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

Use of Risk Assessment in Management of Contaminated Sites

Use of Risk Assessment in Management of Contaminated Sites (RISK-2, 2008)

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

The ITRC Risk Assessment Resources team developed a document titled Use of Risk Assessment in Management of Contaminated Sites (RISK-2, 2008). This Internet-based training is taken from the RISK-2 document and highlights variation of risk-based site management and how to improve the use of risk assessment for making better risk management decisions. This training course looks at how various risk-based approaches and criteria are applied in various states and programs throughout the processes of screening, characterization, and management of contaminated sites.

The document and training course are intended for risk assessors and project managers involved with the characterization, remediation, and/or re-use of sites. Together they provide a valuable tool for federal and state regulatory agencies to demonstrate how site data collection, risk assessment, and risk management may be better integrated. This training course explains:

-- Variation in risk assessment parameters/approaches in various states and their influence on risk management

-- Insights into the use of risk assessment in risk management process through use of specific case study examples

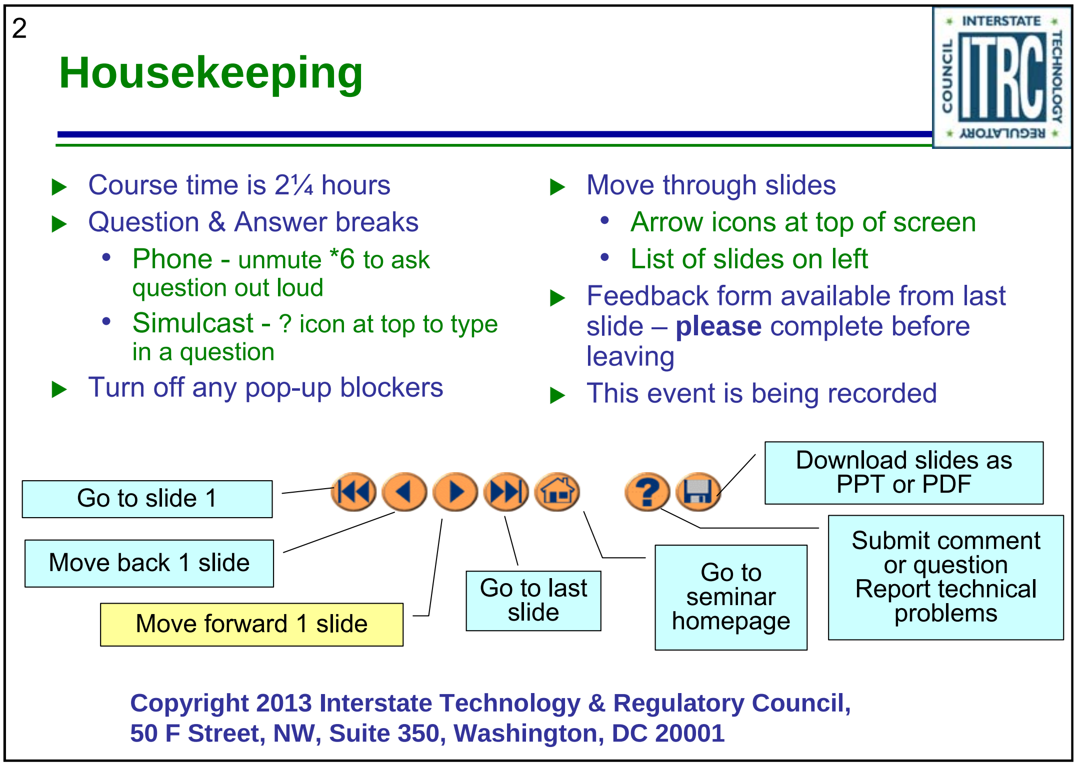
-- An improved process of using risk assessment in risk management

This course builds on the Risk Team's previous work identifying variation in the development of risk-based numerical criteria, specifically soil screening levels. A prerequisite to this training course is the Risk Team's previous Internet-based training (archive is available from http://cluin.org/live/archive.cfm?sort=title#itrc) based on ITRC's Risk Assessment and Risk Management: Determination of Risk-Based Values (RISK-1, 2005). The Electronic Risk Resource Sheet published by the ITRC Risk Team is recommended as an excellent resource for supplemental materials related to risk assessment and risk management.

ITRC (Interstate Technology and Regulatory Council) www.itrcweb.org

Training Co-Sponsored by: US EPA Technology Innovation and Field Services Division (TIFSD) (www.clu-in.org)

ITRC Training Program: training@itrcweb.org; Phone: 402-201-2419



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.

We have started the seminar with all phone lines muted to prevent background noise. Please keep your phone lines muted during the seminar to minimize disruption and background noise. During the question and answer break, press *6 to unmute your lines to ask a question (note: *6 to mute again). Also, please do NOT put this call on hold as this may bring unwanted background music over the lines and interrupt the seminar.

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 presentation overview, 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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ITRC (www.itrcweb.org) – Shaping the Future of Regulatory Acceptance

- Host organization
- Network
  - State regulators
    - All 50 states, PR, DC
  - Federal partners

    DOE DOD EPA
  - ITRC Industry Affiliates Program
  - Academia
  - Community stakeholders
- Wide variety of topics
  - Technologies
  - Approaches
  - Contaminants
  - Sites
- Products
  - Technical and regulatory guidance documents
  - Internet-based and classroom training

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 2013 – More information at www.itrcweb.org

Popular courses from 2012

- Decision Framework for Applying Attenuation Processes to Metals and Radionuclides
- Development of Performance Specifications for Solidification/Stabilization
- Green and Sustainable Remediation
- Integrated DNAPL Site Strategy
- LNAPL 1: An Improved Understanding of LNAPL Behavior in the Subsurface
- LNAPL 2: LNAPL Characterization and Recoverability - Improved Analysis
- LNAPL 3: Evaluating LNAPL Remedial Technologies for Achieving Project Goals
- Mine Waste Treatment Technology Selection
- Project Risk Management for Site Remediation
- Use and Measurement of Mass Flux and Mass Discharge
- Use of Risk Assessment in Management of Contaminated Sites
- Soil Sampling and Decision Making Using Incremental Sampling Methodology (2 parts)
- Bioavailability Considerations for Contaminated Sediment Sites
- Biofuels: Release Prevention, Environmental Behavior, and Remediation

New in 2013

- Environmental Molecular Diagnostics
- Biochemical Reactors for Mining-Influenced Water
- Groundwater Statistics and Monitoring Compliance

2-Day Classroom Training on Light Nonaqueous-Phase Liquids (LNAPLs)

- April 9-10 in King of Prussia, PA
- June 4-5 in Springfield, IL
- (tentative) October in Southern CA

More details and schedules are available from www.itrcweb.org.

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Meet the ITRC Trainers

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Bennett Kottler lives in Cincinnati, Ohio. Previously, he was 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. From 2002-2011, he provided 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.

Marlena (Marty) Brewer works for the Alaska Department of Environmental Conservation (ADEC) Division of Environmental Health specializing in risk assessment and risk management. She is a member of the ITRC Risk Assessment Resources team and Groundwater Statistics and Monitoring Compliance team. Marty earned a bachelor's degree in biology from University of Central Arkansas (UCA) in Conway, Arkansas in 1995 and a master's degree in Occupational and Environmental Health from University of Arkansas for Medical Sciences (UAMS) in Little Rock, Arkansas in 1997.

Jeanene Hanley is a risk assessor. From 1998-2013, she worked for at the State of Arizona in Phoenix. She has conducted numerous risk-based evaluations of UST sites, mining sites, agricultural sites, solid waste and hazardous waste sites, as well as development of risk-based standards. Prior to her work at the State of Arizona, she worked as Technical and Administrative Assistant to the Vice President of Investigations at the private consulting firm of Midwest Environmental Consultants from 1994-1998. Prior to her work in the environmental field, Jeanene conducted toxicological research at the Midwest Research Institute, the University of Kansas Medical Center, and at the Oklahoma Medical Research Foundation. She is a member of the ITRC Risk Assessment Resources team. She earned a bachelor's degree in biology from the University of Missouri at Kansas City in 1984, a master's degree in biochemistry and molecular biology from the University of Oklahoma Health Sciences Center in Oklahoma City in 1992, and a master's degree in environmental sciences from the University of Oklahoma in Norman in 1994.

Kurt Frantzen, Ph.D., CHMM, was a Senior Program Manager/Principal Professional with Kleinfelder in Windsor, Connecticut, and worked for Kleinfelder from 2006 to 2011. He serves clients by interfacing science, engineering, and planning to resolve complex property contamination matters. A biochemist by training, he has over twenty years of experience in environmental risk analysis, hazardous waste site/Brownfields investigation/remediation, environmental R&D, and project management. He is a member of the ITRC Risk Assessment Resources team. Kurt earned a bachelor's degree in (Biology) from the University of Nebraska-Omaha in 1978, a master's degree in plant pathology from Kansas State University in Manhattan, Kansas in 1980, and a doctoral degree in life sciences/biochemistry from the University of Nebraska-Lincoln in 1985. He is a Certified Hazardous Materials Manager (CHMM).

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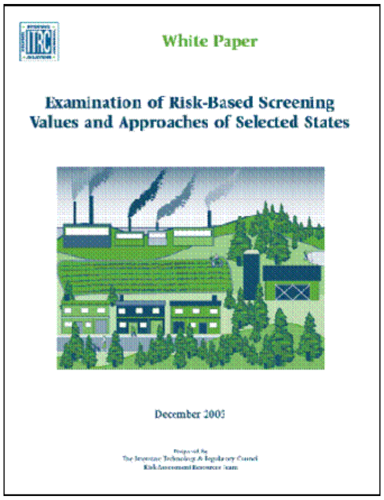
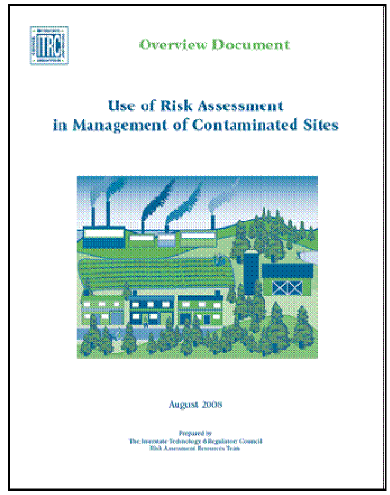
ITRC Risk Team Documents & Training





www.itrcweb.org/Risk

The Risk Resources Team, with representatives from a variety of state and federal agencies, consulting firms, academic institutions as well as public stakeholders, has published two documents:

- In 2005 , the Risk Team published a White Paper entitled *Examination of Risk-Based Screening Values and Approaches of Selected States* document.
- The team continues to offer a companion "introductory" Internet-based training course.
- Hopefully you have had a chance to review the document or participate in that Internet-based training course.
- That Internet-based training covered basic risk assessment concepts, a survey of States screening values, and 2 of the 5 actual case studies that appears in in 2008 document.

Today's training is a companion to the 2008 document

- In 2008, the ITRC Risk Team published an Overview Document entitled *Use of Risk Assessment in Management of Contaminated Sites* (RISK-2)
- This effort builds upon our Team's previous work analyzing the development of soil screening levels (SSL) in ITRC's RISK-1 document.
- We delve into Risk Management (RM) and how risk assessment (RA)-based SSLs are actually used in managing risk at sites.
- This training presumes an advanced understanding of risk assessment.

Examination of Risk-Based Screening Values and Approaches of Selected States (RISK-1, 2005), developed by the ITRC Risk Assessment Resources team

(available at http://www.itrcweb.org/guidancedocument.asp?TID=44).
This associated 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.

You can access an archive (listen/view slides) of a previous offering by going to:

http://cluin.org/live/archive.cfm?sort=title#itrc Courses are listed alphabetically. You will have to scroll down to find the course of interest.

When you choose to view a course on-line, the link will take you to the course overview page. When you are ready to listen to the training, select Go to Training.

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Our Purpose Today

- Provide highlights of the Overview Document: **Use of Risk Assessment in Management of Contaminated Sites (RISK-2, 2008)**
- Significance of the Overview Document
  - Risk assessment use in risk management
  - Sources of variation
  - Comparison of principles and practices ➔ Variation

Our purpose today is to provide you highlights of the Risk Assessment Resource Team's Overview Document: Use of Risk Assessment in Management of Contaminated Sites.

The significance of the Overview Document:

- We tried to provide you a snapshot view of RM decision making - and how risk assessment is used in it

- Our study reflects upon the sources of variability in the risk assessment.

- This effort is the 1st time side-by-side comparison of principles and practices leading to variation of different organizations addressing similar issues

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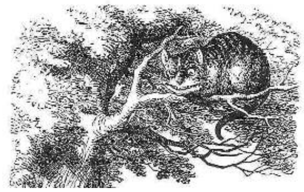
Our Purpose Today

- Describe use of Risk Assessment in Risk Management
  - Management is ALWAYS context bound
- NOT Tech-Reg training



'Would you tell me, please,
which way I ought to go from here?'

'That depends a good deal on
where you want to get to,'
said the Cat.

Because of the nature of RA/RM,

Which is always context-bound and
-begins with different starting point, and
- end by solving different risk needs
this presentation is NOT a presentation of a Tech-Reg document
which may be a more familiar training program you may have participated in from the ITRC.

Risk Assessment and it's use in Risk Management (and frankly much of science)
makes me think of ***Alice in Wonderland*** the children's novel written by Lewis Carroll (1865)
.
It tells the story of a girl named Alice who falls down a rabbit-hole into a fantasy world populated by peculiar creatures.

In one part Alice meets a Cheshire Cat and asks
'Would you tell me, please, which way I ought to go from here?'
The Cat answers 'That depends a good deal on where you want to get to,'

Because Risk management is so context-bound, so linked to the goal/the answer you intend to achieve
***we cannot train you in any one approach to RM /"which way to go"**
because it very much depends on where you (and the RP, project manager, regulator, and other stakeholders) want to "get to."

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Our Purpose Today

- Reveal "Lessons Learned" of state of the practice of Risk Assessment (RA) in Risk Management (RM)

- Improve Risk Assessment and Risk Management

We hope to reveal the current state of the practice of using RA in RM, by offering these "lessons learned."

This make me think of the climax of the movie the Wizard of Oz, in which Toto, Dorothy's dog, pulls aside the curtain to reveal the identity of the Wizard of Oz.

In this photo you can really see the disappointment on the face of Dorothy and the other characters to learn that the Wizard is simply a ordinary person.

We'd like you to think of us as Toto, pulling aside the curtain that shrouds the mystery of RM, so that you may improve your RA/RM

11

Proposal: Improving the Process

Process Review

- Retrospective actual case studies
- Prospective hypothetical case studies

➔ **Key findings**

➔ **Perspectives**

➔ **Recommendations**

Proposal for a better process

Know “players”	Communicate
Use common framework	Iterate

As we will detail in Module 4, the Team:

1) **reviewed** the RA **process**

1a) retrospectively at actual cases and

1b) hypothetically at prospective cases and

2) made **key findings** on how these practices were implemented in the case studies and how they impacted risk management decisions.

3) developed **perspectives** on RA/RM

4) developed **recommendations** for a process that would improve RA/RM.

The proposed improved process is <u>no more difficult</u> than the Classic RA/RM.

It can be simply summed up as in the box in the lower portion of the slide

<u>Process proposal</u> We recommend

- Know “Players” (those who can directly or indirectly impact the risk management decision).
- Communicate (key to developing a common framework).
- Agree upon common framework
- Iterate (to achieve best RA/RM possible)

***Please look for these elements throughout today’s class**

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What You Will Learn

- Review of risk assessment (RA) and risk management (RM) practices across the nation
- Why RA and RM practices are so variable
- Navigate the variation
- Ways to improve RA use in RM decision-making from one site to the next

This is not a tools training, but hopefully

1) starts a dialog for you to consider the sources of variation in the RA process that determine the ultimate RM decision.

Together we will review risk assessment (RA) and risk management (RM) practices across the nation

To determine why RA and RM practices are so variable

We'll teach you what to look for to navigate the variation

And give you ways to improve RA use in RM decision-making

As you work from one site to the next

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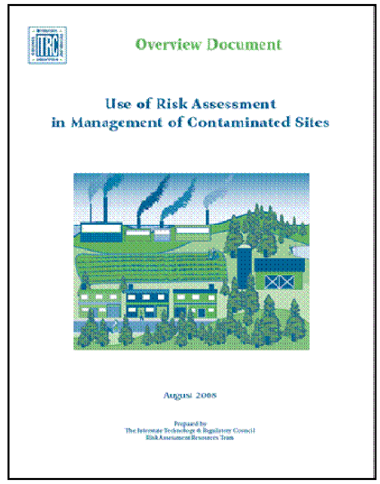
Overview of Today's Training

- Module 1 – Theory and Practice of Risk Assessment: Important Issues
- Module 2 – Actual Case Studies (Retrospective Studies)
- Module 3 – Comparative Case Studies (Hypothetical Studies)
- Module 4 – Perspectives, Summary, & Recommendations



As stated before, today's training is a summary of the Risk Assessment Resource Team's Overview Document: Use of Risk Assessment in Management of Contaminated Sites (RISK-2, 2008).

- This effort builds upon our Team's previous work analyzing the development of RA and SSLs. We now explore RM decision making and how RA and risk-based SSLs are used.

Mod 1 – Marty Brewer Alaska DEC, will introduce some of the issues commonly encountered in the RA process and how they are addressed.

Mod 2 – Bennett Kottler Nevada DEP, will provide a summary of a retrospective study of real sites and real data to evaluate what was done.

Mod 3 - Jeanene Hanley Arizona DEQ, will summarize the findings of a prospective study where two hypothetical sites were assessed to evaluate how RA would be used in RM.

Mod 4 – Kurt Frantzen Kleinfelder, will summarize the various findings and perspectives and how they play a role in the RA/RM process and provide recommendations.

I would like to turn the program over to Marty Brewer, Alaska DEC

Use of Risk Assessment in Management of Contaminated Sites

MODULE 1:

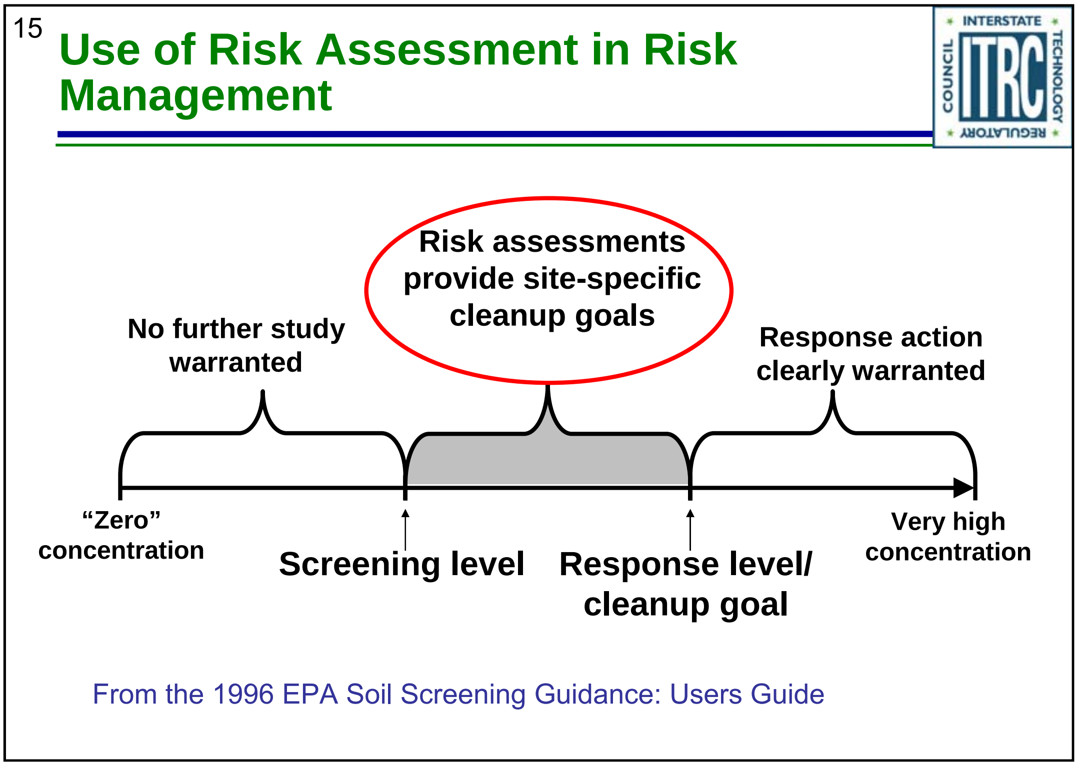
Theory and Practice of Risk Assessment: Important Issues

The team examined the theory and current practice of risk assessment.

We found that although the basic theory is relatively well understood, the actual practice varies.

We present here several issues (but by no means a comprehensive list) which we as risk assessors commonly encounter that result in these variations in the practice of risk assessment.

These observations are based on professional experience, and are not identical to those variations discussed in the case studies.



To step back a moment we take a look at why/how risk assessments are used in the management of contaminated sites.

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

As demonstrated in the ITRC Risk team's last endeavor, soil screening levels (SSL) vary. However, how SSLs are used in risk assessment also varies.

SSL is a numerical criteria, but the site characterization/site assessment gives us the 'exposure concentration' to compare to the SSL. How this exposure concentration is derived is a topic of consideration.

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.

Management decisions are evident when there is clearly problem.

Middle or gray area is the area of uncertainty.

Screening levels are used as the first step in the risk management process to eliminate a site from further study or action.

Risk assessments may in turn be used to develop site specific response levels (cleanup levels).

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Module 1 Learning Objectives

- Insight into the various current risk assessment/management processes utilized by several states
- Side by side comparison of how various risk assessment approaches or criteria are applied throughout the processes of screening, characterization, and remediation of contaminated sites

The team examined the theory and current practice of risk assessment.

We found that although the basic theory is relatively well understood, the actual practice varies.

We present here several issues (but by no means a comprehensive list) which we as risk assessors commonly encounter that result in these variations in the practice of risk assessment. These observations are based on professional experience, and are not identical to those variations discussed in the case studies.

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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
- Cost effectiveness
  - Providing risk-based remediation goals
  - Focusing corrective actions on the exposure pathways that present the highest risks
  - Allowing for site reuse with restrictions

Risk assessment answers the question - is there a risk and in turn whether or not there is a need for any protective action or remediation.

Risk assessment provides a scientific and legally defensible support to base risk management decisions upon. (Supports risk based cleanup)

Cost effectiveness

- Site-specific cleanup goals instead of using background or screening levels, or cleaning a site up to non-detect levels.

- Focusing actions on risk drivers.

- Evaluating exposure pathways and restricting activities to avoid exposure while allowing for the reuse a site

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Risk Management Decision Making

- Risk management - the process of
  - Controlling risks
  - Weighing the alternatives
  - Selecting the appropriate action

- Risk management – ALSO considers
  - Risk assessment information
  - Social and political issues
  - Regulatory/policy issues
  - Technological/economic issues

Risk managers must determine the best way to reduce or eliminate the risk to the receptor population, but also consider other issues.

RMs must also take into account:

- social or political issues involved with the site or the technology - Who are the “Players” and what do they value?

- regulatory approval of the action - regulatory requirements

- cost and feasibility of implementation for each alternative considered – cost/benefit consideration

Consideration of remedial alternative is based on CERCLA Guidance: “Nine Criteria of the National Contingency Plan” (40 CFR 300.410)

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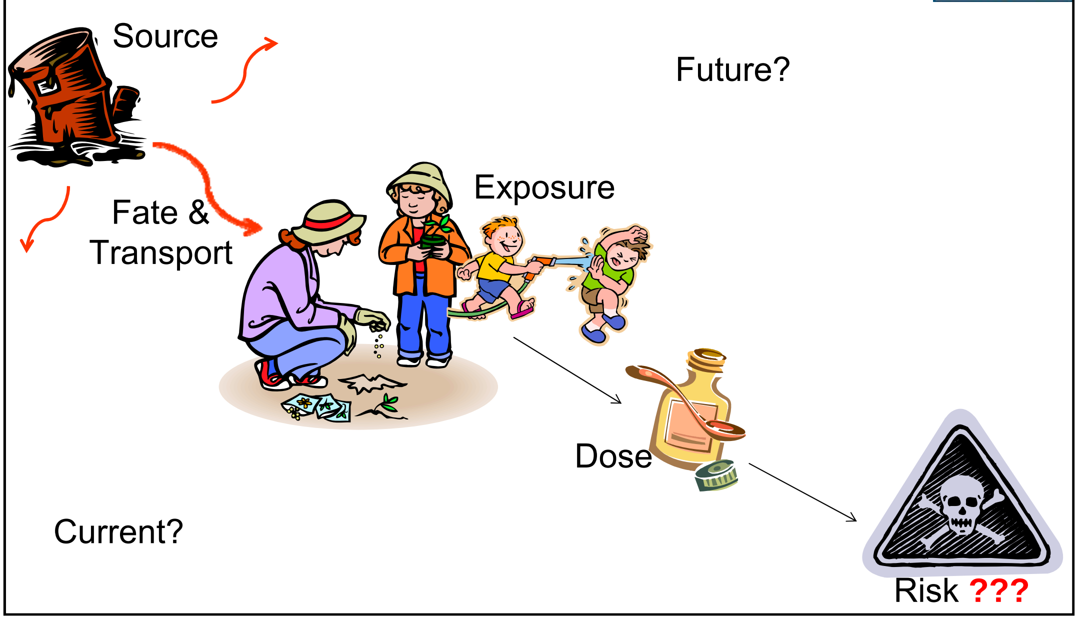
Risk Characterization:
Integrate Information



Variation can exist in various/multiple points in the risk characterization process.

Source ID – sampling variations

Where does the contaminant go? Fate & Transport

Are there receptors and is there potential for exposure? Who are the receptors (kids, residents, sensitive populations)? How do you assess their exposure?

Current and/or future receptors

How is the contaminant taken in (route), metabolized, cleared?

Is that interaction going to cause an adverse effect? Dose

Toxicology and consideration of cumulative effects (additive, synergistic)

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Important Issues for State Risk Assessors

- Background concentration
  - How is it determined?
  - How is it considered in risk assessment?
- "Hot spots"
  - What are "hot spots"?
  - How are they defined?
  - How to assess risk?
- Use of tiered approaches
  - Resource allocation
- Stakeholders/end-user perspectives
  - Role in risk assessment and management

The Risk Team collaborated on what we considered were some of the important issues from our own experiences and perspectives.

We explore several here and in the Overview Document to uncover the variability in the practices used in the risk assessment process.

On this slide I start highlighting some of the considerations I previously mentioned. The first 3 blue bullets are data/tech issues and the last one raises a social/political issue. Risk assessment is fact driven exercise, but stakeholder/end-user values should be considered in the risk assessment inputs to achieve the common goal.

Background concentrations – determination and use in risk assessment/management

Hot Spots – defining them and how to assess risk

Tiers – increasing resources for increasingly complex/important sites

Stakeholder/end user ("players") perspectives in the risk assessment process and ultimately risk management decision making

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Data Issue: Background Concentrations

- Not all states have specific guidance on background, yet all surveyed allow for evaluation of background in risk assessment
- Sampling quantity, types, use of stats vary
  - 1,4,7,10, to "adequate"
  - Discrete, composite, multi-increment
  - Unless specific requirements are spelled out, "*best professional judgment*" is allowed
- What if the background levels exceed risk-based health criteria?

ITRC Risk-2 Section 3.3 Table 3-3

Survey questions asked **(Section 3.3; Table 3-3 of the Overview document):**

Does your state have formal guidance on the use of background in risk assessments? Not all states have specific guidance on background; some defer to Regional EPA guidance.

Does your state consider background in soil risk assessments? All states surveyed said yes.

Do you consider both anthropogenic and natural background? Are they treated the same or differently. Most states said both, but some said only natural background was considered. Note, States may have own definitions of anthropogenic background.

Is background determined using site specific soil samples, literature references, or either one? Either or responses

Literature references? Region 6 Human Health Medium Specific Screening Levels Nov 2005; state specific sources Mass, NJ, WI

Is background from another area/region acceptable in place of site-specific data? Mostly no, but 2 said close by soils were OK.

Is background determined from a heavily industrialized urban area valid for a light industrial suburban area? All said no.

Sampling questions on quantities, types, depths and use of stats. Min # specified (1,4,7,10) to adequate; discrete, composites, MI; most use stats (median, max, UCL)

Unless specific requirements are spelled out for numbers of samples and types of analyses, "best professional judgment" is allowed.

Are alternative cleanup level (ACLs) based on background? Yes.

How do you determine difference between a site and background? Statistical, non-statistical, tiered approach

If the background levels exceed risk-based health criteria, it can be excluded as a chemical of concern for remediation, but may still need to be considered for cumulative risk consideration.

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Data Issue: Hot Spots

- Formal definition
  - 3/20 states have formal
  - 1 has informal
  - Precisely numerical or non-quantifiable definitions
- Numerical criteria
  - Cleanup level (CL)
  - Screening level
  - 10^{-5} and HQ 1
  - Max > acute toxicity level
  - Max > 3X chronic CL
- Area / volume represented
  - Sample
  - Area exceeding CL
  - Mass based

- How do you sample for it?
  - Random, directed, or judgmental
  - Systematic random
  - Best professional judgment
- How to you assess risks?

Refer to Section 3.2.1 of the Overview Document and Table 3-2 Hot Spot Table

Formal definition? Only 3 states surveyed out 20 of said yes (TX, MA, OR). One state has informal definition (MI).

As can be seen in Table 3-2, by and large the characteristics and written definitions of “hot spots” fall into two categories: Non quantifiable and precisely numerical.

However, since neither ‘*area*’ nor ‘*elevated*’’ are specified, the definition may not lead to the same answer to the question, “Is there a hot spot here?” if several different people were viewing the same data set.

Numerical criteria – Either not specified or varied from CL, SL to acceptable risk level to evaluate of site average to surrounding area

Area/Volume represented – sample, area exceeding CL, mass based

How do you sample for it? Random, directed, judgmental , systematic random, *best professional judgment*

Often times hot spots are sampled for in a focused (i.e., biased) manner to determine the magnitude and extent of the contamination. This sampling data then is used for risk assessment. So is this to say that the hot spot is the exposure area to be considered?

Recall that soil screening values are typically developed primarily for evaluating exposure to toxicants in shallow soil in a residential setting. When evaluating possible exposure to toxicants, the average level of a toxicant throughout an exposure unit is generally compared to the numerical soil screening value.

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Data Issue: Tiers

- Tier 1 – “look up table” or “not to exceed”
- Tier 2 and beyond – common issues:
  - Tiers not always clearly defined by all
  - Fate & transport modeling
  - Point or area of consideration
  - Exposure point concentrations
  - Data needs
  - Use of probabilistic risk assessment
  - Use of multiple Tiers simultaneously
  - Cost/benefit considerations

Risk-2 Section 3.4: Tiered Approaches in Risk-Based Investigation and Remediation

Refer to Section 3.4 of the Overview Document for discussion on the use of tiered approaches in risk based investigation and remediation. The idea of using tiers is to appropriately allocate the amount of effort/resources spent on investigation based on the apparent significance/complexity of the site. A simple site may warrant only Tier 1 assessment, whereas a more complicated site may need more sophisticated analysis. Feds typically use 2 tiered approach of risk screening and risk assessment:

EPA guidance – *Soil Screening Guidance* 1996 and *Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites* (2002c)

American Society of Testing and Materials (ASTM) 3 Tiered guidance – *Standard Guide for Risk Based Corrective Actions at Petroleum Release Sites* (1995) and *Provisional Standard Guide for Risk Based Corrective Actions* (1998)

States – majority use 3 tiered approach sharing common elements, but different versions

Tier 1 – use of “look-up table” - little effort/greater uncertainty/more conservative/fewer management options

Tier 2 – some site specific calculations, but many defaults still used – more effort/ more certainty/somewhat conservative

Tier 3 – formal site specific risk assessment – most effort/greater certainty/more realistic/more finite management options

However, Tiers not always clearly defined by states. Some states have specific guidelines (MI, NM, AR, OR, OH, IL, TX, FL, etc.). Some of the issues discussed in Tier 2 and beyond (the more complex the assessment, the more issues to consider):

- Which fate & transport modeling will be accepted or utilized?
- What point or what area must comply with the calculated Tier 2 or Tier 3 standard?
- If different from the representative site concentration, how is the exposure point concentration determined (max, UCL)?
- How much and what types of data collection are required to support each determination of Tier 2 or 3 standard?
- Will probabilistic risk assessment be allowed, and at what tier?
- Can Tier 1 cleanup numbers be mixed or matched with Tiers 2 or 3 in conducting corrective actions? Can you change your mind?
- At what point, if at all, is the cost of data collection in support of and the cost to conduct the Tier 2 or 3 evaluation considered?

Ultimately, successful use of any tiered approach demands that all the players have to be on board and know where they want to go in order to determine how best to get there.

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Social/Political Issues: Stakeholder Participation

- Stakeholder involvement
  - Who are the stakeholders?
  - Bridging the fact value gap
- Importance of risk communication
  - Early and often involvement/participation
  - Incorporate stakeholders' perspectives
  - Relating information on personal level
- Current or future considerations
  - Are current issues driving the process or future considerations playing a role?

In Chapter 6 we explore the various insider's (Regulator, Stakeholder, and End-user) perspectives on use of risk assessment in risk management.

Identifying stakeholders and what they consider important - getting back to the value consideration and bridging the fact-value gap.

Risk assessment is fact driven exercise, but stakeholder values should be considered in the risk assessment inputs to achieve the common goal.

Team concurred on the importance of risk communication –

A better and more refined risk management decision can be made with early/often stakeholder involvement and participation.

Results in more effective risk communication because everyone is on board throughout the process.

Temporal consideration may impact stakeholder perspectives - Current vs. future

As you will see in the case studies, it makes a difference whether or not you are considering a future residential development over a contaminated site as apposed to if you are already living on top of it. What risk level are you willing to accept? At what cost?

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Driving Points

- Variation exists in how risk assessments are carried out by different entities

  WHY? Social, political, technological, or economic

- These variations (not limited to background, hot spots, tiered approaches, and end-user needs) can lead to significantly different risk management decisions
- Risk Management necessitates a balancing act

Variation exists in how risk assessments are carried out by different entities as illustrated in our surveys and team discussions in this module.

-- Why? (Social, political, regulatory, technological, economic)

-- Have you ever conducted a risk assessment in a different state or regulatory program?

These variations (as well as others) can lead to significantly different management decisions as will be demonstrated in the following case studies modules.

How then do you navigate the process?

Risk assessment necessitates a balancing act of all the players (regulators, stakeholders, and end users) to achieve a common goal.

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Use of Risk Assessment in Management of Contaminated Sites

MODULE 2:

Three Retrospective Case Studies

All 5 retrospective case studies
Clu-in "Links" ➔ ITRC Risk-2 Training Course Supplement

In this Module I will present the highlights of 3/5 case studies of actual remediation cases.

From the Risk Assessment Resource Team’s Overview Document: Use of Risk Assessment in Management of Contaminated Sites.

Although we have limited time in this presentation to present only 3 cases studies:

1) There is a PowerPoint compiling all 5 case studies that can be accessed by following our "Links to Additional Resources" page at the Clu-in website

"ITRC PowerPoint presentation with the supplement to today's training with slides describing all 5 case studies”

2) Read the Overview document which provides a discussion of these 3 and 2 additional cases of actual sites that were evaluated.

ITRC PowerPoint presentation with the supplement to today's training with slides describing all 5 case studies is available from

http://www.clu-in.org/conf/itrc/risk2/resource.cfm

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Module 2 Learning Objectives

- **Risk assessment (RA) and Risk management (RM) is a balancing act** among
  - “Players”
  - Communication
  - Data
  - Iteration
  - Variation

In this Module we will take a retrospective look at 3 actual case studies and I’d like you to look for the issues that Marty identified as important in Module #1.

RA/RM practices are a balancing act:
“Players” = Stakeholders
Communication
Data
Iteration
Variation

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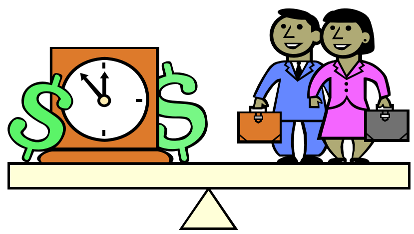
Module 2 Learning Objectives

Risk assessment (RA) and Risk management (RM) is a balancing act among:

Time
Money
Stakeholders
Cleanup



Data analysis
Certainty

Acceptable

Restating the Objectives:

RA/RM is a Balancing Act of what is acceptable among:
(Time Money Players Cleanup) vs. (Certainty Data analysis)
i.e. Want more certainty? Gotta take more time.
Want less data analysis? Gotta do more cleanup.

*Variation results from different balance of considerations and interaction among the players
Thus,
- no two RA/RM approaches are the same.
- as I stated in the introduction, we cannot train you in ”which way to go”
- because it very much depends on where you want to “get to.”

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Case Study Features

- Actual sites retrospectively evaluated
  - Site background
  - Sampling and data use
  - Risk-related information
- “Simple” sites selected to elucidate key variables
  - Soil ingestion
  - Shallow soil contamination
  - One to few chemicals of concern

- **NOT** re-analysis or effort to “fix” these cases

Risk Team retrospectively evaluated cleanups at actual sites with standardized data collection forms

- Allowed consistent means to assemble and compare data from each site

- **Appendix B** of the Risk Assessment Resource Team’s Overview Document: Use of Risk Assessment in Management of Contaminated Sites has completed forms for each case study. Information collected included:

1a) Site background

1b) Sampling and data use

1c) Risk-related information

2) Focus on simple sites to display differences in approaches, rather than complexities of sites

“Simple” sites allow more clearly seeing the ‘principles of risk assessment’ in action

Complicated sites often obscure the effect of RA on RM due to other uncertainties

“Simple” = mostly soil ingestion, one (or few) chemicals, only “shallow soil” contamination

Nonetheless, all sites were fully characterized to rule out exposure to groundwater contamination

3)The retrospective analysis was not an effort to second guess or “fix” RA and RM done improperly

- I know many of you will think midway through this module that you know how to fix or properly conduct the RA/RM at these sites.

- I encourage you to remain focused during this module, as we did in our study, on understanding the sources of variation that affected these cases … and may affect yours.

1a) Site background:

- Site history, nature and extent of the contamination
- Type and size of exposure unit
- Regulatory entity involved.

1b) Sampling and data use

- Sampling design and methodology
- Determination of representative “site” concentration
- Comparison of data to numerical criteria
- Determination of exposure

1c) Risk-related information:

- Derivation of risk-based criteria
- Use of background concentration
- Application of guidance
- Risk management strategies
- Remedial criteria and remedial confirmation approaches.

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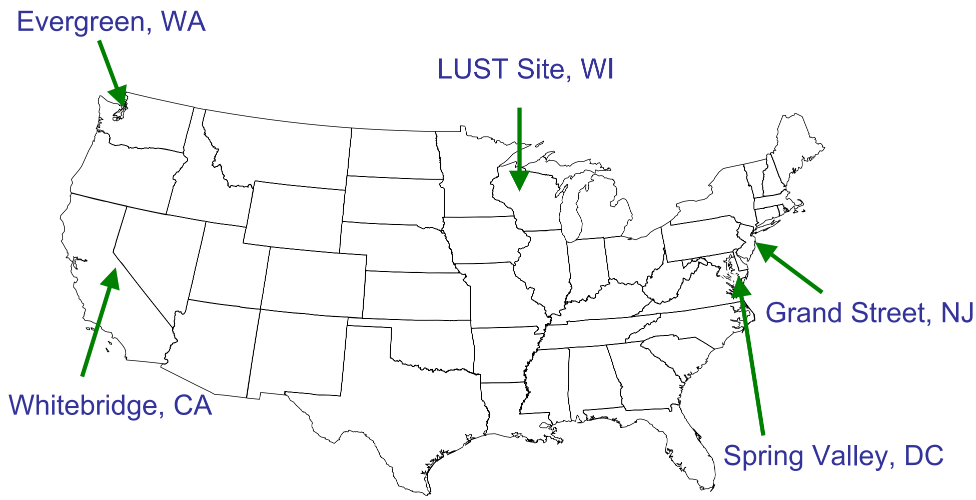
Five Case Study Sites in Document



5 case study sites were reviewed in the document
(Use of Risk Assessment in Management of Contaminated Sites)

From west to east the sites are:

•Army base in Evergreen, WA near Tacoma, WA.

•Former fruit orchard in Whitebridge, CA

•Leaking Underground Storage Tank (LUST) in WI

•FUDS site in Spring Valley, DC

•Former Hg-based manufacturer, on Grand Street in Hoboken, NJ

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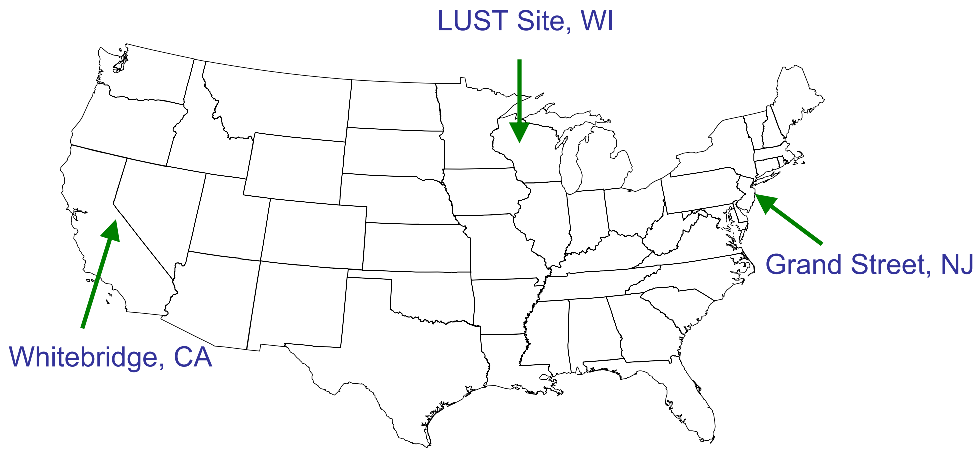
Three Case Study Sites in this Training

5 retrospective cases - Clu-in "Links" ➔ <u>Supplement</u> describing all 5 case studies



However, in the interest in time I will only review 3 of the sites,
Although I will note all 5 sites when I make some conclusions

•Former fruit orchard in Whitebridge, CA
•Leaking Underground Storage Tank (LUST) in WI
•Former Hg-based manufacturer, on Grand Street in Hoboken, NJ

ITRC PowerPoint presentation with the supplement to today's training with slides describing all 5 case studies is available from
http://www.clu-in.org/conf/itrc/risk2/resource.cfm

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Case Study 1 – Whitebridge, CA

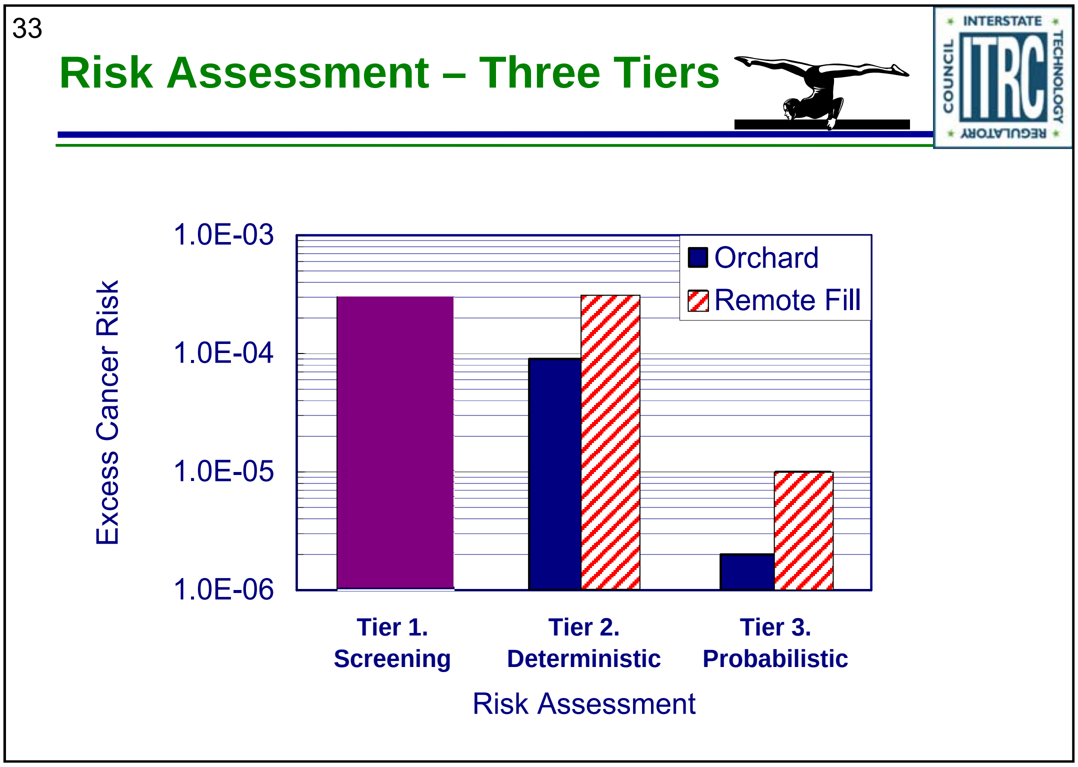
- Former commercial orchard (1930’s to 1980’s) proposed for residential redevelopment
- Eight COPCs: Lead, arsenic, dieldrin, DDT, DDE, endosulfan, sulfate, and endrin aldehyde
- Developer wanted minimal soil removal to meet septic system requirements

Former commercial orchard (1930’s to 1980’s)
Proposed for residential redevelopment

Eight COPCs:
(Lead, arsenic, dieldrin, DDT, DDE, endosulfan, sulfate, and endrin aldehyde.)

Developer proposed a management criterion with goal of minimal soil removal.
to comply with a local ordinance requiring 2 feet of topsoil above septic systems

No problem. However, will have to balance limited excavation/remediation
with high data quality/analysis/certainty.



Three tiers of risk assessment were performed at Whitebridge. This slides summarizes the results of all 3 tiers … only for ILCR for a **child** resident. Additional receptors (Adults and Construction Workers) and endpoints (HQ and blood lead).

Tier 1 Screening (Entire site) (purple) ➔ 3E-04

CALEPA's Preliminary Endangerment Assessment (PEA) guidance (Screening with conservative default assumptions from RAGs equation). PEA conservative assumptions include **Max concentration** of each COPC **Uniformly distributed** across site Conclusion: Certain COPCs may pose a risk to human health, and further evaluation (Tier 2 assessment) warranted

Tier 2 with Site Specific data (Orchard and Remote Fill Area) assessment

Orchard (blue) (Pesticides Applied) **➔ 9E-05**

Remote Fill (hatched red) (Pesticides Mixed & Equipment cleaned) **➔ 3E-04**

Conclusion: Less risk in Orchard; however, may pose a risk to human health in both areas. Thus, preliminary and site-specific risk assessment both showed potential for risk. What now? RP previously communicated less desirable to remediate… so further evaluation

Tier 3 Probabilistic (Orchard and Remote Fill Area) assessment

- Included bioavailability evaluation

Orchard **➔ 2E-06** ➔ Ruled out/Manageable Risk

Remote Fill **➔ 1E-05** ➔ Potentially unacceptable risk from As exposure

Conclusion: (1) Ruled out risk at part of site (i.e. Focuses CAP/remediation effort)

(2) (Although not shown) Reduced number of COCs.

Arsenic was risk driver with RBCL = 36 mg/kg = **95th percentile** value). Arsenic contributes to over 98% of the non-cancer risk.

Therefore, development of a risk-based cleanup level (RBCL) for arsenic in the remote fill area is warranted.

90% = USEPA level of statistical significance

95% = CALEPA level of statistical significance

- Blood level data developed with CALEPA Lead Spread model

IEUBK = absolute (all Pb sources), assumed bioavailability into bloodstream

Lead Spread = incremental (source only), different bioavailability equation

RAGs (Risk Assessment Guidance)

IEUBK (integrated exposure uptake biokinetic model)

Pb criterion = 10 µg/dL

CA using LEADSPREAD for residential exposure scenarios and

USEPA's Worker Model for Lead Exposures for the commercial/industrial, construction worker, maintenance worker, trench worker...

Sampling (Random + Biased within Grid) - Pesticides were surficial, 0-6", 2 ft if background exceeded (27 ppm As) and deeper sampling

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Summary 1 – Whitebridge, CA

- RA/RM Balancing Act:
  Minimal soil removal vs. Risk analysis effort

- 3 tiered iterative approach
  - Preliminary and site-specific risk assessment ➔ Risk Potential
  - Probabilistic modeling ➔ Reduced areas of concern and COCs
- Clear communication of goals
- Contaminated soil ➔ Roadway fill
  Onsite deed-restricted containment cell

Balance between developer goal of minimal soil removal and risk analysis

Illustrates iterative approach noted in Introduction:

3 Tiers

Preliminary and site-specific risk assessment ➔ Potential for risk

Probabilistic modeling ➔ Reduced areas of concern and COCs

Clear Communication of Goals

Contaminated soil ➔ Innovative management

- Roadway fill
- Onsite deed-restricted containment cell

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Case Study 2 – LUST Site, WI

- Operating gasoline station
- Release discovered during tank system replacement
- Benzene primary COC with 13 mg/kg soil

Leaking Underground Storage Tank system (LUST) site
Operating gasoline station with release from tank system being replaced.

Release discovered during replacement of tank system.

Benzene primary COC with 13mg/kg.

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Case Study 2 – LUST Site, WI

- Benzene concentration exceeded

  Direct-contact (WI)

  [Inhalation and ingestion] (USEPA SSG calculator)

- "Hot spot" beneath dispenser ➔ Barrier cover (2 ft clean soil)

- Institutional control to prevent direct-contact exposure

  "Detailed closure letter"

In contrast to the previous case study, a single Tier used to screen a single Benzene hotspot

That benzene concentration exceeded:

- (Wisconsin) Direct-contact Screening
- (USEPA SSG calculator) Inhalation (outdoor) and ingestion concentrations

<u>Remedial Outcome:</u>

"Hot spot" beneath existing dispenser closed in place with barrier to prevent direct-contact human exposure.

"Detailed closure letter" with land-use limitation required.

- Previously required Deed restriction (superseded by legislative change)
  (a) more burdensome and
  (b) encouraged overly conservative approach

Summary 2 – LUST Site, WI

- Soil sampling
  - Contamination extent and magnitude
  - Not systematic
  - Not supportive of risk assessment
- RA/RM Balancing Act:

  Limited soil data vs. Desire for case closure
- Single "Hot spot" drove management
- LUST sites Risk Assessment

I'd like summarize some points from this case. But ***please don't focus on how you would have done this better, but on the lesson learned from this case.**

This "negative control" case illustrates what happens when small LUST sites (e.g., corner gasoline stations), uses soil sampling focused on extent and magnitude of contamination, rather than systematic sampling to support risk assessment.

At LUST sites RP's desire to close a case is often the trigger for remediation and/or closure plans, risk assessments and associated data collection (i.e. backwards investigation)
- Thus, LUST sites tend to be 'reactive' risk assessments
- Risk management decision made by case officer.

RA Balancing Act of LUST site with soil data inappropriate for risk analysis
And remediation/closure plans presented at closure

In the end a single "hot spot" allowed to drive management of the site. (USEPA calculator accepted data from the single hot spot and could not discounted in the Risk assessment.)

This outcome based on a single soil sample "hot spot" illustrates the need for further development of practical risk management/decision-making processes for petroleum contamination.

Although Risk Resource Team members split as to what to say about conducting RA at LUST sites.
- Some said LUST sites are unique
- A state rep from FL, said no, FL has resources and use RBCA
- WI regulator stated
  a) Not cost effective to perform full-blown risk assessment.
  b) Easier to place an institutional control on site rather than RA.

Case Study 3 – Grand Street, NJ

- > 50 years Mercury gas-lamp & connector-switch production

Peter Cooper-Hewitt, 1902

“ the economy of operation [of a mercury gas light in contrast to an ordinary incandescent lamp] will much more than compensate for the somewhat unnatural colour given to illuminated objects. "

Mercury gas-lamp and connector-switch manufacturer for > 50 years

Cooper-Hewitt Company

The case study describes on-site efforts only

There were also additional off-site cleanup concerns

(When critics said the green-colored light of mercury gas-lamps made people look like "bloodless corpses“)

Peter Cooper-Hewitt, responded that “ the economy of operation will much more than compensate for the somewhat unnatural colour given to illuminated objects. "

“… this [mercury gas] light …has an efficiency at least eight times as great as that obtained by an ordinary incandescent lamp, “

Lack of light from the red end of the spectrum.

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Exposure to Building Residents

- 5-story former industrial building ➔ 16 residences/studios (1993-1995)
- 15/16 conversions completed prior to identification of site-wide Hg contamination in flooring, porous wood, and brick
- Residents relocated (1996)
- Urine analysis found 20 residents (including 5 children) with Hg levels of concern for neuro- and hepatotoxicity
- Superfund site

5-story former ➔ 16 residences/studios
industrial building (1993-1995)

15/16 conversions completed prior to ID of site-wide
Hg contamination in flooring, porous wood, brick, and tar.
(Resident was cooking and Hg dripping onto stove)

Residents relocated (1996)

Urine analysis found 20 residents (inc. 5 children) with Hg levels of concern for neuro- and hepatotoxicity

Balancing consideration is that site was Superfund Site

➔ USEPA lead rather than NJDEP

Standard risk assessment

The circus was in the NY-NJ area October 2008 and you can see Nik Wallenda, seventh generation of the Flying Wallendas circus family, walks on a wire 12 stories above the street in Newark, NJ

Different Criteria

Criteria	EPA Region II	NJDEP Site Remediation
Baseline HH RA Required (Human Health Risk Assessment)	Yes	No
Risk Range - Carcinogen	$1x10^{-4}$ - $1x10^{-6}$	$1x10^{-6}$
Hazard Index - Noncarcinogen	1	1
Surface vs. Subsurface Distinction	Yes	No
Depth of Delineation (RDC)	Typically 0-2' for residential	"to a clean zone" regardless of depth
Discrete vs. Composite Surficial Sampling	Both	Discrete only
Grid or Biased Sampling	Either (Gridded)	Biased only

In this slide you can see the results of having two regulatory agencies. Otherwise a conventional risk assessment. USEPA Region II lead because Superfund site (true of all Superfund sites in NJ). (NJ conservative due to large number of industrial sites)

- Colored boxes with red text indicate decisions used in this cleanup.
- As you can see a mixture of two cleanup criteria

Thus, explaining the variation between criteria at this site and

A) others in NJ or

B) states in USEPA R2

HHRA Human Health Risk Assessment

– Not required by NJ statute. NJ Would require comparison screening.
  Done because superfund site with EPA lead

Carcinogen Risk – Nonissue for elemental Hg (would be for methyl-Hg)
NJ does not accept a range

Hazard Index - Same

Surface vs. Subsurface -Typically NJ = 0-2' for residential **direct exposure.** However, NJ required delineation to lower number, 23 mg/kg, throughout site. Drove development of risk-based 520 mg/kg

RDC NJ always required delineation, not always remediation.
NJ has "deed notice"

Sampling - NJ discrete sampling rather than gridded because proscriptive due to industrial sites.

--Gridded vs. Biased – NJ uses Biased because proscriptive (Although in this case gridded due to diffuse nature of a contaminated building)

--NJ concurred with approach. Although extensive (minimum) technical sampling guidance, **variance** route allows other approaches (i.e. large industrial site "back 40")

Additional Questions? Contact Frank Camera , NJDEP

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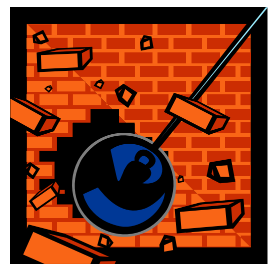
Sampling, Goals, and Remediation

- Surficial soil cleanup goal = 23 mg/kg Hg (2003)
  Soil ingestion + protective of inhalation
- Subsurface soil cleanup goal = 520 mg/kg Hg (2004)
  Protective of utility workers
- Remediation = demolition, excavation, and off-site disposal of contaminated soil and building debris



Iterative approach (Balancing theme)

Surficial soil cleanup goal = 23 mg/kg Hg (2003)

Level is protective of exposure from both inhalation and Soil ingestion

Subsurface saturated soil cleanup goal = 520 mg/kg Hg (2004)

Protective of utility workers

Shallow groundwater table

(ESD – Explanation of Significant Difference)

Remediation = Building torn down. Indoor air objective could not be achieved.

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Summary 3 – Grand Street, NJ

- RA/RM Balancing Act:
  Two regulatory authorities (USEPA and NJDEP)
  Two set of criteria
- Acute hazard
- Remediation = demolition
- Redevelopment

Balance between two regulatory authorities

Superfund Site ➔ USEPA lead

Two sets of cleanup criteria

Acute hazard to existing residents made screening moot

Remediation = demolition

because indoor air objective could not be achieved.

Epilogue – Redevelopment is planned

You can see the real reason Nik Wallenda walked the high wire in NJ,

So he could pedal back and set a Guinness World Record for the longest distance and greatest height ever traveled by a bike on the wire.

(Seventh generation of the Flying Wallendas circus family, 12 stories above the street in Newark, N.J., Wednesday, Oct. 15, 2008)

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Summary Table 1 – Site Information

Site	COC	Acres	Former Land Use	Future Land Use
Whitebridge, CA	Pesticides	184	Commercial orchard	Residential (future)
LUST Site, WI	Benzene	0.70	Gasoline station (currently operating)	Industrial (ongoing)
Grand Street, NJ	Mercury	0.34	Hg gas-lamp + switch manufacture	Residential (current)
Evergreen, WA	Lead	4	US Army firing range	Residential (future)
Spring Valley, DC	Arsenic	0.25	USDOD chemical warfare testing	Residential (current)

I'd like to summarize the information from this Module

I'm going to include some information about all 5 sites in

A) The Overview Document: Use of Risk Assessment in Management of Contaminated Sites

B) They also are compiled into one PowerPoint presentation which you can access from the Clu-in website "Links" page.

Look for "ITRC PowerPoint presentation with the supplement to today's training with slides describing all 5 case studies"

Looking down the columns of information you can see the variation among the sites:

- COCs

Background an issue/high (As) to nonissue/low (others)

- Size

Small to Large

- Former land use

Private or Fed (jurisdiction)

- Future land use/Exposure scenario

Note that two sites were currently occupied by residents

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Summary Table 2 – Risk Assessment

Site	Risk Assessment
Whitebridge, CA	• 3 Tiers (Preliminary, Deterministic, and Probabilistic)
LUST Site, WI	• 1 Tier (No site-specific RA. Screening Level = Cleanup Level) • State and USEPA risk-based screening values
Grand Street, NJ	• 2 Tiers • Both USEPA R2 and NJDEP criteria
Evergreen, WA	• 1 Tier (No site-specific RA. Screening Level = Cleanup Level) • Triad. Statistical criteria
Spring Valley, DC	• 2 Tiers • Integrated into risk management. Community participation

Think back to Marty's slides and her discussion of Tiers in Module 1.

Different number of Risk Assessment (RA) Tiers

LUST Site, WI - Voluntarily used State and USEPA risk-based screening values were used (USEPA Soil Screening Guidance (SSG) Calculator)

Note that use of 1 Tier of screening values may not preclude detailed analysis.

Evergreen, WA site, a site we did not have time to cover also used, only used 1 Tier; however supporting the decision-making with a statistically-based approach as part of **Triad.**

Grand Street St – Superfund status compelled use of USEPA criteria; however hybrid of USEPA and NJDEP values and approaches

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Summary Table 3 – Risk Management

Site	Risk Management
Whitebridge, CA	Developer + PRA → Limited soil excavation (and costs)
LUST Site, WI	Hot spot beneath dispenser closed in place with barrier Detailed closure letter with land-use limitation
Grand Street, NJ	Demolition, excavation and off-site disposal New residential development planned

Evergreen, WA	Quick reuse desire balanced with soil management Soil excavation balanced by RA
Spring Valley, DC	Integrated into risk assessment Community participation

Preliminary Risk Assessment (PRA)

Risk Assessment (RA)

Conclusions

- Risk assessment and risk management balancing act
  - Players
  - Iteration
  - Data
  - Communication
  - Variation
- Programmatic and Technical rationale ➔ Variation
- Transparency is important

"Everyone is on board!!"

Risk assessment and risk management balancing act:

"Players" (Whitebridge)

Iteration (Grand Street)

Data (LUST and Whitebridge)

Communication (Whitebridge)

Variations (All)

Important to make sure **"Everyone is on board!!"**

Variation in risk assessment practices due to
programmatic preferences or in technical differences of opinion.
- Grand St (EPA vs. NJ)

- Thus transparency important

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First Question and Answer Break

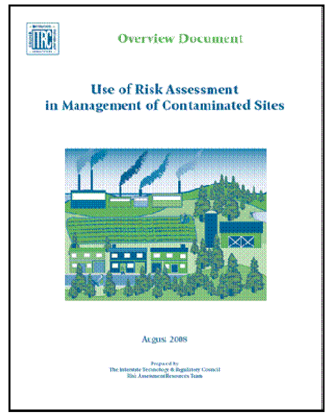
Module 1 –Theory and Practice of Risk Assessment: Important Issues

Module 2 – Actual Case Studies (Retrospective Studies)

First Q&A

Module 3 – Comparative Case Studies (Hypothetical Studies)

Module 4 – Perspectives, Summary, Recommendations



No associated notes.

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Use of Risk Assessment in Management of Contaminated Sites

MODULE 3:

Comparative Case Studies

A Prospective Look

Since we can't relocate any of the sites discussed in Module 2 to other "venues" to observe how the "outcome" might vary, or to observe how the significant steps in the risk assessment practice relates to risk-based regulations may lead to different risk management "outcomes", we developed two hypothetical sites to examine this phenomenon. You will see in this Module how some of these factors are affected more than others. To date, we are not aware that anyone that has examined this before.

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Module 3 Learning Objectives

We will examine how the regulatory "venue" impacts "What" the variations are and "Why" for:

- Numerical risk-based cleanup criterion
- Sampling activities and data use
- Risk assessment practices and risk management options

Here, we are focusing on the regulators' contribution to the "players" identified previously in the risk assessment process. By "venue", we mean the regulatory framework that a site falls under, whether it be state-specific, agency specific, or program specific within an agency. Keep in mind that the regulatory "venue" incorporates both regulatory AND technical guidance and policy, and in some cases where little regulation or guidance exists, it also incorporates best professional practices. For further details specific to the regulatory or regulated participants, please refer to our Overview Document.

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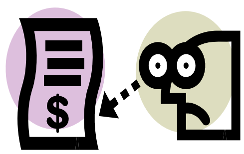
Comparative Studies – Introduction

- Two hypothetical "simple" sites
  - 1 vs. 3 contaminants
  - 'Real' data sets
  - Soil contamination of limited depth
- Standardized questionnaire
- Comparative analysis of responses



What would merit risk management?

The approach to our comparative case studies is KISS: "Keep It Simple Stupid". As you will see by the end of this module, had we not kept it simple, we would not be able to present the results meaningfully.

In the end, we do all these activities of characterizing the contamination, interpreting the data, and writing reports. But when the day is done, was remediation required, was only an institutional control needed, or was no action needed?

Case Study 1 Participants

- Alabama
- Alaska
- California
- Florida
- Georgia (2)
- Massachusetts
- New Jersey
- Tennessee

For specific regulatory requirements and technical guidance with regard to individual states, please contact the corresponding representative listed in our document, “Use of Risk Assessment in Management of Contaminated Sites”.

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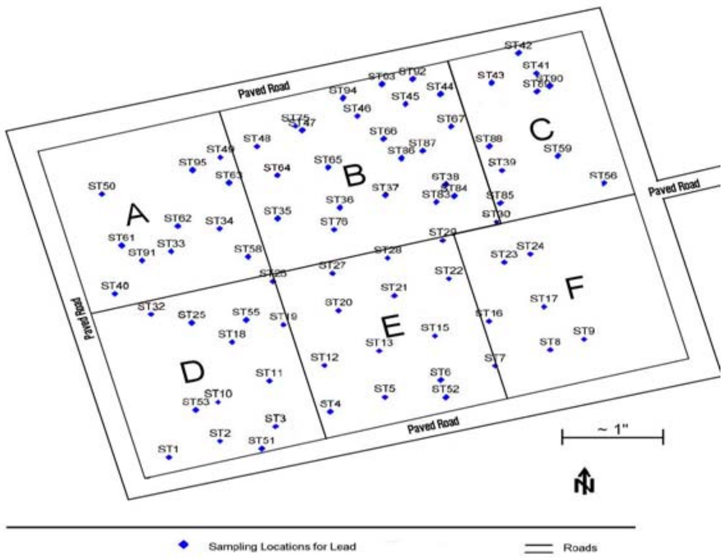
Comparative Study #1



The hypothetical site constructed for the first comparative case study is a former skeet range that is proposed to be developed into a 6-lot residential neighborhood. The former skeet range was sampled at 77 locations for **lead**, for which level varied in soil across the six residential lots. Soil samples were taken from 0”-6” and 6”-12” at each sampling location, and occasionally a third sample was taken 2’ below ground surface. Some duplicate samples were included in the data set. USEPA Method 6010/6020 was the method used to analyze samples, and analytical results were provided. 170 measurements of lead in soil from 77 sampling locations distributed across approximately 1.2 acres, along with a plan for development that would eventually provide six residential lots. Leachibility of lead was provided as a factor which had adequately been evaluated and eliminated from concern.

Participants were asked to complete the case study in the prospective mode—describing what options might be acceptable, and what the preferences and requirements (sampling, removal, etc.) might be for those options.

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Lifecycle Numerical Criteria

Stage	Default Criterion	Site-Specific Criterion
Preliminary Investigation	X	
Remedial Investigation	X	X
Risk Assessment	X	X
Feasibility Study	X	X
Remediation and/or Monitoring	X	X
Confirmation	X	X

75, 150, 300, 400

IEUBK, Adult Pb Model, State-specific Pb Model

The case study respondents were asked to identify the numerical criterion (or criteria) that would be used to evaluate the contamination, given that a residential development would be a future residential exposure scenario, that is applicable for lead in soil throughout the various stages of case development.

The default criterion ranged from 75 to 400 mg/kg, with the latter being the most common among regulatory "venues". All default criterion were based upon USEPA or state-adopted pharmacokinetic model for soil screening levels. Some states require the default criterion to be followed throughout all or some stages of the site's lifecycle, while others allow for selection between the default or a site-specifically determined criterion. The site-specific criterion was either based on some form of site-specific input into a pharmacokinetic model, risk assessment, or risk management implementation. It is important to understand which parameters or methodology a regulatory "venue" will allow site-specific changes in.

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How is the Data Evaluated?

Factors	Range of Responses
Lots: individually vs. all together	Agency-dependent; occasionally program dependent
Exposure unit	Per lot; site-specific; not applicable
Horizontal and/or vertical averaging	Horizontal, typically yes; vertically, yes when a discrete zone is defined
Shallow vs. subsurface soil	Shallow: 0”-6” up to 0’-15’ Deep: 1’ ranging to NO limit
Composites	Yes; no; site-specifically determined
Duplicates	Average; just QC; highest; treated as segregate sample

Because there are numerous methodologies and approaches, as well as regulatory “venue” dependent requirements, this set of questions elucidates the factors which will result in different risk management outcomes for a single site. For individual state responses, please refer to our ITRC document.

Lots: individual or together? The basis varied with the state agency but included dependency upon lot legal descriptions, whether contamination is due to a single source, and whether the exposure area could be defined site-specifically. This provides a big impact on what the exposure concentration will eventually be, i.e., either all 170 data points are used together by some methodology, or individual lots of 6 – 23 samples would then defined the lead concentration. This factor is further impacted when the regulatory “venue” allows 2 sample depths vs 3 samples depths as accepted data points for defining the lead concentration. We’ll see this result later in the Exposure Point Concentrations (EPC) table.

Exposure Unit (EU) is explored to see if it correlates to the concept of how data is evaluated. This is important because the EU defines the area throughout which (in this case of the residential scenario) chronic exposure is assumed. The concentration used when quantifying the risk to a receptor across an EU should be an estimate of the true average concentration for a chemical within that EU. This concentration is referred to as the EPC. As it turns out, the EU is not always the same as either the individual lot or the entirety of the former skeet range. In the case where the EU was not applicable to the determination of the EPC, the state program did not allow averaging. In one state the default EU for a residential lot is defined as ¼-acre.

Averaging: Not surprisingly, all states allow for some form of **horizontal/lateral** averaging of data points (typically the 95% UCL), from a defined soil interval. The one exception was the “venue” where averaging was not allowed because all sample points must comply with the clean up criteria. In another regulatory “venue”, averaging could only be done over ¼-ac defined as the default residential averaging area. Interestingly, only 2 regulatory “venues” distinguished averaging as only over the “contaminated” area, regardless whether it correlated with the residential EU. **Vertical**: Responders from states with a practice of identifying discreet zones or depth intervals generally allow averaging of results throughout that interval, but not across depth intervals.

Shallow vs. Deep: This is relevant in the context of direct exposures to contaminated soil for risk evaluation, which may be defined differently for characterization purposes. At some depth soils are unlikely to be brought to the surface and redistributed for future direct contact exposures. These depths are dependent on human behavior and construction activities. Conveniently, most regulatory “venues” quantitatively define “shallow” vs. “deep” soil. **Shallow**: Depending upon the regulatory “venues”, up to 3 zones can be defined for shallow soil, and some are dependent upon the state of construction, land use, or vertical extent of contamination. Noticeably, the first 6” is typically part of all “shallow” soil zones, leaving the floor on shallow soils as venue-dependent. Regarding “**deep”** soils: the beginning of this interval is usually where the “shallow” left off, the limit typically being set at the water table. However, this is also venue-dependent: 15 feet in one case, and undefined in others.

Composite sampling provides a physical approach to determining an average value throughout an EU or volume. However, it has the disadvantage of not allowing a statistical determination of variance and hot spots. This factor in data evaluation is extremely venue-dependent. **In many circumstances, compositing is discouraged** and perhaps not allowed because it might “miss” something. However, in some other circumstances compositing is allowed and even facilitated (see ITRC document for guidance available from Alabama).

Handling of Duplicates: This aspect of data evaluation has its basis in the usually high variability of chemical concentration “agreement” measured in soil aliquots in close spatial proximity. Whether this is due to the soil characteristics itself, the sampling process, or fate and transport processes, the handling of duplicates presents a regulatory “venue-dependent” variable. In some instances duplicate samples are allowed to be averaged, while others required treatment of each sample as unique and segregate. In other venues, the highest measurement is the one evaluated. In some venues duplicates would be used for QA/QC purposes, but evaluated further for potential “hot spot” identification.

Let’s take a look now at how the regulatory “venue-dependent” variability in these various factors influence the determination of the EPC.

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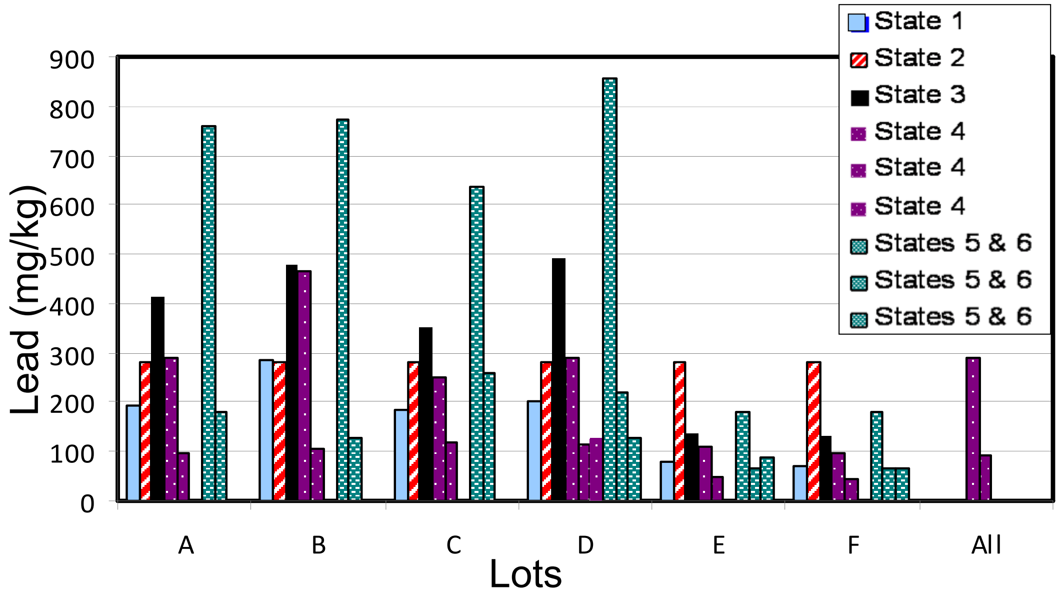
Exposure Point Concentrations (EPCs)



Some states do not calculate an EPC, as each data point must be considered separately.

The EPCs shown above are color-coded by the state that determined the value.

Two states, 5 and 6, were identical in the values calculated for the EPCs.

In some cases, like States 1, 2 and 3, only one EPC was determined per lot. Note that the EPC is the same for each lot for State 2 in red.

Other states, provided two and sometimes three EPCs per lot representing more than one soil interval, as noted by the number of bars having the same color, which is seen in States 4, 5, and 6.

To illustrate the range of EPCs which can be determined, the maximum concentration occurred at Lot D (857 mg/kg – teal high bar for States 5 and 6). In that same lot, the lowest concentration is 116 mg/kg – purple low bar for State 4.

Within any single lot, the magnitude of variation in the EPC did not exceed 7.4-fold between different states.

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EPC Points of Interest

- EPC not derived: every point is considered
- ProUCL 95% UCL
- FL UCL 95% UCL
- Simple average
- All data pulled
- Individual lots
- Interval-dependent

No associated notes.

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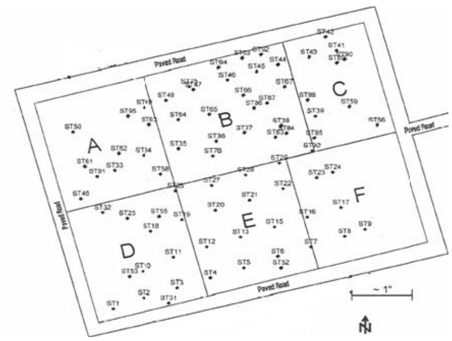
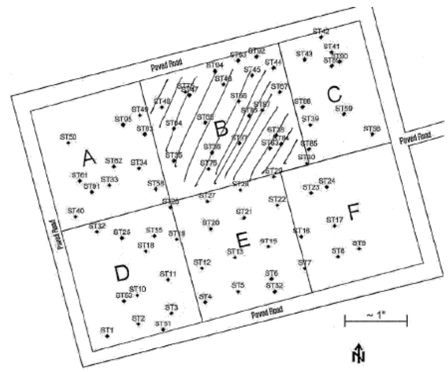
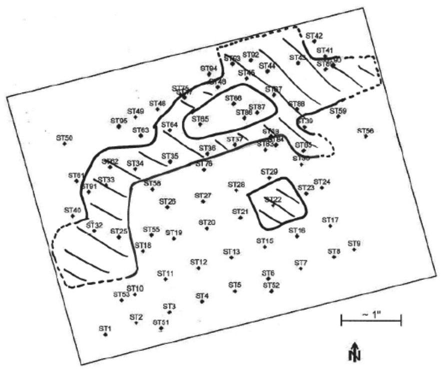
Risk Management Outcomes

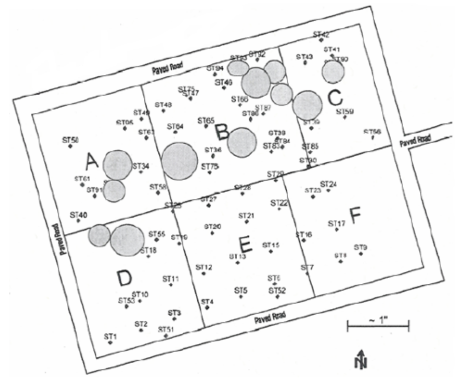




No associated notes.

Risk Management Outcomes





No associated notes.

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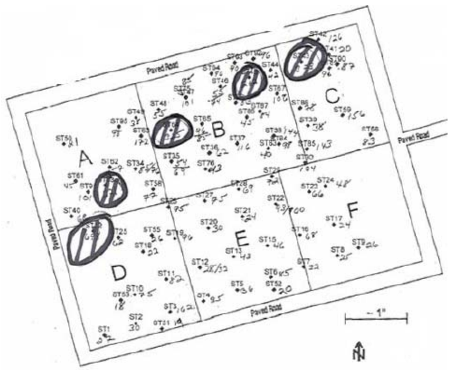
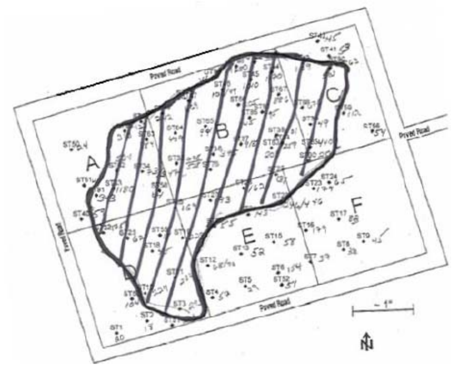
Risk Management Outcomes



6” – 12”



0” – 6”

Please keep in mind that risk management options are not limited only to excavation.

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Additional Risk Management Options

- Potentially Responsible Party's (PRP's) excavation choice provided confirmation sampling proves 95% UCL ≤ numeric action level
- Capping combined with institutional control (deed)
- Additional delineation
- Relocation under buildings
- Removal of contaminating material (Pb pellets)

ANY OTHERS?

What areas of the hypothetical site would merit risk management?

Approaches to this answer varied. Most state responders identified areas bearing risk management based on hand-drawn contours and circles.

One venue-dependent option was to calculate "new" 95% UCLs resulting from "virtual remediation" to determine when/where the 95% UCL would be reduced to or below the numerical criterion. However, the areas of risk management within the EU are left up to the site to determine. Following risk management elections, appropriate numbers of confirmatory samples would need to be taken to verify compliance with the applicable lead criterion.

The largest area identified meriting risk management occurred where the numerical criterion for lead was lower than other regulatory "venues".

Other regulatory-dependent options included no excavation required, and application of engineering and/or institutional controls.

So, now let's summarize what we've learned from the first prospective comparative case in the next slide.

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Comparative Case #1 – The “Points”

- The EPC is greatly impacted by “venue” variability in the data evaluation factors examined
- The “final” goal or regulatory numerical criterion which the site must meet, is also “venue-dependent”
- Everything from “no remediation” to remediation of almost the entire hypothetical six-lot residential development can be the outcome

The determination and implementation of the EPC is key to understanding “venue-dependent” variability. We’ve seen how data can be treated as the grouped vs single point depending on the stage of the site’s lifecycle. As is expected for most states, early in the investigation a single measurement can be evaluated relative to the numerical criterion. As more measurements are made during the remedial investigation (RI), risk assessment (RA), and feasibility study (FS), most regulatory venues deem it worthy to group the data in some manner, such as an EPC, to compare against the numerical regulatory criterion. Only in the later stages of remediation monitoring and confirmation of remediation, do we see a few regulatory “venues” convert back to the single sample basis of comparison to the regulatory numerical criterion.

This results in the enormous variability in the remedial outcome, and sheds light on “why” you can not expect a hypothetical site, if moved from one state to another state, to be treated identically.

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Comparative Case #2 – Introduction

Variable	Comparative Case 1	Comparative Case 2
Numerical Criterion	Venue-dependent	Uniform
Land Use	Future residential	Pre-existing school, residential, commercial
Contaminants	One (Pb)	Three (As, Cu, Pb)
Data Handling	Venue-dependent depth and averaging	Fixed depth and averaging; background

Objectives: To eliminate to the extent possible, regulatory-dependent influences in the risk-based evaluation and management process

1 - how do states deal with synergism/multiple contaminants,

2 - current residence versus future residence,

3 - how is 'background' included in risk assessment.

Many of the parameters allowed to vary in the first comparative case study were fixed for conducting the second comparative case study. For example, it was presented as an existing developed area having fixed lot sizes and boundaries, fixed locations of surface structures, fixed land use, fixed screening values, fixed background levels, and a fixed restriction of contamination to surficial soils.

The goal: to discern what regulatory factors remain, as well as technical factors, which influence the outcome of what would require remediation.

To specific about Case #2, it consists of nine lots that have land uses as either residential, commercial or an elementary school. The chemicals released were arsenic, copper and lead, which were distributed throughout this area of an existing community. Contaminant migration occurred via rainfall-entrapped deposition of suspended particulates, surface water runoff, airborne particulate settling, and human trafficking in and among the affected areas. All direct contact routes of exposure are complete. The leaching to groundwater pathway has been eliminated. No surface water bodies are present. No edible crops are cultivated on these or adjacent properties. All properties were affected over the same release period. Sampling has been conducted at accessible locations where a surface structure did not impede sample acquisition. All contamination is limited to surficial soil. Here, surficial soil is defined as that depth which meets current state requirements. Concentrations are given for surficial soil at that location. Lots are all approximately ½ acre, except Lot 7 which of ¾ acre where the school is located.

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Comparative Case 2 – Participants

- Alabama
- Alaska
- Arizona
- California
- Florida
- Department of Defense

No associated notes.

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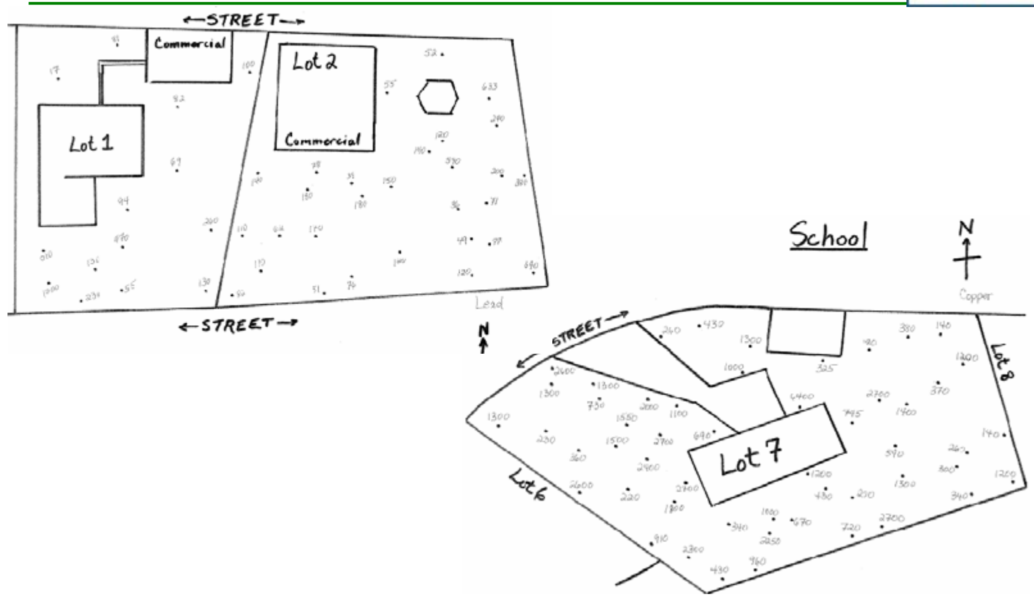
Comparative Case #2 – Example Lots



Describe the site story.

65

Approaches to Data Use and Needs

- Exposure Unit: individual lots
- Composites: not allowed or considered equivalent to average concentration
- Sampling density was typically adequate

Exceptions

1 – values at boundaries exceed adjacent land use criteria

2 – location exceeds background or screening level

Lot	N	Lot	N
1	14	6	34
2	29	7	52
3	16	8	34
4	17	9	18
5	30		

Lots treated separately vs aggregately? This focuses on the concept of the EU. **The EU is either driven by regulations or the Conceptual Site Model (CSM).** Lots are treated separately with one exception, in one "venue" combining adjacent lots if allowed if owned by same owner, or future use. This did not vary regardless whether the case was in the initial characterization stage throughout the remedial or risk management stage. Had the case study involved 50 lots instead of just 9 lots (vast increase in areal extent of the project), all lots are considered their own EU (based on ownership or legal description), with one exception. One "venue" allowed for aggregate treatment of lots due to the magnitude of the project. The last finding from the study was that more one EU within a lot was typically not accepted, with exception occurring only if site-specific uses within that lot supported more than 1 exposure scenario.

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Initial Screening

- Initial screening uses the maximum concentration *

Predetermined Screening Levels

Chemical	Residential	Commercial	Background
Arsenic	1.0	2.0	10
Copper	1,150	3,000	100
Lead	200	800	18

* Exception

Cu – maximum when child is present (acute toxicity)

Pb – maximum, average, or 95% UCL

As – maximum or 95% UCL

{As, Pb must use maximum if > 3x screening level}

Initial Screening Stage: Not only are all sampling and data points considered individually, the maximum concentration for each lot is selected from among them in order to screen out chemicals or lots from further consideration. Neither the 95% UCL or arithmetic average can be used for this purpose. This aspect is apparently not "venue-dependent". There is one exception for one state regarding lead and arsenic (see Overview Document). No venue allows for conducting a risk assessment as part of the initial screening.

Initial Screening Results: Because so many similar technical approaches are shared by the various "venues" (except one), the lots which would be screened out or the chemicals which would be screened out would be expected to be reproducible. However, this is not the case. The different outcome for initial screening was dependent upon whether the "venue" utilized "residential" screening criteria vs. "commercial" screening criteria.

EPC: The EPC is typically determined after the initial screening, and overwhelmingly, the 95% UCL represented the EPC (copper and lead were the only single venue-dependent exception).

Initial Screening Results: Because so many similar technical approaches are shared by the various "venues" (except one), the lots which would be screened out or the chemicals which would be screened out would be expected to be reproducible. However, this is not the case. The different outcome for initial screening was dependent upon whether the "venue" utilized "residential" screening criteria vs "commercial" screening criteria.

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Results of Initial Screening: What Failed

Despite similarities, initial screening was not identical

Group	As/Cu/Pb	As/Cu	As
A	1-9	----	----
B	1, 3-8	2	9
C	1-9	----	----
D	1, 2, 4-8	3	9
E	3-5, 8	6, 7	1, 2, 9
F	1-9$_{\text{(residential)}}$ vs. 1, 2, 9$_{\text{(commercial)}}$		

Group: Indicates the regulatory group or the regulated group (Tri-Services).

The numbers indicated in the table are the lots which failed initial screening for the chemicals indicated.

Initial Screening Results: Because so many similar technical approaches are shared by the various "venues" (except one), the lots which would be screened out or the chemicals which would be screened out would be expected to be reproducible. However, this is not the case. The different outcome for initial screening was dependent upon whether the "venue" utilized "residential" screening criteria vs "commercial" screening criteria.

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Approaches to Data Use and Needs

THE GOLDEN RULE

“EPC = 95% UCL*”

EPC: The EPC is typically determined after the initial screening, and overwhelmingly, the 95% UCL represented the EPC (copper and lead were the only single venue-dependent exception).

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Risk Assessment: 2º Screening

- Risk assessment is a valid consideration for each lot
- Did a reverse risk assessment eliminate any lots or chemicals from further evaluation?

	Residential		Commercial	
Chemical	10^{-6}	HI = 1	10^{-6}	HI = 1
Arsenic	12	33	48	390
Copper	----	3,100	----	5,800
Lead	400		1,000	

Answers

- No, site-specific risk-based levels not used for 2˚ screen
- Pb only allowed (Lots 1,4,6,7)
- Pb, Cu (Lots 1,2,4,6-9) and Cu (Lots 3,5)
- Pb, Cu (Lots 4,5) and Pb (Lots 7,8)

While some venues allowed a site-specific risk assessment to further screen chemicals and lots, not all did. Some required a chemical, though it passed this secondary screening, to be carried throughout the evaluation to account for cumulative considerations. One venue allowed Pb to be screened out further, but not As or Cu. While other venues simply don’t allow it at all to substitute for a cumulative forward risk assessment. This variability results in some chemicals added to or screened out from the final determination of the resultant ELCR or HI.

Hazard Index (HI)

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Excess Lifetime Cancer Risk

Lot	Min	Max
1	1.4×10^{-6}	1×10^{-5}
2	1.4×10^{-6}	1×10^{-5}
3	7.3×10^{-6}	7×10^{-5}
4	4.5×10^{-6}	5×10^{-5}
5	6.5×10^{-6}	7×10^{-5}
6	5.3×10^{-6}	7×10^{-5}
7	6.5×10^{-6}	7×10^{-5}
8	9.5×10^{-6}	1×10^{-4}
9	1.2×10^{-6}	1×10^{-5}

Based on these different factors we've discussed, regarding risk assessment approaches, it is not too surprising to see that the calculated levels of ELCR and HI were not identical.

Some of the participants calculated identical ELCRs. However, it was never the case that all groups unanimously determined the final risk estimate to be the same for a single lot. This table demonstrates the range in ELCRs calculated. As you can see, we can have as much as one order of magnitude difference.

For Lot 7, the school, one group could not determine an ELCR, as it would require further site-specific conditions to be considered.

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Hazard Index (HI)

Lot	Min	Max
1	0.59	2.0
2	0.47	2.1
3	1.8	3.23
4	1.6	2
5	2.4	3
6	1.2	3.04
7	2.4	3
8	1.5	4
9	0.22	1

A similar phenomenon, as seen in the different ELCR values calculated, is also seen in the determination of the HI.

Lot 7, the school, was again not determined by one group due to the requirement for site-specific considerations.

However, we did see that one group did not calculate HI's for Lots 1, 2, 4, 5, and 9 because the non-carcinogens (Cu) had been screened out and the non-carcinogenic contribution of arsenic was not evaluated.

Risk Assessment Approaches

- Lead was always considered separately
- Non-carcinogenic effects of arsenic were always evaluated, except in one venue
- Additive effects are known for As and Pb
  - Qualitative rather than quantitative consideration is given
  - Its use in setting risk management goals are variable
- Background metals
  - Typically not quantified as part of the final risk estimates
  - Sometimes quantified but used only in risk management decision-making
- School evaluation is highly “venue”-dependent
  - Child Lead Model; treat as residential; site-specific parameter values in RA

Now let’s summarize the points that regulatory “venues” have in common and which differ once we have eliminated or “ubiquitized” some regulatory factors.

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Comparative Case #2 – The “Points”

- All venues concluded that site-specific risk assessment afforded different risk management decisions, including different remediation
  - Portions of lots based on site-specific exposure units and exposure point concentration
  - Dependent upon desires of the remediating party
- When most regulatory-specific factors are eliminated, few technical practices vary
- Variations exist because of lack of guidance

The end use of a risk assessment is to inform risk management decisions. Only one respondent provided a map of the areas meriting risk management. In part this is due to the complexity of the data set, with many sampling points provided. However, it also reflected the available options for risk management decisions which are possible. It is also not clear how multiple compounds having potentially additive or synergistic might be quantitatively evaluated. This might be due to a lack of guidance or modeling available. In many cases the data would be worked up and provided by the responsible party, proposing the remedial decision. The latter must meet agency approval and compliance with the numerical criterion.

Of particular interest was to see how regulatory ‘venues’ address an exposure scenario involving a school. A range of approaches were described, ranging from a school-specific model to utilizing residential exposure scenarios. Interestingly, responders indicated that adults—construction workers, landscapers, and teachers—might end up being the more sensitive receptors than students.

A clear conclusion is that risk assessment affords different risk management decisions, including different remediation. And that the outcome is markedly different had the risk assessment not been conducted.

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Comparative Cases 1 and 2 Summaries

- Identified regulatory and technical variations
  - Exposure unit determination
  - Data and EPC evaluation
  - Background
  - Risk-based numerical criteria and their application throughout site lifecycle
- Regulatory-dependent factors influence the balancing between risk assessment practices and risk management decisions

The Team conducted two prospective comparative case studies. State and federal representatives were provided comprehensive data sets representing soil contamination on two hypothetical sites. The participants were asked to address a series of common—and significant—questions that come up when conducting risk assessments at contaminated sites. This allowed a quantitative comparison of approaches among regulatory 'venues'.

The comparative case studies probed issues and complications faced quite frequently by regulators and end-users of risk assessment information. These issues included the non-uniformity between regulatory 'venues' for numerical criteria, how to evaluate exposure units, how to evaluate soil sampling results, how to determine the EPC, and how to compare the data (each sample point or grouped EPC) to the numerical compliance criteria. The most significant complications in risk assessment occur in non-regulatory or technically-based issues: adequacy of sampling, background concentrations, chemical screening practices, potential additive effects, school exposures and risk management.

This demonstrates that risk assessment practices have to be flexible enough to accommodate fixed regulatory rules and technical requirements, using sound science, to desired risk management outcomes of end-users and stakeholders.

Use of Risk Assessment in Management of Contaminated Sites

MODULE 4:

Perspectives, Summary, and Recommendations

No associated notes.

Learning Objectives

In this module we provide:

- Perspectives – of regulators, the public, and end users (Chapter 6)
- Key Findings - from Case Studies (Chapter 7)
- Recommendations (Chapter 7)
- Result: A Suggested Improved Process of Using Risk Assessment in Risk Management (Chapter 7)

No associated notes.

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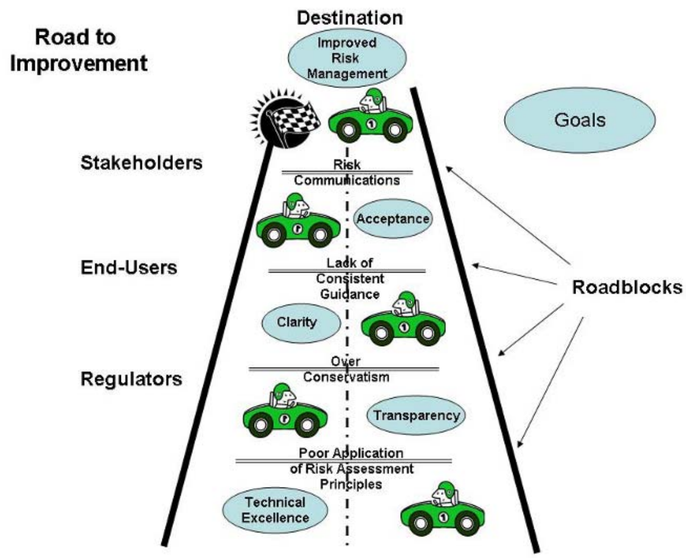
Perspectives on the Road to Improvement

Figure 6-1 from ITRC Risk-2



Regulators, stakeholders and end-users team members contributed suggestions from their unique perspectives

Regulators

- How adequate and accurate is site characterization, and how does it inform estimates of risk?
- What methods for site characterization are best suited and produce quality data for risk assessment?

Stakeholders

- Identify early
- Include throughout the project lifecycle
- Communicate effectively and actively

End-users

- Inconsistent practices confound planning and standardization
- Effectively translate uncertainty and variation to users
- <u>Reasonably</u> expected future land use
- When planning, include those using the data to be collected
- Results are more easily understood when their derivation is known

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An Improved Process

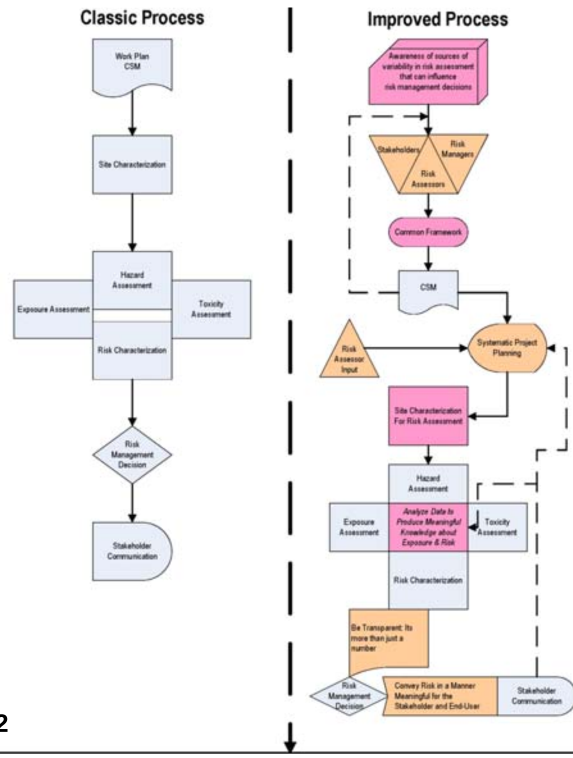

Figure 7-2 from ITRC Risk-2

No associated notes.

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Key Findings

- Selected factors influencing variations in risk assessment
  - Sampling
    - Characterization of “hot spots”
    - Determination of exposure units
    - Use of collaborative data (field vs. laboratory)
  - Treatment of background concentration levels
  - Application of tiered approaches
  - Site characterization
  - Data interpretation
- Simplifying the process (default values, tiers, or flexibility) doesn’t always achieve the desired result
- Range in practice indicates need to improve data collection and interpretation
  - Use of risk assessment principles as a unifying forum

No associated notes.

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Key Findings (continued)

- Use of Risk Assessment in Risk Management of Contaminated Sites – Case Studies
  - Community/stakeholder support can facilitate decisions and implementation
  - Quantity, cost, or time of remediation may be reduced by using risk-based risk management approach
  - Decisions using single discrete samples likely overly restrictive
  - Data collection methods uncommonly used to support risk assessment may be facilitated through careful data quality objective development during project planning

No associated notes.

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Key Findings (continued)

- State Regulators' Perspectives: Comparative Case Studies
  - Variations arise from programmatic preferences or technical differences of opinion
  - Major source of variation how EU is defined, sampled, and evaluated
  - Variation in the application of fundamental risk assessment principles under simple conditions has implications for complicated sites

No associated notes.

Recommendations

- Goal: collapse the fact-value gap between risk assessors and others using these recommendations
- Recommendations:
  - Anticipate decision-maker and end-user needs
  - Be aware of sources of variation in risk assessment
  - Communicate regularly
  - Plan systematically
  - Collect data essential to risk assessment
  - Analyze to produce meaningful knowledge about exposure and risk, now and in the future
  - Clearly inform managers about the risk and how it was assessed
  - Convey risk in a manner meaningful for the stakeholder and end user

A *fact-value gap* often exists between assessors, regulators, stakeholders, and end users

•Risk assessors involved in a fact-intense business

•Stakeholders and end-users are value driven

•Values can and should equally frame the effort

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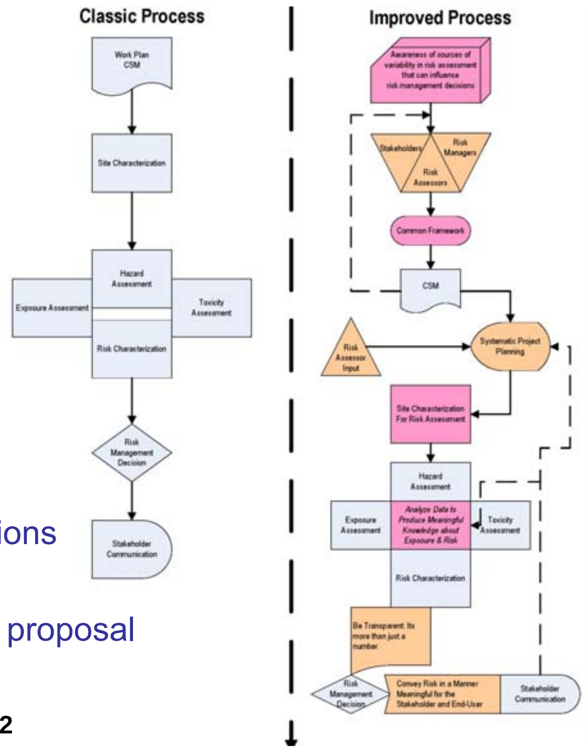
Team Effort



- Perspectives
- Key findings
- Recommendations

- Led to process proposal

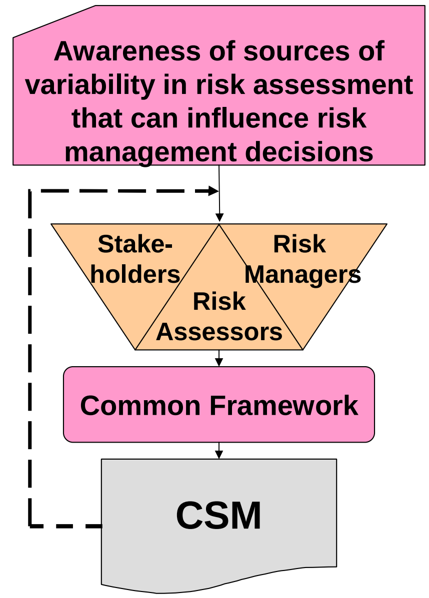
Figure 7-2 from ITRC Risk-2

No associated notes.

From Figure 7-2 from ITRC Risk-2

Awareness

Improved Process



- Variation sources
- Know the “players”
- Communicate
- Common framework
- Iterate, as necessary

Classic Process

The Team revealed sources of variation that can influence the risk management decisions.

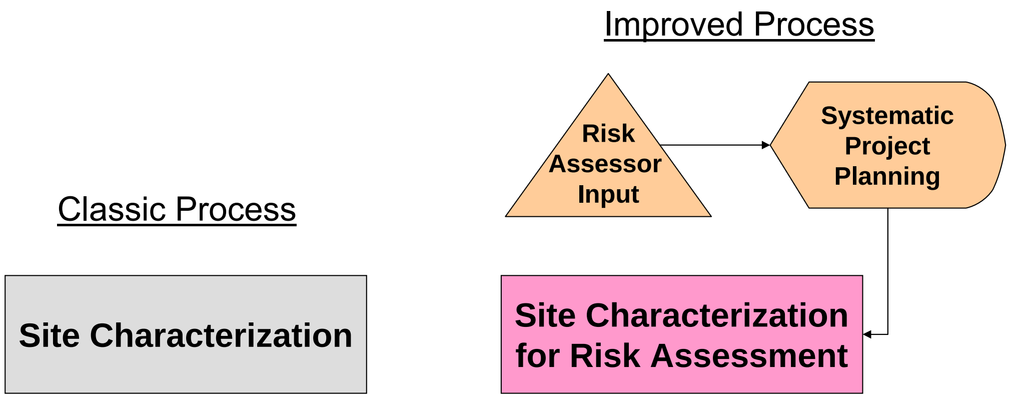
The “players” are those who can directly or indirectly impact the risk management decision.

Communication is key to developing a common framework.

Site Characterization

From Figure 7-2 from ITRC Risk-2

- Plan systematically
- Collect data essential to risk assessment



Systematically planning to incorporate risk assessors' input in the site characterization process assures that the right data is collected to support the risk assessment.

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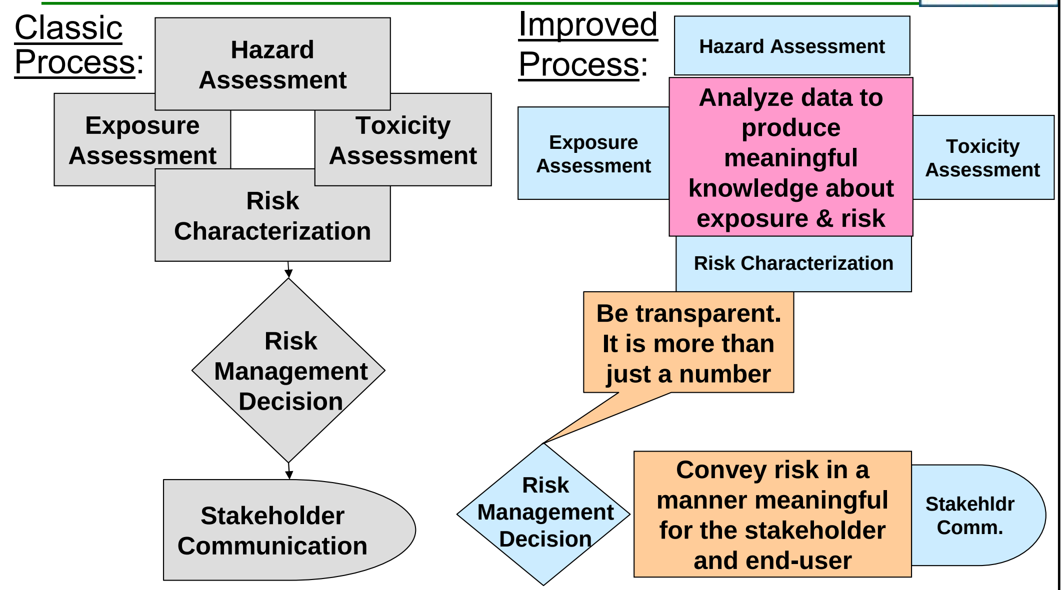
An Improved Process

From Figure 7-2 from ITRC Risk-2



As a result of the Team's key findings, an improved process is proposed assuring that:

•meaningful information is produced about the exposure and risk;

•the process is clear in how the resulting risk estimate was calculated; and

•risk is effectively communicated to all the "players" (stakeholders)

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Thank You for Participating

- **2nd question and answer break**
- **Links to additional resources**
  - http://www.clu-in.org/conf/itrc/risk2/resource.cfm
- **Feedback form – *please* complete**
  - http://www.clu-in.org/conf/itrc/risk2/feedback.cfm

Need confirmation of your participation today?

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

Links to additional resources:
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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