Planning Risk Assessments

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NEWFIELDS
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Risk Assessment

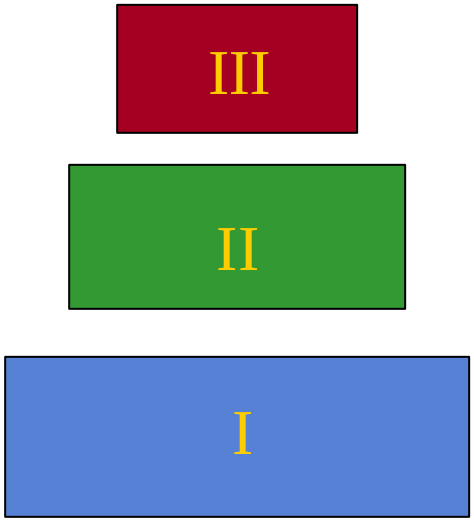
$$Risk_C = Conc. \times Exposure \times Toxicity$$

$$Risk_{NC} = \frac{Conc. \times Exposure}{Reference\ Dose}$$

Math is simple

Impact of each input is important

Tiered Risk Assessment & Management



Tier III Remedy Evaluation Risk Assessment

Assess the risk of the remedial action(s)

Tier II Baseline Risk Assessment

Assess the risk at the site

Tier I Screening

Demonstrate that the site is below a health protective level

Screening or Risk Assessment

- Screening - always
  - Provides information on potential risk
  - Provides additional understanding of site characteristics relative to risk
  - May eliminate sites and/or constituents from further evaluation
- Risk Assessment – sometimes
  - Screening indicates a potential risk
  - NPL site (ROD)

Where to Sample?

It Depends On The Purpose:

Define Nature And Extent Of Contamination

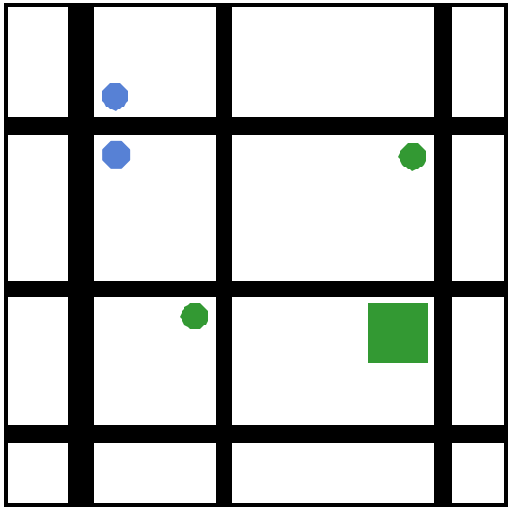
Goal Of PA/SI

Estimate Human Exposure To Chemicals

Goal Of Risk Assessment

Purposive Sampling Inappropriate

"Although areas of concern are established purposively (e.g., with the intention of identifying contamination), the sampling locations within the areas of concern generally should not be sampled purposively if the data are to be used to provide defensible information for a risk assessment."



(RAGS, Part A)

Random Sampling Appropriate

"For example, if you assume that an exposed individual moves randomly across an exposure area, then the spatially averaged soil concentration can be used to estimate the true average concentration contacted over time."

(RAGS, Part A)

Purposively Collected Data Use in Risk Assessment ?

"If a contaminant is widely distributed throughout the site, the exposure point concentration should be based on the 95% UCL of the arithmetic average… However, if the contamination is unevenly distributed, i.e., 'hotspot' areas exist… A percent of time on the site… should be factored into the intake equation with the FI term."

Consider the exposure

(EPA Region 4, Supplemental Guidance)

Exposure Point Concentrations

Maximum not representative of concentration contacted over time

"...because in most situations, assuming long-term contact with maximum concentration is not reasonable."

Calculate

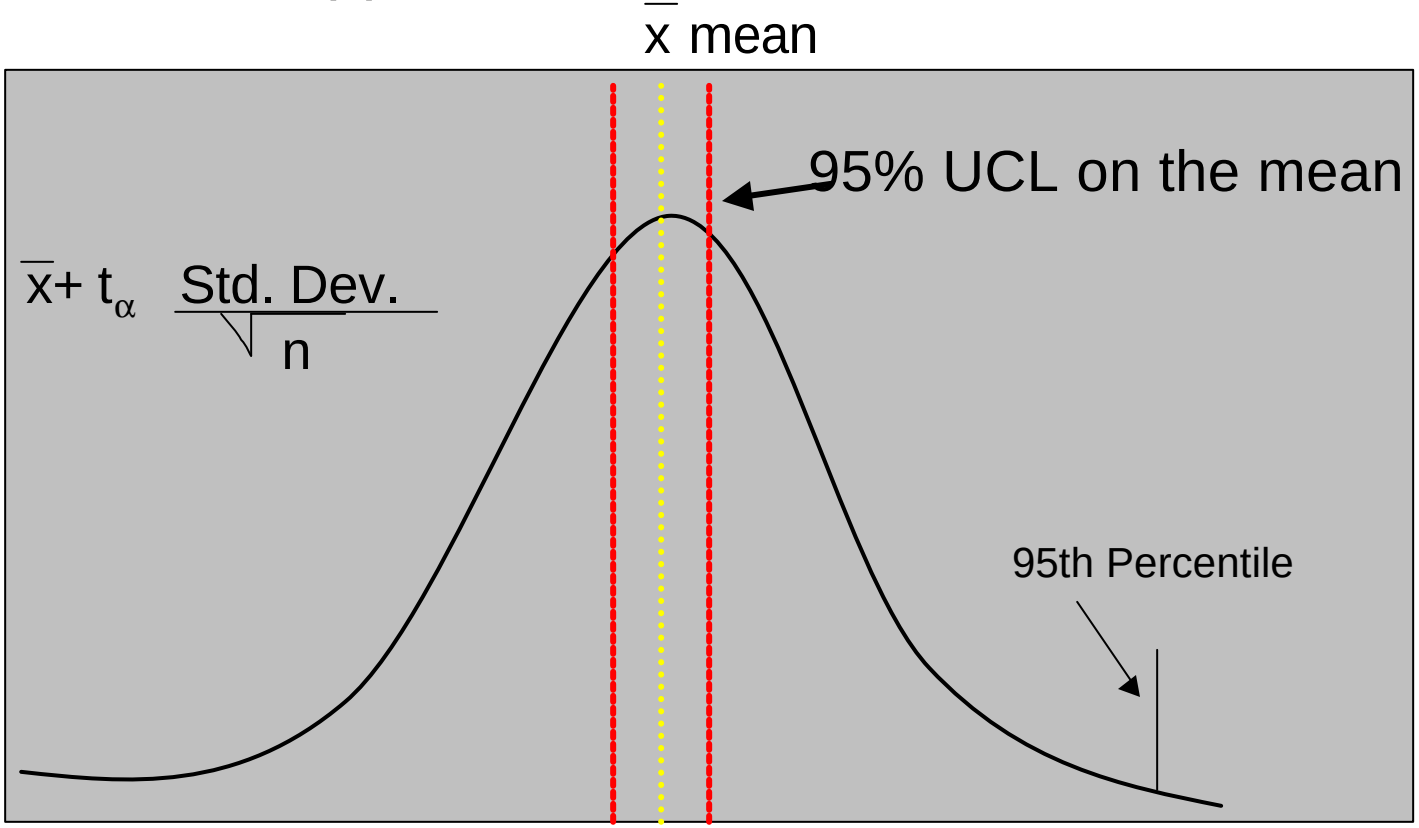
The upper confidence limit (95% UCL) on the arithmetic average

(RAGS, Part A)

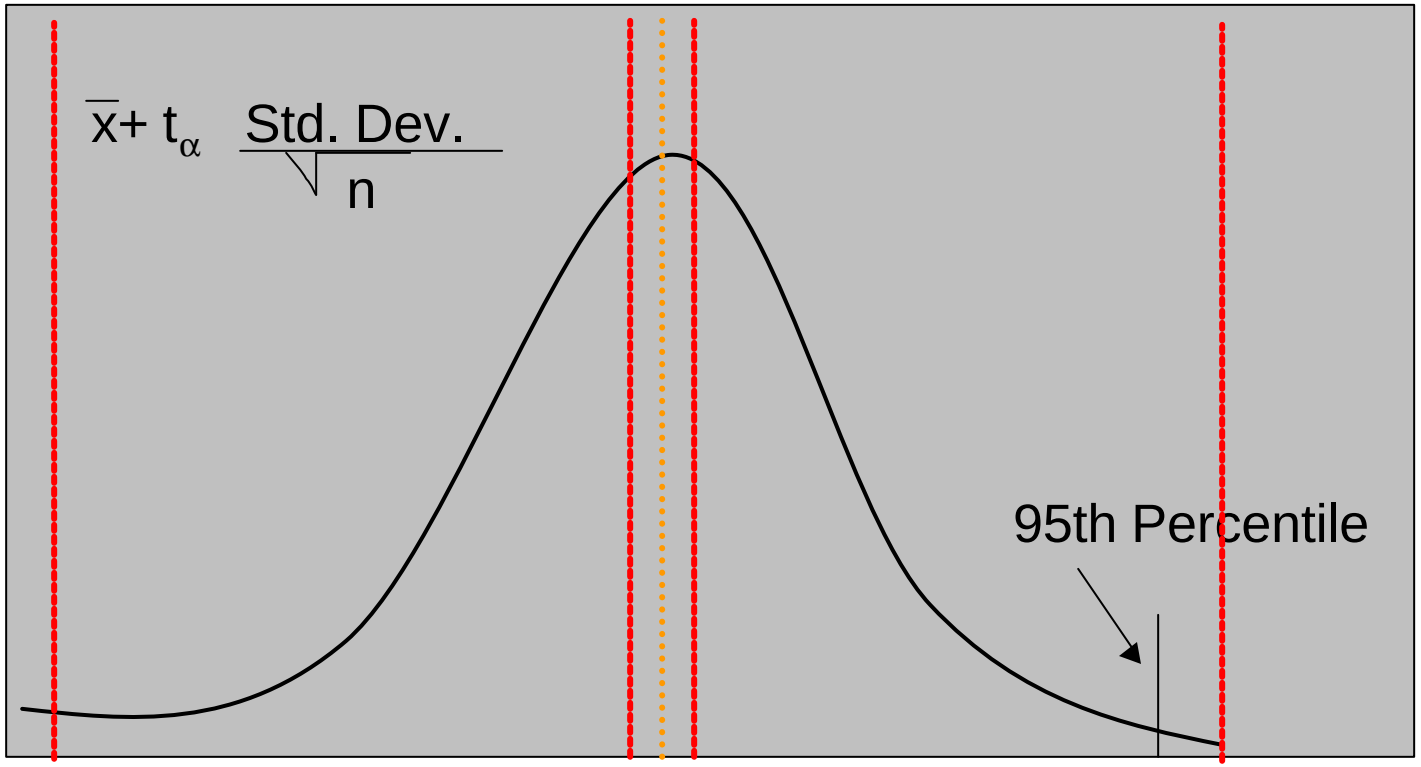
Exposure Concentrations

95 % UCL on the mean

Upper Confidence Level



Impact of Sample Number



mean

95% UCL

Small number of samples

Large number of samples

Number of Samples

	Number of Samples			
Maximum	4	10	60	3000
	1000	1000	1000	1000
Average ($\bar{x}$)	251	107	107	107
95% Upperbound Average	839	290	172	116

As *n* increases, the 95% UCL approaches the true mean ($\bar{x}$)

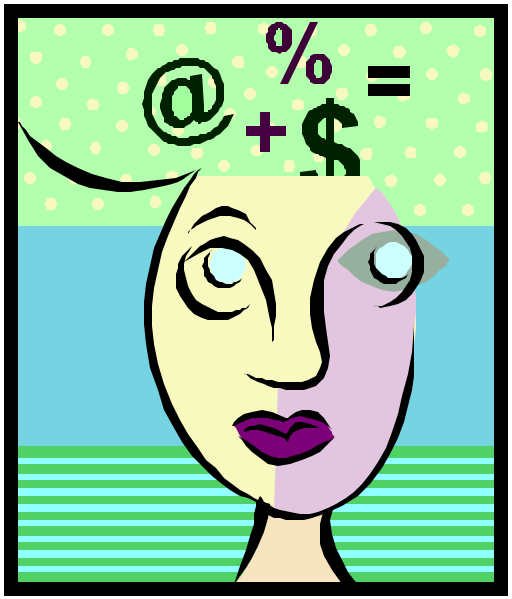
Methodologies

Calculating Exposure Point Concentration

Recommended methods in RAGS

-- Classical statistics

-- Geostatistics



Classical Statistics with Environmental Data

Ideal Data Set:

- Random samples
- Unclustered data
- Uncorrelated data

Typical Field Data:

- Biased toward impacted zones = Non-random
- Clustered around critical spots
- Correlated due to release patterns

Geostatistics

- Advantage:
  - Designed for biased, clustered and correlated spatial data
- Disadvantage:
  - Computationally intensive

Regulatory Acceptance

- **EPA** promoted use of geostatistics in site investigations since 1980s
  - EPA's pioneering study of lead patterns in Dallas
  - Produced two public domain software packages
    - GEO-EAS and GEOPACK
  - Recommended in Cleanup, DQO, and Risk Assessment Guidance
- **ASTM** has published standard guidance for geostatistical applications

Statistics

Classical

Used to calculate

- mean (average) - CTE
- standard deviation (measure of variability)
- 95 UCL - RME

Assumes random sampling (unbiased)

Assumes data not correlated

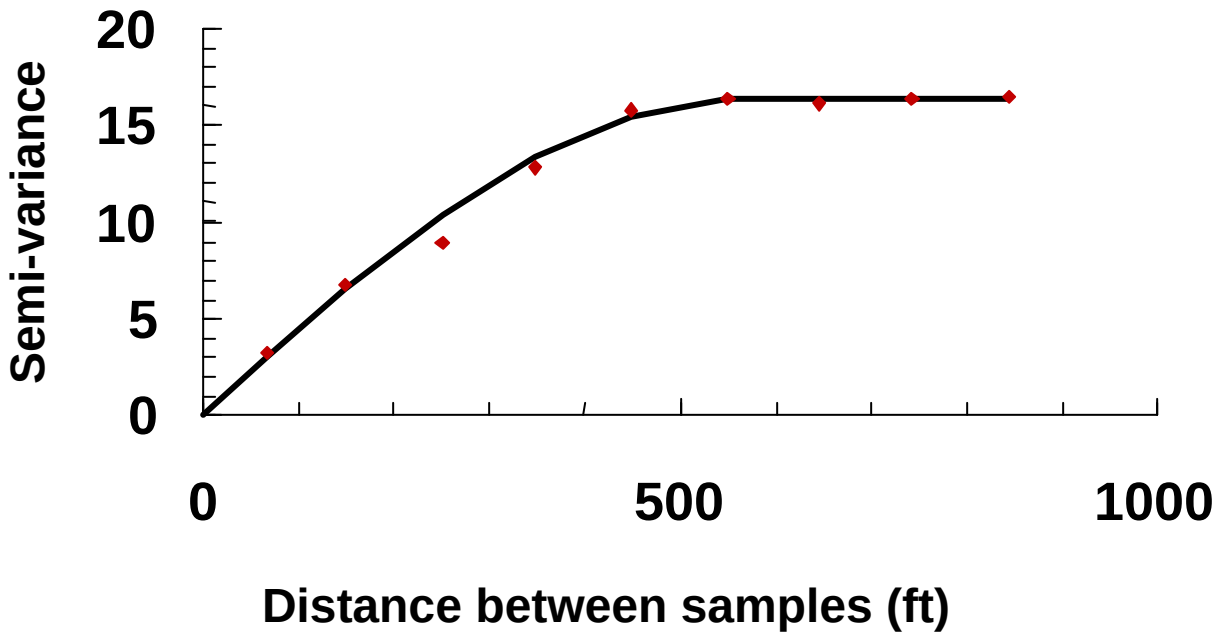
Geostatistics

Designed to evaluate biased and/or correlated samples

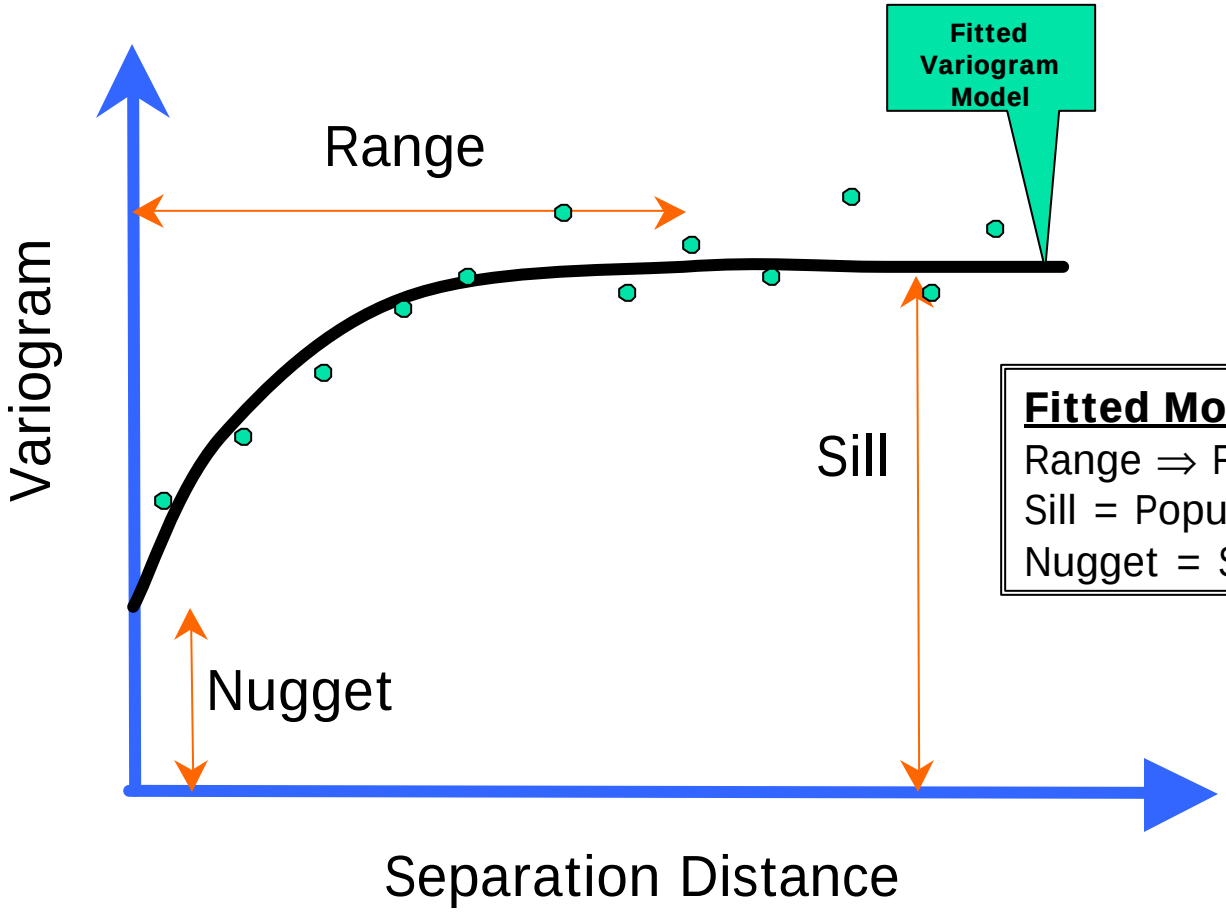
Supplemental Guidance to RAGS:
Calculating the Concentration Term

Variography

- Variogram = Measure of spatial correlation
  - Models differences between measured values as a function of their separation distance
  - Variograms are direction-specific



Variogram Computational Steps



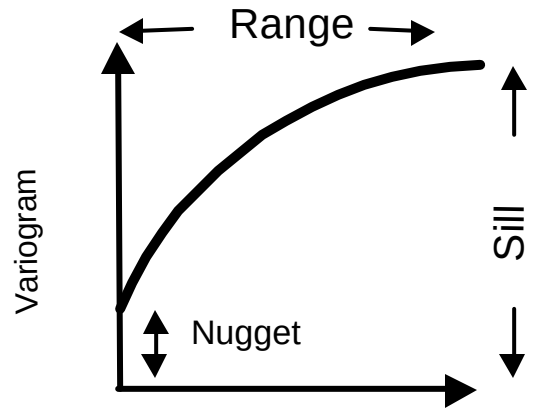
Fitted Model Parameters

Range ⇒ Radius of influence

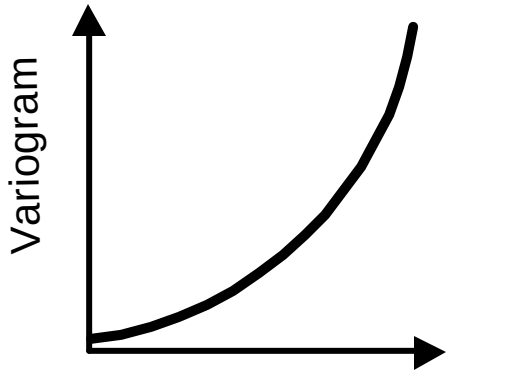
Sill = Population variance

Nugget = Small-scale variations/noise

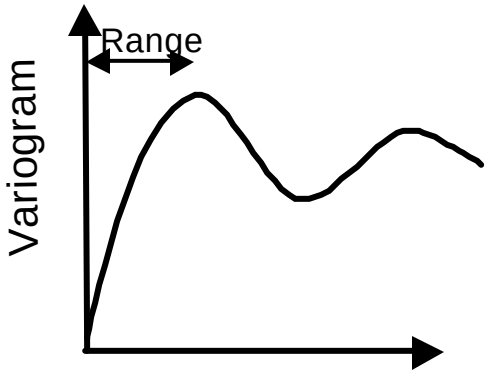
Typical Variogram Results



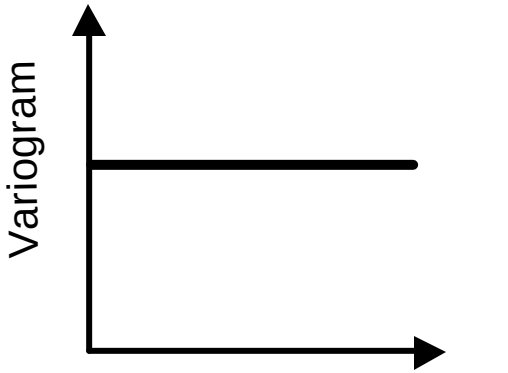
Structure



Trend



Hole Effect



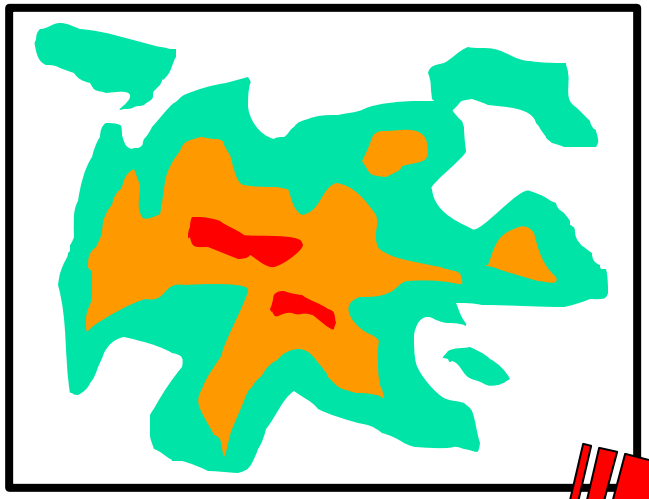
Pure Nugget

Typical Contamination Patterns

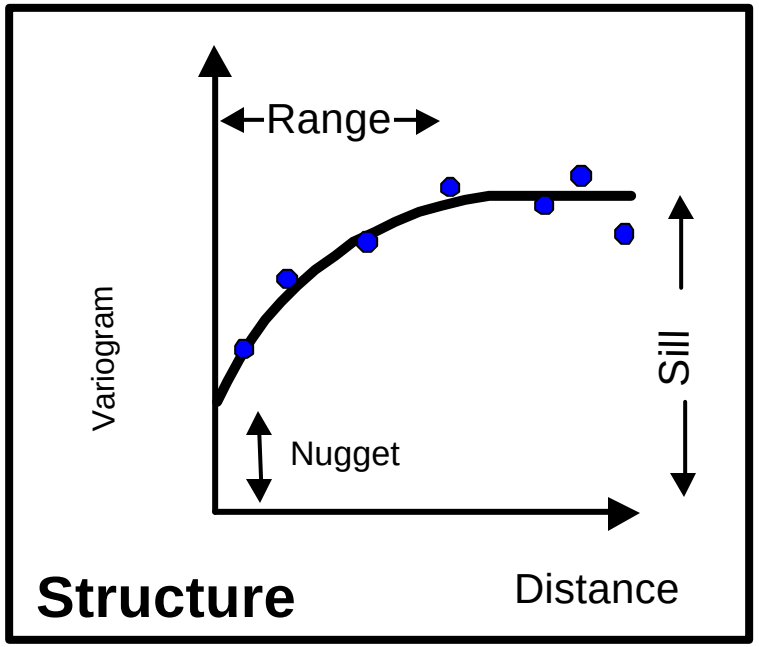
- Structured
- Trend
- Isolated Hot Spots
- Noise/Ambient Conditions

"Each pattern has its own distinct variogram"

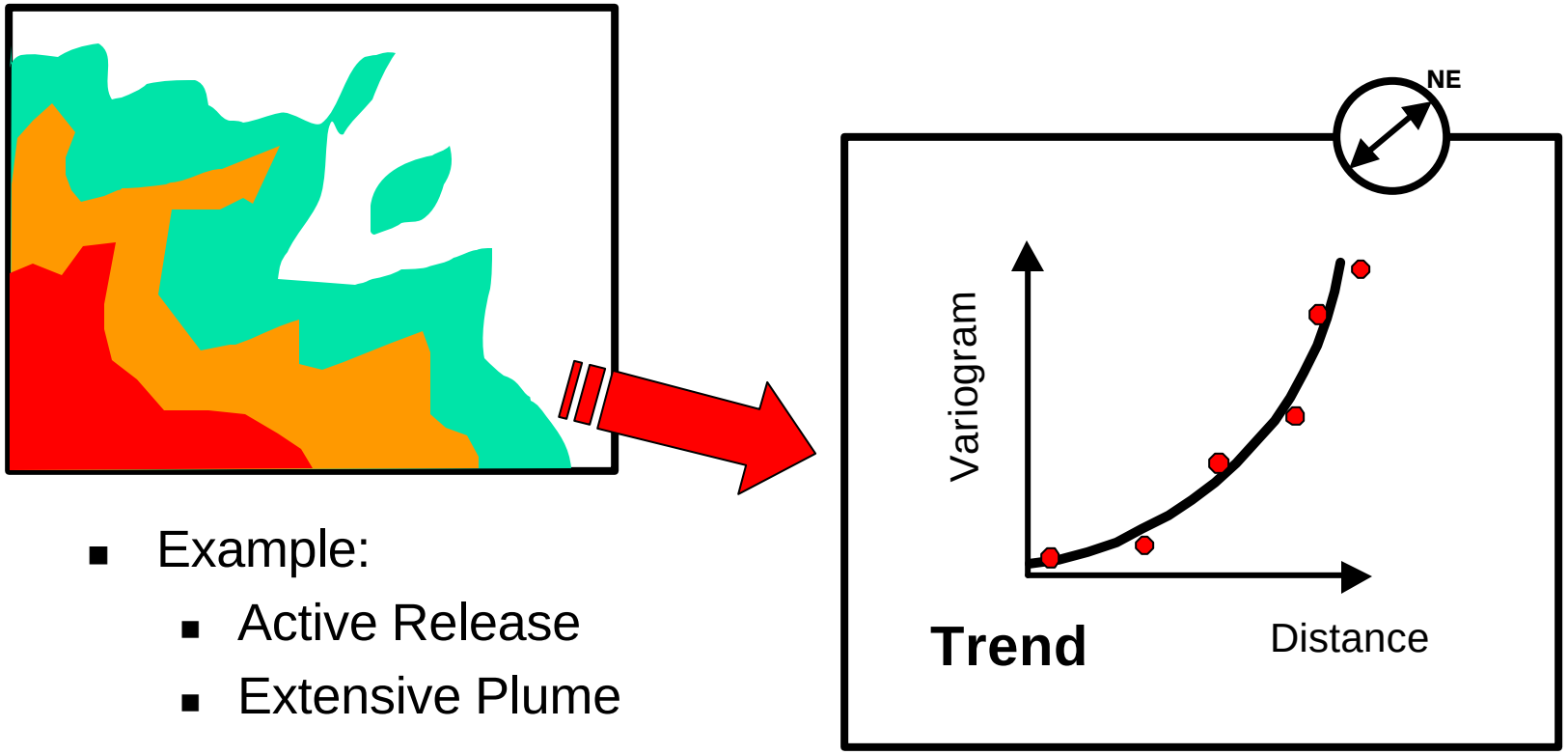
Structured Contaminations



- Example: An Aged/ Weathered Plume
  - Range ~ extent of correlation

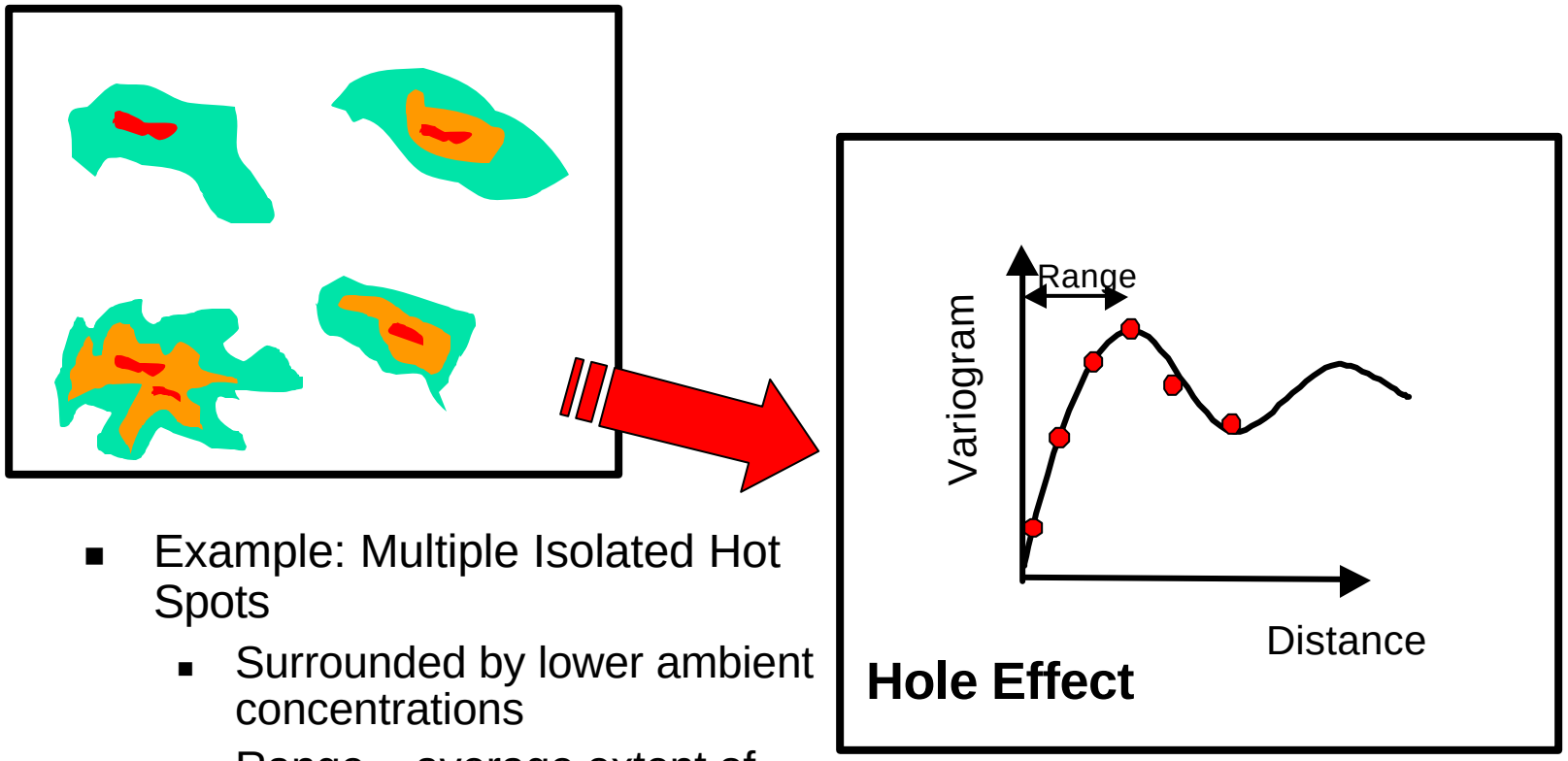


Trend Contaminations



- Example:
  - Active Release
  - Extensive Plume

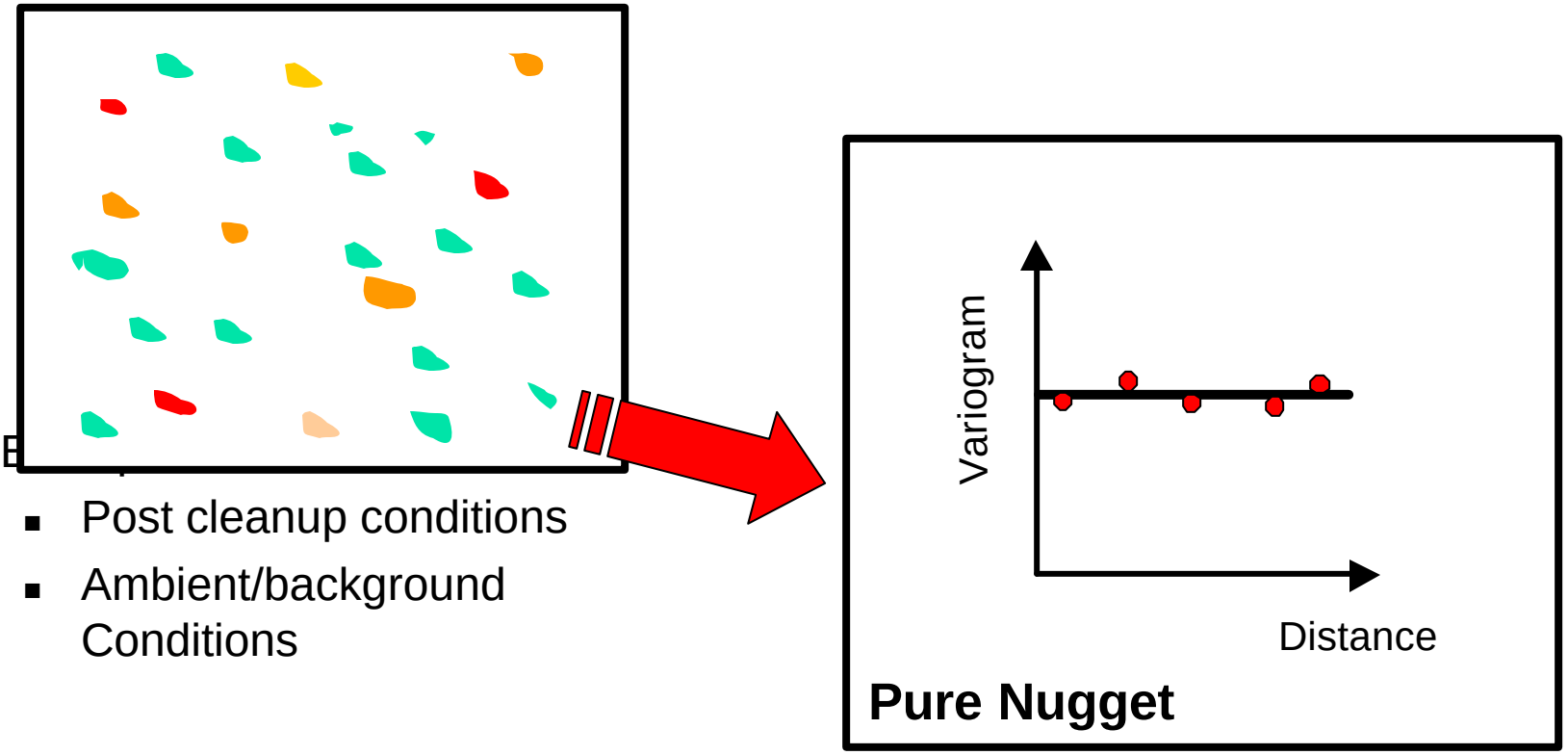
Isolated Hotspots



- Example: Multiple Isolated Hot Spots
  - Surrounded by lower ambient concentrations
  - Range ~ average extent of hot spots

Noise Pattern

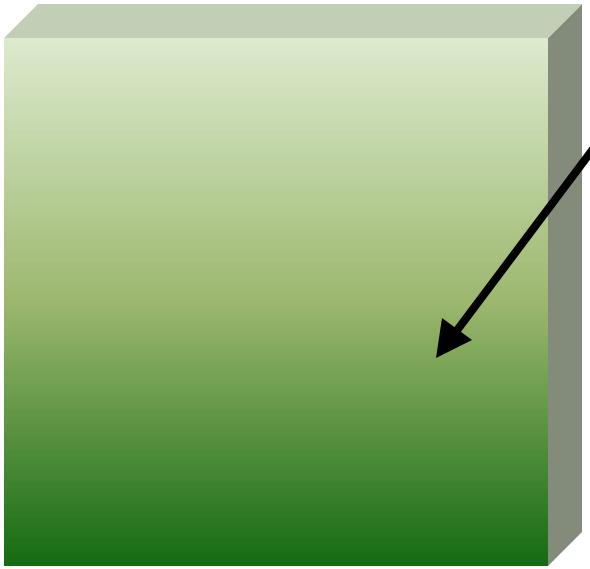
- E
  - Post cleanup conditions
  - Ambient/background Conditions



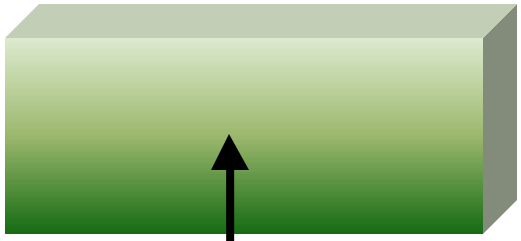
Typical Environmental Uses of Geostatistics

- Sampling Assessment:
  - Evaluate the adequacy of existing data
  - Determine optimal sampling locations
- Site Characterization:
  - Evaluate spatial structure of field data
  - Generate delineations
- Risk Assessment:
  - Calculate most-accurate representative concentrations over exposure domains

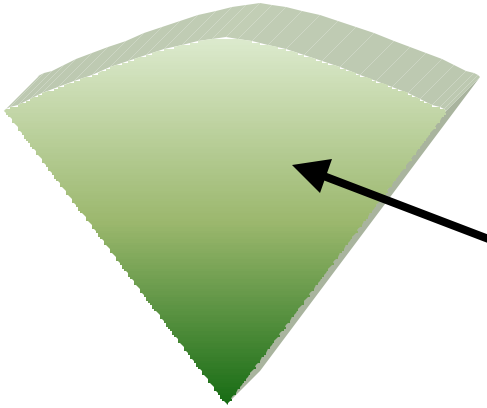
Distinct Exposure Domains



Residential Scenario
Future Use

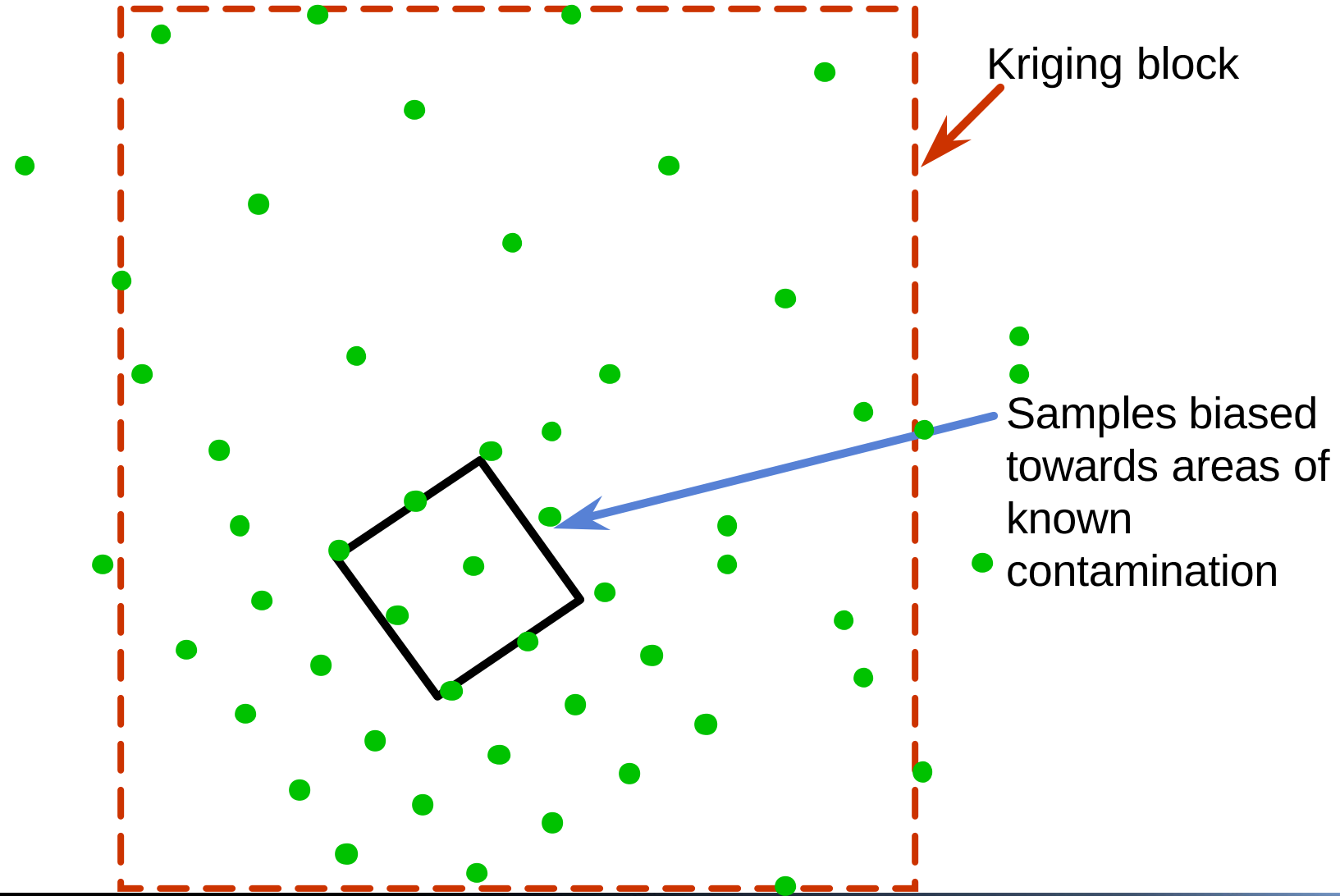


Restricted Magazine Area
Maintenance workers



Baseball Field
Athletic Camps

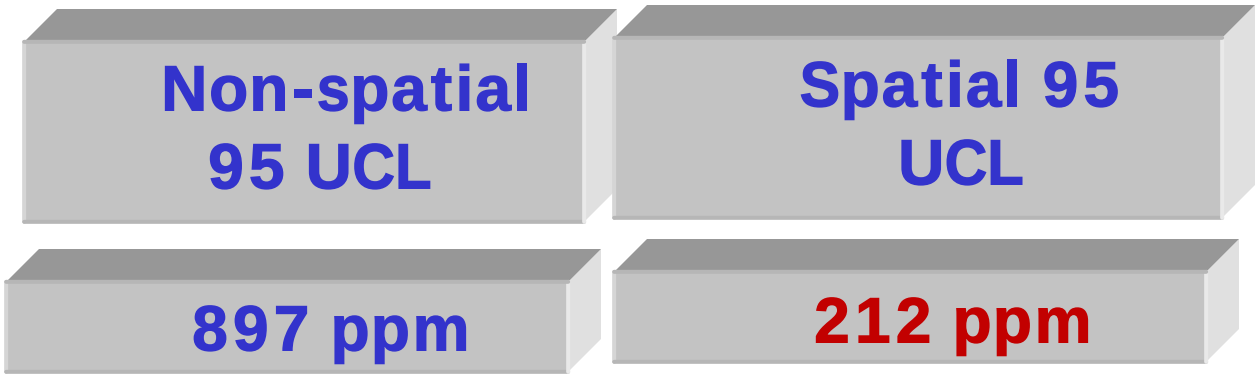
Calculating Exposure



Exposure Domain Solution

Hot spots or data clustered in contaminated areas

Dramatically over-estimated the level of contamination
Incorrectly assessed area's true risk

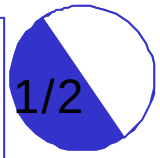


Non-detect Data in the Risk Assessment

When nondetect data is present in a data set:

"Use one-half the SQL as a proxy value when it is possible the chemical may be present in the sample just below the detection limit."

SQL – sample quantitation limit (actual sample detection limit)



(RAGS, Part A)

Spurious Non-Detect Data

"Eliminate high nondetect data when they cause the exposure point concentration to exceed the maximum detected value."

Average for the four samples:
5052

(USEPA, 1989; HHEM, Part A)

EXAMPLE OF UNUSUALLY HIGH QUANTITATION LIMITS

In this example, concentrations of semivolatile organic chemicals in soils have been determined using the CLP's RAS.

	Concentration (ug/kg)			
Chemical	Sample 1	Sample 2	Sample 3	Sample 4
Phenol	330 U[a]	390	19,000 U	490

[a] U = Compound was analyzed for, but not detected. Value presented (e.g., 330 U) is the SQL.

The QLs presented in this example (i.e., 330 to 19,000 ug/kg) vary widely from sample to sample. SAS would not aid in reducing the unusually high QL of 19,000 ug/kg noted in Sample 3, assuming it was due to unavoidable matrix interferences. In this case, the result for phenol in Sample 3 would be eliminated from the quantitative risk assessment because it would cause the calculated exposure concentrations (from Chapter 6) to exceed the maximum detected concentration (in this case 490 ug/kg). Thus, the data set would be reduced to three samples: the non-detect in Sample 1 and the two detected values in Samples 2 and 4.

Unacceptable Risk at Detection Limit

EXAMPLE OF HEALTH RISKS FROM INGESTION OF WATER CONTAMINATED WITH SELECTED CHEMICALS AT THEIR QUANTITATION LIMITS[a]

Chemical	CAS #	CRQL or CRDL (ug/L)[b]	CRDL/RfC[c]	Cancer Risk at CRQL or CRDL[d]
Antimony	7440-36-0	60	4.3	
Arsenic	7440-38-2	10		$5x10^{-4}$
Benz(a)pyrene	50-32-8	10		$3x10^{-3}$
Bis(2-Chloroethyl)ether	111-44-4	10		$3x10^{-4}$
2,4-Dinitrotoluene	121-14-2	10		$2x10^{-4}$
Hexachlorobenzene	118-74-1	10		$5x10^{-4}$
N-Nitroso-di-n-dipropylamine	621-64-7	10		$2x10^{-3}$
PCB-1254	11096-69-1	1		$2x10^{-4e}$
PCB-1260	11096-82-5	1		$2x10^{-4}$
Styrene	100-42-5	5		$4x10^{-4}$
Vinyl chloride	75-01-4	10		$7x10^{-4}$

Note: Risk-based screening may not be possible for these chemicals

Detection Limits in Risk Assessment

- ½ detection limit for non-detects
- Elevated detection limits can result in nondetect values in risk assessment posing potential risk
- Older data often have elevated detection limits
- Decision on using “all” data or “reliable” data

If you are in the planning stages – *carefully* evaluate detection limits prior to sample collection

Background Definition

Background Constituents

Constituents whose presence can be attributed to naturally occurring or anthropogenic processes

Two Types of Background

Naturally occurring

Ambient concentrations of constituents present in the environment that have not been influenced by human activity

Anthropogenic

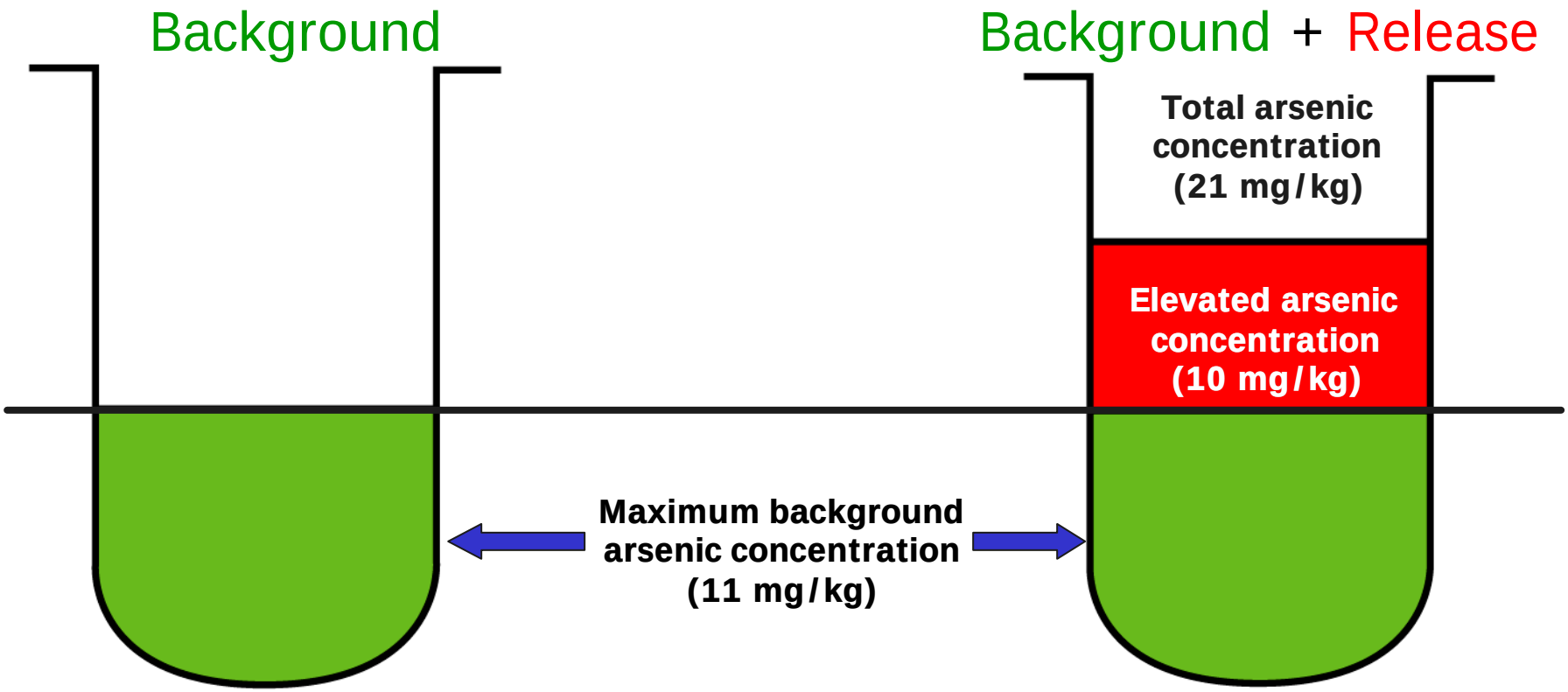
Widely distributed chemicals present in the environment due to human activities, but are non-site sources

Can range from localized to ubiquitous

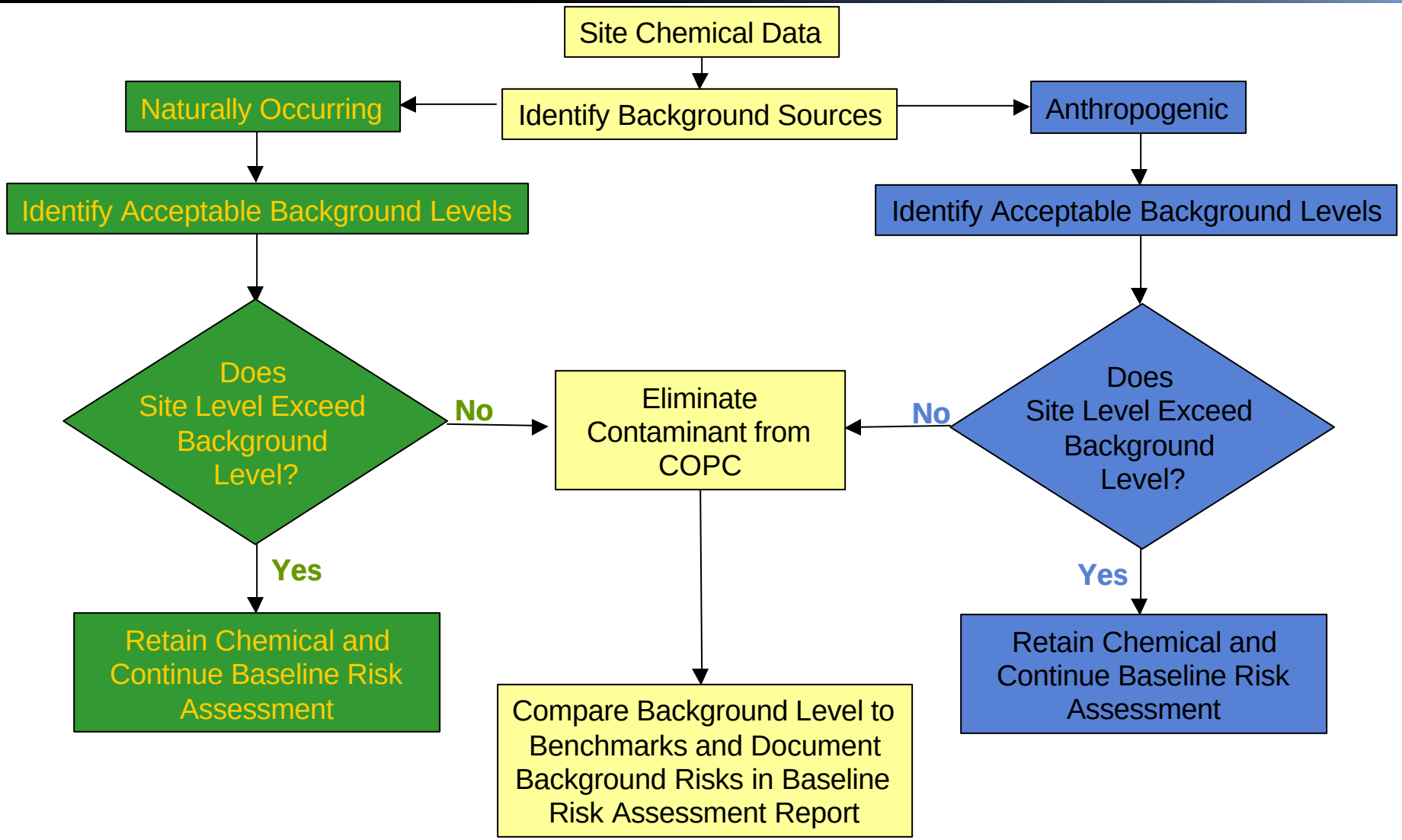
Attributed to past legal applications

Where's Background?

"Background" is in all soil samples



Use of Background Levels



Typical Background Problems

- Determining COPCs vs. background constituents:
  - Distinguish risks posed by COPCs and background constituents in the *risk assessment*
- Defining background levels of COPCs:
  - Delineate the impacted areas in the *site characterization*
  - Distinguish "incremental" risks posed by above-background COPCs in the *risk assessment*

Consistent with new EPA guidance – April 2002
Role of Background in the CERCLA Cleanup Program

Avoid Flawed Background Application

"Threshold comparison"

Compare individual site measurements to some threshold value calculated from background to distinguish COPCs vs. background chemicals

Probability of Obtaining at Least One Value Greater Than the Established Threshold

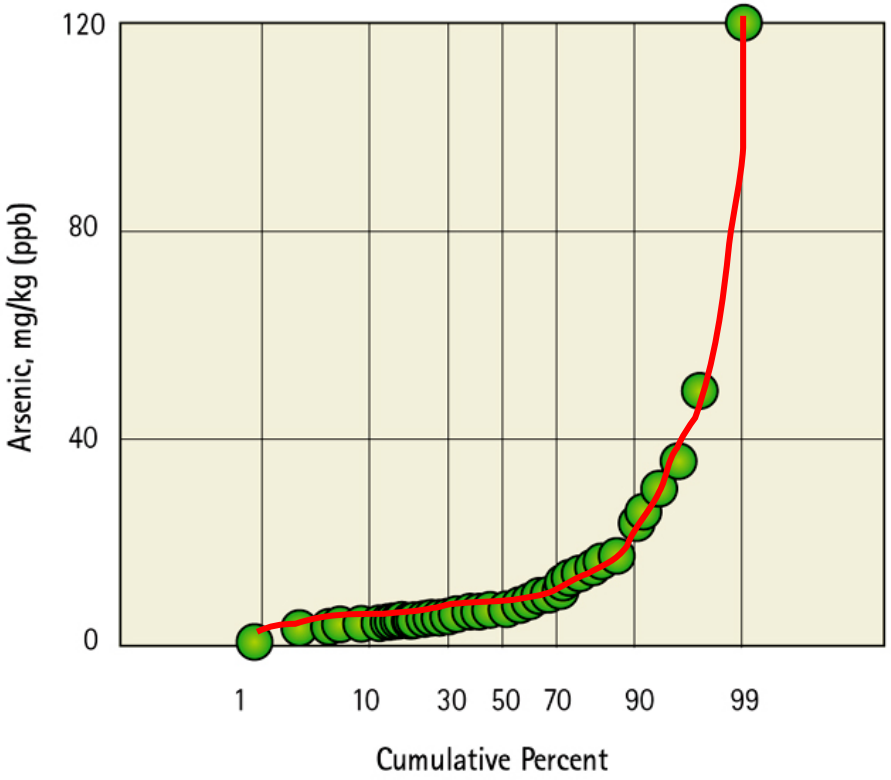
Sample Size (n)	$1 - q^n$
5	0.23
6	0.26
7	0.30
8	0.34
9	0.37
10	0.40
11	0.43
12	0.46
13	0.49
14	0.51
15	0.54
16	0.56
17	0.58
18	0.60
19	0.62
20	0.64
21	0.66
30	0.79
42	0.88
64	0.96

Hotspot Evaluation

- Hotspot defined as elevated concentrations AND increased exposure

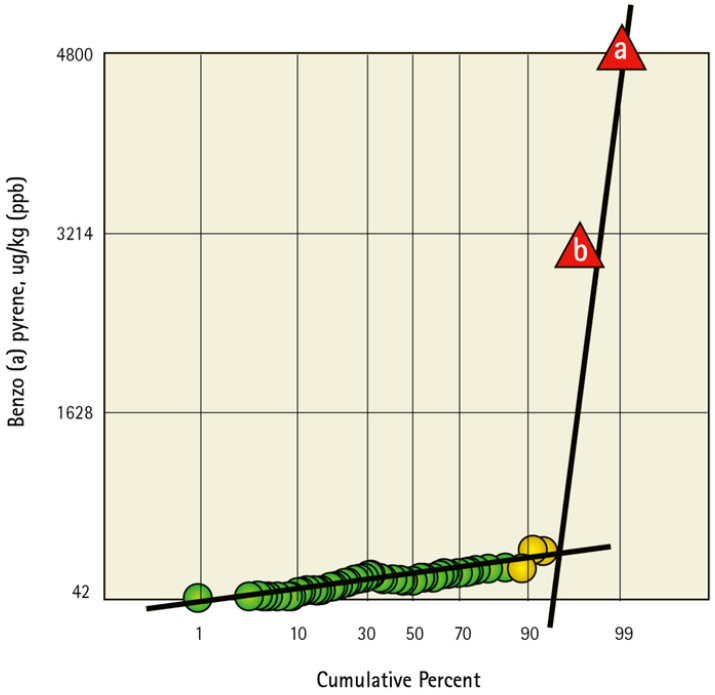
RAGS, Part A

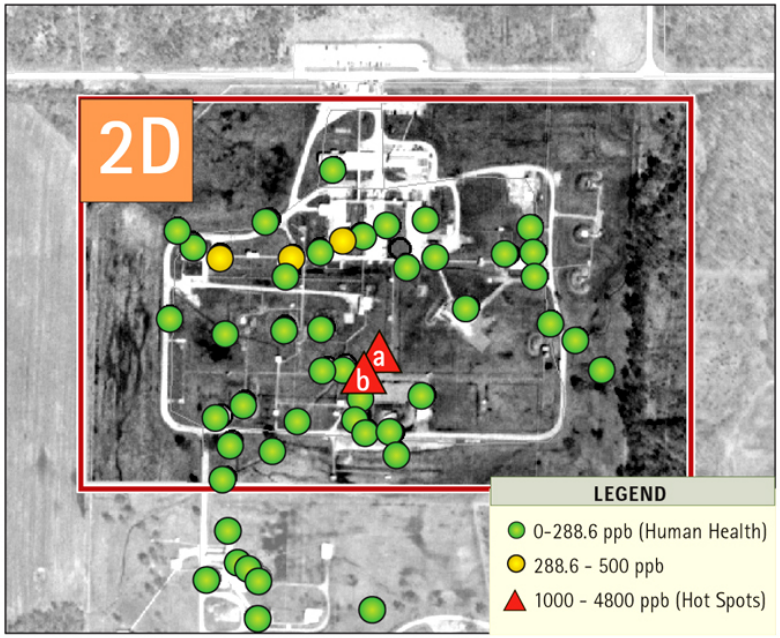
Hotspot Evaluation



Prepare a probability plot of all the data
Determine “ambient population”

Hotspot Evaluation





Two distinct slopes – ambient and hotspots
Can be used to establish background

Summary

Planning issues - screening through baseline risk assessment

- Where and how to sample
  - Purposive
  - Random
- Statistical evaluation
  - Classical
  - Geostatistics
- Detection limits
- Background concentrations
- Hotspot evaluation