ERT PRESENTS DEVELOPMENT OF ECOLOGICAL PRELIMINARY REMEDIATION GOALS

presented by

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COURSE ***Risk Assessment Guidance for Superfund (RAGS)***

MODULE ***Orientation and Introduction***

TIME LIMIT ***30 minutes***

MODULE GOALS

At the completion of this module, students will be able to describe applicable legislation for U.S. EPA Superfund risk assessments, the development of specific guidance, and the risk assessment process.

STUDENT PERFORMANCE OBJECTIVES (SPOs)

1. Describe the student requirements for the successful completion of this course.
2. Identify the goals and objectives for this course.

ALSO APPLIES TO OTHER REMEDIATION SITES SUCH AS BROWNSFIELDS

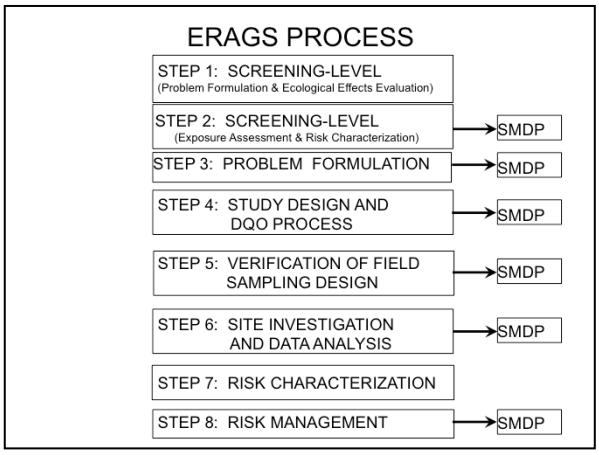
BACKGROUND INFORMATION

ERT PROGRAM TRAINING COURSES

- This training is one module of an ecological risk assessment course which is offered through the EPA training system
- Course Descriptions, Class Schedules, and Registration Information are available at:
  - www.trainex.org
  - www.ertpvu.org

ASSUMPTIONS FOR THIS TRAINING

- First Assumption:
  - Although we are working within the CERCLA or Superfund Program, most concepts and approaches should be applicable or adaptable to other Programmatic or legal situations such as RCRA
  - Primary guidances are from Superfund Program:
    - ✓Ecological Risk assessment Guidance for Superfund (ERAGS): Process for Designing and Conducting Ecological Risk Assessments Interim Final. EPA 540-R-97-006. OSWER 9285.7-25. June 1997
    - ✓Guidelines for Ecological Risk Assessment. EPA/630/ R-95/002F. April 1998



S-4 ERAGS Process

STATE: Here is the 8-step process of the Ecological Risk Assessment Guidance for Superfund or ERAGS again.

CLICK [Steps 1 and 2 are highlighted]

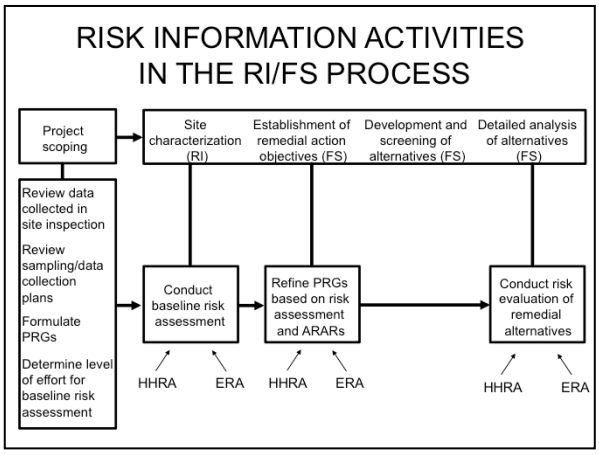
STATE: Let's start with the first two steps of ERAGS, Steps 1 and 2 which make up the Screening Level Ecological Risk Assessment or SLERA

STATE: Steps 1 & 2 are represent an abbreviated consideration of each step of the complete Ecological Risk Assessment Framework.

A SLERA is a simplified risk assessment that is conducted with limited data by assuming values for parameters for which data are lacking. Conservative assumptions regarding the receptors and the contaminants must be as protective as possible. A high degree of conservatism helps to reduce the likelihood that potentially significant risk is overlooked before an in depth evaluation is conducted.

ASSUMPTIONS FOR THIS TRAINING

- Second Assumption:
  - An ecological risk assessment has been conducted (according to EPA Guidance) with a conclusion that ecological risks **do** exist
    - ✓Would not calculate PRGs unless there is a risk and that a remediation is being developed



S-41 2. **Briefly** review the RI/FS process using slide

a. Development of preliminary remedial goals/conceptual model,

b. Conduct baseline risk assessment,

c. Define PRGs based on risk assessment and ARARs, and

d. Conduct risk evaluation of remedial activities.

[click] **State:** Note that HHRA and ERA play equal roles in providing information in the baseline risk assessment.

State: Although human health risk assessments focus on human health issues and ecological risk assessment focus on ecological issues, there are similarities between the two risk assessments.

WHY IS IT IMPORTANT THAT THE BASELINE ERA IS COMPLETED?

- Although PRG development is a Feasibility Study (FS) function, PRGs are often developed and documented while the baseline ERA is being completed
- Also, although PRG development is typically an extension of Step 7 risk characterization, it is still a FS function

PRGS AND RISK ASSESSMENT

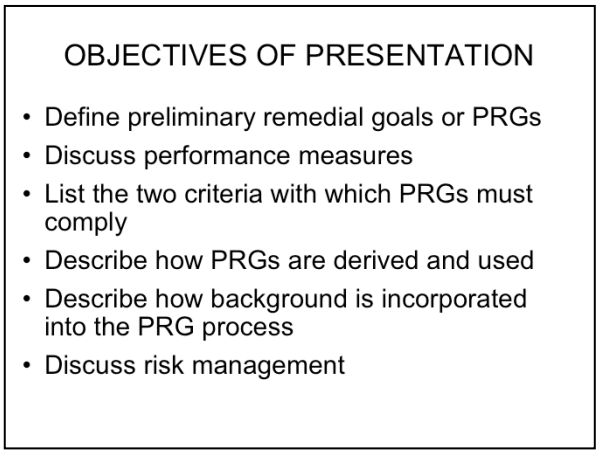
- Under CERCLA (and following ERAGs) the baseline ERA is done to assess current risk “should no action be taken”
- Once there has been the determination (with documentation) that there is substantive ecological risk, under CERCLA, EPA has authority to evaluate remediation alternatives (conduct the FS)
- This means that within PRG development, the ecological risk “evaluations” can incorporate risk management options (follow the ERA guidelines 1998). However, the baseline ERA is completed and should not change based upon the PRG assessments

PRGS AND RISK ASSESSMENT

- The site manager is now at Step 8 of ERAGs and must now select a protective remedy for the site (final site action)
- PRG development uses the site conceptual model from the baseline ERA and may utilize the same or similar techniques but the questions or goals are different

What you can not do is move into the FS, evaluate PRGs and then say, no risk – no remediation.

DEVELOPMENT OF PRGS



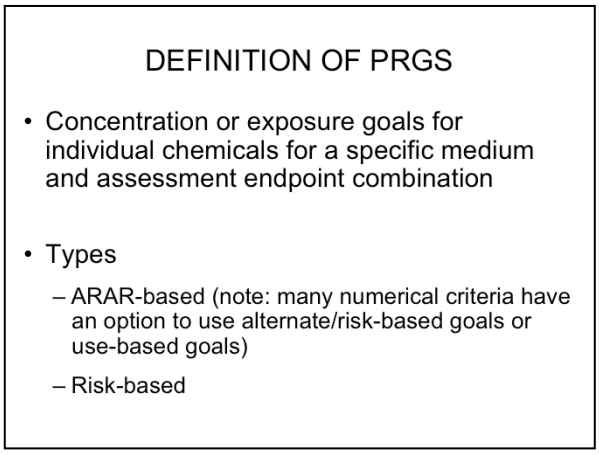
Instructor Note: [click] indicates "clicking" the remote or mouse to display an additional segment of text, a graphic or to activate animation of text or a graphic.

S-2 *Student Performance Objectives*

A. **State** the goal of this module.

At the completion of this module, students will be able to:

1. Define preliminary remedial goals or PRG
2. Describe the guidance associated with the development of PRGs
3. List the two criteria with which PRGs must comply
4. Describe how PRGs are derived and used



S-5 *Preliminary Remediation Goals (PRGs)*

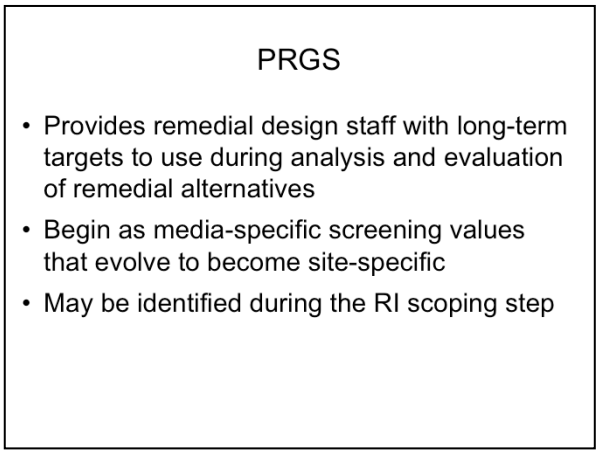
B. **Define Preliminary Remediation Goals or PRGs:**

1. PRGs are concentration/exposure goals for individual chemicals for a specific medium and land use combination.

Assessment endpoint – basically it is what we are trying to protect . For example, fish, invertebrates, plants, mammals, etc. You can therefore have different PRGs for different receptors.

2. PRGs may be published standards/criteria or **ARAR-based PRGs**
   a. Not many ARAR-based PRGs for Ecological receptors (the State Water Quality Standards.

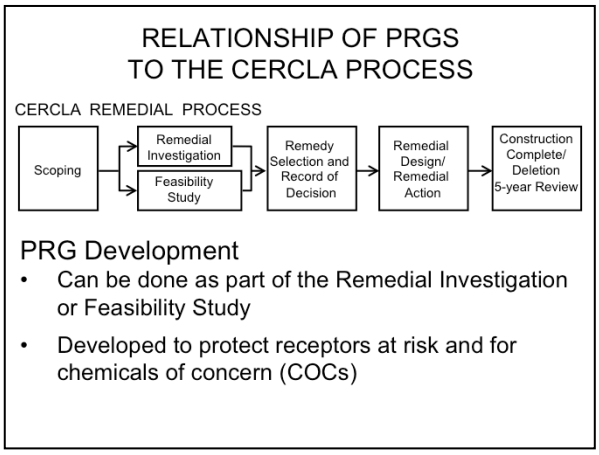
For this talk, we will focus on the risk-based PRGs. The ones that we will calculate using site-specific data such as toxicity tests, bioaccumulation tests, biological surveys, etc.



S-6 *Preliminary Remedial Goals (PRGS)*

1. PRGs provide remedial design staff with long-term targets to use during analysis and selection of remedial alternatives. They are one yardstick for measuring the effectiveness of the alternatives under consideration (i.e., is the alternative capable of reducing contaminant concentrations to this level?)
2. PRGs are ultimately site-specific. However, they often start as preliminary, default risk-based concentrations, such as those developed by EPA Regions 3, 6, 9, etc.
3. PRGs are identified at the scoping stage of the RI/FS. They are further modified as needed during the RI/FS process as site and BRA information becomes available and project goals are refined.

State: PRGs may ultimately be selected as the final clean-up goals for a site. However, PRGs are NOT necessarily "not-to-exceed" values, but are risk-based values that exposure concentrations would try to attain. For residential, the PRG may not be a not-to-exceed value because of the smaller exposure unit size (i.e., the house lot of a ¼ acre or so) but for larger exposure units, such as for commercial/industrial scenarios, concentrations may still be present that are greater than the PRG, but remember that the UCL (upper confidence limit) concentration for the area would be less than the PRG.



S-3 *Relationship of the Human Health Risk Assessment to the CERCLA Process*

B. **State** the relationship of this module to the course.

1. **State** that this slide shows the relationship of RAGS (Risk Assessment Guidance) within the CERCLA process.
2. Thee guidances compliment each other. Each Part was designed to answer a specific question(s):

   Part A - Is there an unacceptable risk associated with contaminated environmental media under the "no action alternative"?

   Part B - What are the ARAR-based (e.g., standards/criteria) and risk-based preliminary remediation goals (PRGs) that must be considered in the evaluation of remedial alternatives and in the determination of the final clean-up goals for a site?

   Part C - What are the short-term and long-term risks associated with each of the remedial alternatives?

Note: RAGS Part D and Part E compliment RAGS A, B, and C.

Part D was designed to assist remedial project managers, risk assessors, and other personnel by standardizing risk assessment planning, reporting, and the review at CERCLA sites. Part E (Review Draft status) provides guidance on the evaluation of the dermal route of exposure. (PRGs and final remedial goals often consider this exposure pathway.)

PERFORMANCE MEASURES

- Performance measures are the criteria by which a remediation is evaluated (i.e., how well it performed.) They can be:
  - Engineering-based (e.g. volume of material to be dredged or an excavation depth)
  - Functionally/structurally-based (e.g. percent plant cover or stream community diversity)
  - Concentration-based (e.g. a chemical-specific clean up goal)

100 x 50 x 3 ft – easy to measusre engineering performance

Poor benthic community before remediation, - doe the benthic community recover and does the diversity meet the specified measure?

PRG – for example – if PRG is 1 mg/kg are all detections aboe that value removed? Could also be an average concentration of 1 mg/kg

PERFORMANCE MEASURES

- Site remediation typically is either engineering-based or chemical concentration-based
  - Risk assessment generates the information needed to develop a concentration-based performance measure
  - Risk assessment can also be conducted such that ecological function or structure may be used as the performance measure

PERFORMANCE MEASURES

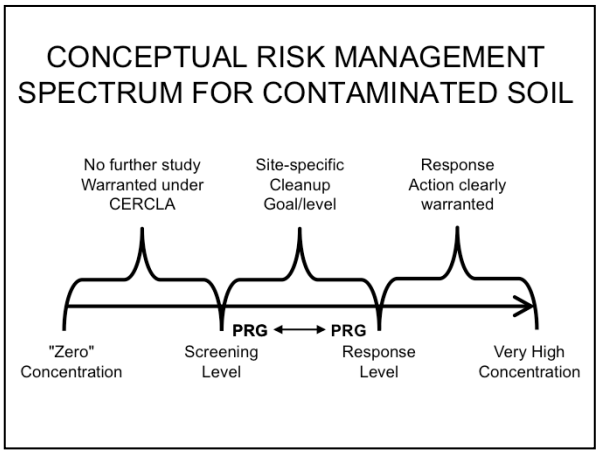
- Site manager makes remedial decisions based on the risk assessment/nature and extent of contamination
- Different remediation options require different risk management decisions, different levels of certainty, and therefore different levels of risk-based information
  - Throughout the site investigation/risk assessment planning step, the site manager needs consider the possible remediation options (including site/land use)
    - ✓Will the site be developed for industrial or residential property?
    - ✓Or will it be open space – wildlife habitat?

S-__

PERFORMANCE MEASURES

- PRGs are typical chemical/media specific performance measures which are used to ensure that ecological receptors are protected.

S-__



S-7 *Conceptual Risk Management Spectrum for Contaminated Soil*

D. **State** that this slide depicts the intended relative position of SSLs with respect to the spectrum of potential concentrations and associated risks.

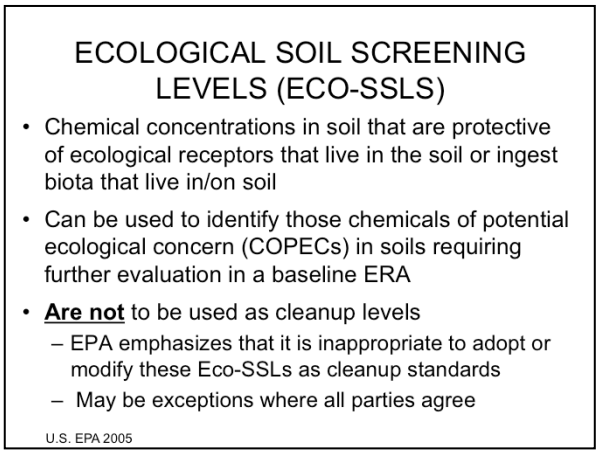
1. SSLs are at the lower bound of a range of values that may require a response.

[CLICK] = "PRG" floats within bracket of screening level and response level

2. The final cleanup goal/level will lie within that range and be determined by the baseline risk assessment and the remedial process.
3. **State** that in order to obtain lower bound (i.e., conservative) screening levels, EPA has selected conservative parameters for substitution into appropriately crafted equations. Again, this is why screening levels may not necessarily be suitable as PRGs in some cases.

State: Important points to remember:

1. Reiterate the point that PRGs may ultimately be selected as the final clean-up goals for a site. However, PRGs are NOT necessarily "not-to-exceed" values, but are risk-based values that exposure concentrations would try to attain.



S-9 *Soil Screening Levels*

I. **Define Soil Screening Levels**

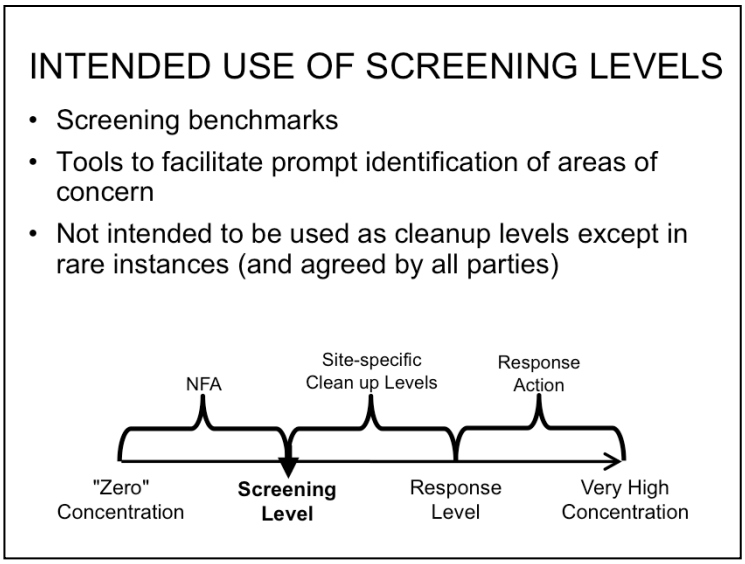
A. Eco-SSLs are site ***screening*** concentrations used to identify areas, chemicals, and pathways of concern at NPL sites that require further investigation under CERCLA

1. Risk-based PRGs and SSLs are calculated in a very similar manner. They are both based on target risk levels and a defined set of exposure assumptions.

However,

SSLS should not typically be used as cleanup levels except in some cases:

- They are very conservative and based on no-effects levels
- Very small sites
- Conducting remediation for HH and can remove a little more and not have to further evaluate eco risks



S-9 *Intended Use of SSLs*

C. **Describe** the intended use of SSLs.

1. **State** that Eco-SSL are screening levels

SSL's are a tool to quickly identify areas within a site that do not require further investigation, not necessarily whether or not an area has to be cleaned or remediate. If an area fails the SSL screen, then that simply means that more investigation is warranted to determine the level of activity will be required to remediate the site.

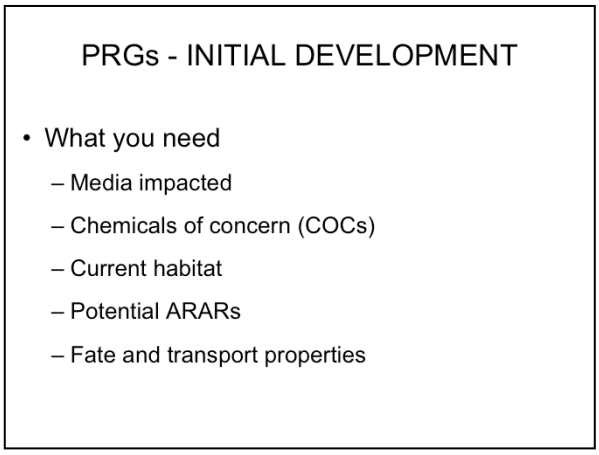
"SSLs are not national cleanup standards. SSLs alone do not trigger the need for response actions or define

Instructor note: The concept of screening is very important for the student to comprehend. Please make sure your statement impresses on the student that any screening level is use to determine level of effort to put forth on an area - how much work is required to determine a clean up level. If an area can "pass" a screen using concentrations that were determined in a very conservative manner, one can be pretty assured that no further action is necessary and saves time and money to focus on those areas of a site that need further attention.

Eco-SSLs may be used as PRGs cleanup to SSL is less expensive than developing site-specific values.

INDICATE TO STUDENTS THAT BY USING SITE SPECIFIC INFORMATION THE NUMERICAL VALUE OF THE SSL BECOMES CLOSER TO A REMEDIAL CONCENTRATION. USE THE GRAPHIC ON THE SLIDE TO ILLUSTRATE THIS. THE YELLOW ARROW AND TEXT INDICATE WHERE AN SSL LIES IN THE SPECTRUM OF REMEDIAL CONCENTRATIONS. INDICATE THAT A PRELIMINARY REMEDIAL GOAL DEVELOPED VIA SSL GUIDANCE WOULD LIE WITHIN THE RANGE BETWEEN SCREENING AND RESPONSE LEVELS- THE RANGE OF CONCENTRATIONS SOUGHT AFTER FOR REMEDIAL ACTIVITY.

THIS IS HOW THE SSL GUIDANCE HELPS TO DETERMINE PRELIMINARY REMEDIAL GOALS.



S-21 *Identification of PRGs - Initial Development*

B. Identification of PRGs

1. Initial development of PRGs:

a. **STATE:** As noted previously, PRGs evolve throughout the RI/FS process. Site-specific information is needed for development of PRGs. In some cases, this may be fate and transport information that allows for the accurate estimate of the potential for chemical migration. Alternatively, this may be accurate information on the proposed future land use of the site.

Remind students that the quality of inputs for the PRG is often limited at the beginning of the RI/FS process because the risk investigation and risk assessment have not yet been completed.

b. The following information is needed for PRG development:

[*click*] (1) Media of concern

This goes without saying. You need to know what media (soil, water, groundwater, food) that you are developing PRGs for. Media characteristics will have an effect on the calculation of PRGs.

[*click*] (2) Chemicals of potential concern

This information is gathered from the Conceptual Site Model (CSM). Emphasize that a good CSM is fundamental to the identification of critical receptors, pathways, and ultimately the risk managers ability to demonstrate that the selected remedial alternative is protective of human health.

Note: Ultimately, all significant media, receptors and pathways identified by the CSM developed for the RI, must be address in the development of PRGs.

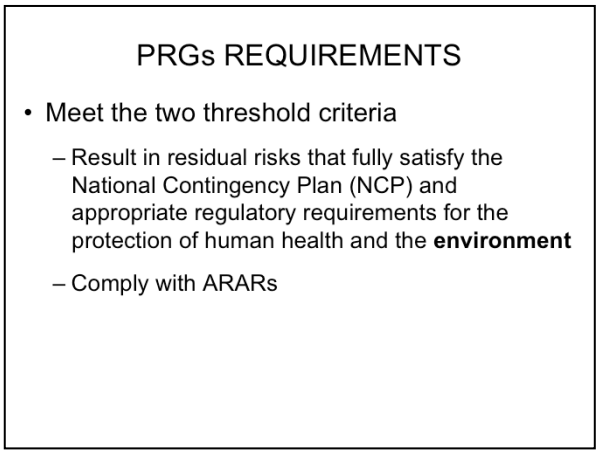
[*click*] (3) Current and future land use

(a) Determine a reasonable future land use.

STATE: This information (i.e., media, chemical and future land use) can be found in the reports generated during the PA/SI (Preliminary Assessment / Site Investigation) stage. Once these are known, then all potential ARARs should be identified.

[*click*] (4) Potential ARARs

(a) You should find ALL ARARS (i.e., Federal and State) that MAY apply to the site.



S-22 *Preliminary Remediation Goals (PRGs)*

A. **State** that PRGs should:

a. Comply with Applicable or Relevant and Appropriate Requirements (ARARs).

b. Result in residual risks that fully satisfy the NCP requirements for the protection of human health and the environment.

(1) The NCP actually indicates that PRGs are developed at scoping or concurrent with the initial RF/FS activities.

(2) Must be protective of human health and the environment. **State:** Remember the nine criteria and the three that relate directly to risk assessment! These apply here as well. PRGs must meet those requirements of protectiveness (#1), long-term effectiveness (#3) and short-term effectiveness (#5)

Years ago people focused /cared about protecting humans, and not so much ecological. However, that has changed and we are actually seeing more cleanups based on ecological risks, especially sediment sites.

ECOLOGICAL PRGS

- Site-specific or literature-based
- Variety of methods based on:
  - Chemicals
  - Receptors
  - Available data
- Remember: Screening levels are not PRGs

Literature-based – ER-M

Chemicals – Bioaccumulative vs direct toxicity

Receptors – plants, birds, mammals, invertebrates

Available data – typically not generating new data as part of this process. Should use existing data from the BERA such as toxicity testing, etc. However, if no site-specific data were collected as part of the ERA, the data could be collected after and used to develop the PRGs. It could turn out that all concentrations are then below PRGs

ECOLOGICAL PRGS

- Two primary chemical types
  - Bioaccumulative
    - ✓Protective of upper trophic level receptors from impacts though the food chain
  - Direct Toxicants
    - ✓Protective of lower trophic level receptors from impacts though direct exposure

State that after the risk evaluation step there is the risk description step.

Risk description in an ERA documents the environmental contamination levels that bound the threshold for adverse effects on the assessment endpoints and provides information to the risk manager to help him/her judge the likelihood and ecological significant of the estimated risks.

The key to the Risk Description is identifying thresholds for the risk estimation metrics that are reflective of significant risk.

For example, it may be necessary to determine how great an HQ or HI is indicative of significant possible risk (the lower threshold can be 1.0 or some other threshold agreed to and justified by the Risk Assessor and Risk Manager).

State that the identification of upper as well as lower thresholds is encouraged.

For example, an HQ ≥ 1 based on a NOAEL might constitute a lower threshold indicative of possible risk, and an HQ ≥ 1 based on a LOAEL might constitute an upper threshold indicative of possible severe risk.

Explain that Risk Description can also involve generating additional risk information beyond just thresholds of risk.

As with non-cancer elements of HHRA, a probabilistic approach to an ERA involving the direct expression of risk using probability figures is possible but difficult. It is rare now but might become more common in the future.

The development of graphical presentations that depict the spatial extent of contamination exceeding one or more risk thresholds. – Very useful.

It may be of interest to determine the degree to which the threshold for contamination is exceeded or is likely to be exceeded in the future, particularly if exposure-response functions (toxicity test results) are available.

ECOLOGICAL PRGS

- Bioaccumulative chemicals
  - Back-calculation of acceptable levels using food chain exposure models:
    - ✓Exposure parameters (i.e., ingestion rate, body weight)
    - ✓Diet composition
    - ✓Toxicity Reference Value (TRV)
    - ✓Bioaccumulation Factors (BAFs) (site-specific)
    - ✓Area Use factor (AUF)

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BIOACCUMULATION FACTOR (ESTIMATE TISSUE CONCENTRATIONS)

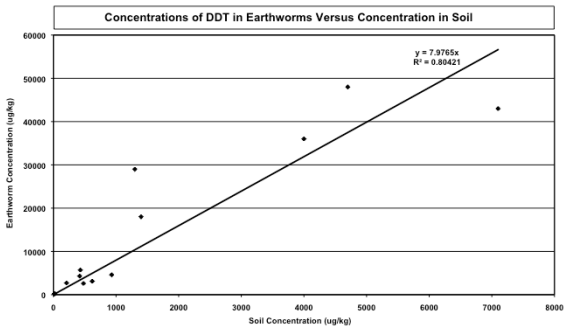
$$BAF = \frac{Ct}{Cs}$$

Rearrange Equation

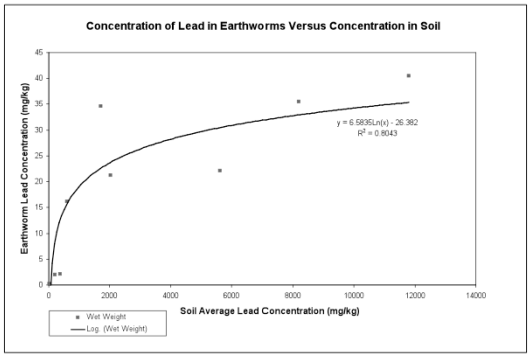
$$Ct = Cs * BAF$$

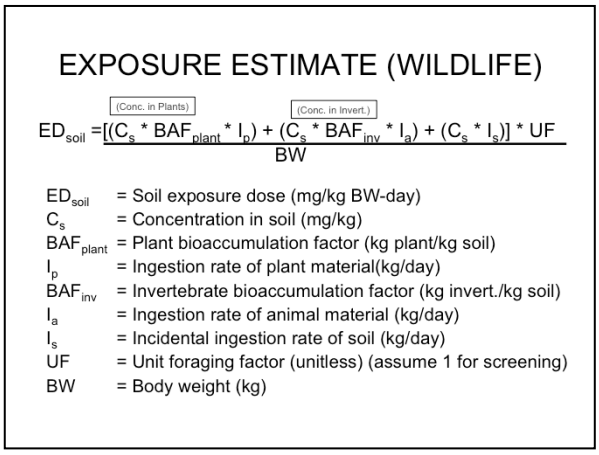
BAF = Bioaccumulation Factor (unitless)
Ct = Chemical concentration in tissue (mg/kg)
Cs = Chemical concentration in soil (mg/kg)

EXAMPLE OF SITE-SPECIFIC BAF



EXAMPLE OF SITE-SPECIFIC BAF



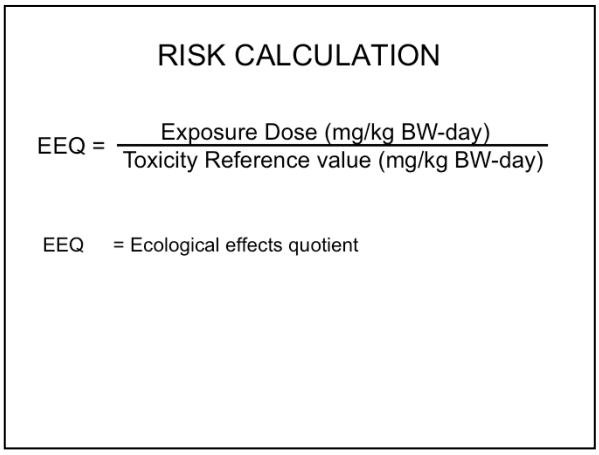


S-24 ERAGS STEP 2: Screening-Level Exposure Estimate (Wildlife)

STATE: This slide depicts a generic exposure calculation.

This equation is for demonstration purposes to show the students how one would calculate the Exposure dose for an ecological receptor. Indicate to the students the differences between this equation and one that would be used for a human receptor.

Acknowledge that exposure calculations, while sometimes cumbersome, are generally intuitive and are not mathematically complex.



S-25 ERAGS STEP 2: Screening-Level Risk Calculation

3. **State** that a quantitative screening-level risk calculation is performed using the following:
   a. Exposure estimates developed in the screening-level exposure assessment, and
   b. Screening ecotoxicity values developed according to screening-level ecological effects evaluation.

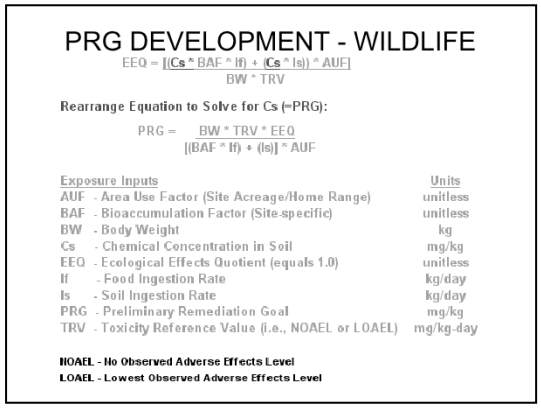
Tell students that for screening-level risk calculation, the hazard quotient (HQ) approach is used to calculate risk.

b. Compares estimate exposure levels (media concentrations) to measured or predicted threshold value for effects.

HQ = Dose mg/kg-day / NOAEL mg/kg-day or HQ = EEC mg/L / NOAEL mg/L

But both equations are basically the exposure dose divided by the Screening value (much like human health RA)

4. **Tell** students to include the following with the preliminary risk calculation:
   a. A description of the exposure route
   b. Hazard quotient calculations
   c. Uncertainty discussion
   d. Summary of overall confidence in the assessment



S-29 *Background Sampling Example*

Answer: All three are important to risk managers.

[*click*]

Arsenic and Dieldrin are soil contaminants for which clean up goals should be derived. These are site-related contaminants.

[*click*]

DDT was shown not to be related to site releases.

The fact that arsenic and DDT are present on site could pose a possible risk communication issue

[*click*]

Risk characterization will communicate how DDT contamination will be addressed

The project manager may consider whether other regulatory programs or authorities can address area-wide contamination issues of arsenic and DDT. (See EPA, 1996. Soil Screening Guidance)

ECOLOGICAL PRGS

- Direct toxicants
  - Protective of plants, invertebrates, fish
  - Use toxicity tests and/or field survey data to develop PRGs
    - ✓Correlate toxicity tests/biological survey results to chemical concentrations in media

State that after the risk evaluation step there is the risk description step.

Risk description in an ERA documents the environmental contamination levels that bound the threshold for adverse effects on the assessment endpoints and provides information to the risk manager to help him/her judge the likelihood and ecological significant of the estimated risks.

The key to the Risk Description is identifying thresholds for the risk estimation metrics that are reflective of significant risk.

For example, it may be necessary to determine how great an HQ or HI is indicative of significant possible risk (the lower threshold can be 1.0 or some other threshold agreed to and justified by the Risk Assessor and Risk Manager).

State that the identification of upper as well as lower thresholds is encouraged.

For example, an HQ ≥ 1 based on a NOAEL might constitute a lower threshold indicative of possible risk, and an HQ ≥ 1 based on a LOAEL might constitute an upper threshold indicative of possible severe risk.

Explain that Risk Description can also involve generating additional risk information beyond just thresholds of risk.

As with non-cancer elements of HHRA, a probabilistic approach to an ERA involving the direct expression of risk using probability figures is possible but difficult. It is rare now but might become more common in the future.

The development of graphical presentations that depict the spatial extent of contamination exceeding one or more risk thresholds. – Very useful.

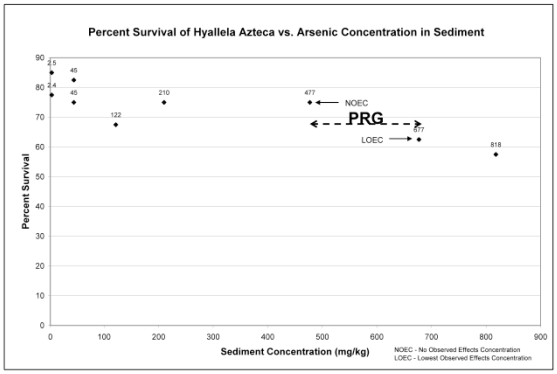
It may be of interest to determine the degree to which the threshold for contamination is exceeded or is likely to be exceeded in the future, particularly if exposure-response functions (toxicity test results) are available.

PRG DEVELOPMENT – TOXICITY TEST

- Determine whether there is a dose response relationship
  - Group samples into toxic and non-toxic data sets
    - ✓Determine NOEC (highest concentrations in the non-toxic data set)
    - ✓Determine LOEC (lowest concentrations in the toxic data set – must be greater than the NOEC)
- Other methods can be used as well
  - Calculation of threshold levels (EC_{50})
  - Base cleanup on locations that are toxic
  - Others...

NEED TO HAVE A DOSE RESPONSE RELATIONSHIP – IF NO RELATIONSHIP THAN CANNOT DETERMINE WHETHER THE CHEMICALS ARE THE SOURCE OF THE TOXICITY OR SOME OTHER FACTOR

PRG DEVELOPMENT-TOXICITY TEST



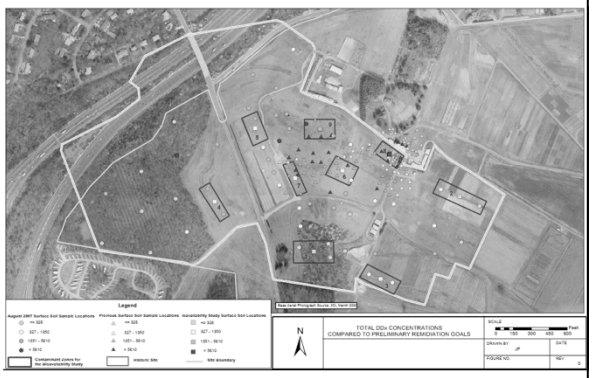
PRG CALCULATION - TOXICITY TEST

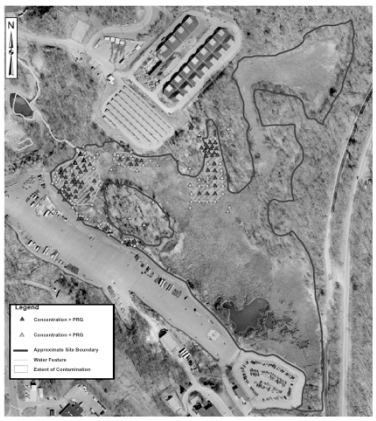
Sample Identification	Concentrations of metals (mg/kg)			
	Antimony	Copper	Lead	Zinc
Non-Toxic Samples				
SS116	2.9	19.9	52.1	186
SS101	4.2	132	452	576
SS102	**6.1**	**253**	**648**	1270
SS103	4.3	170	422	**1510**
SS109	3	135	277	1130
Toxic samples				
SS104	**6.4**	216	**1030**	**1950**
SS106	1.9	112	318	932
SS112	10.8	57.9	175	706
SS114	2.2	31.8	77.2	2250
NOEC	**6.1**	**253**	**648**	**1510**
LOEC	**6.4**	NA	**1030**	**1950**
Geometric mean of NOEC and LOEC	6.2	NA	817	1716

NOEC - No Observed Effects Concentration. (Highest concentration in a non-toxic sample)

LOEC - Lowest Observed Effects Concentration. (Lowest concentration in a toxic sample > NOEC)

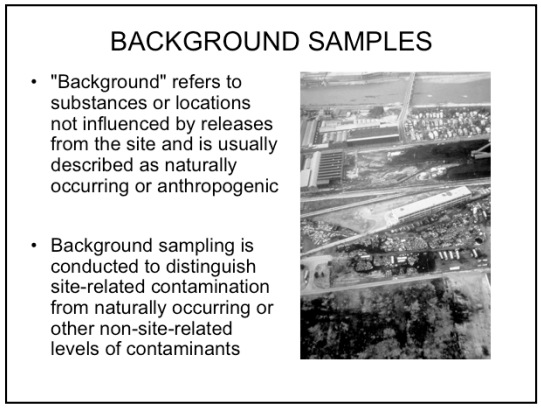
COMPARISON TO PRGS




N
Legend
Concentration > PRG
Concentration < PRG
Approximate Site Boundary
Water Feature
Extent of Contamination

ECOLOGICAL PRGS - BACKGROUND

- Ecological screening values and State numerical criteria are often < background
  - Typically, the “actual” State criteria defaults to background when this occurs
- If PRGs are potentially at background levels, you may want to determine site-specific background concentrations
  - PRGs should not be less than background
  - Natural concentrations vary with local geology/ other conditions
  - Background is not “a number” it is a range



S-24 *Background Samples*

1. Elevated background levels and their contribution to site risks are now discussed during the risk characterization.

   a. Risk Characterization discusses naturally occurring elements that are not CERCLA releases, but exceed risk-based screening levels.

2. Some risks, such as background, might not be addressed by the CERCLA remedial action, but are still important to those potentially exposed (EPA, 1989 RAGS). Risks associated with background contamination is a risk communication issue.

State that background sampling is conducted to distinguish site-related contamination from naturally occurring or other non-site-related levels of contaminants. In other words to assist in the determination of the nature and extent of site contamination. The EPA policy with regard to how background samples are handled has changed since RAGS was written, so we will look at this issue a little closer

ELK Example

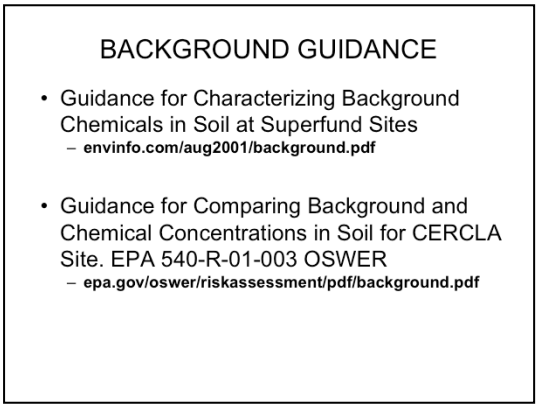
M. Power and L.s. McCarty. 1997. Fallacies in ecological risk assessment practices. Environmental Science & technology news. Vol 31, no 8 pg 370-375.

Myths include:
a “sensitive” or “sentinel”, species can be selected and appropriately used;
chronic data are better suited to regulatory needs than are acute data;
and controlled experimental data can be accurately extrapolated to the field.

Add

The environment is naturally chemically safe

(Elk exposure to arsenic in geothermal watersheds of yellowstone national park, Usa. Kocar et al. 2004. environmental toxicology and chemistry, vol 23, no 4 pp 982 -989.



S-25 *Background Guidance*

State that the guidance documents on the slide provide information on background sampling at Superfund sites. Students should also consult with regional EPA staff to learn of any regional preferences.

Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites. EPA 540-R-01-003 OSWER 9285.7-41 September 2002

TELL STUDENTS:

This guidance states that "in cases where background levels are high or present health risks, this information may be important to the public….This policy recommends a baseline risk assessment approach that retains constituents that exceed risk-based screening concentrations. This approach involves addressing site-specific background issues at the end of the risk assessment, in the risk characterization. Specifically, the COPCs with high background concentrations should be discussed in the risk characterization, and if data are available, the contribution of background to site concentrations should be distinguished. COPCs that have both release-related and background-related sources should e included in the risk assessment. When concentrations of naturally occurring elements at a site exceed risk-basked screening levels, that information should be discussed qualitatively in the risk characterization."

INSTRUCTION NOTE: Tell the students the above message - either read word-for-word, or explain in your own words.

Web page is on slide.

SUMMARY FOR PRG DEVELOPMENT

- Use screening value or State numerical criteria as the PRG if functional given the site setting and conditions
- Evaluate background concentrations with respect to the site setting and conditions
- Determine a site-specific PRG by conducting site-specific risk assessment potentially including bioaccumulation, toxicity, and/or field population/ community assessment studies
- Evaluate the remedy objectives for alternative performance measures (to numerical criteria) for ecological protection

Use screening value or State numerical criteria as the PRG if functional given the site setting and conditions.

- (note: many States have an option to generate alternative risk based criteria)

Conduct site specific risk assessment potentially including bioaccumulation, toxicity, and/or field population/community assessment studies , to determine a site specific PRG (alternative process (to State numerical criteria) for developing the PRG)

Determine a site-specific PRG by conducting site-specific risk assessment potentially including bioaccumulation, toxicity, and/or field population/community assessment studies,

(alternative process (to State numerical criteria) for developing the PRG)

- Used to determine causality and threshold for effects (i.e., NOECs)
- Large scale field population studies costly and time consuming and may not yield definitive results (causal linkage and exposure level) – There are many confounding issues in the real world.

Used to determine causality and threshold for effects.

- In complex samples it is valuable to assess the highest concentration at which there is no adverse effect.

- Site specific toxicity tests – determine causality and threshold for effects. Note in complex samples it is valuable to assess the highest concentration at which there is no adverse effect.

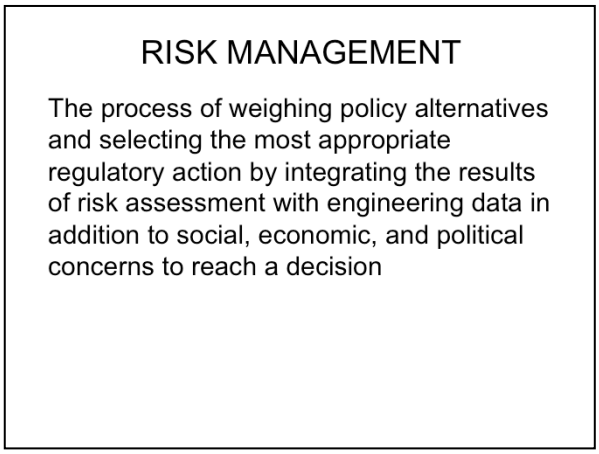
Site specific toxicity tests

Used to determine causality and threshold for effects (i.e., NOECs)

Large scale field population studies

Costly and time consuming and may not yield definitive results (causal linkage and exposure level)

RISK MANAGEMENT



S-10 *Risk Management*

1. **Define** risk management:

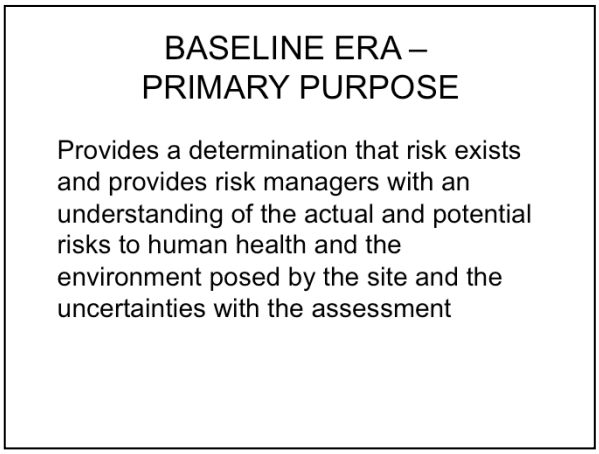
The process of weighing policy alternatives and selecting the most appropriate regulatory action, integrating the results of risk assessment with engineering data and with social, economic and political concerns to reach a decision.

2. **Differentiate** risk assessment from risk management:

[SPO-5] a. **Risk assessment** is the process used to evaluate the degree and probability of harm...from stressors such as pollution....

b. **Risk management** entails determining whether and how risks should be managed or reduced. Risk Management decisions are based on the results of the risk assessment as well as public health, social, and economic factors.

Tell students that this course focuses on risk assessment and thus will not address risk management in much detail.



S-39 2. **State:** The primary purpose of baseline risk assessment is to provide risk managers with an understanding of the actual and potential risks to human health and the environment posed by the site and the uncertainties with the assessment.

E. Human Health and Ecological Risk Assessments

STEP 8: RISK MANAGEMENT

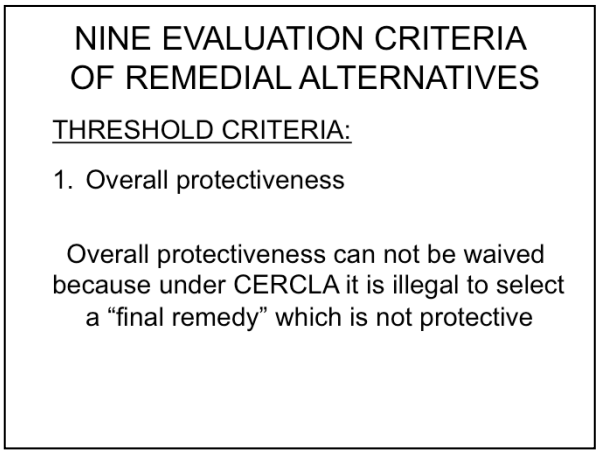
- Not part of risk assessment conclusions or determination of risk
- Integrate risk assessment results with other considerations to make and justify decisions
  - **Responsibility of risk manager, not risk assessor**
  - Primarily part of the Feasibility Study

Source: U.S. EPA 1997a

Define Risk Management in the context of ecological risk assessment – the process of integrating risk assessment results with other considerations to make and justify decisions. Review the respective roles of the Risk Assessor and the Risk Manager. State that the Risk Manager should have been involved throughout the ERAGS process, and should not be initially consulted as part of Step 8. State that the Risk Manager for EPA fund-led Superfund sites is typically the Remedial Project Manager (RPM), who commonly relies on the BTAG for risk management guidance. Briefly remind students of the BTAG, which was introduced in the SLERA lecture module.

SO HOW DO THE PRGS FIT IN?

- PRGs are developed to match with the construction aspects of the remediation and are evaluated against the nine criteria for remedy selection
- The selected PRGs will become remediation goals or cleanup levels in the Record of Decision (ROD)



S-28 *Nine Evaluation Criteria of Remedial Alternatives*

4 . **NINE EVALUATION CRITERIA of Remedial Alternatives**

State: A Remedial Investigation is conducted to gather sufficient information to support the selection of a site remedy that will reduce or eliminate risks associated with the contamination a site.

The NCP outlines the requirements that an RPM or OSC must use when selecting a remedy or remedial action. These requirements are referred to as the Nine Evaluation Criteria.

a. The nine evaluation criteria are categorized into three groups:

i. Threshold Criteria: These two criteria MUST BE MET when evaluating a remedy for clean up.

1. Overall Protection of human health and the environment
2. Compliance with ARARS (unless waived)

Define ARARs:

1. Laws that are applicable to a specific situation of contamination.
2. Cleanup standards, standards of control, and other substantive criteria designed to ensure environmental protection or limits promulgated under federal or state law that specifically address problems or situations that often are found at CERCLA sites.

RISK MANAGEMENT

- Risk management is not deciding to leave risk
  - You must justify why any residual risk is “acceptable” in the final remedy – that the remedy is protective once the remediation is complete
  - This should be based upon the information in the baseline ERA, such as the severity of the potential adverse effect, uncertainties in the exposure estimates, etc.
- Note: Interim remedies do not need to meet the threshold criteria but then you are not finished

SELECTION OF PRGS

- Conservative PRGs and set them as the active remediation performance measure
  - Assured of contaminant protectiveness – but the PRGs could be difficult to implement (either cost or size of area problematic; not technically achievable; secondary problems)
- Conservative PRGS (remediation goals) along with construction action triggers and construction performance measures, then use an alternative remediation technology to achieve the protective level
  - Need to monitor the site until you achieve the remediation goal – the site can not be closed out

SELECTION OF PRGS

- Less conservative PRGS with justifications, based upon the baseline ERA, explaining why the remedy is protective
  - May still need to monitor the site to demonstrate the protective conclusion

S-36 *Any Questions?*

[*click*]

INSTRUCTOR NOTE: Spend a few moments (5 - 10 at most) recapping the module:

1. RAGS Part B focuses on the PRG development and soil screening levels.
2. Soil Screening Levels (SSLs) can be used as Preliminary Remediation Goals (PRGs) provided that site-specific data/information is used.
    a. Parts of SSL Guidance supersedes Part B guidance (i.e., inhalation of GW vapors) as well as provide additional exposure scenarios (i.e., future off-site resident)

Ask students whether they have any questions concerning this module.