The Rule of Five:

A Novel Approach to Derive PRGs

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Objectives

- To provide a simple and logical method for the development of defensible clean up goals following the ecological risk characterization.
- To provide a flexible framework within the risk range from which the clean up number can be selected.

Introduction

- Risk-based CUG
  - Should be from risk-based concentration range stated in BERA!!
  - Critical information needed by risk managers for remedy evaluation and final clean up decisions for the hazardous chemicals that pose unacceptable risks
- The method proposed here brings the lines of evidence from the BERA (i.e., the science that has already been conducted) into the decision process for establishment of clean up goals

Introduction: Challenges to determining CUGs

- What technical methods to use?
  - Precautionary principle?
  - Logistic regression?
  - Probabilistic techniques?
  - Back-calculation (to hazard quotients <1) from risk models?
- Reasons behind the selection of the CUG are not often transparent

Introduction: Challenges to determining CUGs

- Weight of evidence evaluation has been used in Superfund site risk assessments
  - Often determines degree of risk (i.e., high, medium or low risk) in risk characterization
  - Unclear with regards to developing clean up numbers (risk management)
- NOT appropriate, nor cost-efficient, after a rigorous ecological risk assessment to base selection of CUG on one end or other of the NOAEL-to-LOAEL risk range

“Rule of Five”

- There are typically no more than three lines of evidence for a given assessment endpoint (*e.g.*, abiotic media concentrations, toxicity data, tissue concentrations, community composition).

- Therefore, we provide five positions within the NOAEL-to-LOAEL risk range from which a clean up goal can be selected

- The “Rule of Five” is especially useful for selecting a protective value within a wide risk range

Technical Approach

- A clean up goal can be selected within the NOAEL-LOAEL risk range of an assessment endpoint based on consideration of points in a geometric progression:

$$A_n = A_0 * r^{n-1} \qquad (eq.\ 1)$$

Initial	**Clean Up Goal is in Here!**					**Final**
NOAEL	←				→	LOAEL
node 1	node 2	node 3	node 4	node 5	node 6	node 7

The five nodes between the NOAEL and LOAEL are considered

Technical Approach

$$A_n = A_0 * r^{n-1} \qquad (eq.\ 1)$$

A_n = the *n*th value in the geometric progression (LOAEL is the 7th value in this progression; A_7);

A_0 = the initial node (NOAEL; A_1) in the geometric progression sequence;

r = the common quotient (constant) between any two consecutive nodes in the progression sequence, and

n = the nth term being solved for in the progression sequence

Initial			**Clean Up Goal is in Here!**			**Final**
NOAEL	←				→	LOAEL
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Technical Approach

- To calculate the constant, *r*, the equation is:

$$r = e^{\left[\frac{\ln\left(A_n\right) - \ln\left(A_0\right)}{n-1}\right]} \qquad (eq.\ 2)$$

- Let's derive this using the NOAEL and LOAEL. . .

Justification

- Mathematics and statistics support preference of a geometric over an arithmetic progression for this purpose
  - Environmental data are often positively skewed and modeled with a lognormal distribution
  - Toxicologists commonly use geometric mathematics to calculate toxicity point estimates such as the MATCs or CVs from aquatic toxicity test results
- EPA uses geometric mathematics in developing protective water quality criteria
  - SMAV, FACR (final Acute-to-Chronic Ratio), WERs

Justification

- Geometric mathematics are used in the NCP as a method for choosing parameter values for assigning groundwater mobility parameters (e.g., geomeans of water solubility and K_d data)

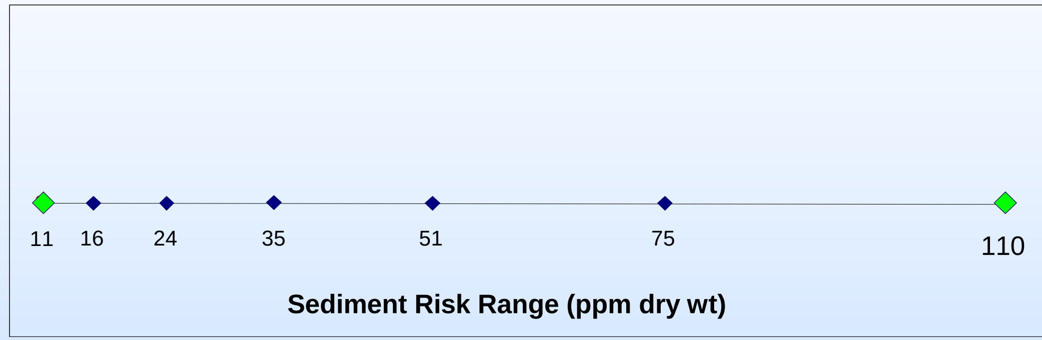
- Used in development of EcoSSLs

- Because geometric progression (compared to arithmetic) biases calculation of nodes toward the lower end of the risk range (*i.e.*, geometric mean < arithmetic mean) this is viewed as "appropriately conservative" to provide the "intended level of protection" from a regulatory standpoint

Pearl Harbor Sediments ERA

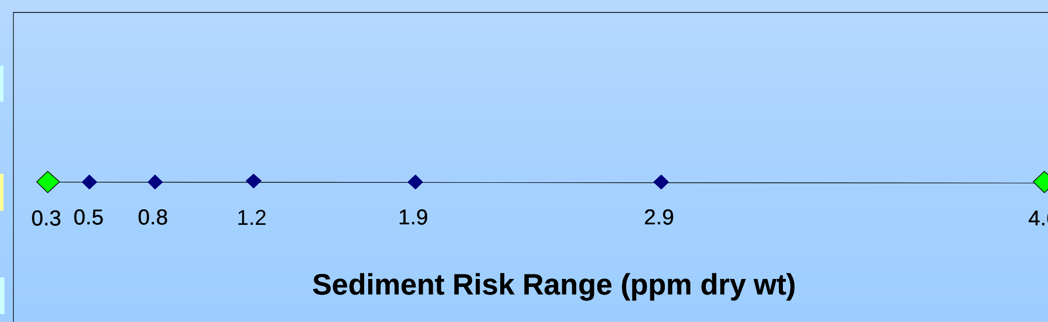
Lead: AE -4 waterbirds (tern consuming goatfish)

n	Sediment Concentration (Csed)	
1	11 ←	bounded NOAEL (REP)
2	16	progression node 2
3	24	progression node 3
4	**35**	**PRG = progression node 4**
5	51	progression node 5
6	75	progression node 6
7	110 ←	lowest LOAEL (REP)



Total PCB NOAA18: AE-1 invertebrates living in sediments (macrofauna)

n	Sediment Concentration (Csed)	
1	0.3 ←	bounded NOAEL (GRO)
2	0.5	progression node 2
3	0.8	progression node 3
4	**1.2**	**PRG = progression node 4**
5	1.9	progression node 5
6	2.9	progression node 6
7	4.6 ←	lowest LOAEL (MOR)



Selecting the Value

- ***The ERA studies and analyses have already been conducted* by the time we use the Rule of Five**

- We need to make a decision on the value from within the NOAEL-to-LOAEL range that will be protective of ecological receptors.
  - This ecological risk information is then considered with other site factors to make the risk management decision

Application

Initial			Clean Up Goal is in Here!			Final
NOAEL	←				→	LOAEL
node 1	node 2	node 3	node 4	node 5	node 6	node 7

- **Starting Assumption**: The third point above the low end of the risk range is protective of growth and reproduction endpoints (sublethal chronic effects).
  - This point is equivalent to the geometric mean of the NOAEL and LOAEL.
  - If the basis of the risk range is survival or mortality (acute effects) the initial point is the second point above the NOAEL.

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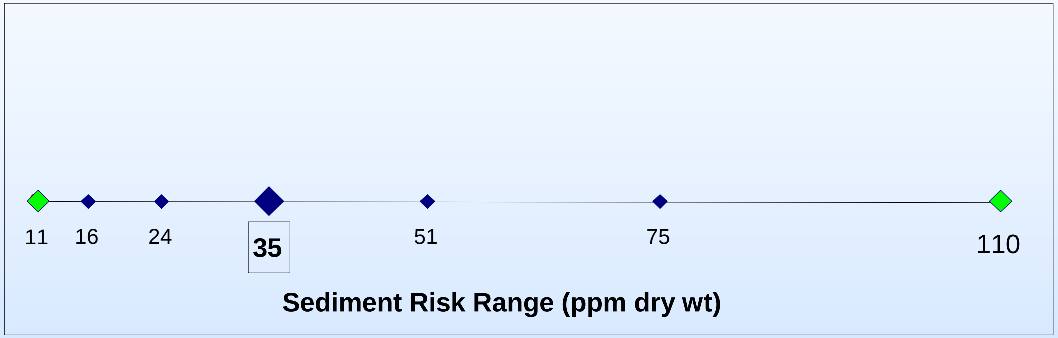

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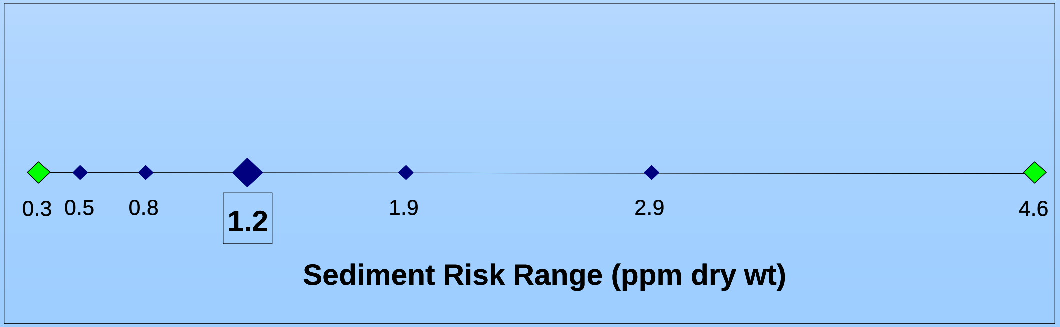
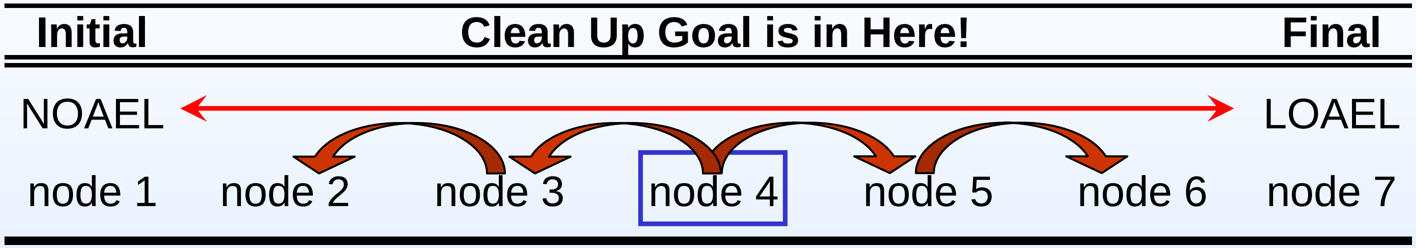


Application



- **Discriminating lines of evidence** provide information that can be used to raise or lower the clean up value from the initial starting point (e.g., concentration-response relationship, gradients of effect or impact)

- **Equivocal lines of evidence** include tests or measures that do not technically support moving about the nodes
  - Results are either confounded, unable to discriminate among experimental points, or highly uncertain

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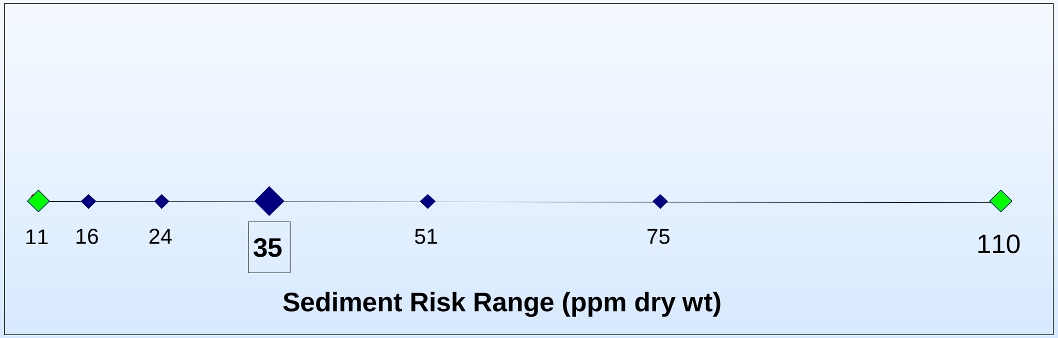

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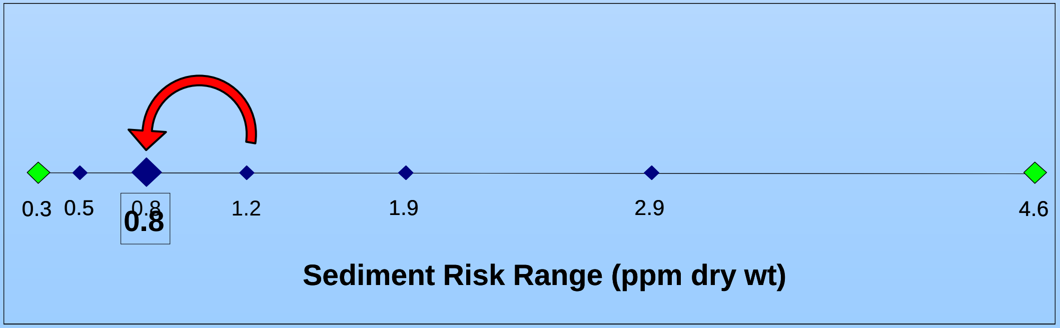

Application

4,4'-DDE		1	2	3	4	5	6	7
AE#3	Benthic Community	0.002	0.004	0.008	0.013	0.024	0.042	0.075
AE#4	Piscivorus Bird	0.02	0.031	0.045	0.068	0.1	0.15	0.2

4,4'-DDT		1	2	3	4	5	6	7
AE#3	Benthic Community	0.001	0.003	0.011	0.037	0.12	0.41	1.4
AE#4	Piscivorus Bird	0.44	0.65	0.95	1.4	2	3	4.4

Total DDX		1	2	3	4	5	6	7
AE#3	Benthic Community	0.12	0.19	0.3	0.46	0.72	1.1	1.7
AE#4	Piscivorus Bird	0.12	0.18	0.26	0.38	0.56	0.83	1.2

Discussion & Conclusions

- The Rule of Five is most applicable to deterministic ERAs with limited data.
- Visualization tool allowing decision makers to work within the risk range to derive a technically defensible, ecological risk-based remedial clean up goal.
- The approach also allows some of the ecological parameters that do not lend themselves to calculating CUGs to be incorporated into the risk assessment where they have been excluded previously as non-decisional.
  - e.g., ecological community analysis, biological indices, biomarker data, and stressor-response correlations

Discussion & Conclusions

- The Rule of Five has it's greatest value in determining a point of departure in those risk ranges where there is an order of magnitude or more between the NOAEL and LOAEL

- However, it creates a useful model for supporting a specific risk based number in situations where there is a relatively small risk range.

- The Rule of Five can potentially reduce conflicts in stakeholder meetings—*Through cooperative development and selection of the CUG*

Discussion & Conclusion

- The Rule of Five is useful for focusing the BERA and ensuring compliance with the **EPA policy requirement that a risk assessment determines numerical clean-up goals**
  - OSWER Directive 9285.7-17 (1994)
  - ERAGS (1997)
- The selected goal within the risk range:
  - More transparent and easily explained to the public
  - The clean-up goal is a point that the risk managers can understand and incorporate into remedial decisions