes to Metals and Radionuclides
- LNAPL Part 3: Evaluating LNAPL Remedial Technologies for Achieving Project Goals
- Mining Waste
- Remediation Risk Management: An Approach to Effective Remedial Decisions and More Protective Cleanups

ITRC 2-day Classroom Training: Vapor Intrusion Pathway

More details and schedules are available from www.itrcweb.org under “Internet-based Training” and “Classroom Training.”

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Meet the ITRC Instructors

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Bennett Kottler is a branch supervisor of the State of Nevada Petroleum Fund at the Nevada Division of Environmental Protection's Bureau of Corrective Actions located in Carson City, Nevada. Since 2002, he has given technical, regulatory, and fiscal oversight on remediation cases ranging from residential heating oil tanks to a 1,600-acre site used to test engines for the Gemini, Lunar Module, Apollo, and Space Shuttle programs. For four years previously, Bennett served as an assistant professor and taught environmental science, policy, and education at the University of Nevada Reno in Reno, Nevada and Southern Connecticut State University in New Haven, Connecticut. Bennett spent four years teaching science in New York City to students ranging in age from 6 to 60. Bennett has served as a team member of the ITRC's Risk Resources Team since its inception in 2003. Bennett earned a bachelor's degree in biology from Boston University in Boston, Massachusetts in 1985, and a master's degree in 1994 and a doctorate in 1998, both in environmental toxicology from Cornell University in Ithaca, New York for his research on microbial ecology and the fate of organic pollutants in soil, respectively.

Anna H. Butler is a technical manager for the HTRW/Geotechnical Branch of the Savannah District of the U.S. Army Corps of Engineers. The Savannah District provides environmental restoration services to Department of Defense facilities in Georgia, South Carolina, and North Carolina. Since 1995, Anna has worked in various capacities for sites located in these states and has provided assistance for other districts along the east coast as well. Most recently, Anna has worked with risk assessors on the preparation and interpretation of risk assessments for multiple RCRA sites as well as the corrective action decisions. In previous years, Anna gained teaching experience as a graduate teaching assistant at the Georgia Institute of Technology and was assigned to the corporate training center for Gearhart Industries in Fort Worth, TX for two years. Anna has been an active member of the ITRC's Risk Assessment Resources and UXO Teams since 2004. Anna earned a bachelor’s degree in geology from the University of Georgia in Athens, GA in 1976; and a master’s degree in geophysical sciences from the Georgia Institute of Technology in Atlanta, GA in 1990. Anna is currently a registered Professional Geologist in Georgia.

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What You Will Learn…

Understanding the determination, and application of risk-based values is important for risk management.

- Module 1 - Introduction
  - Highlight concepts
- Module 2 – Screening values variation
  - Survey results
  - Approaches, Assumptions, and Algorithms
- Module 3 – Use of risk-based values
  - Two case studies
- Resources
  - Examination of Risk-Based Screening Values and Approaches of Selected States (RISK-1, 2005)
  - Electronic Risk Resources Sheet (2006)
  - Use of Risk Assessment in Management of Contaminated Sites (RISK-2, 2008)

** Understanding basis, approaches, and uses of values is more important than the values themselves**

1. Values change more often than do risk assessment paradigms

2. Application & basis of values is more useful

Two years surveying regulators, reviewing data, and discussing the ways U.S. States use risk assessment to screen and ultimately clean-up contaminated sites.

State and federal regulators, representatives from Army Corp. of Engineers, citizen stakeholders, Industry, Navy, and DOE.

Presentation divided into 3 Modules.

- Assume literacy but a limited understanding,

(perhaps a risk manager; risk assessors - already wrestled w/ many issues we'll address)

1) Begin with an Introductory Module. Sets foundation for the other modules; clarifies key concepts:

(**Screening levels** vs. Cleanup vs. target levels)

2) 2nd Module. Present the results of survey of 13 States:

- Compared screening levels

- Dig into assumptions & algorithms used to *develop* risk-based screening levels to uncover approaches

3) Last Module - 2 case studies of risk-based remediation"

- How risk assessment is *actually used* in site remediation.

(Info from Washington state and Washington D.C., supplement 13 States)

Uncover the differences in approaches

Throughout the presentation, we'll reference the ITRC Risk Assessment Resources Team

The published States Screening Values Document

An electronic fact sheet with links to key internet resources

Risk-2 document that is the basis for Module 3, the Case Studies

- Check links to some 3 dozen links to additional resources.

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Benefits to Regulators and Risk Managers

- Better understanding of risk assessment
  - Improved skills and project planning
- Comparison of risk assessment approach
  - Inter-state information transfer
  - Improved transparency
    Publishing values is not enough

- Evaluate risk assessment in managing cleanup

Hope training is quick way to see how U.S. States handle risk-based cleanups from screening levels to the basis of screening levels, to cleanup goals.

1) Increased understanding of development & application of risk-based levels to screening & remediating

➔ improved oversight, project management, case oversight . . . and work w/toxicologists

1a) Screening levels change

1b) Exposure scenarios change

i.e. NV

- Applicability of Fed guidance?
- Most urbanized State
- Varied environments inc. Mountain & Deserts

What is applicability of Fed guidance i.e. USEPA Region 9 PRGs

2) Comparison of States' regulatory approach - Valuable

2a) Work inter-state? From federal agency? New regulations and policies?

Comparison ➔ **Apply information from one State to the next.**

i.e. DoD and DOE covering NV and CA.

2b) Value of increased **transparency** to regulated community: policymakers and public.

- Challenge regulators about inter-State variation.
- Numbers don't speak for themselves.
- i.e. Acceptance of Science
- i.e. FL stakeholders IMPROVED exposure assessment.

3) Review cleanup goals and approach in two case studies

Module 1 - Anna H. Butler, technical manager, Savannah District of the U.S. Army Corps of Engineers.

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Risk Assessment and Risk Management: Determination and Application of Risk-based Values

MODULE 1:

Risk Assessment and Risk Management

No associated notes

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Learning Objectives

- Review basic risk assessment concepts that will be illustrated in Modules 2 and 3
  - Risk-Based Screening Levels
    - Use and variability in risk assessment vs. risk-based remedial levels
- Use of risk assessment in risk management
- Identify the role of risk communication

In this module we will look at the larger picture of risk management and the relationship of risk assessment and screening levels with risk management. We will review the basic concepts of risk assessment, how they are applied to screening levels and the risk management decision-making processes.

This training session will focus on risk management as applied to “hazardous waste sites.” To illustrate the concepts discussed and to simplify the discussion, this training session will focus on one media – soil.

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Electronic Risk Resource Sheet

- Developed by ITRC Risk Team
- Located http://www.itrcweb.org/gd_Risk.asp
  - Listed at bottom of the page
- Compilation of web-based resources for human and ecological risk assessment
  - Tutorials
  - Guidance documents
  - Databases
  - Special topics
  - Risk communication

The Interstate Technology Regulatory Council (ITRC) Risk Assessment Resources Team (Risk Team) has developed. This resource sheet of internet-based resources is available from the Guidance Document page at the ITRC website (www.itrcweb.org). Click on the link for the additional resource pages.

The resource sheet (Risk Assessment Fact Sheet) is divided into five sections:

Understanding Risk Assessment, which includes tutorials at both the introductory and advanced level

Human Risk Assessment, which includes links to (1) databases such as Integrated Risk Information System (IRIS) and Health Effects Assessment Summary Tables (HEAST) and (2) guidelines such as Risk Assessment Guidance for Superfund (RAGS)

Ecological Risk Assessment

Special Topics such as vapor intrusion, perchlorate

Additional Links

Most links connect to databases, tools, and topics that address risk assessment.

(Disclaimer – it is not intended to be comprehensive and does not address such issues as tribal risk assessment, chemical-specific data, and uncertainty.)

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Risk Management

- Risk management - the process of
  - Controlling risks
  - Weighing the alternatives
  - Selecting the appropriate action
- These decisions take into account
  - Risk assessment information
  - Social and political issues
  - Regulatory/policy issues
  - Technological/economic issues

Risk Management is the action taken to protect human health or the environment from exposures to a hazardous substance or situation. Risk Managers must determine the best way to reduce or eliminate the risk to the receptor population.

Risk Managers must also take into account the cost and feasibility of implementation for each alternative considered, as well as regulatory approval of the action and any social or political issues involved with the site or the technology.

The framework for these risk management decisions and for selecting the remedial alternative is based on CERCLA Guidance: “Nine Criteria of the National Contingency Plan” (40 CFR 300.410)

This guidance directs that each remedial alternative be compared against nine criteria identified, then the alternative that best fits is selected. These nine criteria are divided into three subgroups:

Threshold Criteria –

Be protective of human health and the environment

Comply with applicable or relevant and appropriate requirements (ARARs)

Balancing Criteria –

Long term effectiveness and permanence

Reduction of mobility, toxicity, or volume

Short term effectiveness

Implementability

Cost

Modifying Criteria –

State/ regulatory acceptance

Community acceptance

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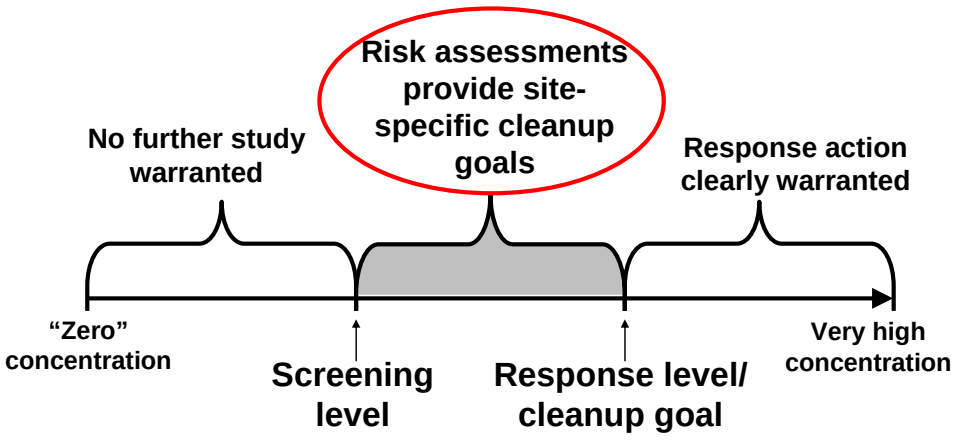
Conceptual Risk Management Spectrum for Contaminated Soil



From the 1996 EPA Soil Screening Guidance: Users Guide

This slide shows the continuum of where risk assessment is used in managing risks at hazardous waste site cleanup.

Not all sites will need the same level of remediation or management. The magnitude, type, and number of contaminants will the dictate level of remediation and management that is warranted. The figure in the slide above is a graphic illustration of the relationship between the magnitude of soil contamination and the relative management response.

Some decisions are clear cut, very low levels – no action; very high levels – remediation is necessary. It is the middle area is where choices/decisions are not clear cut – that is where screening levels and risk assessment become valuable and where this and the following modules will focus. As you can see from the figure above, screening levels are used as the first step in the risk management process to eliminate a site from further study or action. The response levels are site-specific cleanup levels calculated from site data, above which remediation could be necessary.

Risk Assessments are the tools used to develop screening and remediation levels, for making these risk management decisions.

Module 2 will discuss screening levels in more detail and examine the sources of some of the differences observed in the screening levels between various agencies. Module three will illustrate how these two levels are utilized in site investigations and remediation.

The next slides are about risk and basic components of risk assessment, the final slides explain the relationship of screening levels to risk assessment and risk management.

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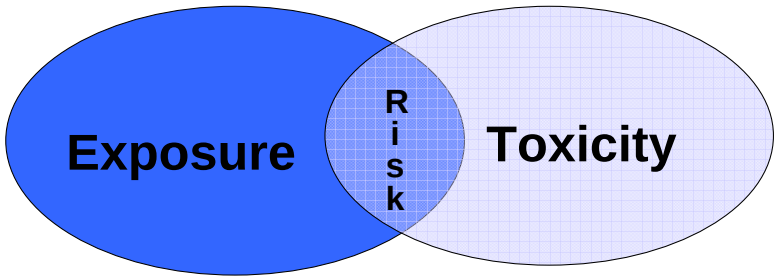
What do We Mean by Risk Assessment?

Risk = Probability of suffering harmful effects due to exposure to site related constituents



Provides information and characterizes any potential adverse effects of human exposure

What do we mean by risk assessment? The qualitative or quantitative characterization and estimation of potential adverse health effects associated with individuals or populations to hazards. These hazards could be materials (physical, chemical or microbial in natures) or situations.

The assessment is the process involved to determine whether a substance poses a risk, what population is susceptible to the risk and the extent (magnitude) that risk.

The risk is the probability that these adverse effects will occur.

Risk management-Uses the results of the risk assessment to determine the best way to reduce or eliminate the risk to a receptor (population) by controlling or eliminating one of the three basic components; i.e.; eliminate the source, the pathway, or receptor.

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What Value is a Risk Assessment?

- Evaluates the need for protective action at a site
- Provides a scientific and legally defensible basis to support risk management decisions
- Can result in cost and time savings by
  - Focusing corrective actions on the exposure pathways that present the highest risks
  - Providing risk-based remediation goals

A risk assessment will evaluate the potential hazards to identified receptors from exposures to all site hazards via the exposure pathways. Through this evaluation the need for any protective action or remediation can be identified. It will provide a scientific and legally defensible support to base risk management decisions. Providing site-specific cleanup goals can result in cost savings instead of using background levels or screening levels for cleanup goals, or cleaning a site up to non-detect levels.

It can also allow for reuse of site by evaluating exposure pathways and restricting activities to avoid exposure while allowing for the reuse a site

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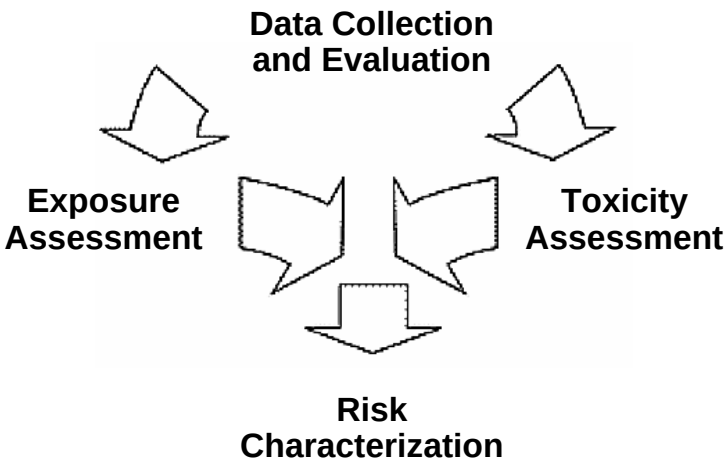
Basic Components of a Risk Assessment



The next few slides review the basic components or processes involved in a risk assessment.

4 basic steps:

1. Data collection
2. Toxicity Assessment
3. Exposure Assessment
4. Risk Characterization

3 Basic Components for Risk from substance to occur.

Source

Pathway

Receptor

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Data Collection and Evaluation

- Evaluate entire site and site history
- Identify
  - Source
  - Media
  - Pathways
  - Receptors
- Develop a site conceptual model
  - Use to plan sampling/data needs
- Review and evaluate site data

The first step involved is to develop a sampling plan that will address all exposure pathways from the source of the suspected hazard to the receptors. A good way of doing that is to develop a site conceptual model that will identify all the media, pathways, and receptors of concern. The site conceptual model can be used to plan sampling and data needs for the site investigation and risk assessment to make sure that there will be no data gaps.

The purpose of sample collection is to evaluate the site data to characterize the exposure for each receptor from all media. Environmental samples can be collected for different purposes. Sampling data collected to delineate fate and transport of chemicals may have provided insufficient data for risk assessment purposes. Samples needed for risk assessment purposes are not necessarily the same as those to characterize the nature and extent of a contaminant. For a realistic exposure assessment, samples should come from all media that receptor would be exposed to and from the entire site area, not just those parts of the site that contain concentrations of the contaminant. There also need to be a sufficient number of samples collected to perform valid statistical functions used in the risk assessment processes.

Sampling Plan

Are the number of samples collected adequate for data needs and use.

Is the coverage adequate to characterize site based on site size and history.

Samples collected from all media of concern, are all pathways represented?

Analytical Needs

Does analytes list match chemicals of concern?

Use recent, approved analytical methods?

Evaluate reporting/detection limits vs. screening levels, data use

Module 3 will discuss two case studies that illustrate how sampling plans are tailored to fit the needs of each site investigation based on the risk assessment or remediation needs.

This is the point in the risk assessment process at which the screening levels are employed. Chemicals detected in the samples from each media are compared to the approved screening levels for each media. Those chemicals that exceed the screening levels are identified as chemicals of potential concern for further evaluation, while those that do not exceed can be eliminated.

Module 2 will discuss screening levels in more detail. There are several sources of screening criteria and they will vary based on the regulatory program that a particular site investigation falls under. Different sources screening criteria will have different values listed for the same chemical allowing that chemical to be eliminated at this point under some programs, while classified for further evaluation under other programs. Module 2 will examine the sources of variance for some of the parameters that make up the differences in the various screening criteria.

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Toxicity Assessment

- Provides a summary of toxicity and potential effects from exposures
  - Toxicity Values are selected for risk calculations
- Two classifications for toxic effects
  - Carcinogenic
    - Exposure has potential to result in cancer
    - Toxicity values described by a “cancer slope factor”
  - Noncarcinogenic
    - Anything else
    - Exposure above a threshold level could result in adverse effect
    - Toxicity values described by a “reference dose”

Toxicity assessment is not a risk assessment, but simply the assessment of whether a chemical detected in a media will have an adverse effect on the receptor. The toxicity assessment uses information from experiments in animals to infer that the same results will occur in humans and describes the relationship between the amount of exposure and the extent of harmful effects.

During the toxicity assessment, toxicological information is reviewed for each site related chemical of concern to select the most appropriate toxicity value for use in the risk calculations. Toxicity values are derived from the dose-response studies.

Two classifications for these adverse effect based on the weight of evidence from the various studies documenting long-term/short term effects.

1. Carcinogenic Effects

   An exposure has the potential to keep causing the effect, so that one molecule could cause cancer (unlikely but possible). Potency described by Cancer Potency Factor (Slope Factor) in units of (mg/kg-day)-1 The Cancer Slope Factor is the 95% UCL of the slope of the dose-response curve.

2. Noncarcinogenic Effects

   Chemicals have a threshold based on studies; exposures below this level will not have adverse effects. If you remove the exposure, you stop the effect.

   Potency described by reference doses in units of mg/kg-day

Noncarcinogenic effects include health effects like organ damage. For instance, at low doses Tylenol is therapeutic but at high doses can damage the kidneys

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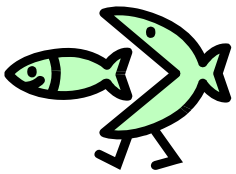
Exposure Assessment

- Identifies and describes
  - Receptors to site related constituents
  - Pathways for exposure
  - Concentration and length of time of exposure
- Calculate the Average Daily Intake (Dose)
  - Each receptor
  - Each pathway
  - Each site-related constituent of concern



The exposure assessment is the part of the risk assessment process that describes the type and size of the population at risk (receptors) and the extent and duration of their exposure. These can be current, past, or future exposures. During the exposure assessment the potential daily dose of the suspected chemical that a receptor will be exposed to via all exposure pathways is calculated

Exposure Pathways: Three Main Exposure Pathways

1. Dermal - skin exposure from dust, surface soils from work activities, recreational activities, groundwater by bathing, showering, swimming.
2. Oral - ingestion of soils (dust), water
3. Inhalation - breathing contaminated dust or vapors- Activity dependent

In some rare cases there could also be an intravenous exposure - a cut that exposes blood vessels.

Exposure is generally expressed in terms of how much a receptor will be exposed to in one day with an Average Daily Intake (Also commonly termed Chronic Daily Intake)

Start by using default exposure parameters. Then ask if these default exposure parameters (very conservative) are reasonable or too conservative based on site history and expected use.

As you will see in Module 2, risk based screening levels use very conservative exposure parameters for these exposure assumptions. In a site-specific risk assessment, there might be e more reasonable exposure parameters for a particular site based on expected use or site history.

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Exposure Assessment (continued)

$$\text{Average Daily Dose (Intake)} = (\text{Chemical Concentration}) \frac{(\text{Ingestion Rate})(\text{Exposure Duration})(\text{Exposure Frequency})}{(\text{Body Weight})(\text{Averaging Time})}$$

- Exposure parameters
  - Terms used to calculate an average daily intake or "dose" per chemical per media per receptor for a specific exposure time
- Exposure parameters vary per receptor
  - i.e.; for an adult the default exposure duration is 24 years, while for a child 6 years is commonly used

This is the most basic general equation. This equation can be modified based on compound, pathway, or receptor by adding other terms to the equation. Some of these terms are:

PC: Permeability coefficient

DA: Dose adsorbed per surface area

SA: skin surface area

V: volatilization factor

PEF: Particle emissions factor

Exposure concentration: Average concentration for each chemical receptors exposed to (Site Specific-95% upper confidence level (UCL))

Exposure frequency: Days per year exposed / Default value = 365 days

Exposure duration: Number of years exposed / Default value = 24 yrs for resident

Body weight: Of receptor exposed / Default value = 70 kg for adult

Averaging time: Number of years exposure is averaged/ Default value = 70 yrs for resident

There are two common methods used to estimate the exposure concentration.

1. RME : Reasonable Maximum Exposure -Uses upper percentile (90-99) estimates for some exposure parameters and for toxicity estimates; Uses average estimates for remaining exposure parameters.

2. CTE: Central Tendency Exposure - Uses average estimates for all exposure parameters (toxicity values remain as upper percentile estimates of risk)

Module 2 will show you how simple things like a different approach to the average body weight for adults will change the estimated average daily dose.

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Risk Characterization

Risk is characterized by combining exposure and toxicity assessment

- Carcinogenic chemicals

$$\text{Risk} = (\text{Average Daily Dose})(\text{Cancer Slope Factor})$$

  - Note: Risk calculated is an incremental lifetime cancer risk (ILCR) – probability of cancer from exposure above risk from non-exposure (currently 33-50% risk of cancer for average adult)

- Non-carcinogenic chemicals

$$\text{Hazard Quotient} = \frac{\text{Average Daily Dose}}{\text{Reference Dose}}$$

Risk Characterization – combines both the exposure assessment and toxicity/dose assessment to calculate the estimated excess risk for both non-carcinogenic and carcinogenic substances.

1. Carcinogenic Risks- expressed as a probability by multiplying dose by a cancer potency.

$1 \times 10^{-6} = 1E\text{-}06 = 0.000001 =$ one-in-a-million

The resulting risk is actually a incremental risk of contracting cancer from the site-specific exposure above and beyond the receptors probability of contracting cancer during a lifetime without the exposure: This is termed the incremental or excess lifetime cancer risk (ILCR).

2. Noncarcinogenic Risk- ratio of the average daily dose divided by the reference dose

This ratio is termed a “Hazard Quotient”. A hazard quotient less than one means that the average daily dose is lower than the safe dose (reference dose) and no health effects are predicted.

$$\text{Average Daily Intake} = \frac{\text{Body Weight} \times \text{Exposure Frequency} \times \text{Exposure Duration} \times \text{Exposure Concentration}}{\text{Averaging Time}}$$

Risks are summed for each pathways for all chemicals and for each receptor for both carcinogenic and non-carcinogenic chemicals:

Incremental (Excess) Lifetime Cancer Risk (ILCR) = Risk (pathway 1) + Risk (pathway 2)+ Risk (pathway 3) …

Hazard Index (HI) = HQ1 + HQ2 + HQ3+…

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Major Factors Influencing Variation in Values

- Cancer Slope Factor (CSF) and Reference Dose (RfD)
  - Different sources list different CSFs and RfDs for same chemical
  - Different agencies will approve different CSFs or RfDs
  - OSRTI toxicity hierarchy
- Exposure Parameters
  - Default or site-specific parameters can vary
  - Method of calculating the average daily dose will vary with states and/or agencies
  - Different risk assessment tools used in calculations
- Evaluation of the likelihood of exposure
  - Limitations of data
  - Limitations of exposure assumptions
  - Variability in receptor populations

Identify the source of slope factor or reference does at this stage. Follow Office of Superfund Remediation and Technology Innovation (OSRTI) hierarchy for toxicity information.

Some sources for toxicity data are:

1. IRIS – Integrated Risk Information System
2. HEAST – Health Effects Assessment Survey Tables
3. USEPA NCEA – National Center for Environmental Assessment
4. Other Sources include : withdrawn EPA numbers, Agency for Toxic Substances and Disease Registry (ASTDR), World Health Organization (WHO), State Agencies such as Cal EPA.

The averaging time assumed will also cause a variation i.e. 24 years vs. 30 years, some agencies might want to include the childhood years with the adult years for purposes of estimating carcinogenic exposures to a human receptor.

Very important part of a Risk Assessment is to describe all the uncertainties and limitations used in the input parameters. A risk characterization is incomplete without presenting all the assumptions made and the related uncertainties, i.e. the confidence in the data presented. The uncertainties section should summarize and evaluate important uncertainties, likelihood of exposure happening, what the likelihood that exposure and toxicity assumptions are over or under estimated.

Variability is defined a the true heterogeneity or diversity that characterizes an exposure variable or response in a population. Further study (e.g., increasing sample size) will not reduce variability, but it can provide greater confidence (e.g., lower uncertainty) in quantitative characterizations of variability. For instance, we could weigh everybody and document the range of weights.

Module 2 will show an example of how different parameters affect screening levels.

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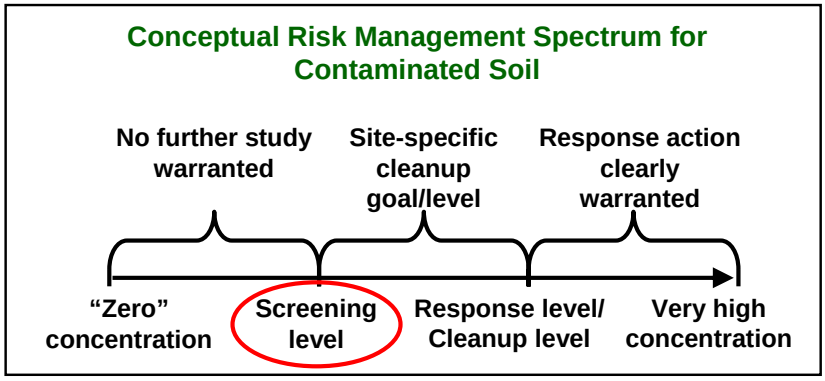
What are Screening Levels?



Chemical concentrations below which no additional regulatory attention is warranted

In the risk assessment process, screening levels are distinct from cleanup levels or remedial goals although some states use clean up levels as screening levels.

As you can see from the figure above, screening levels are used as the first step in the risk management process to eliminate a site from further study or action. The response levels are site-specific cleanup levels calculated from site data, above which remediation could be necessary.

Module 2 will discuss screening levels in more detail and examine the sources of some of the differences observed in the screening levels between various agencies. Module 3 will illustrate how these two levels are utilized in site investigations and remediation.

If exceeded, then additional evaluation is necessary and possibly remediation could result.

Many State and Federal Agencies publish lists of approved levels below which no action is necessary.

Examples of some sources of screening levels:

EPA Region 3 Risk-Based Concentrations (RBCs)

EPA Region 9 Preliminary Remediation Goals (PRGs)

EPA Soil Screening Levels

EPA Maximum Contaminant Levels (MCLs)

Background levels

Practical Quantitation Limits (PQLs)

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Two Basic Types of Screening Levels

- Risk-based
  - A chemical concentration that is derived using toxicity data, generic exposure assumptions, and a chosen risk level (usually 1 x 10^{-6})
- Non risk-based
  - Published values for chemicals set by regulating agencies to be protective of human health, but not based on probabilities or risk

Examples of risk based screening levels include USEPA Soil Screening Levels, Region 9 Preliminary Remediation Goals (PRGs), and Region 3 Risk Based Concentrations (RBCs), USEPA Soil Screening Levels.

Even though the basic exposure parameters are the same, there are some differences in the equations and in how these parameters are utilized with the screening levels published by various agencies. You should investigate the exposure parameters and equations used by each i.e. Region 3 EPA doesn't include inhalation of VOCs in water or dermal exposure while Region 9 EPA does.

Non Risk-Based Levels may be background concentrations, analytical limits, or regulatory standards that are designed to be health protective. (i.e. EPA MCLs).

Module 3 will illustrate two case studies, one (Spring Valley) which used risk based screening levels and non-risk-based screening levels (i.e. background levels) as a decision-making point for further action and the other (Fort Lewis, WA) that used the risk-based screening levels as remediation levels..

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Risk Based Screening Levels are Based on same exposure parameters

$$\text{Average Daily Dose} = \frac{\text{Risk Level}}{\text{Cancer Slope Factor}}$$

$$\frac{(\text{Chemical Concentration})(\text{Ingestion Rate})(\text{Exposure Frequency})(\text{Exposure Duration})}{(\text{Body Weight})(\text{Averaging Time})} = \frac{\text{Risk Level}}{\text{Cancer Slope Factor}}$$

Use an appropriate risk level (10^{-6}, 10^{-5}, 10^{-4}) to solve for the chemical concentration - result is the Risk Based Screening Level

$$\text{Risk Based Screening Level} = \frac{(\text{Body Weight})(\text{Averaging Time})(\text{Risk Level})}{(\text{Ingestion Rate})(\text{Exposure Frequency})(\text{Exposure Duration})(\text{Cancer Slope Factor})}$$

For risk-based screening levels, the same equations from the risk characterization process is used, but with conservative exposure parameters and a set risk level to solve for the concentration that equates to that risk level. This concentration becomes the screening level and because very conservative parameters are used, and the screening level can be related to an acceptable risk level, they provide a basis to allow a decision to be made that either further investigation is necessary or not.

Typically based on generic and very conservative default exposure assumptions. Can be calculated for cancerous or non-cancerous compounds. They are not site specific, but are media and chemical specific.

In Module 2, we will demonstrate how using the same exposure parameters but slightly different equation will affect the resulting screening level.

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How are Screening Levels Used?

Data can be compared by one of two methods

1. Direct comparison of one sample result – maximum detected value
   a. Discrete sample
   b. Composite sample – for soils, with regulatory approval (not appropriate for some types of analytes)
2. Statistical – samples from entire site used
   a. Average
   b. 95% upper confidence level (UCL) of the mean

Screening levels are used after the initial site data is collected. Most commonly, the maximum detected concentration (to be conservative) for each chemical detected is compared to the screening level.

In some cases, the mean or the 95% UCL of the site data is used for these comparisons.

Because screening values are health protective, and based on conservative assumptions. if site data does not exceed the screening values you can determine with some confidence that the site does not present any unacceptable risk

Risk Based Screening Levels	Non-Risk Based Screening Levels
Compare Site data to screening levels, if exceeds then:	Compare site data to screening levels. If exceeds, then:
baseline risk assessment is performed. Risk managers and regulators review short and long term risks, decide on action.	some type of remediation indicated, Risk managers and regulators decide on action.
If remediation indicated, then Remediation Goals calculated based on site-specific data and agreed upon risk levels	Screening Levels most often serve as remediation goals
Risk Managers evaluate remediation technologies for cost, effectiveness; make decision.	Risk Managers evaluate remediation technologies for cost, effectiveness; make decision.

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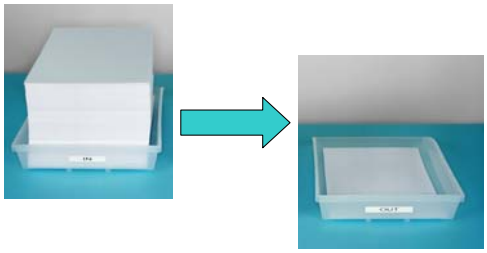
Value that Using Screening Levels Provide

- A decision point for risk management
  - Does the site warrant further investigation or assessment
  - Eliminate a site from further investigation
- Reduces the number of substances that need to be evaluated
  - Indication of extent or magnitude of site risks



Without the use of screening levels in the risk assessment process, all detected chemicals for all media would need to be taken through the risk assessment processes for a site, resulting in a very lengthy assessment with many equations. Using screening levels in the initial assessment of the site data allows you to focus the risk assessment to those chemicals that present a potential risk.

Advantages of using screening levels:

1. Reduce the number of substances that need to be evaluated further.
2. Gives some idea about the extent or magnitude of risks/issues at site.
3. Can eliminate a site from further investigation.
4. Can use initial screening to focus additional investigation/ assessment.

Some Disadvantages:

1. Screening levels (and their exposure parameters) are not site specific.
2. Very conservative.
3. Often rely on maximum detected concentrations instead on a more representative concentration for site data.

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Risk Based Remedial Levels

- Use the results of a risk assessment
  - Site-specific exposure parameters
  - Site-specific exposure point concentration
  - Site-related risks and hazard quotients calculated by risk assessment
- Target risk level can be different than that used for screening levels
  - Agreed upon during risk management process

$$\text{Remedial Level} = \frac{(\text{Target Risk Level})\ (\text{Exposure Point Concentration})}{(\text{Site Risks or Hazards})}$$

Risk Based Remedial Levels (RLs) differ from preliminary remediation goals (PRGs) or other risk-based screening levels.

PRGs and screening levels are developed to be used as a screening level tool and use generic default exposure parameters.

RLs are developed from site-specific information generated during the baseline risk assessment and an agreed-upon target risk level.

Since RLs are used to make choices and decisions involving the remedial design and technologies, they must be both protective of human health and the environment and practical.

The uncertainties in the RL calculations and exposure parameters should also be documented and discussed. Calculated RLs can be modified based on site conditions, economic and technical feasibility, regulatory policies, and social/political conditions.

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Risk Communication

- Risk management decisions involve many people with differing
  - Backgrounds
  - Experience
  - Authority
- Risk assessments
  - Result in a large quantity of specialized information and numbers
- Goal is to communicate technical information
  - In terms that are clear
  - In a manner that all can understand

Many people involved with decision-making process will not have a technical or scientific background. Risk communication means finding a way to explain the technical information in non-technical terms.

Module 3 will illustrate how important that risk communication can be between the public, stakeholders, and regulators and how the risk communication process relate to the can outcome of a remediation effort.

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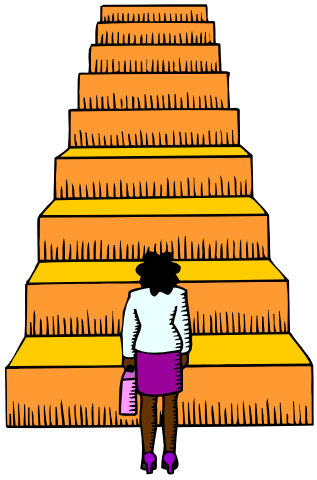
Few Key Challenges of Risk Assessment and Risk Management

- Risk communication with
  - Regulators
  - Stakeholders
  - Public
- Acceptable risk levels
- Sampling
  - Limitation of data
  - Site coverage
- Are all states/regions conducting risk assessment and risk management the same way?
- Next we will examine some of these differences and see how some states differ in their assumptions in Module 2



Risk communication is still one of the greatest challenges in risk management and risk assessment. Communication that the risk involved is an incremental excess risk and a probability, as well as agreement on the level of probably that is acceptable can be challenging.

Sampling is another area- ensuring adequate coverage to represent entire site, not just focused on highest contamination areas requires a greater number of samples to be collected but will allow a more representative site comparison (i.e. mean or 95 % upper confidence level (UCL) instead of the minimum detectable concentration (MDC)) as well as a more realistic exposure point concentrations.

•Adequate number of samples (at least 20 to allow elimination of compounds based on <5% frequency of detection)

•Detection limits low enough

•Number and location of background samples

•Special analysis i.e. Chromium (Cr) +6

•Right media (surface vs. subsurface vs. sediment)

Module 2 will examine risk based screening levels used by various member states and how they are developed, their similarities and differences.

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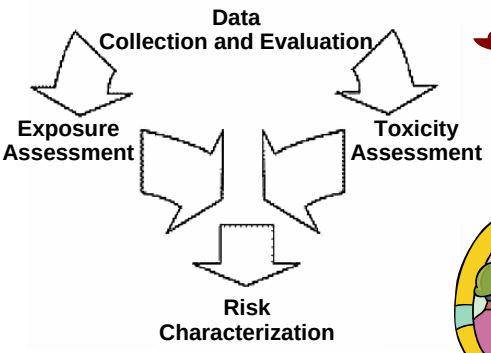
Questions and Answers

MODULE 1: Risk Assessment and Risk Management



No associated notes

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Risk Assessment and Risk Management: Determination and Application of Risk-Based Values

MODULE 2:
Examination of Risk-Based Screening Values and Approaches of Selected States

When the ITRC's Risk Resources Team first met in 2003, the state regulators in the room immediately asked each other each other about two issues:

“What values do you use?”

“What approach do you use?”

Thus, we undertook a survey to address these concerns.

- In December 2005, ITRC published the survey.

-Same name as module, "Examination of Risk-Based Screening Values and Approaches of Selected States."

-Throughout this presentation I will refer to it as States Screening Values Document

-Download a PDF or order a CD for free at the ITRC website.

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Learning Objectives

- Document differences in screening levels
- Determine basis for the development of levels

In Module 2, we will tell you about the results of our survey. By the end of this module you will be able to:

- Document differences in screening levels used by various U.S. States
- Determine the basis for how levels are developed

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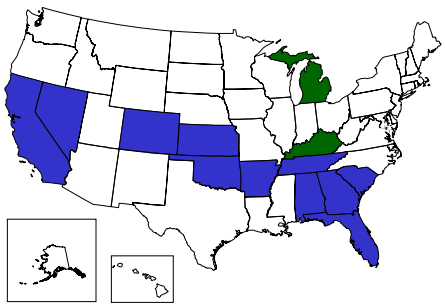
Survey: Participating States

- 11 of the 13 states surveyed
  - Regulator is member of ITRC Risk Team
  - Alabama, Arkansas, California, Colorado, Florida, Georgia, Kansas, Nevada, Oklahoma, South Carolina, Tennessee
- Other 2 of the 13 states surveyed
  - Unique screening values?
  - Kentucky and Michigan



The survey was based on 13 U.S. States

-11/13 States had a regulator as a member of the ITRC Risk Team... present/interested

(Missing 4/10 EPA Regions, i.e. Region I (New England), III (Mid-Atlantic) X (Alaska)

– however, we now have a team member from NJ in Region II (NY, NJ, & PR)

-Valuable. Provided institutional knowledge not be captured by published regulations or policies.

-Especially valuable to understand the basis or the approach used by a particular State.

-2/13 included. Previous survey by CA-based non-profit indicated that these states may have unique values.

Hoped further investigation of "outliers" ➔ additional insight

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Survey: Chemicals

Chosen by prevalence and regulator interest

- Trichloroethylene (TCE)
- Lead
- Benzo(a)pyrene
- Arsenic
- Polychlorinated biphenyls (PCBs)

No associated notes.

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Survey: Exposure Scenarios

- Oral, dermal, and inhalation
- Residential child
  Residential, industrial adult
- Soil, ground water, surface water, and leachability

-3 environmental exposure routes, 3 receptors, and 4 environmental media.

- Even at this stage we found differences.

- Some States had values for another receptor, commercial workers, handled differently among States.

i.e. Arkansas equates commercial and residential adults.

**Published not = Operational (i.e. Teaching curriculum)

-Kentucky also has a set of values for outdoor workers

-Michigan also has a set of values for underground utility workers.

Exposed to contaminated groundwater at higher than rates.

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Survey: Risk Level

- Target excess risk
  - Carcinogens
  - Excess cancer cases
  - 1 x 10^{-6} to 1 x 10^{-4}
- Hazard quotient (HQ)
  - Non carcinogens
  - Reference dose without adverse effect
  - 0.1 to 1

-Screening levels for both carcinogens and noncarcinogens.

- In Module 1, previously discussed that in the case of carcinogens, target risk level and for noncarcinogens a hazard quotient is used.

**Noted that target risk refers to a probability of occurrence not an effected population size.

-Note as per USEPA guidance U.S. states select from a *range* of Target Excess Risk levels and HQs:

-Many states select a a target risk level of 1.0 x 10^{-6}

-MI has a target risk level of 1.0 x 10^{-5}. Effectively sets carcinogen screening levels

10-fold higher than majority 1.0 x 10^{-6}

-Many states select an HQ = 1.0

-GA's HQ = 0.1 (CA's HQ = 0.2)

-The 0.1 HQ of GA effectively sets screening values 10-times lower than majority HQ = 1.0.

-Reasons for variation is not clear, **Number do not speak for themselves**

(although GA HQ = 0.1 based on USEPA R4 risk-based concentration (RBC) guidance which presumed additivity of risk contaminant of concern (COC))

- U.S. States regulations and agency policies may clearly states the risk level;

- However, basis often absent.

- Can't be certain if modification of risk levels have a scientific or non-scientific basis.

-As part of study, normalized screening levels to Target Risks of 1.0 x 10^{-6} and HQs to 1.0.

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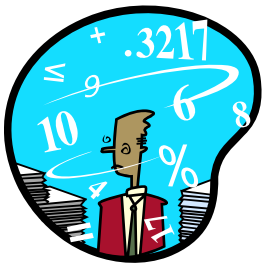
Survey Results

- Screening levels
  - 650 data points
- Exposure assumptions
  - 169 data points
- Additional comments and data collected



-Compounds, exposure scenarios, carcinogen and non-carcinogens, 13 U.S. States.
-Amassed 650 screening values

- In addition, collected 13 exposure parameters from 13 states = 169 data point
- To understand exposure assumptions integrated into screening levels

- Lastly non-quantitative information as part of the survey
-i.e. "hotspot" "screening value" and "remediation goal."

- Led us to refine the survey. At first we requested cleanup values.
- Realized that most states don't publish "cleanup values"
- States published “screening” values
- Likely develop site-specific levels based on each individual case.

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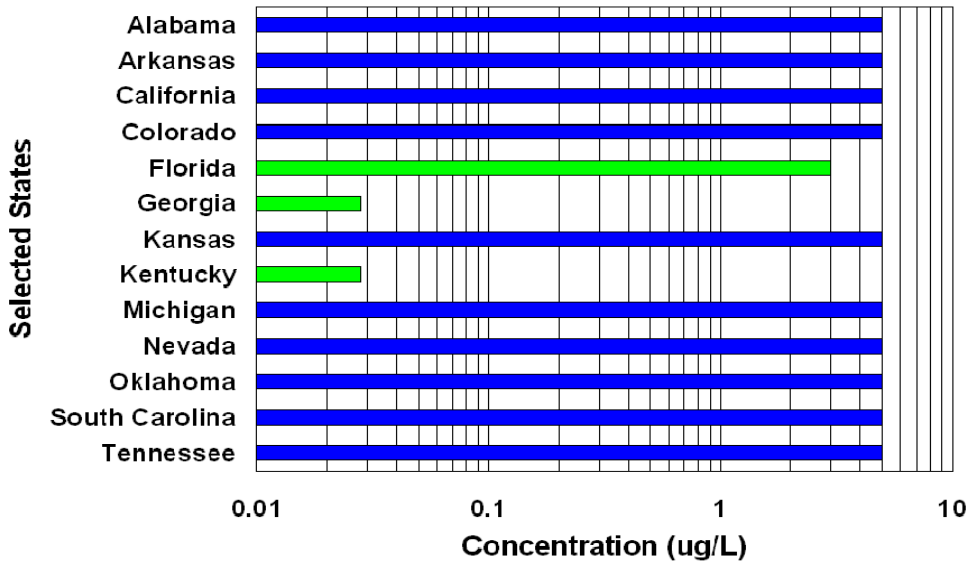
Ground Water Screening Value: TCE



-Will not present *all* data. Will present selected data to illustrate findings.

-State colored blue have the same value

-Ground Water Screening Value: TCE

-10/13 (76%) U.S. States have identical groundwater screening values for TCE.

-Extraordinary. U.S. States from east coast to west, and w/ arguably high and low level of regulation

(i.e. CA vs. NV) all have the same 5 µg/L screening value for TCE .

- Not surprising. 5 µg/L is the U.S. Federal MCL.

-Many states have adopted value.

-Many states lack the resources to conduct their own risk assessments.

-One conclusion: Many states do have similar values.

-Notice 3 states, **FL**, GA, and KY do have different values.

-What is the reason ?

-Not apparent looking at their screening values.

-Let's move on and see if looking at additional data reveals any clues.

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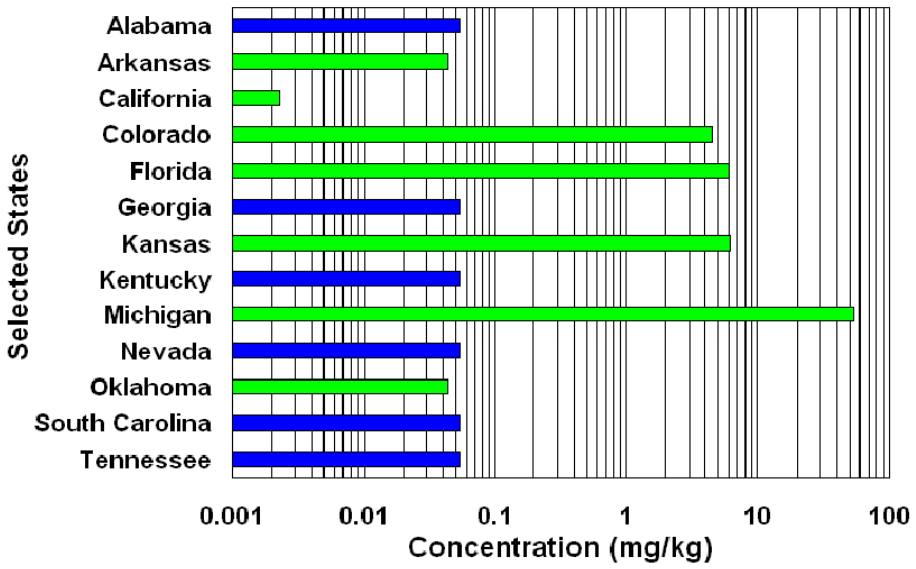
Residential Soil Screening Value: TCE



-Residential Soil Screening Value: TCE

-State colored blue have the same value
- 6/13 States (46%) use the same screening value for TCE
- Greater variation compared to the TCE values in groundwater.

- Absence of a Federal MCL for soil.
-Fate of a VOC such as TCE in soil is less predictable than in water.

-The State of Michigan uses the soil saturation concentration of TCE.
- Note that among states with unique values, **FL** appears again

Residential TCE Soil Screening Value [mg/kg]	State
0.043	AR OK
0.0023	CA
4.54	CO
6.0	FL
0.053	AL GA KY NV OK SC TN
6.2	KS
53	MI

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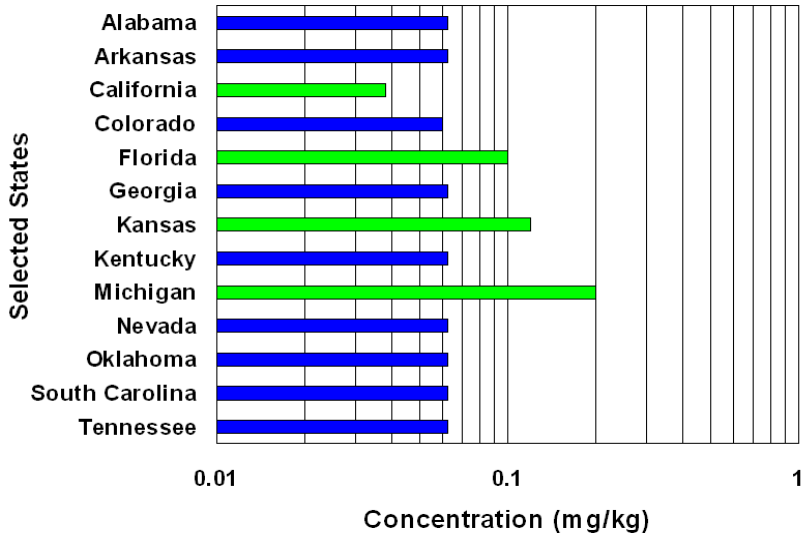
Residential Soil Screening Value: Benzo[a]pyrene



-Residential Soil Screening Value: Benzo[a]pyrene

-State colored blue have the same value

- 8/15 (54%) U.S. States have the identical screening values
- Low volatility compound i.e. B(a)P, even less variation

- Note that among states with unique values FL appears again

Residential B[a]P Soil Screening Value [mg/kg]	State
0.062	AL AR GA KY NV OK SC TN
0.038	CA
0.060	CO
0.100	FL
0.120	KS
0.200	MI

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Learning Objectives

1. Document differences in screening levels
2. Determine basis for the development of levels

- Easy to document 46 to 76% of states had identical screening values depending on compound and environmental medium.

- In the States Screening Values Document, we details the differences for 5 chemicals.

- Same effort could be done for many more compounds
- However, determining the *basis* for these differences is more difficult. In part because such documentation does not usually accompany final published values.

- - I'd like to turn the program to our moderator.

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Sources of Screening Values

- Federal Drinking Water Maximum Contaminant Level (MCL)
  - All U.S. States
- U.S. EPA Region 9 Preliminary Remediation Goals (PRGs)
  - AL, GA, KY, NV, SC, and TN
- U.S. EPA Region 6 Screening Levels (SSLs)
  - AR and OK
- State derived
  - CA, CO, FL, KS, and MI

One way to understand the basis for screening values is to note source.

1) All U.S. States adopt the Federal MCL when available.

- What happens when no MCL?

2) Several States, AL, GA, KY, NV, SC, and TN, tend to refer to USEPA Region 9 PRGs when no MCL available.

** Because USEPA Region 9 PRGs are popular, we'll look a them further**

3) Another set of States, AR and OK, use values from USEPA Region 6.

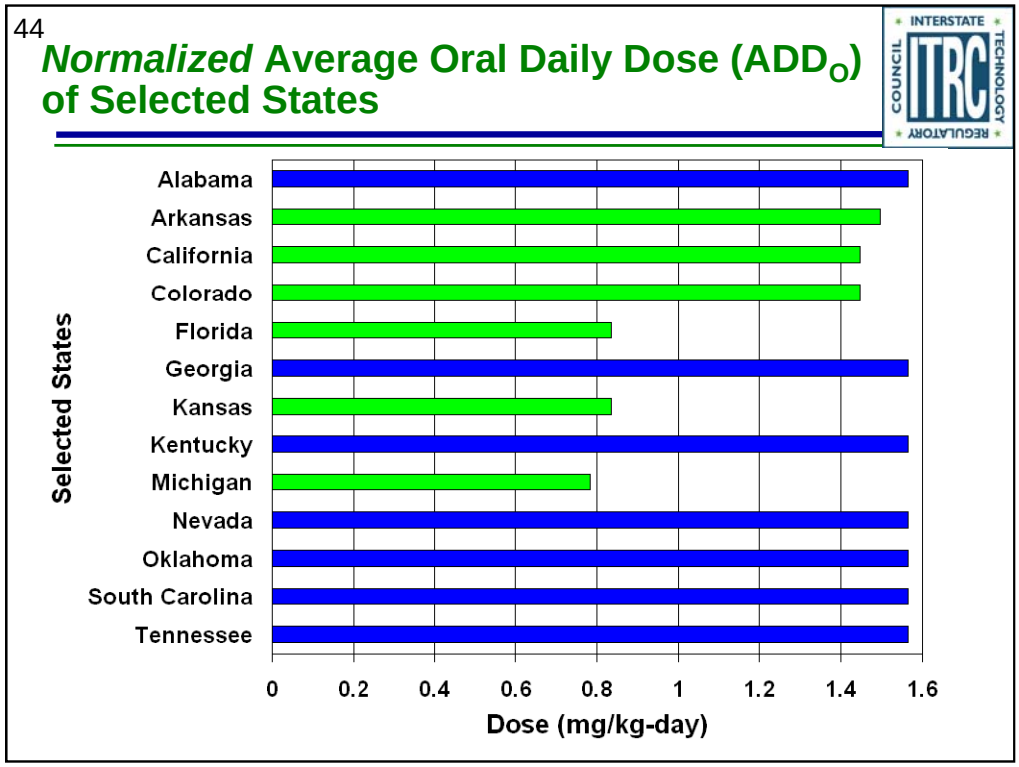
4) States have technical resources and legislative mandate to develop screening values. Partially explains why States such as FL had unique values in figures just presented.

- FL developed *Cleanup* target level ➔ screening values

** Because FL had unique value 3 times in a row, we'll look at it further.

FL indicative of State-derived values**

Keep in mind that the same number may be used by different States.



-Recall from Module #1, an exposure assessment is one of the 4 components of a risk evaluation.

-If there variation in a risk-based screening value, logical that exposure assessment ➔ some of variation

-Isolate exposure assumptions ➔ Investigate the source of variation in screening values.

-Team developed the Normalized Average Daily Dose (ADD).

In Module 1, Anna showed you that the ADD includes [chemical]

-Normalized ADD useful way to probe risk-based screening values, in particular the exposure parameters, without the confusion of comparing compounds of different toxicities. (i.e. Cancer slope factor, oral for TCE ~6x higher than PCB)

-This metric factors out differences in slope factors and references doses by assuming all [contaminant] = 1mg/kg.

-For the rest of Module recall that ADD is always normalized and thus, missing consideration of [chemical]/toxicity assessment

-In this slide oral ADD that States assume over the course of a **lifetime for carcinogens.**

-7/13 (54%) States have identical values. Once again FL and others states have unique values.

ADDo [mg/kg-d]	State
0.836	FL KS
1.566	AL GA KY NV OK SC TN
1.497	AR
1.448	CA CO
0.782	MI

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Algorithms for ADD_O

- US state derived (i.e. Florida)

$$ADDo = \frac{(\text{Ingestion Rate})(\text{Exposure Duration})(\text{Soil Absorption Efficiency})(\text{Exposure Frequency})}{(\text{Body Weight})(\text{Averaging Time})}$$

-Algorithm to calculate ADDo (Average Oral Daily Dose) for FL, both carcinogens and noncarcinogens.

**Variation among ADDo, as in previous figure, the source(s) of variation must lay in the exposure assumptions that comprise them. **

-Several terms appear in the equation

Focus on one of these parameters, body weight.

-If you download the full States Screening Values Document from the ITRC website, page 29 and 30, two terrific tables, Table 6 and Table 7. The first lists a total of 13 exposure parameters for 13 States for carcinogens as well as the Target Excess Cancer Risks. Table 7 lists exposure assumptions for noncarcinogens.

-In the States Screening Values Document you'll also see that that ADDs for dermal, inhalation, as well as oral exposure routes were combined into a single Soil Screening Level (SSL)

- Determined that the oral ADD is the driver of the combined SSL.

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Selected Exposure Assumption: Body Weight

Adult = 70 kg
(154 lbs)

- Focus on one parameter: Body weight.
- U.S, States that base risk assessment on *USEPA's (1997) Exposure Factors Handbook*, evaluate risk of exposure to contaminants to *populations* of adults assumed = 70 kg.
- Based on 2nd National Center for Health Statistics (1987)
- 70 kg = conservative estimate of body weight for *most individuals*

1) Both at extreme ends of distribution of *Body Weight Exposure Parameter* for 18-74 yr olds

FYI – Smaller man (45 kg) w/body weight < 70 kg = Higher dose.

2) Remaining Exposure Parameters ??

- Normal? Upper bound?
- Central tendency for exposure parameters (i.e. Body weight)
- Upperbound for duration and frequency (i.e. 30 Year exposure to carcinogen)

3) Taken together, risk assessments are conservative and intended to account for uncertainty and protect adults for the variability in a variety of pharmacokinetic and -dynamic concerns from differences include: body weight, age, physiological and immunocological states

(Willie Shoemaker = < 100 lbs., 4'11". Most jockeys = 110-115 lbs..
2.5 lbs when born in 1931

Wilt "the Stilt" Chamberlain = 275 pounds 7'1"

(Shaquille O'Neal = 325 pounds 7'1")

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Selected Exposure Assumption: Body Weight

Adult = 70 kg
(7 to 30 years)

Child = 15 kg
(0 to 6 years)

Risk assessments based on *Exposure Factors Handbook* also assume children = 15 kg. (yes for all 0-6 years)

**Problem: What if assumed 30 year exposure to a carcinogen spans childhood and adulthood?

Given two broad group, U.S. States *age-adjust* exposure parameters such as body weight.

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Age-Adjusted Body Weight

- Age adjustment of parameters improves representation of exposed populations

Age adjustment of exposure parameters is a valuable to better represents possible exposure scenarios to populations.

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Age-Adjusted Body Weight: Florida (Pre-2005)

$$\text{Age Adjusted Body Weight} = \frac{\left[\left(\text{Body Weight}\right)(\text{Years})\right]_{\text{Child}} + \left[\left(\text{Body Weight}\right)(\text{Years})\right]_{\text{Adult}}}{\text{Exposure Duration}}$$

For example, let's look at how the State of Florida handles age adjustment of body weight.

Data at the time we conducted our survey in 2003,

In above equation we see FL adjusted body weight by multiplying body weight by the number of years spent as a child and then adds that multiplying body weight by the number of years spent as an adult.

- This value is then divided by the total number of years of exposure.

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Age-Adjusted Body Weight: Florida (Pre-2005) – Example Calculation

$$\text{Age Adjusted Body Weight} = \frac{\left[\left(\text{Body Weight}\right)(\text{Years})\right]_{\text{Child}} + \left[\left(\text{Body Weight}\right)(\text{Years})\right]_{\text{Adult}}}{\text{Exposure Duration}}$$

$$59\ kg = \frac{(15\ kg)(6\ years) + (70\ kg)(24\ years)}{30\ years}$$

Inserting values for these parameters we find = 59 kg.

The age adjusted body weight that FL of in it's exposure algorithms ... at that time.

Note 59 kg body weight < 70 kg body weight

(Lower body weight assumption ➔ Higher dose.

To protective ➔ Lower screening)

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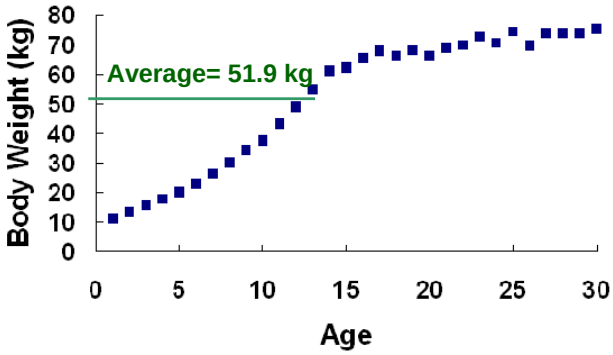
Age-Adjusted Body Weight: Florida 2005

- Final Technical Report: Development of Cleanup Target Levels (2005) Division of Waste Management, Florida Department of Environmental Protection



HOWEVER, February 2005 Florida updated it's Cleanup Target Levels (CTLs).

- Florida did this in response from stakeholder input

Stakeholders challenged FL regulators to do better than

1) only two broad groups (adult and children) and

2) apparent lack of actual data.

-*Thus Florida develop more representative numbers.

-Actual and updated body weight data from the ***3rd*** National Center for Health Statistics (NCHS)

-Data from *yearly increments,* ages 1 to 31 years averaged ➔ represent "Aggregate resident"

-Thus FL uses average body weight=51.9 kg rather than 59 kg assumed by USEPA Region 9 data

-To reiterate, FL is using a different, if not better, representation of exposed populations than an average of *two broad age intervals* (1-6 years and 7-31 years).

-Underlying assumptions regarding risk are unchanged.

-Thus, Florida parted with USEPA Regional offices, when able to improve this component of exposure assessments ... as suggested by stakeholders.

Note 51.9 kg body weight < 59 kg body weight < 70 kg

(Lower body weight assumption ➔ Higher dose.

To protective ➔ Lower screening)

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Body Weight in Exposure Algorithm

Different age adjustment?

Yes!

Different incorporation into exposure algorithm(s)?

Yes!

Compare Florida to USEPA Region 9 Preliminary Remediation Goals

- Saw two different age adjustments . . . by same State, FL.

- Can we incorporate an age-adjusted value into exposure algorithm(s) differently?
- Certainly
-Let's compare FL to USEPA Region 9 and it's Preliminary Remediation Goals

-Recall – FL had unique values (State derived)
USEPA R9 popular

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Different Algorithms for ADD_O

- US state derived (i.e. Florida)

$$ADDo = \frac{(\text{Ingestion Rate})(\text{Exposure Duration})(\text{Soil Absorption Efficiency})(\text{Exposure Frequency})}{(\text{Body Weight})(\text{Averaging Time})}$$

- USEPA Region 9 PRGs

$$ADDo = \frac{(\text{Age Adjusted Soil Ingestion Factor})(\text{Soil Absorption Efficiency})(\text{Exposure Frequency})}{(\text{Averaging Time})}$$

-Two *different* algorithms for calculating normalized ADD_o for both carcinogens and non-carcinogens.

-Top of this slide, Florida's ADD_o. Note age-adjusted body weight in the bottom.

** This explains why LOWER body weight ➔ Higher Dose**

- We also see the ingestion rate term.

- Bottom of slide USEPA Region 9 algorithm.

- No *ingestion rate*, but an *age-adjusted ingestion factor.*

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Selected Exposure Assumption: Age-Adjusted Soil Ingestion Factor

$$\text{Age Adjusted Soil Ingestion Factor} = \left[\frac{(\text{Ingestion Rate})(\text{Exposure Duration})}{(\text{Body Weight})}\right]_{\text{Child}} + \left[\frac{(\text{Ingestion Rate})(\text{Exposure Duration})}{(\text{Body Weight})}\right]_{\text{Adult}}$$

Looking at only the age-adjusted ingestion factor:

USEPA Region 9 calculates one age-adjusted soil ingestion *factor* for a child, calculates a second *factor* for adults, and then adds the two to represent the total 30 years of soil ingestion.

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Similar Exposure Algorithm Parameters: Average Oral Daily Dose (ADD_O)

- US State Derived (i.e. Florida)

$$ADDo = \frac{(\text{Ingestion Rate})(\text{Exposure Duration})(\text{Soil Absorption Efficiency})(\text{Exposure Frequency})}{(\text{Body Weight})(\text{Averaging Time})}$$

- USEPA Region 9 PRGs

$$ADDo = \frac{(\text{Age Adjusted Soil Ingestion Factor})(\text{Soil Absorption Efficiency})(\text{Exposure Frequency})}{(\text{Averaging Time})}$$

If we take another look at the algorithms for normalized ADD_o, we see:
-on the right , a set of parameters that are identical for both USEPA Region 9 and Florida
-on the left, 3 parameters that FL handles separately, incorporated into soil ingestion factor.

I'd now like to insert the values for each of these parameters.

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Exposure Algorithm Parameters: Average Oral Daily Dose (ADD_O)

- US State Derived (i.e. Florida)

$$ADD_O = \frac{\left(120\ {}^{mg}/_{d}\right)(30\ y)(1.0)\left(350\ {}^{d}/_{y}\right)}{(59\ kg)(25{,}550\ d)}$$

- USEPA Region 9 PRGs

$$ADD_O = \frac{\left(114\ \frac{mg-y}{kg-d}\right)(1.0)\left(350\ {}^{d}/_{y}\right)}{(25{,}550\ d)}$$

-In blue on the right are identical in both equations:

- Fraction (1.0) of Soil Absorption efficiency into the body,
- 350 days per year exposure to carcinogen (with a 2 week vacation)
- Average lifetime of 70 years.

-In red on bottom left is age-adjusted soil ingestion *factor.* Similar in magnitude to soil ingestion *rate* in equation at top of slide; however, units are different. Comparing apples and oranges.

-In green in the top equation are 2 parameters that remain split out of the top equation.

-These 2 parameters insert a value of 30/59, nearly ½, into Florida's algorithm.

** Thus, expect FL ADDo ~ ½ that of USEPA Region 9 PRGs.

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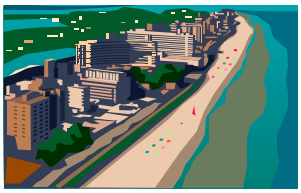
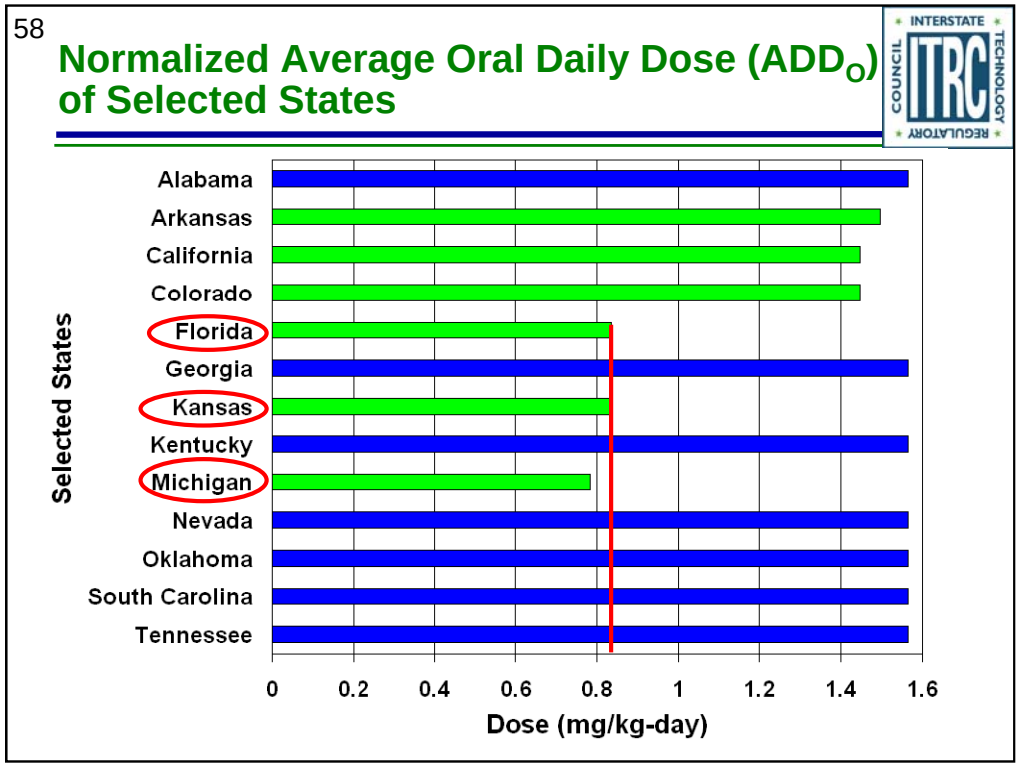
Sample Calculation of ADD_O: State of Florida

$$0.836\ {}^{mg}/_{kg-d} = \frac{\left(120\ {}^{mg}/_{d}\right)(30\ y)(1.0)\left(350\ {}^{d}/_{y}\right)}{(59\ kg)(25{,}550\ d)}$$



-If we complete the calculation at the tope of the previous slide, we obtain an ADD_o of 0.836 mg/kg-d for the State of Florida.



Here is the figure presented at the start of this discussion, normalized oral ADD **for carcinogens.**

-Blue States have the same values

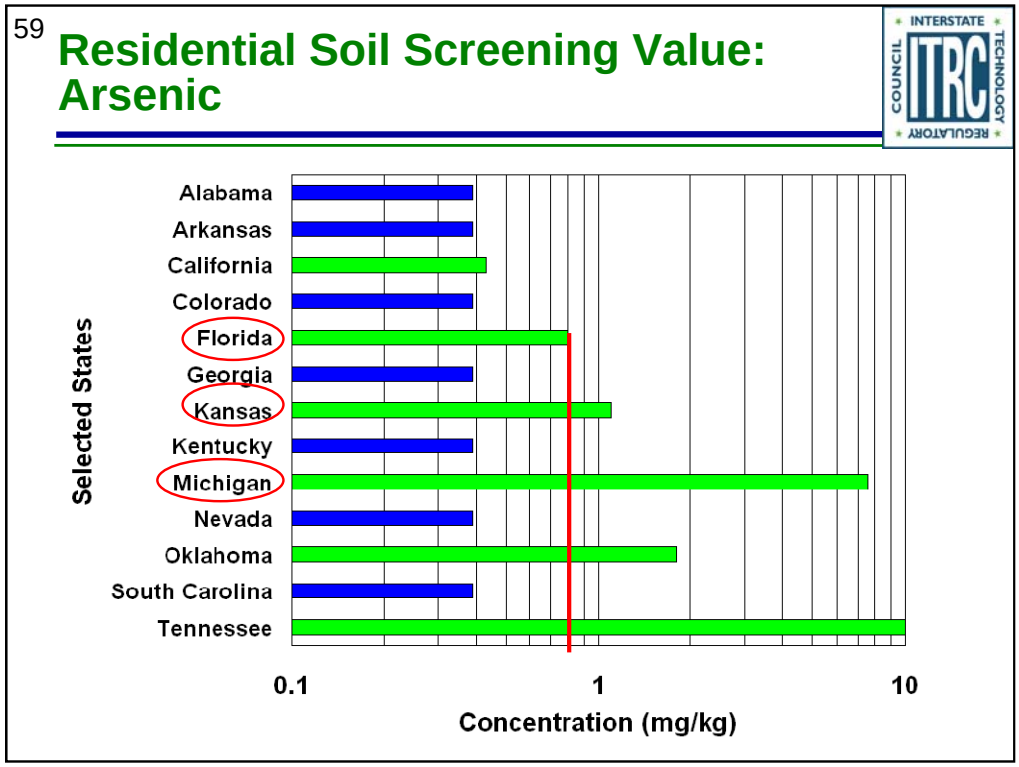
-Florida's ADDo (0.836) = ~ ½ USEPA Region 9 PRGs.

Take note that KS and MI also have ADDos approximately ½ that of USEPA R9.

Let's try to predict the effect on Soil Screening Values?

- Lower dose
- To protective ➔HIGHER screening ➔ SAME risk level

ADDo [mg/kg-d]	State
0.836	FL KS
1.566	AL GA KY NV OK SC TN
1.497	AR
1.448	CA CO
0.7828	MI



Look at screening values of Arsenic, focus of Module 3.

-Blue States, reference USEPA R9 screening levels = 0.39 mg/kg soil.

- Florida's screening value at the time we conducted the survey, 0.80 mg/kg is approximately 2x higher, than these States.

- KS & MI, previous slide, assume lower ADDo, have higher screening values (also refer to background)

- Sensible. LOWER Dose assumed ➔ HIGHER Screening Value ➔ SAME risk level/Level of Protection

** Predicted FL's value ~ 2x USEPA R9 level w/o consideration of dermal or inhalation dosages.**

- Due to the *dominance of oral dosage in ADDs*

-Other States vary due to:

Referring to background (TN, KS, MI)

Referencing a different guidance source (OK and CA),

In 2005 FL raised screening value to 2.1 mg/kg due to incorporated a bioavailability factor*

Supports trends and conclusions

Residential Arsenic Soil Screening Value [mg/kg]	State
0.80	FL
0.39	AL AR CO GA KY NV SC
1.10	KS
7.60	MI
1.80	OK (USEPA R6 Medium–specific screening level)
10.00	TN (Background)
0.43	CA = USEPA R3

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Discussion and Conclusions

- Mostly minimal differences
- Many U.S. states rely on U.S. EPA values
- U.S. EPA values vary between regional offices
- States refine default values

Thus in conclusion

-Saw limited number of differences in part because many states rely on USEPA values.

Differences for compound such B[a]P involved minute amounts and varied ~3-20 µg/kg.

Despite 3 orders of magnitude variation for TCE in soil, even this number is conservative.

As noted in Module 1, these levels are protective of 1 in a million additional cases of cancer against a background of ~1 in 3.

- We did note that USEPA regional office may differ from one another.

-The refinement of values by individual states results in the highest amount of variation

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Discussion and Conclusions (continued)

- Different applications of screening values
  - Legislation or policy
    - Target excess risk (i.e. 1.0 x 10^{-6} vs. 1.0 x 10^{-5})
    - Multiple agencies
    - Definitions (i.e. surface soil sample)
  - Technical
    - Screening vs. clean-up
    - Ground water vs. drinking water
    - Background concentration
    - Fate of chemicals
    - Sampling
- Transparency easily lost
  - Values are not enough

-Although not included in this presentation, we noted in our survey that even with the same screening values, different legislative mandates influence how the data are used

-Multiple agencies and definitions of parameters may be sources of differences despite same screening value

In addition technical consideration may obscure origin and intended use of screening values. (i.e. Intended sampling depths published)

- As noted transparency to regulated community (policymakers and public) is important. Stakeholders may challenge regulators about variation observed from State to State.
- FL *benefited* from input. *Did* publish basis for values.
- Numbers don't speak for themselves.
-Confidence in risk assessment, regulators, science ... may be lost

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Recommendations

- No one approach advocated
- Publish basis of criteria and assumptions
- Publish intended application
- Provide training and communication tools

Because of limited authority and considering it unwise to second-guess the legislative intent of the relevant promulgated environmental laws, the ITRC Risk Resources Team does not advocate for any one particular approach to risk-based screening of soil.

The group does advocate for the sake of transparency:

- publishing the basis of criteria and underlying assumptions
- publishing the intended application
- providing training and communication tools

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Future Work

- Additional media and pathways
- Additional states, federal agencies, compounds, and exposure scenarios

- Derivation and application of screening values
- Collection and use of site-specific data
- Risk-based clean-up goals and remedy selection

Group considered the following work:

- Additional media and pathways
- Additional States, USEPA Regions, federal agencies, compounds, and exposure scenarios

Group considered started work on last 3:

- Derivation and application of screening values
- Collection and use of site-specific data
- Risk-based clean-up goals and remedy selection

Fran Collier, CA EPA Dept. of Toxic Substances Control, will tell you our findings in the next module, Module 3

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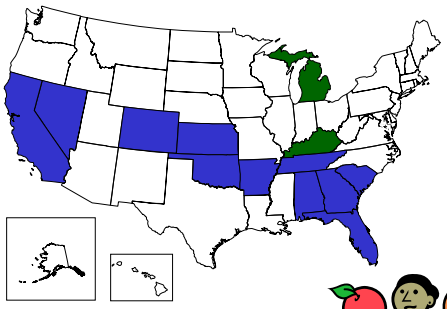
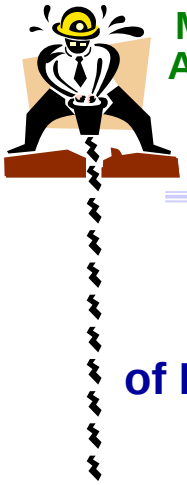
Questions and Answers

MODULE 2: Examination of Risk-Based Screening Values and Approaches of Selected States



No associated notes

Risk Assessment and Risk Management: Determination and Application of Risk-Based Values



MODULE 3:

Case Studies to Examine Use of Risk Assessment in Site Cleanup

•Module 1: reviewed basic principles of site characterization and risk assessment

•Module 2: reviewed similarities and differences in screening levels

•Module 3: two case studies to see how screening levels used and basis for development and application of site specific cleanup goals

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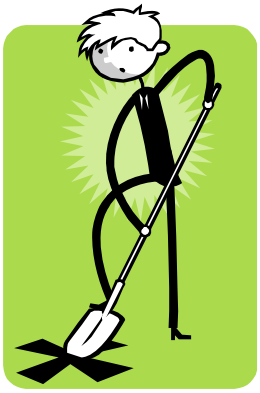
Learning Objectives for Case Studies Module

- How “risk assessment” is incorporated into the “risk management “process for site cleanup
- Differences in risk management approaches
- How risk based screening criteria and site specific risk assessment were used in the case studies
- Ways that risk-based criteria are used to confirm successful remediation



To help us focus where to dig, The specific objectives for this module are identified in this slide.

•briefly review the Case Studies Project that the Risk Assessment Resources Team is developing

•present two cases studies with emphasis on site specific sampling approaches and how screening levels and risk assessment were used for making decisions about the sites.

•present a summary comparison of the two studies, followed by lessons learned.

To do this we will focus on:

•How were screening levels applied throughout the project life cycle?

•How was the numeric criterion utilized throughout the site cleanup process?

•What sampling approaches were used, and why?

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Case Studies Project – Approach

- Consider simple sites where risk-based numbers are incorporated (or not) during the site cleanup process
- Identify technical and programmatic practices and preferences (i.e., Triad)
- Build on Risk Team's first effort on soil criteria
- Look for links between sampling objectives, sampling methodologies, and use of criteria

Case Studies Project:

•examine several site cleanups from various areas of the United States

•compare the approaches used in collecting information to evaluate sites

•use of screening levels for making site decisions

•how and when site specific risk assessment is used

•how cleanup levels are developed and applied

For today's session, we will look at only two of these case studies.

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Case Study Project – Questionnaire

- Site background
- Status, parties, etc.
- Risk information
- Phases utilized and do the values change
- Criterion and basis for decisions
- Sampling strategies and how information was used
- Stakeholder involvement

"Case Study Questionnaire" used to focus the case write-ups.

Topics are identified in this slide. The case study document is expected to be available in 2007.

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Risk Management

- Risk management - the process of
  - Controlling risks
  - Weighing the alternatives
  - Selecting the appropriate action
- These decisions take into account
  - Risk assessment information
  - Social and political issues
  - Regulatory/policy issues
  - Technological/economic issues

Anna, presented this slide in Module 1 and I am using it here to set the stage for our case study review to see how risk based criteria were used in making site specific risk management decisions. This slide illustrates that Risk Managers consider more than risk assessment when making decisions about sites.

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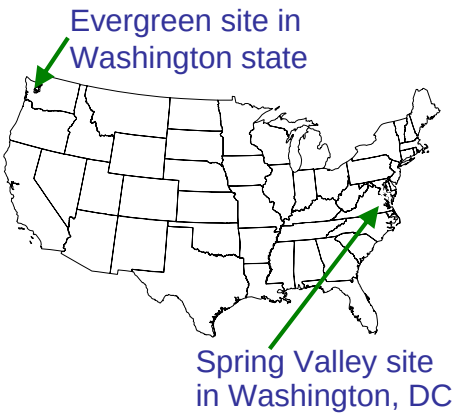
Case Studies Project – Primary Interests

- How were screening levels applied throughout the project life cycle?
- How were numeric criteria selected and used throughout the site cleanup process?
- What sampling approaches were used, and why?



The sites are:

•the Spring Valley site located in Washington, D.C. and

•the Evergreen site, located on the Fort Lewis Army base near the City of Tacoma in Washington State.

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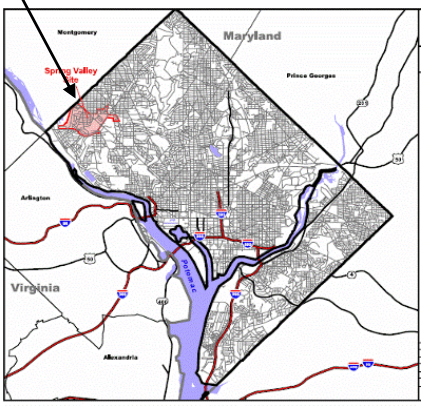
Case Study #1 – Spring Valley

- Spring Valley Formerly Utilized Defense Site (FUDS)
- Northwest Washington, D.C.
- Regulating entities
  - District of Columbia Department of Health
  - U.S. EPA Region 3
- Parties conducting investigation
  - U.S. Army Corps of Engineers (USACE)



Washington, DC Area Map

The Spring Valley site:

• 600 acre former military site

• used during World War I.

•located in what was then the rural outskirts of Washington D. C.

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Spring Valley – Site History

- **WWI**: American University Experiment Station (AUES) established by U.S. government
- Research and testing
  - Chemical warfare materials
  - Including mustard, lewisite agents, adamsite, irritants, and smoke
- **1921**: area restored, property returned to owners and eventually redeveloped

During WWI:

• used for testing explosives and firing mortars and rockets containing chemical warfare agents

Following WWI:

• cleaned up

• returned to the pre-WWI land owners

•Redeveloped

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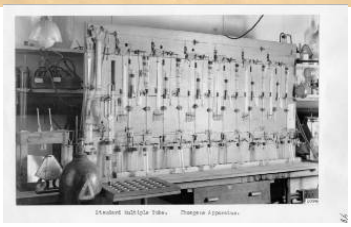
Spring Valley – Site Historic Pictures



These photos illustrate the testing that was conducted. Note the smoke plumes and the weapons launchers as well as the personal protective gear worn by soldiers.

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Discovery and Investigation Overview

- **1993:** Buried ordnance found
- **1993 to 1995**: Initial investigation
- Initial Sampling strategy
  - Biased grab samples
  - Background samples
- Arsenic was identified as the primary contaminant of potential concern (COPC)

•1993 a utility contractor uncovered buried ordnance

•Remedial investigation was conducted over what was then believed to be the entire area within the FUDS boundary.

•Sample locations based on historical photos and maps along with projections of where ground surface was during WWI

•Sample density was low to identify areas of concern for further assessment and possible remediation.

•42 background samples were collected from unaffected native soils in the Spring Valley Area.

•Arsenic was the only metal that exceeded background concentrations.

•Background arsenic concentrations ranged from 0.9 to 18 mg/kg.

•The background arsenic concentration that was chosen is 12.6 mg/kg which represents the 95^{th} percentile of the background sample data.

•While other contaminants of concern were found throughout the site, arsenic will be topic of this case study.

•A site-wide risk assessment was done in 1995 that found arsenic concentrations exceeded health protective levels.

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Sampling Strategies and Screening Levels

- **1997**: Investigation area expanded
  - Active Test Area Parcels
  - Adjacent to Active Test Area Parcels
- Screening levels
  - Background arsenic concentration of 12.6 mg/kg
- Boundaries for potential remediation delineated using arsenic background concentration

•1997 investigation focus shifted from the general site characterization to identifying areas needing remediation on individual lots.

•Two types of lots identified:

- •Active Test Area
- •Adjacent to the Active Test Area

•Potential remediation areas based on the background concentration of arsenic.

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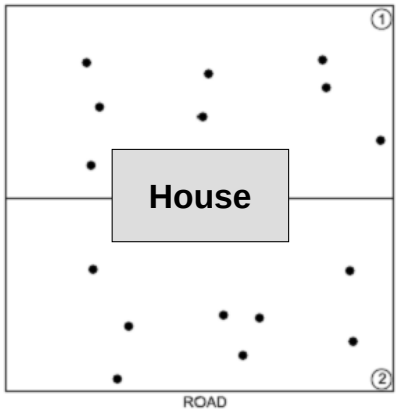
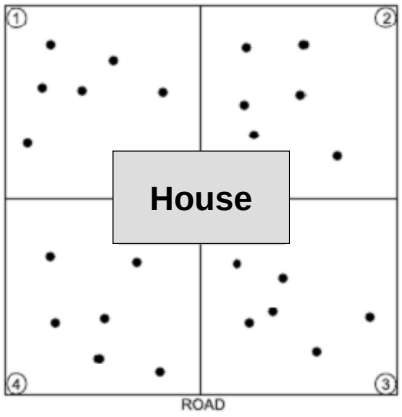
Composite Sampling Strategies

Adjacent to Active Area



Properties in Active Area



•This slide shows the *Active Area* and *Adjacent to Active Area* strategies for sampling.

•Lots in the *Adjacent to the Active Area* were divided into 2 equal areas and random samples collected and composited.

•Lots in the *Active Area* were divided into 4 equal parts with random samples collected and composited within each of the 4 parts yielding 4 sample results per lot.

•A circular hot spot with a contamination radius of 10 feet would likely be detected.

•Any sample result exceeding 12.6 mg/kg, triggered additional discrete sampling to define potential removal areas.

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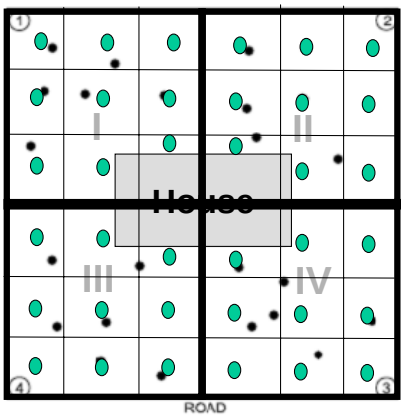
Grid Sample Example

- The composite sample represents the exposure unit concentration for a given quadrant (I through IV)
- If the concentration of a composite sample exceeded 20 mg/kg the entire property was sampled on a 20 x 20 grid

Properties in Active Area



Not to scale

- Composite sub-sample location
- Grid sample location

This slide shows the grid pattern for further sampling. Note the small black dots show the locations of the original grab samples that were composited.

If the composite sample result exceeded 12.6 mg/kg a 20' by 20 ' grid was used to further sample the entire property (not just the quadrant or half as suggested by the EPA's SSL guide).

A sample was collected from the center of each grid. If the center of the grid was inaccessible (e.g., due to the house or patio) a sample was collected from elsewhere within the grid.

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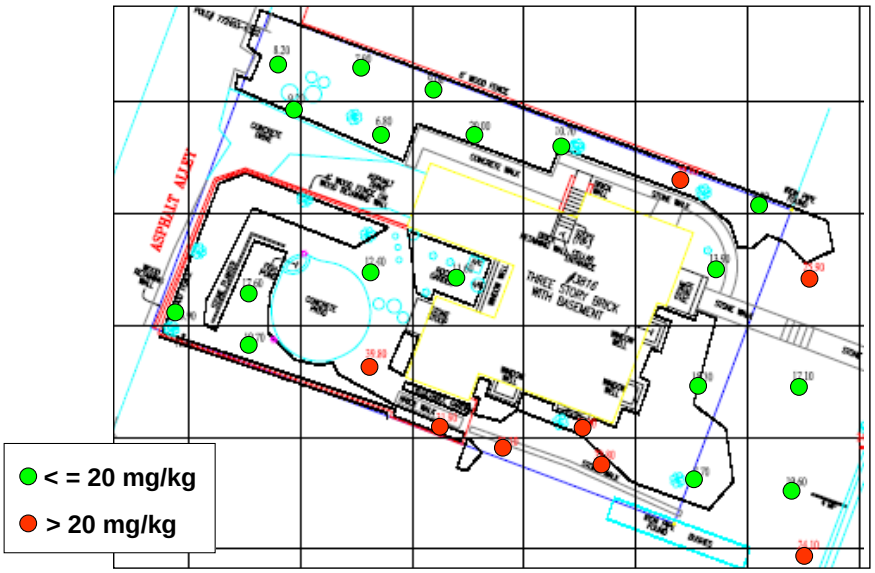
Grid Sample Approach



This map shows the results of grid sampling at one property where three out of the four composite samples exceeded 12.6 mg/kg.

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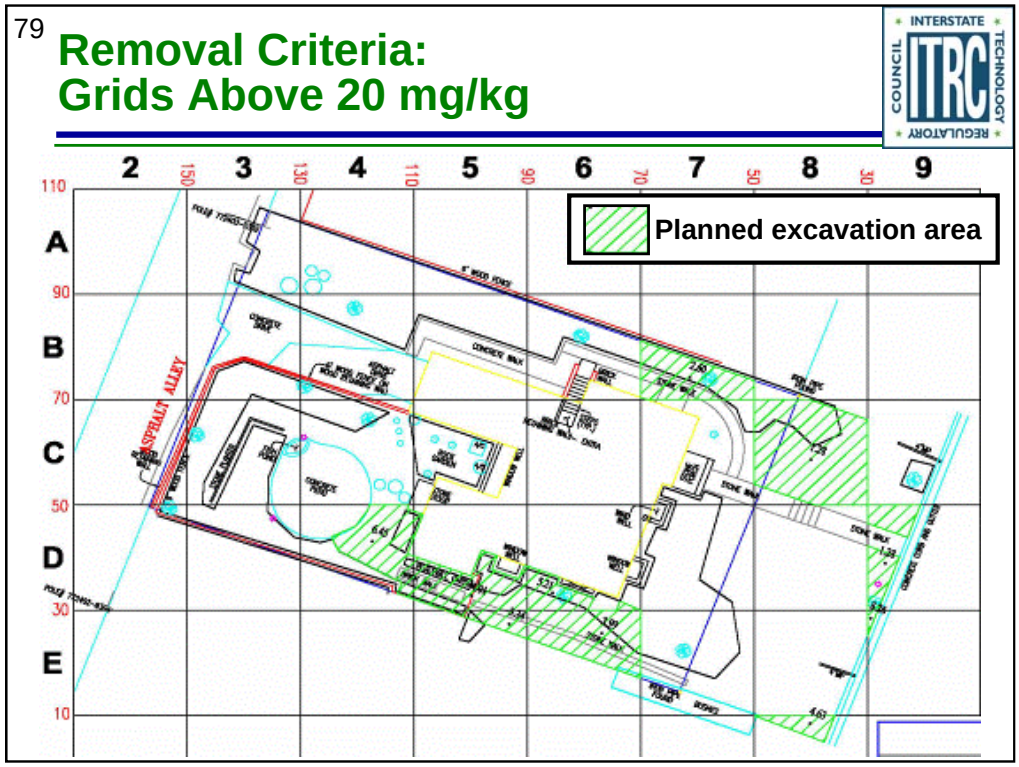
Removal Criteria: Grids Above 20 mg/kg



Extensive community meetings were held and property owners had major input into determining the cleanup criteria.

•20 mg/kg in accessible areas and

•43 mg/kg in areas that were difficult to access such as wooded land.

This map is an example of a typical residential parcel that was sampled and determined to need remediation.

• Initial excavations removed the top 2 feet of soil.

•Confirmation samples were collected from the floor and side walls of the excavation.

•Areas exceeding the 20 mg/kg cleanup criteria were further excavated until criteria were met.

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Numerical Criteria Used at the Site

Arsenic Concentration	Source and Use
0.43 mg/kg	EPA Region 3 residential risk-based concentration (RBC); initial site screening
12.6 mg/kg	Site-specific statistical estimate of 'background' used as screening level triggering additional sampling
20 mg/kg	Consensus value remediation goal for soil removal
43 mg/kg	10^{-4} cancer risk. Used as remedial goal with home owner approval to preserve landscape features.

This slide illustrates the progression of different numerical criteria used at the site.

- 0.43 mg/kg is the calculated risk-based screening level for a 10^{-6} incremental potential cancer risk
- 12.6 mg/kg represents the 95th percentile of 42 background sample results
- 20 mg/kg for exposed soils that could be excavated
- 20 ug/kg is close to a hazard Quotient of 1 for arsenic
- 43 mg/kg for areas where removal was difficult (e.g. under trees) with land owners' consent
- 43 mg/kg represents an estimated 10^{-4} incremental potential cancer risk

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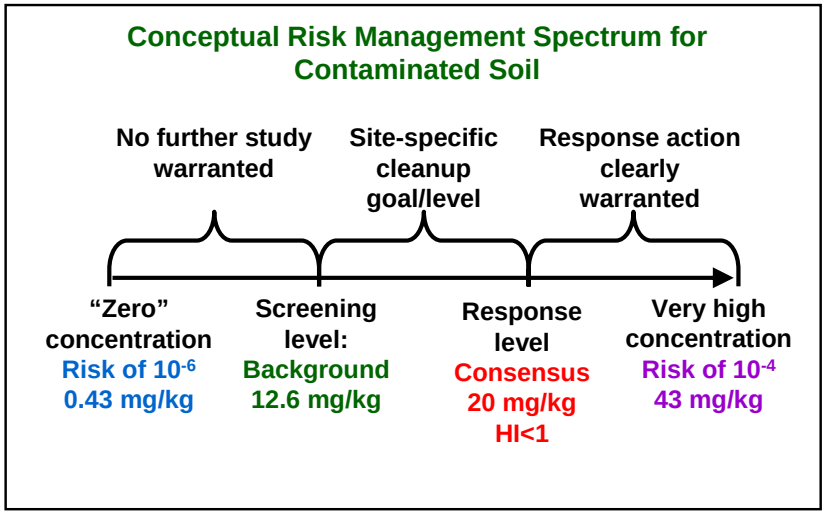
Risk Management at Spring Valley



Anna talked about the risk management spectrum in Module 1. If we apply this spectrum to the Spring Valley site we see the progression of numerical criteria considered at the site.

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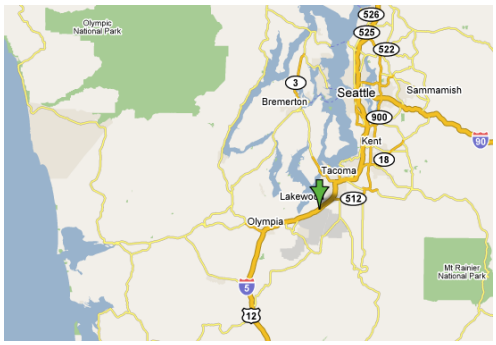
Case Study #2 – Evergreen



- Fort Lewis, Washington
- Active military base
- Firing range
- Army wanted to redevelop area for military housing

The second case study is the Evergreen Firing Range remediation at Fort Lewis Washington.

•Active military base located near Tacoma, Washington

•Used as a firing range at the Fort Lewis base for many years

•1990s the Army decided to close and cleanup the firing range

•Intent of building military housing

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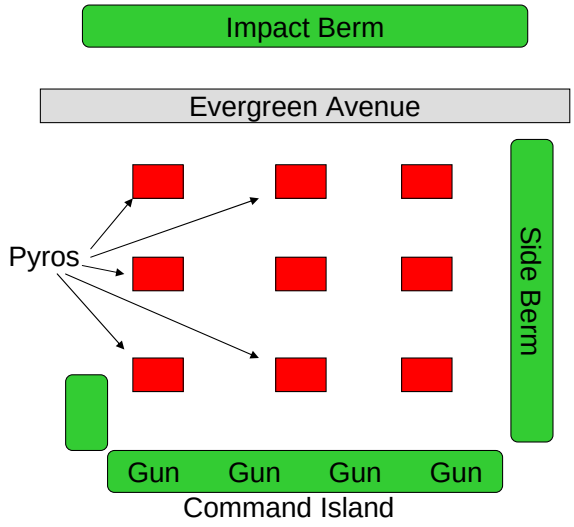
Illustration of the Infiltration Range



(Not Drawn to Scale)

The Evergreen Firing range was used to train soldiers to gain experience in moving under live fire in combat situations

The graphic shows the general layout of the firing range.

As seen in the photo, soldiers crept through the range while machine guns sprayed bullets above them and explosives were detonated around them

The Gun signifies the location of the fixed machine guns and “Pyro” shows the location of craters were explosives were detonated.

Machine gun bullets were shot into an earthen impact berm located about 300 feet from the machine gun firing site. The impact berm was 40 feet high, 400 feet long, and 100 feet wide at its base.

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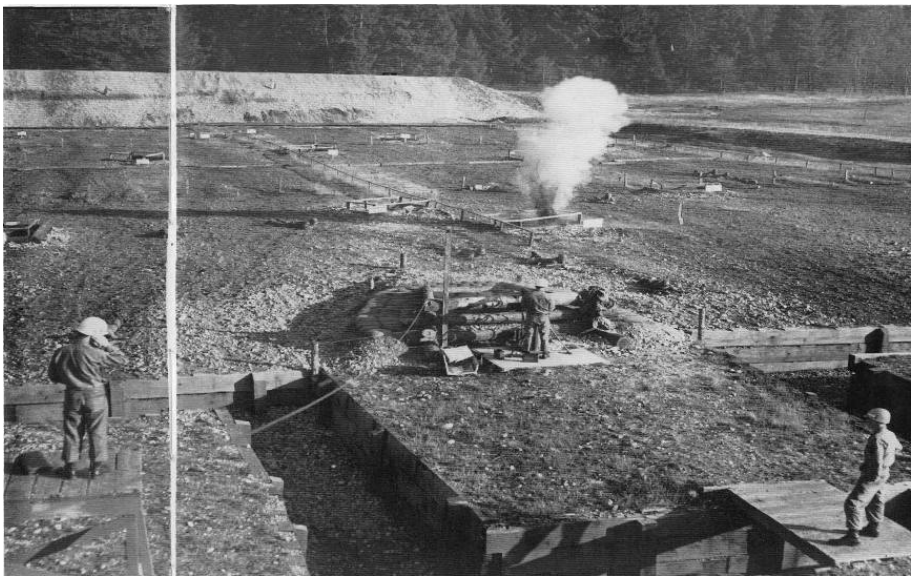
Evergreen Firing Range



This is an actual photo of the firing range. Note the berm in the upper portion of the photo

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Evergreen – Investigation

- Sampling was designed to evaluate potential exposure pathways and possible remedies.
- Triad Approach used from the beginning of the project.
  - Real time data acquired in field using portable X-Ray Fluorescence (XRF)
  - Field data used to determine extent of area sampled
  - Validated by 10% laboratory analyses

Triad approach was used for investigating and remediating the site.

One aspect of Triad emphasizes the use of collecting real-time data to evaluate contaminant concentrations in the field.

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Characterization Goals

50 mg/kg	Detection limit for lead using XRF and screening level for ecological assessment used by Washington State
250 mg/kg	Washington State human health protection screening level
400 mg/kg	USEPA Region 9 screening level (Preliminary Remediation Goal (PRG))
1000 mg/kg	Hazardous waste screening level

- Sample results confirmed that lead was the primary contaminant of concern
- Slide shows characterization criteria that were delineated for lead.
- 250 mg/kg for lead for human health protection for unrestricted land uses
- 50 mg/kg detection limit for XRF
- Background metal levels were not used for this site

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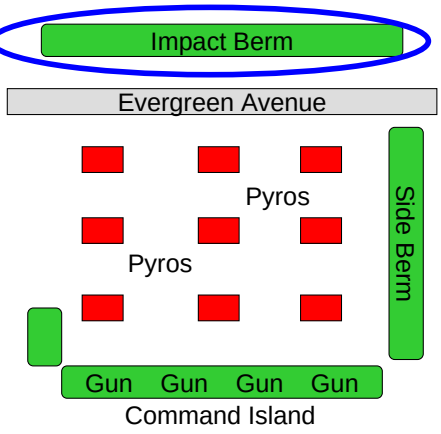
Evergreen – Cleanup Goal

- Result: the impact berm area was the only candidate for remedial action
- Risk-based screening criteria were also used for cleanup goals
  - 250 mg/kg cleanup level based on human health criteria



(Not Drawn to Scale)

•A site specific risk assessment was not conducted for the firing range.

•Cleaned up as a RCRA “interim action” using the screening level of 250 mg/kg of lead in soil.

•May undergo additional analysis for protection of ecological systems

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Evergreen – Remedial Compliance Sampling Objectives

- Compliance sampling
  - Samples collected from excavation floor and sidewalls
  - 5 areas of excavation established based on proposed excavation depths
  - 30’ x 30’ grid established for each excavation area
  - Each grid divided into 9 sections
  - 5 discrete grab samples collected randomly from 5 of the 9 sections within each grid
- Grids failing clean up levels were over-excavated and re-sampled
  - New sample data replaced old results
  - Areas between “hot spots” were automatically excavated

This slide shows the sampling strategy that was used to determine if remediation was successful. Areas within the firing range were identified for excavation. Each excavation area was divided into grids and randomly sampled. Grids where sample results failed to meet the cleanup criteria were over-excavated and then resampled until criteria were met. Grid dimension based on excavation efficiency and balance between representation of the remediation area and a logical minimum response to discovery of additional contamination

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Evergreen – Criteria for a Successful Remediation

- No sample within an excavation area had a lead detected **>500 mg/kg**
- 95% upper confidence level (UCL) of mean of data for entire site did not exceed **250 mg/kg**
- 10% of samples or less can exceed the **250 mg/kg** cleanup level
- Entire site had to pass clean up criteria as whole

Washington State criteria were used to determine when to stop excavating. Note that a statistical approach using the 95% UCL of the mean was used to determine success, also that a ceiling concentration was identified and that the maximum percentage of samples exceeding the numerical cleanup criteria was specified. In addition, sampling results from the entire site had to successfully meet the remediation criteria.

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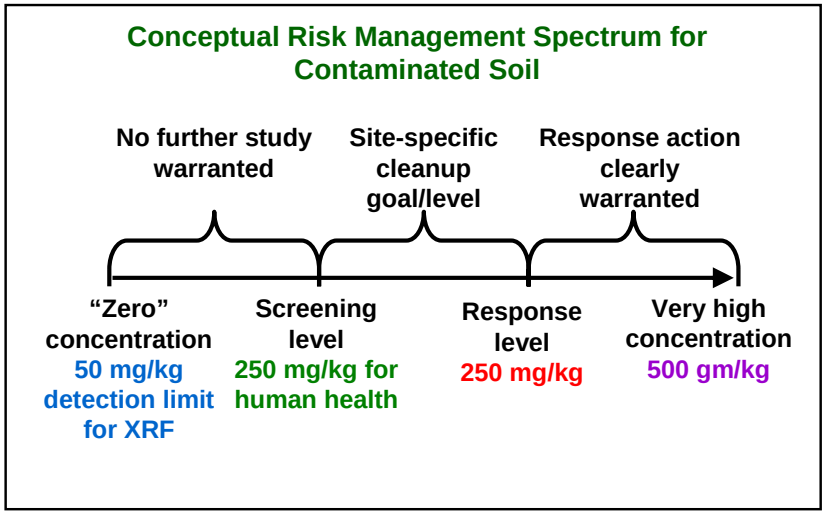
Risk Management at Evergreen



If we apply the risk management spectrum to the Evergreen site we see the progression of numerical criteria considered at the site.

Lead concentration contours were established based on 4 levels previously described. The lowest concentration is based on ecological protection. The human health screening level established by Wash. State for human health protection is 250 mg/kg. As we see this was also used as the cleanup number. The 500 mg/kg was a not to exceed concentration criteria for confirmation sampling.

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Summary – Two Case Studies

Topic	Spring Valley	Evergreen
Compound	Arsenic (As)	Lead (Pb)
Land use	Residential (current)	Residential (future)
Background	Determined (12.6 mg/kg)	Not considered
Field Methods	No	Yes XRF for real-time sample analysis
Sampling and Analysis	Evolved over time Discrete/averages (risk) Composite (more sampling) Discrete/grid (removal) Discrete within grid (confirmation)	Discrete, statistical sampling strategy for investigation and cleanup

This slide and the next slide compare the two case studies

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Summary – Two Case Studies (continued)

Topic	Spring Valley	Evergreen
Range in risk based criteria	0.43 ppm (PRG) 12.6 ppm (bkg) 20 ppm (cleanup) 43 ppm (not to exceed)	50 ppm (ecological) 250 ppm (residential)
Exposure Area	Half acre residential lot	Entire site
Removal Criteria	Consistent w/res. Exposure (2' depth, near surface)	Mixed based on depth and location of contamination
Criteria for Successful Removal	No sample greater than 20 mg/kg or 43 mg/kg	10% cannot exceed criteria no sample > 2X 95% UCL (entire data set) (30' x 30' grid)
Risk management decision	Residents had a big say in final cleanup level	Cost benefit analysis showed that using screening level was most cost effective

- Approaches used in both case studies were valid
- Public input played
  - Strong role at the Spring Valley site
  - Minimal role at the Evergreen site
- Screening criteria
  - Changed at the Spring Valley site
  - Stayed the same at the Evergreen site
- Both sites have accepted cleanups, even though the cleanup goal numbers may be different than used in other states

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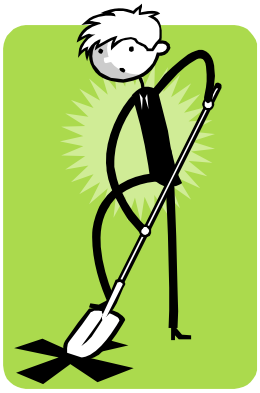
Learning Objectives for Case Studies Module

- Examine how “risk assessment” is incorporated into the “risk management “process for site cleanup.
- Examine differences in risk management approaches
- Show how risk based screening criteria and site specific risk assessment were used in the case studies
- Show ways that cleanup criteria are used to confirm successful remediation.



To review: The specific objectives for this module are identified in this slide.

•briefly review the “Case Studies Project that the Risk Assessment Resources Team is developing

•present two cases studies with emphasis on site specific sampling approaches and how screening levels and risk assessment were used for making decisions about the sites.

•present a summary comparison of the two studies, followed by lessons learned.

To do this we will focus on:

•How were screening levels applied throughout the project life cycle?

•How was the numeric criterion utilized throughout the site cleanup process?

•What sampling approaches were used, and why?

We have discussed all of these points during the third module. We looked at how screening levels were applied at both Spring Valley and Evergreen, we traced the progression of developing risk management numeric criteria for each site and we discussed and compared the sampling approaches and the rationale for using them during each case study.

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Recommendations

Risk Assessment and Risk Management

- Publish the basis for characterization criteria
- Publish the basis for remedial goals
- Make the underlying assumptions and values transparent
- Publish the intended use of cleanup criteria and how success will be determined.
- **Make the process and decisions transparent**

•The ITRC Risk Assessment Resources team recognized the need to see how screening levels were used so that we could learn from the information and improve in the future.

•Similarly a goal of the case study project is to learn from specific site cleanup examples how sampling strategies are developed and change over time, how risk based criteria were used in managing risk, and how a successful remediation was determined.

•ITRC Risk Assessment Resources team members spent considerable time reviewing and following up with individual case studies in order to understand the nuances of each case study and how screening criteria and site specific risk assessment were used.

•This slide shows the ITRC Risk Assessment Resources team recommendations to demystify the basis for site specific cleanup numbers.

Thank you for your attention.

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Thank You for Participating

- **2nd question and answer break**
- **Links to additional resources**
  - http://www.clu-in.org/conf/itrc/risk/resource.cfm
- **Feedback form – *please* complete**
  - http://www.clu-in.org/conf/itrc/risk/feedback.cfm

Need confirmation of your participation today?

Fill out the feedback form and check box for confirmation email.

Links to additional resources:
http://www.clu-in.org/conf/itrc/risk/resource.cfm

Your feedback is important – please fill out the form at:
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The benefits that ITRC offers to state regulators and technology developers, vendors, and consultants include:

✓Helping regulators build their knowledge base and raise their confidence about new environmental technologies

✓Helping regulators save time and money when evaluating environmental technologies

✓Guiding technology developers in the collection of performance data to satisfy the requirements of multiple states

✓Helping technology vendors avoid the time and expense of conducting duplicative and costly demonstrations

✓Providing a reliable network among members of the environmental community to focus on innovative environmental technologies

How you can get involved with ITRC:

✓Join an ITRC Team – with just 10% of your time you can have a positive impact on the regulatory process and acceptance of innovative technologies and approaches

✓Sponsor ITRC's technical team and other activities

✓Use ITRC products and attend training courses

✓Submit proposals for new technical teams and projects