*External Review DRAFT*

GEORGIA
DEPARTMENT OF NATURAL RESOURCES
ENVIRONMENTAL PROTECTION DIVISION

**Land Protection Branch**
**Hazardous Waste Corrective Action Program**
**Hazardous Waste Management Program**
**Response & Remediation Program**
2 Martin Luther King, Jr. Dr. SE
Suite 1054
Atlanta, Georgia 30334

# Area Averaging Approach to Soil Compliance for Direct Contact Exposure Scenarios

December , 2020

***Note: This is an external review draft to assist stakeholders in providing feedback as part of a guidance development process. Final agency approval of this document is pending.***

## ACKNOWLEDGEMENT

The following current and former staff of the EPD Land Protection Branch participated in the development of this document:

- Kevin Collins – Team Lead (Response & Remediation Program)
- Shanna Alexander (Formerly Risk Assessment Program)
- Antonia Beavers (Response & Remediation Program)
- Mauri Centis (Hazardous Waste Corrective Action Program)
- Heather Clark (Hazardous Waste Management Program)
- Laura Dahlgren (Formerly Response & Remediation Program)
- Robin Futch (Formerly Response & Remediation Program)
- Mike Gillis (Hazardous Waste Management Program)
- Yue Han (Response & Remediation Program)
- Jane Hendricks (Formerly Hazardous Waste Management Program)
- Amy Potter (Risk Assessment Program)
- Bill Williams (Response & Remediation Program)
- John Williams (Risk Assessment Program)
- Jill Clark (Risk Assessment Program)

Additional EPD staff and management provided technical review of this document.

# REGULATORY APPLICABILITY

This document provides technical guidance for developing and evaluating an area averaging approach to soil compliance for direct contact exposure scenarios under applicable Georgia statutes and regulations administered by the following programs of the Land Protection Branch:

- Hazardous Waste Corrective Action Program
- Hazardous Waste Management Program
- Response & Remediation Program
- Risk Assessment Program

This guidance document is intended for use by environmental professionals who have experience in the investigation and remediation of soil contamination. The guidance provided within this document includes methods and recommendations that can be used to meet the direct contact soil exposure pathway evaluation requirements of applicable statutes and regulations; however, this document is not a statute or a regulation. This document may be revised in the future based on comments and/or new information. This guidance is not intended to be comprehensive or all inclusive; however, using the methods and recommendations in this guidance document will provide for streamlined EPD review of site-specific area averaging direct contact soil exposure pathway evaluations. The use of trade names does not constitute endorsement by EPD.

# Table of Contents

## Tables

## ACRONYMS AND ABBREVIATIONS

| | |
|---|---|
| ASTM | American Society for Testing and Materials |
| BGS | Below Ground Surface |
| CERCLA | Comprehensive Environmental Response, Compensation, and Liability Act |
| CFR | Code of Federal Regulations |
| CoC | Chemical of Concern |
| CRG | Confidence Response Goal |
| CSM | Conceptual Site Model |
| DQO | Data Quality Objective |
| DU | Decision Unit |
| EPC | Exposure Point Concentration |
| EPD | Georgia Environmental Protection Division |
| EU | Exposure Unit |
| FAQs | Frequently Asked Questions |
| HSRA | Hazardous Site Response Act |
| IC | Institutional Control |
| ITRC | Interstate Technology and Regulatory Council |
| KM | Kaplan-Meir |
| MDC | Maximum Detected Concentration |
| OSWER | Office of Solid Waste and Emergency Response |
| PAHs | Polycyclic Aromatic Hydrocarbons |
| PNNL | Pacific Northwest National Laboratory |
| Q-Q | Quantile-Quantile |
| RAGS | Risk Assessment Guidance for Superfund |
| RCRA | Resource Conservation and Recovery Act |
| RRP | Response and Remediation Program |
| RRS | Risk Reduction Standard |
| STP | Selected Technical Paper |
| UCL | Upper Confidence Limit |
| UEC | Uniform Environmental Covenant |
| USEPA | United States Environmental Protection Agency |
| VOC | Volatile Organic Compound |
| VRP | Voluntary Remediation Program (VRP) |
| VSP | Visual Sampling Plan |

# 1.0 INTRODUCTION

There are various remedial strategies that may be employed at a site in order to demonstrate compliance with the applicable statutes and regulations pertaining to soil. The area averaging approach is one of the viable approaches to compare soil concentrations at a site with risk-based cleanup values for the protection of human health.

The area averaging approach to soil compliance can be defined as the utilization of discrete soil data to demonstrate that the average concentration of contaminants in soils at a site is less than the applicable cleanup level (USEPA, 2005). This approach may or may not include the removal of impacted soil and differs from the “not-to-exceed,” “bright line,” or the point-by-point approach to soil cleanup. There may be compliance scenarios where the calculated average meets the cleanup level, but some individual discrete sample locations remain above what would be considered the “not-to-exceed” level in a point-by-point analysis. When applied accurately, the quality assurance and control measures typically entrained within the statistical methods can be used to efficiently and economically test for attainment of cleanup standards, as they allow for specifying and controlling the probabilities of making decision errors (USEPA, 1994).

The area averaging approach to soil compliance is most applicable to those exposure scenarios where routine surficial contact occurs, as the calculated exposure concentrations are intended to be average “site-related” concentrations routinely contacted by a human receptor. This guidance primarily pertains to direct contact exposure scenarios for soil and does not cover ecological risk or soil leaching determinations. For guidance related to demonstrating compliance with leaching values for the soil to groundwater pathway, including the use of area averaging approaches to demonstrate compliance with this pathway, see EPD’s *FAQs for Evaluating the Soil to Groundwater Pathway*. It is important to note that the fate and transport of certain contaminants may extend beyond soil into other media such as surface water and sediment (via runoff), groundwater (via infiltration/percolation), and/or air (via particle/dust). However, these pathways are beyond the scope of this guidance.

Typically, a certain degree of statistical expertise is needed to perform and evaluate the statistical methods used when applying this approach; therefore, it is assumed that the users of this guidance possess a working knowledge of general statistics and statistical applications. Please note that to remain consistent with most other state and federal guidance on soil area averaging the scope of this guidance document pertains primarily to the use of discrete sample data to demonstrate soil compliance through area averaging and does not recommend the statistical analysis of composite sampling data. While composite soil sampling does not utilize the same statistical methodologies and approaches identified herein to demonstrate soil compliance, composite soil sampling is an accepted form of data collection that may be used to represent the average conditions in the sampled body of material. In addition, incremental sampling methodologies, when conducted in accordance with the procedures established in the most recent version of the Interstate Technology and Regulatory Council “Incremental Sampling Methodology” guidance (ITRC, 2012), are considered another acceptable form of soil sampling to provide an estimate of mean constituent concentrations in a specified Decision

Unit. For additional information on composite soil sampling methodologies please see the following:

- USEPA, 1995. EPA Observational Economy Series; Volume 1: Composite Sampling, EPA-230-R-95-005. USEPA. Washington, DC. August.
- USEPA, 2002. Guidance on Choosing a Sampling Design for Environmental Data Collection for Use in Developing a Quality Assurance Project Plan, EPA QA/G-5S. USEPA. Washington, DC. December.

## 2.0 KEY AREA AVERAGING CONCEPTS

The definitions established within this document are intended to support the various Georgia EPD Programs that utilize a soil area averaging approach, and they do not replace or supersede any definition established within any applicable statute or regulation.

**Decision Unit (DU)**

The DU, for purposes of this guidance document, will be defined as a volume of soil within which a receptor comes in contact over an established exposure duration. Generally, the "DU" term defined in this document can be used to describe terms such as "exposure area", "exposure unit", "exposure domain", "area of concern", or "RCRA solid waste management unit". The size and placement of the DU is site specific and may be based on the exposure scenario, investigative phase, and regulatory program.

**Residential DU**

While established DUs will vary based on site-specific characteristics, it can be assumed that for a residential scenario the DU size does not exceed 0.5-acre (i.e., the typical size of a suburban residential lot), consistent with USEPA's *Soil Screening Guidance* (USEPA, 1996a). For residential-driven compliance goals, large residential properties should be divided into DUs of 0.5-acre to account for the future potential that the property is parceled out into smaller residential lots, which will allow for the property to maintain the designation of unrestricted future use. However, multi-family structures, such as townhomes, condominiums, and apartments, may extend over surface areas greater than 0.5-acre, and the size of the DUs for these multi-family properties may be determined on a site-specific basis.

**Non-residential DU**

DU's for non-residential scenarios can exceed 0.5-acre in size, and it is recommended that these DUs be developed on a site-specific basis. According to the USEPA *Soil Screening Guidance: User's Guide*, the DUs should not be laid out in such a way that they unnecessarily combine areas of high and low levels of contamination to deliberately manipulate the mean (USEPA, 1996b).

**Exposure Point Concentration (EPC)**

As defined in the *Risk Assessment Guidance for Superfund: Volume III – Part A* (USEPA, 2001), an EPC is the arithmetic average long-term concentration of a chemical (within an DU) to which receptors are exposed. The EPC is often estimated as the 95% upper confidence limit (UCL) of the arithmetic mean and may be used to demonstrate compliance with the direct contact exposure soil cleanup criteria. When utilizing soil area averaging to determine compliance with a numerical soil cleanup standard, discrete soil data should be used to determine the 95% UCL for the mean of the contaminant concentrations in soil.

## Hot Spots

For the purposes of this guidance document and for use with the area averaging approach, a hot spot can be defined statistically as one sample, or more than one adjacent sample locations, at which concentrations are above the remediation/screening criteria and significantly higher than concentrations found surrounding the location(s) (i.e., spatially correlated concentrations sufficiently above criteria) to indicate that they:

a. Represent a different statistical population; and
b. Pose a potential risk that should not be masked by a statistical analysis (Michigan DEQ, 2002).

## Randomness

For the purpose of this guidance document, randomness implies that nothing impedes, prohibits, or concentrates exposure (e.g., physical barriers and prohibited access). For instance, allowing soil contamination to remain in place in areas that are frequented more often than other areas (not randomly visited) within a DU (e.g., child's playground, garden, etc.) may result in exposures to unacceptable levels of risk.

## Release Area

While "hot spots" are primarily defined through the use of site data, "release areas" are typically defined through the interpretation of site information and site observations. The following general criteria may be applied to locate, determine, and define a release area:

- Areas with stained soil, known contamination, or obvious releases;
- Areas where contaminants were suspected to have been stored, handled, or disposed; and/or
- Areas of soil contamination associated with the generation, management, treatment, or disposal of known hazardous wastes.

## Surface Soil

For the purposes of this guidance, soils from 0-12 inches are generally considered as available for direct human contact and will be considered as "surface soil" [USEPA Region 4 Human Health Risk Assessment Supplemental Guidance (USEPA, 2018)]. For sites demonstrating soil compliance through the VRP Act (O.C.G.A. 12-8-100), please note that Sections 12-8-102(6) & 12-8-108(5) of the VRP Act define surface soils as being from ground surface down to a depth of two feet.

## "True" Average

The "average", for the purposes of this guidance, refers to the "true" average or "arithmetic mean" of a set of values, (i.e. the sum of all values divided by the number of values).

# 3.0 GENERAL SITE ASSESSMENT CONSIDERATIONS

Decisions about whether to use soil area averaging or to demonstrate soil compliance utilizing a not-to-exceed or point-by-point approach can depend on the quantity and quality of site characterization data. EPD recommends the use of the USEPA *Data Quality Objectives Process for Hazardous Waste Site Investigations* (USEPA, 2000) for guidance on developing a sampling strategy focused on collecting the right type, quality, and quantity of data needed to support soil area averaging decisions.

One of the early steps during a site assessment involves gathering and documenting site-specific information, which may be used as an initial screening for environmental concerns and as a basis for the conceptual site model (CSM). The CSM is an integral part of the area averaging approach to soil compliance and can be used to help develop and perform an effective sampling and analysis investigation. Site-specific information acquired in the early part of the project lifecycle may also help to potentially screen out uncontaminated areas of the site.

While this section of the guidance provides information on general site assessment considerations and key CSM components associated with the soil area averaging approach, please note that it may not include all the necessary information to complete a site-specific investigation and CSM. For program-specific details not covered within this document in relation to completing a CSM, it is recommended that the regulatory compliance officer be consulted during the site assessment process, even if an area averaging approach for soil compliance is not being considered.

## 3.1 Conceptual Site Model

Once the site-specific information has been gathered, a CSM should be developed and updated throughout the project lifecycle. The CSM will help to identify the data necessary to support further decision-making at the site. As more data becomes available, the CSM will allow the facility to continually refine the model and provide a clearer picture of the soil compliance issues at a site.

The major components of a CSM are described in various USEPA documents and the ASTM Standard Guide E 1689, and can be helpful when developing and implementing an area averaging approach to soil compliance. For direct contact to soil contaminants, important CSM inputs include, but are not limited to, the following:

- Historical site uses
- Location of contaminant sources
- Identification of contaminants of concern and associated concentrations
- Variability / heterogeneity in soil media or contaminants
- Spatial variability and distribution pattern (i.e., uniform, randomly scattered, dumped, etc.) of contaminant concentrations

- Chemical/physical properties of contaminants
- Receptors and associated exposure pathways
- Current and potential future site use
- Identification of data gaps

One of the key components of a CSM that can influence the development of an area averaging approach to soil compliance is the identification of hot spots and release areas, which can bias existing data sets that may not have been developed with the initial intention of area averaging (USEPA, 2013). Site assessment plans should include the characterization of hot spots and release areas through extensive sampling, field screening, visual observations, or a combination of the above (USEPA, 1989). Note that while a release area may be identified visually (i.e. stained soil, free product), a hot spot can be identified through statistical analyses of soil sampling results. Both hot spots and release areas may be identified using a line-of-evidence or weight-of-evidence approach, provided that the evidence is technically and regulatorily acceptable and supported by adequate site-specific data. Depending upon the established compliance objectives for the site, these identified hot spots and release areas may or may not need to be remediated in order to demonstrate compliance.

### 3.2 Exposure Pathway & Exposure Scenario

Another key component of a CSM that can influence the development of an area averaging approach to soil compliance is the determination of which exposure pathways are complete and incomplete. When direct contact is the exposure pathway in question, soil area averaging can provide an estimate of the true populations based on an assumption that contact with soil is spatially random (see page 6-28, RAGS Part A).

An exposure pathway generally consists of four elements: (1) a source and mechanism of chemical release, (2) a retention or transport medium (or media in cases involving media transfer of chemicals), (3) a point of potential human contact with the contaminated medium (referred to as the exposure point), and (4) an exposure route (e.g., ingestion) at the contact point (page 6-8, RAGS Part A). These four elements and the current and future use of property can be combined to establish a preliminary exposure scenario. The exposure scenario can be used to help focus investigative efforts.

For the purpose of this guidance, the exposure pathway and corresponding exposure scenario will typically consist of a release source (if known); soil as the exposure media; direct contact (inhalation, dermal, and/or incidental ingestion) as the exposure route, and the human receptor (resident, industrial worker, construction worker, etc.) as the contact point.

Please note that groundwater compliance and the associated groundwater exposure pathway should be taken into consideration when utilizing an area averaging approach for soil compliance, as there may be some site-specific exposure scenarios where the requirements to demonstrate groundwater compliance may influence the upper bound concentration limit for soils left in place at a site.

## 4.0 CHOOSING A SAMPLING DESIGN

In order to design an efficient and focused sampling plan that can meet the established decision objectives associated with an area averaging approach, it is important to utilize the CSM and the DQO process. Specifically, the following factors should be taken into consideration as the decision objectives are established and the associated sampling plan is developed: 1) site use (current and future) and source information presented in the CSM, 2) sampling strategy and field protocols that are optimal to achieve the investigation objectives specified in the DQO process, 3) potential presence of hot spots and release areas, and 4) pertinent regulatory requirements. For instance, areas where site operations or known releases are observed in the field will most likely be incorporated into the sampling plan, but it is also important to sample other portions of the decision unit (DU) and/or site based on future use or locations where exposures may occur.

There are many potential sampling plan variations that may work for your site, some of which are described in the USEPA document entitled "*Guidance on Choosing a Sampling Design for Environmental Data Collection*" (USEPA 2002a). Out of the many sampling designs that are available, the most commonly accepted sampling design plans throughout the applicable EPD compliance programs are: systematic or grid sampling and biased or judgmental sampling. Some basic information on these two commonly used soil area averaging sampling plans, and on random sampling plans, are included in this Section of the guidance.

Biased sampling designs are relatively easy to implement and depend on knowledge of the site and its operations; however, statistical analysis of the biased sampling data, which is usually clustered in one area of a DU, cannot be used to draw conclusions about the entire site. Conversely, data generated using systematic or grid sampling designs are appropriate when little or no information is known about the DU (e.g., what chemicals were managed within the DU, where releases may have occurred, etc.) and can provide more complete coverage of a DU than simple random sampling. Grid sampling can also provide the ability to make statistical inferences including an evaluation of the uncertainty associated with the estimate of the parameter of interest.

Simple random and stratified random sampling designs, as defined by USEPA Guidance 2002a, are also used at some sites. Simple random sampling often follows a non-linear pattern and is most appropriate when contamination within the DU has a relatively uniform distribution. For sites with a non-uniform distribution of contamination, stratified random sampling allows the sampler to divide the DU into three different types of areas (e.g., areas unlikely to be contaminated, areas known to be contaminated, and areas that may be contaminated and cannot be ruled out) and design a sampling plan for each area that yields a representative dataset [See Section 2.3.1 and 2.3.2 of the *Soil Screening Guidance: User's Guide* (USEPA, 1996b) for more information on using this method].

Random sampling can also be achieved by applying a grid system over the sampling area and assigning each cell within that grid a binary 'yes or no' value, such as 1 and 0. These values can be generated using 'random number generators,' such as the "=RANDBETWEEN(0,1)" command in Microsoft Excel. Using random number generators should eliminate any unintended bias that may be present when selecting sample locations. It is recommended that the regulatory compliance officer be consulted prior to active sampling when establishing the appropriate number of grids and/or sampling locations.

The soil sampling methodology for the chosen sampling design should consist of the collection of discrete (grab) soil samples obtained in accordance with the most current version of the *USEPA Region 4 Science and Ecosystem Support Division Soil Sampling Operating Procedure SESDPROC-300*. For sites where alternate sampling methodologies may be implemented or where the DQOs change throughout the investigation and corrective action process, coordination with the regulatory compliance officer is recommended to ensure that sampling data needs are addressed.

**Identifying whether a release has occurred**

If the decision objective is to identify a release area, the CSM should first be consulted to determine whether site-specific information and/or data has been collected that could help determine sample locations near the suspected origin of the release. If information is available, then the release area can be characterized using biased sampling.

An alternative approach to identifying a release based on biased sampling is to stratify the site into three areas (e.g., strata): 1) areas that are unlikely to be contaminated; 2) areas of suspected contamination; and 3) areas of known contamination. This basic strategy of stratified sampling is described in Section 2.3.1 of USEPA's *Soil Screening Guidance: User's Guide* (USEPA, 1996b). For those areas of suspected contamination, various statistical sampling strategies, such as grid or random sampling, are used to determine whether an area should be further investigated. This stratified sampling approach may be advantageous when an investigation occurs over relatively large areas or for areas with a high degree of soil variability/heterogeneity.

**Complete Characterization of a Contaminated Area**

Once a known area of contamination has been identified, the CSM and exposure scenario should be consulted to determine the data needs for the project. Known contaminant release areas can either be characterized using biased and/or statistical (e.g., grid or simple random) sampling. Grid spacing can be calculated based on the area to be sampled and number of samples [see Chapter 7 (USEPA, 2002a)].

Complete characterization of an area of contamination using biased sampling may be effective when there is knowledge of current and historical site operations; an iterative sampling approach is being used to characterize a release; investigating a relatively small area; a small number of samples are needed to characterize the release; and/or time sensitive information is needed. Statistical sampling may be needed on other portions of the DU where exposures may occur in the future.

### Determining a hot spot

As stated in Section 2, a hot spot can be defined statistically as one sample, or more than one adjacent sample locations, at which concentrations are above the remediation/screening criteria and significantly higher than concentrations found surrounding the location(s) (i.e., spatially correlated concentrations sufficiently above criteria) to indicate that they:

a. Represent a different statistical population; and
b. Pose a potential risk that should not be masked by a statistical analysis (Michigan DEQ, 2002).

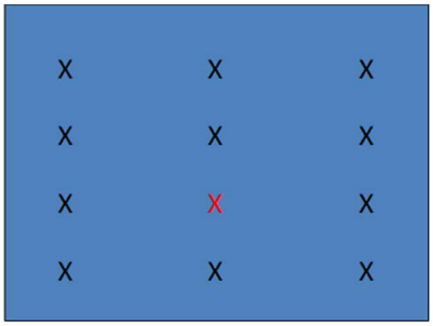
When determining whether a location meets the definition of a hot spot, a sufficient number of samples should be collected to support the conclusion. When using grid sampling to sample a site, the maximum grid spacing necessary to locate a hot spot of a given size with a specified probability can be calculated using the method described in Chapter 10 of *Statistical Methods for Environmental Pollution Monitoring* (Gilbert, 1987).

An evaluation of populations within a dataset and potential hot spots is critical. Areas that are determined to be hot spots should be handled independently from the surrounding population, and a statistical outlier test may be used to identify these possible hot spots. To identify different populations within a dataset, ProUCL's Q-Q Plot or a histogram can be used. While professional judgement has been used at some sites in support of determining if the magnitude of concentration and/or number and proximity of spatially correlated samples above criteria are sufficient to classify a hot spot during facility characterization, it is recommended that these professional judgement determinations be supported with other lines of evidence, including but not limited to the above noted data evaluations.

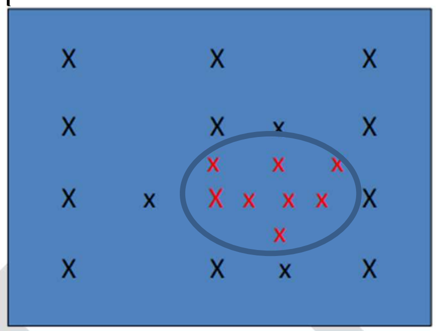
When evaluating site data for hot spots, it is also important to identify any contaminant concentrations detected within the DU that exceed a cancer risk of $10^{-4}$ and a Hazard Quotient of 3. In general, soils that exceed this risk threshold should be remediated, as these risk levels represent the highest end of USEPA's acceptable risk range. USEPA's Removal Management Level (RML) calculator can be used to calculate concentrations representing a cancer risk of $10^{-4}$ and/or a Hazard Quotient of 3 (https://epa-prgs.ornl.gov/cgi-bin/chemicals/csl_search?tool=rml). Should concentrations above the established upper bound threshold limits be left in place and not be remediated, additional justification(s) may be required and collaboration with EPD is recommended. Please note that the use of site-specific RMLs or other upper bound risk threshold limits may be acceptable and it is recommended to contact EPD to discuss the site-specific exposure factors that may be used to calculate these site-specific values if default RMLs will not be used.

### Soil Sampling Approach - Examples

When information about site operations or contamination is unknown, it is best to select statistical sampling by gridding off the site and sampling each grid systematically. Grid sampling provides uniform coverage of a site and allows for the calculation of a grid size that will provide adequate coverage of the site. The Visual Sample Plan software (PNNL, 2007) can be used to design a statistically valid sampling plan or grid. Once the site is sampled and results are evaluated, you may have areas of contamination that have been identified. Additional sampling may be needed to determine the size of the contaminated areas, which would be biased toward locating the contamination. Additionally, a finer grid could be set up around the contaminated area/suspected hot spots to determine their extent.

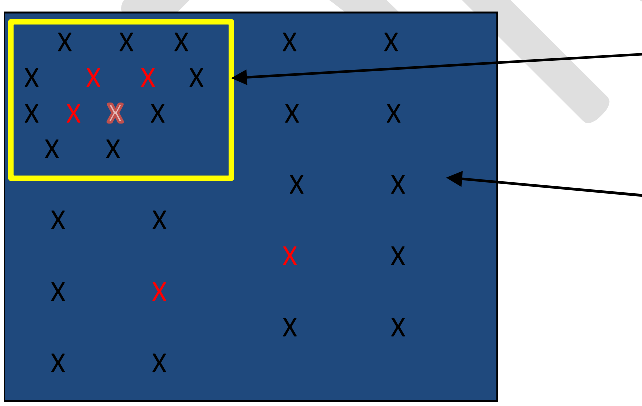


Phase 1 of Sampling: Use grid sampling to determine if there is any contamination within DU. One sample was identified as a hot spot. Implement Phase 2 sampling to delineate size of hot spot.



Phase 2 of Sampling: delineate hot spot using biased sampling. Sample locations are indicated by lowercase "x". Entire hot spot is represented by ellipse.

Another instance is when releases at the site are known through biased sampling. This sampling approach usually leaves a cluster of samples in a certain area; however, not much is known about the remainder of the site. A grid sampling approach for the remainder of the site is probably the best design to implement in this case.



Phase 1: Delineate known location of hot spot X using biased sampling

Phase 2: Use grid sampling to sample remainder of DU to determine if contamination is present.

At least two statistical populations are present in the data for this DU.

Contaminated samples = X
Uncontaminated samples = X

As the soil area averaging approach is based on the evaluation of a statistical parameter (i.e., the EPC associated with a DU is calculated as the 95% UCL of the mean), it is recommended that the data set for a specific DU consist of sampling data generated using 1) a grid sampling design; or 2) a combination of biased, and grid, or random sampling. For a detailed description of biased, grid, and random sampling, refer to USEPA's "*Guidance on Choosing a Sampling Design for Environmental Data Collection"* (USEPA, 2002a). In addition, specialized software (e.g. Visual Sampling Plan) may be used to aid in the selection of a sampling design that is appropriate to achieve the sampling objective(s).

The following information should be provided to EPD, if requested, to support the chosen sampling and analysis design:

1. A description of the sampling design and objectives, including a summary of the DQO process leading to selection of the chosen sampling and analysis design;
2. The rationale for the choice of sampling locations for each analytical parameter / matrix;
3. Field Quality Control / Quality Assurance requirements;
4. A list of Action Levels for the constituents of interest (if available);
5. A detailed Site Map with anticipated sampling locations;
6. A description of field analytical and screening techniques (if applicable); and
7. A list of analytical methods requirements that are needed to achieve the objectives of the investigation (e.g., Practical Quantitation Limits consistent with current Regional Screening Levels, background, etc.) and name of Analytical Laboratory.

# 5.0 ESTABLISHING A DECISION UNIT

As noted in the Key Concepts in Section 2, the DU is defined as a volume of soil within which a receptor comes in contact over an established exposure duration. The DU can be further described as an area where human receptors may come into contact with contaminants in soil on a regular basis (USEPA, 1989), the size and location of which may depend on known or anticipated uses of the site (ITRC, 2012). Please note that the size of the DU can have a significant impact on the outcome of the area averaging calculations and could potentially dilute a dataset depending upon how the lateral extent of the DU is established. Therefore, it is recommended that the DU should not include areas that are beyond the lateral extent of delineation and assessment established by the applicable regulatory program requirements. The requirements for investigation and assessment areas can differ by regulatory program and it is recommended that the regulatory compliance officer be consulted when establishing the DU(s), especially for instances when the DU may incorporate areas beyond these investigation and/or assessment requirements.

Within this established DU, the receptor is assumed to be equally exposed to all parts of the area by moving randomly across the area. The assumption of equal exposure to any and all parts of the DU is a reasonable approach (USEPA, 2002b) which allows a spatially averaged soil concentration to be used to estimate the average exposure concentration contacted over time (ITRC, 2012).

The DU is an important component in the development of an area averaging approach as it will establish the spatial (geographical) boundary(s) of the soil dataset(s) and can influence the location and number of samples collected. Information gathered from the CSM and decision objective(s) will help determine these spatial boundaries, and may include:

- An explanation as to how the size and orientation of the DU is appropriate for the receptor(s) being considered;
- A consideration of pre- and post-remediation land use; and
- The location of release area(s) and/or hot spots.

EPD recommends that the soil area averaging approach be applied primarily to those DUs where routine surficial contact occurs, as the exposure concentrations are intended to be average "site-related" concentrations routinely contacted by a receptor. Should a site choose to utilize the area average approach for subsurface soils DUs, it is important to clearly establish and justify both the vertical and horizontal extent of the DU(s) and provide representative datasets from all applicable vertical depth ranges.

It should be noted that since utility and construction work tend to vary in location, depth, and duration, it may be impractical (at some sites) to 1) establish an accurate DU specific to these activities, and 2) acquire the necessary supporting data. It is recommended that the applicable regulatory compliance officer be consulted when planning a subsurface soil area averaging approach.

If the DU is larger than the area of anticipated exposure, the average concentration for the larger area may not accurately reflect the exposure concentrations for smaller DUs for a given receptor. This is particularly important when evaluating the complete exposure pathways at a site as there may be differences in property use, exposure pathways, and the resulting DUs when it comes to exposure for an adult versus a child. DUs should also not be laid out in such a way that they unnecessarily combine or straddle areas of high and low levels of contamination (USEPA, 2002a).

It is important to identify any unique site characteristics that may influence the development of the DUs, factors affecting the size and shape of the DU include the following:

- Adequate site characterization within the proposed or anticipated DU(s)
- Nature and extent of the release
- Lateral and vertical extent of the expected exposure pathway
- Release area(s) and/or hot spots
- Contaminant transport
- Heterogeneity of the soil and boundaries of geologic formations
- Exposure characteristics

Ideally, the discrete sample data sets used for derivation of an EPC should generally meet the criteria for determining the number of discrete samples needed as specified in the USEPA: Guidance for Data Usability in Risk Assessment, Part A (USEPA, 1991). It is worth noting that collecting the number of discrete samples sufficient to make a defensible soil area averaging decision at a site may at times be precluded by cost considerations (ITRC, 2012). Factors affecting the number of samples include:

- Known or anticipated uses of the site
- Receptors (residential, industrial/commercial, etc.)
- Acreage
- Potential contaminants
- Previous data
- Regulatory investigation and/or assessment requirements

Sample size within each DU should be sufficiently representative of site conditions. Small sample sizes can translate to large uncertainty in estimating the EPC. While there have been some “rule-of-thumb” suggestions regarding adequate samples sizes (e.g. minimum sample size requirement of 10) based upon professional judgement and experience of the developers of ProUCL, it is important to ensure that the sample size is reflective of site conditions and sufficient for the statistical analysis used to derive the EPC.

The DQOs sample sizes module (Chapter 12) of ProUCL can be used to assist in developing the number of proposed samples collected from each DU (USEPA, 2015a).

# 6.0 DATASET AND ACTION LEVELS

One of the fundamental benefits of an area averaging approach is that this type of soil compliance approach allows for the acquisition of data that is designed to support decision-making about an area or volume of material that may be impractical or impossible to analyze in its entirety. Consequently, the representativeness of the sample data set becomes vital to the soil area averaging approach.

In order to evaluate the results of soil sampling activities, an action level will have to be established. Specifically, an action level is the threshold value that provides the criterion for choosing the course of action relating to soil compliance. The action level at a site can be developed from the risk-based exposure value that is calculated for the soils at a site. In general, identifying the appropriate action level for soil concentration comparison will depend on the decision objective(s) and the applicable regulatory program.

Another important factor to consider when evaluating the site data and information is whether any hot spots or release areas exist, as these areas are generally incorporated into the remedial strategy for the site. As noted in Section 4 above, should any soils that exceed an upper bound risk threshold be left in place and not be remediated, additional justification(s) may be required and collaboration with EPD is recommended. In addition, it is recommended to contact EPD to discuss the site-specific exposure factors that may be used to calculate any site-specific upper bound risk threshold limits if default RMLs will not be used to establish these values.

Please note that an RML is not available for Lead. Therefore, a threshold for Lead concentrations in soil has not been provided in this document. Lead is regulated based on blood Lead concentration. Risks to Lead contaminated soils are evaluated by predicting blood Lead concentration and the probability of a child's blood lead concentration exceeding 10 µg/dL. Two models are used to calculate risks associated with exposure to Lead: The Integrated Exposure Uptake Biokinetic Model (IEUBK) for residential exposure and the Adult Lead Model (ALM) for industrial exposure. Lead should be evaluated separately from other substances using the above referenced models and on a site-specific basis. For sites demonstrating compliance through HSRA, there is additional information on both the IEUBK and ALM in the Rules for Hazardous Site Response Section 391-3-19-.07(7)(c)3, -.07(9)(d)2(i), and Appendix IV.

## 6.1 Determining an Exposure Point Concentration (EPC)

**95% UCL**

For the majority of risk-based decisions, the EPC is the 95% UCL, which is a conservative statistical measure used to estimate the upper limit of the true mean. USEPA guidance provides methods for conservatively estimating the EPC term (USEPA, 2015b). The Pro UCL

User Guide (USEPA, 2015a) recommends using the latest version of ProUCL for most statistical evaluations (http://www.epa.gov/land-research/proucl-software) to calculate the 95% UCL; however, it is acceptable to use other free or commercially available statistical software applications that may be available (i.e., the SADA application for computing univariate statistics (http://www.sadaproject.net/)). Please note that for Lead, the EPC is calculated differently than other constituents/substances; the EPC for Lead is the arithmetic mean.

Once a site has been adequately characterized, the number of samples necessary to compute an EPC will depend upon the method chosen for calculating the EPC. If using ProUCL to calculate a 95% UCL as the EPC, the ProUCL User Guide recommends that a minimum of ten (10) samples be collected, analyzed and used for calculating the EPC. Please contact the EPD regulatory program overseeing the site investigation with questions regarding the number of samples needed to calculate an EPC for a particular site.

Statistical methods to compute an EPC (e.g., 95%UCL) are based on certain assumptions. Specifically, the ProUCL User Guide states that the UCL of the mean should be computed using a randomly collected data set representing a single statistical population. If multiple populations are present in a data set, appropriate decision statistics (e.g., 95%UCLs) should be computed separately for each identified population. Graphical methods such as Quantile-Quantile (Q-Q) plots and histograms have been successfully used to identify if multiple populations are present in a data set (Wisconsin DNR, 2015).

The presence of more than one population within a DU:

- May indicate source material or uncontaminated areas;
- May indicate hot spots (refer to Section 3.6); and
- Should not be applied so that an area straddles high and low contamination.

**Weighted Averages**

When sampling data is not randomly distributed throughout the DU, there are other options for determining the EPC. For instance, an area-weighted average could be calculated using Thiessen polygons. Additionally, a weighted UCL on the mean of the data could be calculated when a combination of biased and statistical sampling has been used within the same DU. These methods are described in Sections 6.2.4.2 and 6.2.4.4 of the ITRC document *Decision Making at Contaminated Sites: Issues and Options in Human Health Risk Assessment*, January 2015 (ITRC, 2015). Please consult with your regulatory compliance officer before using one of these methods.

**Geostatistics**

Geostatistical methods are statistical procedures designed to process spatially correlated data and interpolate between known data points. These methods are especially useful at sites where contaminant concentrations may reveal spatial patterns of highly impacted zones surrounded by marginally impacted areas with gradually decreasing contaminant concentrations. This type of spatially correlated data is suitable for geostatistical analyses, but typically requires specialized software and advanced statistical knowledge.

Kriging or co-kriging are methods used to extrapolate and estimate concentration gradients based on the spatial correlation. Common applications of kriging in environmental and geotechnical engineering include delineation of contaminated media, estimation of average concentrations over exposure domains, as well as mapping of soil parameters and piezometric surfaces (Rouhani, 1996). These methods can also be used to develop excavation limits based on the estimated concentrations rather than having excavation limits to known sample locations.

Additional information on these methods and others can be found on the ITRC "Geospatial Analysis for Optimization at Environmental Sites" website (https://gro-1.itrcweb.org/) and in the ASTM STP 1283 (1996).

**Multiple CoCs**

Although most area averaging scenarios for soil are associated with the evaluation and potential corrective action of one primary chemical of concern (CoC), it is worth noting that the area averaging approach may require the calculation of multiple EPCs and a demonstration that the cumulative cancer risks and non-cancer hazards are in compliance with applicable soil criteria for sites with multiple CoCs. Additional information associated with the calculation of risk-based exposure criteria and cumulative risk is under development and will be included in the Georgia Risk Assessment Guidance.

**Reporting**

When presenting EPCs in submittals to EPD, the EPCs should be summarized on a table. Table 1 is an example of the type of information that should be included in an EPC summary table.

It is recommended in addition to a summary table, that the following information also be included in any sampling report with EPC calculations:

- Input and Output from ProUCL software (if used to calculate an EPC);
- If methods other than ProUCL are used, describe the method used for calculating EPCs and all work demonstrating how the EPC was calculated;
- Maps indicating the DU and sample locations within the DU; and
- Tables with all sampling data (including sample identification number, sample depth, date of sample, analytical results).

## 6.2 Achieving Compliance

### Area Averaging Considerations for Site Closure

Once an EPC and an action level are calculated, a direct comparison will reveal whether the EPC exceeds the action level for a certain substance. If the EPC for a DU exceeds the action level, a corrective action strategy must be developed to address the exceedance, which can include removal, treatment, and/or some combination of institutional and engineering controls that can be designed to mitigate the exposure pathway(s) of concern.

If excavation or treatment of soils has occurred, confirmation sample data typically must be provided to verify compliance with action levels. EPD's 2017 "Guidance for Demonstrating Completion of Soil Removal Actions at Corrective Action Sites in Georgia" (https://epd.georgia.gov/land-protection-branch-technical-guidance) can assist with determining the number of verification samples that will be necessary to demonstrate compliance with action levels. Any fill material must be sampled and must not contain hazardous constituents or substances exceeding EPD-approved background levels or applicable residential screening levels prior to placement within any excavated area.

Risk management plans for closure of sites that use area averaging to meet applicable cleanup standards may include environmental covenants and other institutional controls.

### Iterative Truncation Method

One commonly used method to determine where to remove or treat soil is the Iterative Truncation Method. In general, the following criteria should be met if using iterative truncation: the site is adequately characterized (sample size is sufficient for the size of the site); the sampling design used at the site yields a representative distribution of measurements within the DU; and assumptions about the post-remediation distribution of concentrations are reasonable for long-term exposure by receptors.

Iterative truncation involves the following steps: removing (truncating) the highest sample concentration in the dataset; replacing it with the detection limit value, or the arithmetic mean concentration of clean fill and then calculating a hypothetical post-remediation EPC and comparing that concentration to the action level. This process is repeated until the estimated post-remediation EPC is at or below the action level. The areas containing the sample concentrations removed in the truncation calculation should be excavated and properly disposed of based on waste determinations. It is recommended that the amount of fill material samples to be collected be determined by coordinating with the regulatory compliance officer for the site prior to implementation, as the amount may vary depending upon the fill material characteristics, background information on the borrow area, and volume of fill material required. For additional information on the number of fill material samples needed, please refer to the EPD 2017 *Guidance for Demonstrating Completion of Soil Removal Actions at Corrective*

*Action Sites in Georgia*, which is available online at: https://epd.georgia.gov/about-us/land-protection-branch/land-protection-branch-technical-guidance.

**Geospatial Analysis**

When utilizing complex geospatial statistical analysis, such as block kriging, the DUs may be subdivided into or comprised of smaller equally sized and spaced volume areas (i.e., blocks). Should this statistical approach be utilized at a site and the calculated EPC exceeds the action level for the DU, the remedial strategy typically involves the removal or treatment of one or more of these subdivided areas in order to meet the action levels. Please note that subdividing the DU into smaller areas is not required for most soil area averaging compliance approaches but can be a useful tool when developing a removal strategy in order to reduce the EPC below the established compliance standard (ITRC, 2012).

For additional information on the pros and cons of utilizing the two methods for compliance area averaging noted above please see the attached Table 2.

**Software/Modeling Recommendations**

For basic statistical evaluations of the discrete sampling data sets used in the area averaging approach, EPD recommends the use of the latest version of USEPA Office of Research and Development software ProUCL (http://www.epa.gov/land-research/proucl-software).

Visual Sample Plan (VSP) is a freely available software from the Pacific Northwest National Laboratory (PNNL) at http://vsp.pnnl.gov/ (12-2017 / Version 7.10). VSP is useful for taking into account different standard deviation and population distributions in calculating the number of samples needed to achieve specific confidence requirements in a sample population. VSP can utilize variograms to determine a range and an associated confidence in the range, and should the confidence not meet a certain criterion, it can indicate that additional sampling points may be needed.

Should a geostatistical methodology be used in support of the area averaging approach, ArcGIS Pro 2.1 (https://www.esri.com/en-us/arcgis/products/arcgis-pro/overview) with the Geostatistical Analyst Package, or similar licensed and available software may be used to evaluate the data presented.

For links to available free software for processing and analysis of spatial data used in conjunction with geostatistical software, please go to the EPA Region 5 FIELDS (Field Environmental Decision Support) Team website: https://response.epa.gov/site/doc_list.aspx?site_id=7313.

Additional information regarding various geostatistical software is available from ITRC in the web-based "Geostatistics for Remediation Optimization" guidance (http://www.itrcweb.org/).

## 7.0 REFERENCES

ASTM. 2006. *Standard Guide for Sampling Waste Piles*. D 6009-96. Available Online: https://www.astm.org/Standards/D6009.htm

ASTM. 2014. *Standard Guide for Developing Conceptual Site Models for Contaminated Sites*. Method E 1689-95. Available Online: http://www.astm.org/Standards/E1689.htm.

California Environmental Protection Agency (CalEPA), 2001. Department of Toxic Substances Control, *Information Advisory Clean Imported Fill Material*, October. Available Online: https://rfs-env.berkeley.edu/sites/default/files/dtscsmp_fs_cleanfill-schools.pdf

E.H. Isaaks, 1994. *Risk Qualified Mappings for Hazardous Waste Sites: A Case Study in Distribution Free Geostatistics*. Master's thesis, Stanford University,

EPD, 2017. Guidance for Demonstrating Completion of Soil Removal Actions at Corrective Action Sites in Georgia. Available online at https://epd.georgia.gov/about-us/land-protection-branch/land-protection-branch-technical-guidance

Gilbert, 1987. *Statistical Methods for Environmental Pollution Monitoring,* Van Nostrand Reinhold COMPANY. Available online at https://www.osti.gov/biblio/7037501

ITRC, 2012. *Incremental Sampling Methodology Representative Sampling, Confident Decisions.* Interstate Technology & Regulatory Council, February. Available online: http://www.itrcweb.org/ism-1/

ITRC, 2008. *Use of Risk Assessment in Management of Contaminated Sites. RISK-2.* Washington, D.C.: Interstate Technology & Regulatory Council, Risk Assessment Resources Team. Available online: https://www.itrcweb.org/GuidanceDocuments/Risk_Docs/RISK2.pdf

ITRC, 2015. *Decision Making at Contaminated Sites: Issues and Options in Human Health Risk Assessment*, January 2015

Leonte, D. and Schoefield, N. 1996. *Evaluation of a Soil Contaminated Site and Clean-Up Criteria: A Geostatistical Approach*, ASTM special technical publication / v.1283. 1996, pp.133-145, January. Available Online: https://www.astm.org/DIGITAL_LIBRARY/STP/PAGES/STP16118S.htm

Michigan DEQ, 2002. *Sampling Strategies and Statistics Training Materials for Part 201 Cleanup Criteria,* Michigan Department of Environmental Quality Remediation and Redevelopment Division, 2002. Available Online: https://www.michigan.gov/documents/deq/deq-erd-stats-s3tm_250015_7.pdf

Official Code of Georgia (O.C.G.A.), Title 12, Chapter 8, Article 3, Pat 3: Georgia Voluntary Remediation Program Act, Code 1981, § 12-8-100, enacted by Ga. L. 2009, p. 714, § 1/HB 248.

PNNL, 2007. Visual Sampling Plan v7.0 (PNNL-23211) Pacific Northwest National Laboratory, U.S. Department of Energy. User guide: http://vsp.pnnl.gov/docs/PNNL-23211.pdf Download available online: http://vsp.pnnl.gov/

Rouhani, S., et. al, 1996. Geostatistical Estimation: Kriging, "*Geostatistics for Environmental and Geotechnical Applications*, ASTM STP 1283. Available Online: https://www.astm.org/DIGITAL_LIBRARY/STP/SOURCE_PAGES/STP1283.htm

Srivastava, R.M. and H. Parker, 1988. Robust Measures of Spatial Continuity, M. Armstrong (ed.), Third International Geostatistics Congress, D. Reidel, Dordrecht, Holland.

USEPA, 1989. *Risk Assessment Guidance for Superfund, Volume I – Human Health Evaluation Manual (Part A). Interim Final.* Office of Emergency and Remedial Response *EPA 1540/1-89/002,* December. Available Online: https://www.epa.gov/sites/production/files/2015-09/documents/rags_a.pdf

USEPA, 1992a. *Guidance for Data Usability in Risk Assessment, Part A,* Office of Solid Waste and Emergency Response, April. Available Online: https://semspub.epa.gov/work/05/424356.pdf

USEPA. 1994. *Statistical Methods for Evaluating the Attainment of Cleanup Standards*, EPA 230-R-94-004, Washington, DC. Available Online: https://nepis.epa.gov/Exe/ZyPDF.cgi/200082GP.PDF?Dockey=200082GP.PDF

USEPA, 1996a. *Soil Screening Guidance: Technical Background Document*, Publication EPA/540/R95/128, Office of Solid Waste and Emergency Response, May. Available Online: https://semspub.epa.gov/work/11/175241.pdf

USEPA, 1996b. *Soil Screening Guidance: User's Guide*, Publication 9355.4-23, Office of Solid Waste and Emergency Response, July. Available Online: http://semspub.epa.gov/src/document/HQ/175238

USEPA, 2000. *Data Quality Objectives Process for Hazardous Waste Site Investigations, QA/G-4HW Final,* EPA 600-R-00-007, Office of Environmental Information, January. Available Online: https://www.epa.gov/sites/production/files/2015-07/documents/g4hw-final.pdf

USEPA, 2001. *Risk Assessment Guidance for Superfund: Volume III – Part A, Process for Conducting Probabilistic Risk,* EPA 540-R-02-002, Office of Solid Waste and Emergency Response, *Assessment,* December. Available Online: https://www.epa.gov/sites/production/files/2015-09/documents/rags3adt_complete.pdf

USEPA, 2002a. *Guidance on Choosing a Sampling Design for Environmental Data Collection, for Use in Developing a Quality Assurance Project Plan.* EPA/240/R-02/005, Office of Environmental Information, December 2002. Available Online: https://www.epa.gov/sites/production/files/2015-06/documents/g5s-final.pdf

USEPA, 2002b. *Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites*, OSWER 9285.6-10, Office of Emergency and Remedial Response, December, 2002. Available Online: https://nepis.epa.gov/Exe/ZyPDF.cgi/P100CYCE.PDF?Dockey=P100CYCE.PDF

USEPA, 2005. *Peer Review Draft Guidance on Surface Soil Cleanup at Hazardous Waste Sites: Implementing Cleanup Levels*, Office of Emergency and Remedial Response, April.

Available online: http://www.epa.gov/sites/production/files/documents/guidance-cleanup-April-05.pdf

USEPA, 2006. *Guidance on Systematic Planning Using the Data Quality Objectives Process,* EPA 240/B-06-001, February, 2006. Available Online: https://www.epa.gov/sites/production/files/documents/guidance_systematic_planning_dqo_process.pdf

USEPA, 2009. *Statistical Analysis of Groundwater Monitoring Data at RCRA facilities Unified Guidance,* EPA 530/R-09-007, Office of Resource Conservation and Recovery, March. Available online: https://nepis.epa.gov/Exe/ZyPDF.cgi/P10055GQ.PDF?Dockey=P10055GQ.PDF

USEPA, 2014. *Soil Sampling.* SESDPROC-300-R3. Science and Ecosystem Support Division, August. Available online:

http://www.epa.gov/sites/production/files/2015-06/documents/Soil-Sampling.pdf

USEPA, 2015a. *ProUCL Version 5.1.00 User Guide.* Washington D.C., EPA/600/R-07/041, Office of Research and Development, May. Available online: https://www.epa.gov/sites/production/files/2016-05/documents/proucl_5.1_user-guide.pdf

USEPA, 2015b. *ProUCL Version 5.1 Technical Guide.* EPA/600/R-07/041, Office of Research and Development, September. Available online: https://www.epa.gov/sites/production/files/2016-05/documents/proucl_5.1_tech-guide.pdf

Wisconsin DNR, 2015., *Averaging of Soil Contaminant Concentration Data*, RR-991, Wisconsin Department of Natural Resources, October 2015. Available Online: https://dnr.wi.gov/news/input/documents/guidance/RR991Draft.pdf

# Tables

**Table 1: Example Table for Reporting EPCs**

**Site Name: ABC Waste Disposal**
**Receptor: Commercial/Industrial Worker**

| Chemical | Units | Range of Detection Limits | Range of Detected Concentrations | Detection Frequency | Arithmetic Mean | 95% UCL and statistical method used | Data Distribution | EPC and basis for selection |
|---|---|---|---|---|---|---|---|---|
| Arsenic | Mg/kg | 1-5 | 3-100 | 9/20 | NA | 29.42, (95% KM (t) UCL) | Normal | 29.42 (95% KM (t) UCL) |
| Barium | Mg/kg | 1-10 | 15-30 | 2/10 | NA | NA | NA | 30 (maximum detected concentration) |

**Table 2. Pros & Cons of Iterative Truncation & Geostatistical Methods For Implementing Cleanup Levels As Area Averages**

| |
|---|
| **Iterative Truncation Method**<br><br><u>Pros:</u><br>• Simple; no statistical expertise needed.<br><br><u>Cons:</u><br>• Very sensitive to highest contaminant concentrations in the sample; if the highest sample concentrations are not representative of the highest concentrations at the site, the resulting action level may not be protective.<br><br><u>Cautions:</u><br>• Inappropriate for use with composite data.<br>• Inappropriate for use with spatially correlated data.<br>• If sampling data are biased such that higher concentration areas are over-sampled, the resulting action level will be unnecessarily low. |
| **Geostatistical Method**<br><br><u>Pros:</u><br>• Can be used with spatially correlated data.<br>• Can be used with biased sample data (e.g., over-sampling of hot spots).<br>• Can reduce the amount of excavation by only digging to estimated concentration gradients rather than known sample locations<br><br><u>Cons:</u><br>• May entail geostatistical expertise and specialized software.<br>• More costly and time consuming than non-spatial methods.<br><br><u>Cautions:</u><br>• Consider the value of the information gained from geostatistical approach to ensure that the anticipated benefits justify the costs. |