ATSDR Office of Community Health Hazard Assessment
Exposure Point Concentration Guidance for Non-Discrete Sampling

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Contents:

List of Abbreviations

ADS	Associate Director for Science
ATSDR	Agency for Toxic Substances and Disease Registry
CV	comparison value
DQO	Data quality objective
EPA	U.S. Environmental Protection Agency
EPC	exposure point concentration
HDOH	Hawaii State Department of Health
ISM	incremental sampling methodology
ITRC	Interstate Technology and Regulatory Council
MDEQ	Michigan Department of Environmental Quality
mg/kg	milligram per kilogram
PAH	polycyclic aromatic hydrocarbon
PHA	public health assessment
PHAGM	*Public Health Assessment Guidance Manual*
QA	quality assurance
QAPP	quality assurance project plan
QC	quality control
RSD	relative standard deviation
SAP	sampling and analysis plan
VOC	volatile organic compound
µg/kg	microgram per kilogram
95UCL	95 percent upper confidence limit of the arithmetic mean

1.0 INTRODUCTION

Environmental samples provide insight on contamination levels at sites of interest. But those insights are never complete: health assessors will never have sampling data from every particle of soil that people ingest or from every drop of water that people drink. To evaluate the human health risks to exposures to contamination levels that are not fully known, health assessors therefore need access to environmental sampling data that are reliably representative of exposure units. These data can come from discrete or non-discrete sampling methods. A discrete sample (sometimes referred to as a "grab sample") is an individual environmental sample collected at a given point and time that is independent of other samples. Non-discrete sampling methods are considerably different in that multiple samples are taken and then combined into a single sample for laboratory analysis.

This document presents the Agency for Toxic Substances and Disease Registry's (ATSDR's) preferred approach for estimating exposure point concentrations (EPCs) from non-discrete sampling data for use in the public health assessment (PHA) process. By applying this guidance, health assessors can be more confident that estimated EPCs do not significantly understate or overstate actual exposures, despite uncertainties associated with environmental data.

Health assessors should use this guidance for two purposes:

1. To determine EPCs when working with *incremental sampling methodology* (ISM) data.
2. To determine EPCs when working with *composite sample data.*

This guidance first presents background information on discrete and non-discrete sampling methods (Section 2) and then provides guidance for evaluating ISM data (Section 3) and composite sample data (Section 4). Key terms are defined in Appendix A, and simple example EPC calculations are provided in Appendix B and C.

1.1 When to Use This Guidance

During the PHA process, health assessors perform many activities, including developing a site conceptual model, evaluating exposure pathways, identifying exposure units, compiling and reviewing environmental data, and screening those data against health-based comparison values (CVs). Note that ATSDR has developed various guidance documents to assist health assessors with these and many other steps in the process. These documents include the *Public Health Assessment Guidance Manual* [PHAGM – ATSDR 2005] and guidance on *Identifying Exposure Units for the Public Health Assessment Process* [ATSDR 2020].

After health assessors have determined that there are completed or potential exposure pathways and screened maximum concentrations detected in environmental samples against CVs, contaminants are identified for further health evaluation [ATSDR 2005]. [1] When working with ISM data, health assessors should use the maximum ISM result collected within a given exposure unit and analyzed for a given

[1] Health assessors are cautioned when screening maximum concentrations against CVs in certain situations. For example, if a health assessor is not confident that the maximum concentration represents the higher end of the exposure unit's contamination distribution and if the maximum concentration is only marginally lower than corresponding CVs, a strong case can be made for recommending additional sampling or further evaluating the potential for harmful effects regardless of the results of this initial screening step. Health assessors should consult their ADS group if there is any uncertainty around this point.

contaminant for initial screening. When ISM replicates are collected in an exposure unit, the maximum ISM result across replicates should be use (see Section 3.0 for more information on ISM replicates). Similarly, when working with composite sample data, health assessors should use the maximum composite sample result for a given exposure unit for screening. If only one ISM or composite sample result is available for an exposure unit and the data are assumed to adequately represent the exposure unit, results from the single sample can be used for screening.

Health assessors must then perform exposure dose calculations for each contaminant measured above applicable CVs for a given exposure unit and exposure pathway. A critical step in this process is determining what EPCs to use in exposure dose calculations. Calculated average daily doses are then compared to established toxicity values for non-cancer evaluations (e.g., ATSDR Minimal Risk Levels, U.S. Environmental Protection Agency [EPA] reference doses) and cancer evaluations (e.g., oral slope factors) to determine whether harmful health effects are possible.

Health assessors should consult this guidance when estimating EPCs with environmental data collected by non-discrete sampling methods (sometimes also referred to as "infinite element media" sampling methods). These methods are considerably different than discrete sampling, where a random mass of soil is collected from a specific location and analyzed independently of other samples. In some cases, non-discrete sampling methods offer more reliable and efficient means for estimating EPCs. Samples collected by non-discrete sampling methods are sometimes referred to as a type of "composite" sample.

- *Composite sample collection* is a loosely defined sampling approach where multiple discrete (also known as "grab") environmental samples (e.g., soil, sediment, biota) are collected and combined into a single sample that is then sent to the laboratory for analysis. In this way, a composite sample is made up of discrete samples collected at different locations. No specifications are made on the number of individual discrete samples to be collected and combined or the manner in which the final composited sample is to be processed at the laboratory. This can lead to significant error in the representativeness of the resulting data [Brewer et al. 2017a, 2017b], which is of particular concern when estimating EPCs. Section 4 of this guidance discusses composite sampling further.
- *ISM* resembles composite sampling but incorporates very specific requirements for the number of points or "sample increments" that must be collected from a given exposure unit, as well as specific requirements for processing and subsampling the field sample at the laboratory. Under this approach, multiple

What Is a "sample"?

Seemingly straightforward, the word "sample" has different connotations among scientific disciplines:

- For statisticians, a "data sample" typically refers to all observations from a data set. For instance, if 100 out of 125 people submit a survey, the data sample in this case would be the 100 completed surveys.
- For environmental scientists, an "environmental sample" typically refers to a physical quantity of an environmental medium—soil, water, air, and food items—that is collected for measurement. For instance, six ounces of tap water collected in a vial for laboratory analysis is one environmental sample. A kilogram of soil collected and combined from fifty points in a large stockpile is also a single sample. Unless otherwise noted, all references to "sample" in this guidance describe environmental samples.

increments of soil (ideally 50 or more) are collected from an exposure unit and combined to form a single ISM sample of a specified mass (typically one to two kilograms) for laboratory processing and analysis. ISM is better suited than composite sampling to reduce error introduced by sampling and laboratory practices and is specifically designed to characterize the overall average contamination level within an area of interest. This method is most often used for soil but has also been applied to sediment. Section 3 of this guidance discusses ISM further.

This guidance walks health assessors through key considerations for evaluating the representativeness of ISM and composite sample data, as well the process of estimating EPCs for both types of data (when appropriate).

Also note that ISM is most commonly used when investigating soil contamination, and ATSDR's guidance for ISM (Section 3.0) is therefore largely framed around soil sampling issues tied to ISM. This document also outlines ATSDR's recommended approach for estimating EPCs with composite sample data (Section 4.0). For simplicity, that part of the document similarly focuses on soil, however, ATSDR recognizes that health assessors may occasionally be required to collect and assess composite sample data from other media (e.g., sediment, biota). In these cases, the general approaches presented in this guidance still apply.

1.2 Topics Not Covered by This Guidance

This guidance applies to determining EPCs from environmental data collected by ISM and composite sampling approaches. It does not apply to:

- *Identifying exposure units.* The general process of identifying an exposure unit is described in *Identifying Exposure Units for the Public Health Assessment Process* [ATSDR 2020]. Health assessors should consult that guidance before evaluating ISM or composite sample data.
- *Calculating EPCs for discrete samples*. The general approach for calculating EPCs with discrete sampling data is outlined in *Exposure Point Concentration Guidance for Discrete Sampling* [ATSDR 2019a]. Health assessors should consult that guidance document when working with discrete sampling data but should be aware of the potential limitations of the data provided by discrete sample data. A detailed discussion of the nature and limitations of discrete sample data is provided by Brewer et al. [2017a, 2017b].
- *Toxicity weighting schemes for certain contaminants.* Some substances have special considerations beyond those listed in ATSDR's EPC guidance documents. When evaluating EPCs for dioxin and dioxin-like compounds or polycyclic aromatic hydrocarbons (PAHs), health assessors should refer to the corresponding chemical-specific guidance [ATSDR 2019b, 2021- *in development*].

1.3 Resources for Further Information

This guidance was developed to help make EPC determinations with non-discrete sampling data a straightforward process. While it provides general background information on both types of non-discrete sampling approaches (i.e., ISM and composite), it is not meant to serve as a guide for designing or implementing either sampling approach. Some health assessors may wish to review additional

background information on these sampling methods, particularly for ISM which may be new to many. For additional information on ISM, refer to:

- The Interstate Technology and Regulatory Council's (ITRC's) *Incremental Sampling Methodology Update* document [ITRC 2020].
- Sections 3 through 5 of the Hawaii State Department of Health's (HDOH) *Technical Guidance Manual for the Implementation of the Hawaii State Contingency Plan* [HDOH 2016]. Health assessors may also refer to guidance from the Michigan Department of Environment [MDEQ 2015].
- Deanna Crumbling's (EPA) publication *Hot Spots: Incremental Sampling Methodology (ISM) Frequently Asked Questions* [Crumbling, 2014].

For additional information on composite samples, refer to:

- Section 10 ("Composite Sampling") of EPA's *Guidance on Choosing a Sampling Design for Environmental Data Collection* [USEPA 2002].
- Volume 1 ("Composite Sampling") of EPA's 1995 *Observational Economy Series* [USEPA 1995].

Health assessors interested in further information should consult with their Associate Director of Science (ADS) group. Health assessors should also plan to attend any supplementary ATSDR trainings/webinars on these topics.

1.4 How to Use This Guidance

Health assessors will find all guidance in this document's text. References are provided in Section 5.0, and a glossary is shown in Appendix A. Further information is provided in text boxes, as follows:

Key Point

Blue text boxes summarize major elements of this guidance.

Additional Information

Yellow text boxes provide scientific background information on non-discrete sampling issues.

2.0 BACKGROUND

The primary objective behind the non-discrete sampling methodologies described in this guidance is to minimize sampling errors associated with the heterogeneous nature of environmental media. Heterogeneity occurs when all individual items within a population (e.g., particles within a given volume of soil) are not identical with respect to a specific characteristic of interest (e.g., mass of a contaminant). Conversely, homogeneity occurs when all individual items within a population are identical. Since ISM is largely used to evaluate soil, the remainder of this discussion focuses on the heterogeneous nature of soil. Similar concerns apply for other media (e.g., biota) when working with composite sample data.

Soil is a heterogeneous matrix composed of multiple mineral and organic substances in many different particle sizes and masses. This heterogeneity must be considered during environmental sampling and when calculating EPCs as part of the PHA process. While soil heterogeneity may seem complex, the sources of heterogeneity fall into two broad categories [USEPA 1999; Minnitt et al. 2007; AAFCO 2015; Pitard 2019]:

- Compositional heterogeneity—variability in the physical properties and chemical composition between individual soil particles.
- Distributional heterogeneity—spatial variability of soil particles and contaminant distribution across an area and within a volume of interest.

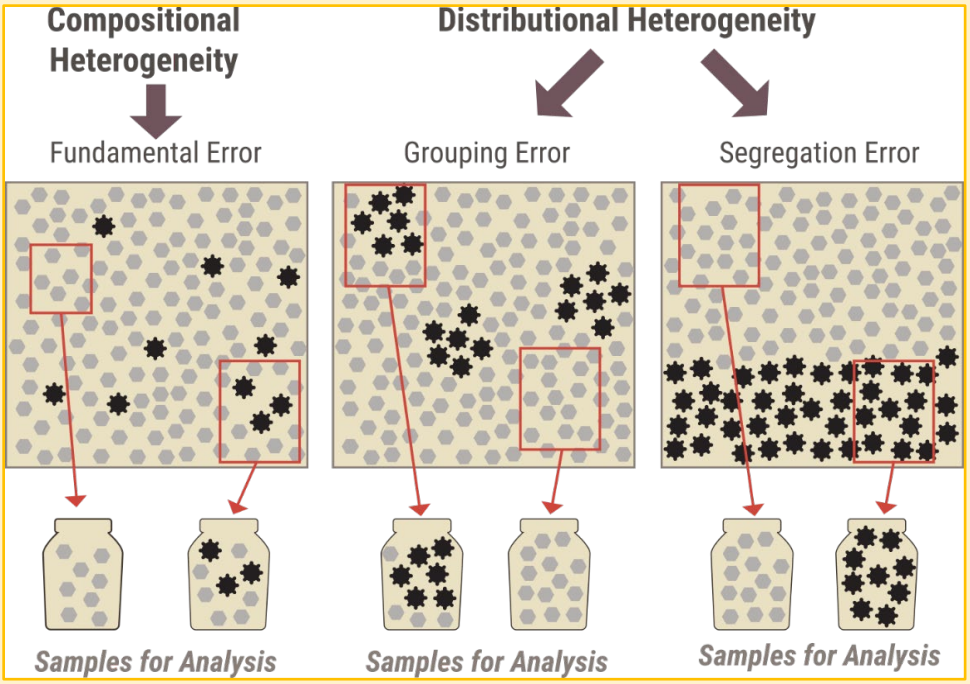
These soil characteristics are of varying concern regardless of whether exposures are estimated from discrete or non-discrete (i.e., ISM or composite) sampling methods. Refer to the yellow text box on the next page for additional information and figures illustrating these concepts. Differences between discrete and non-discrete sampling methods are discussed immediately after.

Additional Information: Heterogeneity Associated with Soil Sampling

Heterogeneity is the primary factor affecting sampling error and the quality of exposure estimates derived from soil samples collected in the field. The particulate composition of soil and its chemical interaction with contaminants, as well as the distribution of particles within a given volume of soil, result in two types of heterogeneity that must be considered when quantifying exposure, as described and illustrated below.

Compositional heterogeneity: This type of heterogeneity results from variable contaminant concentrations between the particles that make up a given volume of soil. Soil particles are of many different sizes, shapes, and densities, each with their own unique propensity to bind contaminant molecules (i.e., contaminant molecules "stick" better to certain particles than others). Pure particles or "nuggets" of contaminants might also be present. This means that contaminants are not uniformly spread out through an exposure unit or even within a sample jar. For example, imagine a laboratory scooping out subsamples from a field sample jar for analysis. Due to the heterogeneous nature of soil, repeated scoops of soil from the same sample jar will undoubtedly contain different amounts of contamination, even if the field sample was collected from an exposure unit assumed to exhibit homogenous contamination. This type of error is commonly referred to as "fundamental error," and can be managed by increasing sample mass and improving sample processing at the laboratory (e.g., sieving or grinding samples to create equal size particles).

Distributional heterogeneity: This type of heterogeneity results from the uneven, nonrandom distribution of contaminated particles within a given area and volume of soil. For example, certain areas of an exposure unit may contain more particles of specific shapes, sizes, and contaminant masses than other areas, resulting in *grouping* of contaminants. Samples collected at various locations in the exposure unit will therefore contain different amounts of contamination. Distributional heterogeneity can also be of concern at the spatial scale of a single sample jar. For example, imagine a sample jar of soil that has been shaken during transport from the field to the laboratory. This may cause fine particles to drop to the bottom of the sample jar and larger particles to remain at the top, resulting in *segregation* of the contaminants. If a laboratory scooped out a sample from the top of the jar for analysis, it would collect a different amount of contamination than if the sample was collected from the bottom of the jar. This type of error is commonly referred to as "grouping and segregation error," and can be managed by collecting a sufficient number of sample increments across an exposure unit, and subsampling and processing at the laboratory.



Figures were recreated from ITRC 2020

2.1 Discrete Sampling Strategies

For many years, environmental investigations have largely relied on discrete sampling practices. These methods can provide useful information to support site delineation and identification of "hotspots," and are often appealing in terms of their cost and ease of implementation. However, simulation studies and empirical evidence suggest that discrete sampling methods do not always provide the accurate and reproducible data needed to confidently estimate average exposures [Brewer et al. 2017a, 2017b]. This is largely due to errors related to compositional and distributional heterogeneity (see text box on the previous page) that are not sufficiently addressed by the sampling and laboratory analytical methods traditionally used for discrete environmental samples. Since ISM methods are more developed for soil than other media, a detailed discussion of heterogeneity specific to the soil medium follows.

Soil heterogeneity can result in a high degree of variability between contaminant concentrations measured in discrete field samples. Imagine collecting two separate scoops of surface soil within a 20-square-foot residential yard. The question of whether those two samples sufficiently characterize contaminant concentrations for the entire yard can be difficult to answer due to variability in contamination concentrations across the area. If small numbers of discrete samples are collected, large-scale contaminant trends and "hotspots" may be missed and therefore not represented in the EPC. To achieve reasonably representative environmental data using discrete sampling methods, large numbers of samples of sufficient and equal mass are required, which in some cases may be impractical.

Heterogeneity is also a concern during laboratory analysis. Typically, laboratories collect a random, single, one- to ten-gram aliquot of soil from the field sample. This approach may not result in a soil concentration that is representative of the whole field sample, especially if the sample is segregated. In fact, multiple subsamples taken from a single discrete field sample will not likely result in the same measured concentrations.

Interpretation of discrete sampling data may also be limited by the biased sampling strategies and low sampling densities often used in the field. Biased sampling strategies (i.e., sampling only in the most highly contaminated areas) limit the ability to accurately quantify average concentrations across an exposure unit. Low sampling densities (i.e., using only a few discrete samples to draw inferences for a large volume of soil) limit statistically valid interpretations of the data. Unless discrete samples can adequately characterize heterogeneity throughout the exposure unit, relying solely on discrete sampling data may result in decision errors. Error associated with non-representative sampling would only be identified if replicate sets of discrete sample data were collected for comparison, which is rarely done.

ISM (and to some extent, simpler compositing approaches) are specifically designed to address some of the shortcomings of discrete sampling data. In certain cases, due to the use of statistically based sampling approaches and specific laboratory processing methods (e.g., sieving, subsampling), ISM samples can offer a more reliable and efficient means for characterizing environmental contamination and estimating EPCs.

Nevertheless, discrete sampling has been used for decades, and this approach continues to be applied. ATSDR's *Exposure Point Concentration Guidance for Discrete Sampling* has information on how to calculate EPCs for acute, intermediate, and chronic exposures with such data [ATSDR 2019a]. Health assessors should use that guidance when estimating EPCs with data from discrete samples.

2.2 Non-Discrete Sampling Strategies

Non-discrete sampling strategies (if applied correctly) can provide more representative estimates of an exposure unit's average contaminant concentrations than traditional discrete sampling approaches. This is especially true for ISM, with statistical underpinnings in Pierre Gy's theory of sampling (see Section 3.1). In addition to better data reliability and representativeness, this approach has the added benefit of potentially lowering site investigation costs by decreasing the number of samples required to characterize a site under investigation. ISM builds loosely on the idea of composite sampling, as follows.

- Composite sampling involves collecting and physically combining several individual grab samples into a single sample. The composite sample is then analyzed at the laboratory and the resulting concentration is meant to represent the average contaminant concentration across the volume of material from which the combined grab sample was collected. In some cases, this volume of material (e.g., soil) may represent an exposure unit; however, that is not always the case.
- ISM can be thought of as a specialized type of composite sampling with specific requirements that stand apart from common compositing practices. This sampling method involves collecting and combining many equal mass increments of material across an area or volume of soil (e.g., an exposure unit). The combined sample is sieved and ground to obtain a consistent particle size and then subsampled and processed by the laboratory following specific protocols. Due to the sampling density afforded by collecting many increments, ISM results can provide more precise and less biased estimates of average concentrations in soil than simple compositing approaches.

Both ISM and simpler compositing approaches rely on similar collection methods but provide considerably different information. ISM samples are collected within a defined area and the results are expected to represent average exposures within that area. This is because ISM requires that samples be collected with appropriate tools, be of a sufficient mass, and consist of a high number of increment samples (ideally 50 or more). Composite samples, on the other hand, may be collected without full consideration of distributional heterogeneity and often have far fewer soil mass increments. This can introduce significant error in the resulting data.

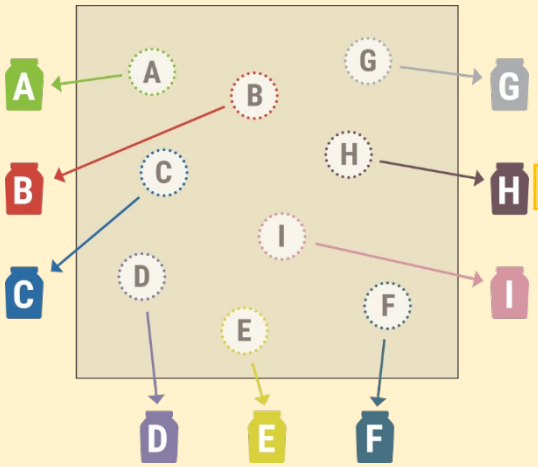
When determining the appropriate EPCs for an exposure unit using discrete sampling data, health assessors use statistical tests to address variability in the data and to estimate the EPC [ATSDR 2019a]. These tests are unable to address potential errors tied to the manner in which the samples were collected or subsampled for testing. Conversely with ISM, these errors are addressed by the sampling method itself, providing a direct estimate of the EPC and negating the need for subsequent statistical evaluation. Additional benefits of ISM (and in some cases composite sampling) can include (1) more representative and reproducible data[2], (2) reduced potential for sampling error, and (3) reduced potential to miss or underestimate significant contamination.[3] Both methods are illustrated below.

[2] Neither ISM or more simple compositing methods necessarily result in representative and reproducible data. Environmental data from either method must be rigorously vetted to ensure they follow the principles of the theory of sampling (see Section 3.1) and are consistent with DQOs and the goals of the PHA.

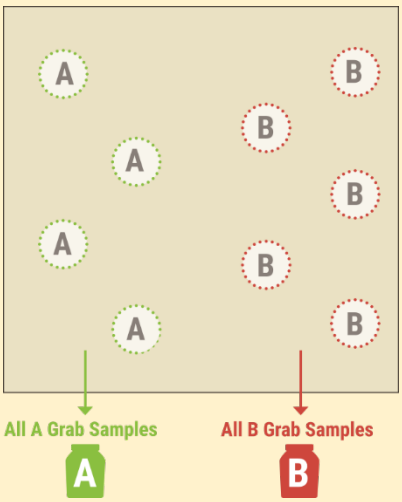
[3] ISM samples that are of sufficient mass, based on a high number of increments, and adequately representative of an exposure unit can reduce the likelihood of missing a "hotspot" within that exposure unit. However, given insufficient bulk ISM sample mass, you are unlikely to capture the rare high contaminant fragment of soil in a sample. Similarly, having a low number of sample increments will also increase the chance that contamination is missed in a sample. If the objective is to identify distinct "hotspots" in an area, then subdivision of the initially targeted area into smaller decision units or use of discrete sampling approaches may be necessary.

Additional Information: Discrete Versus Non-Discrete Sampling Methods

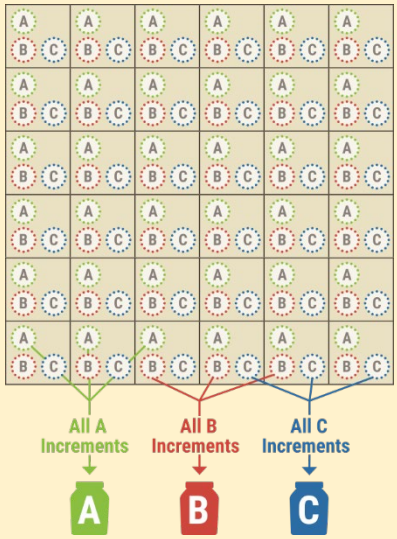
Discrete, composite, and ISM samples are collected with different methods, as illustrated below.



Discrete sampling: A method that obtains a sample from a single sampling point or location for analysis. For example, in the illustration shown to the left, nine discrete samples (locations "A" through "I") are collected from the exposure unit, and the nine samples are sent to the laboratory, which analyzes each sample separately.



Composite sampling: A method that combines several grab samples into a single sample for analysis. These samples represent average contaminant concentrations over the area and volume of material from which the combined grab samples were collected. For example, in the illustration shown to the left, separate samples are collected at the four "A" sampling locations and combined into a single composite sample for analysis; and separate grab samples are collected at the five "B" sampling locations and similarly combined into a single composite sample.



ISM sampling: A structured composite sampling and processing method that combines many (typically a minimum of 30) increments into a single homogenized sample for analysis. The result represents the mean concentration for the exposure unit from which the increments were collected. For example, the illustration to the left shows a scenario in which field samplers systematically collected three separate incremental samples, each with 36 increments: 36 increments at the "A" locations; 36 increments at the "B" locations; and 36 increments at the "C" locations.

Figures were recreated from ITRC 2020.

3.0 GUIDANCE RECOMMENDATIONS FOR INCREMENTAL SAMPLING DATA

This section describes how health assessors should review ISM data, and if appropriate, estimate EPCs with ISM data for PHA purposes. The section covers the following topics:

- Section 3.1 provides background information and common applications for ISM.
- Section 3.2 lists important considerations for health assessors when evaluating ISM data for PHA purposes.
- Section 3.3 outlines ATSDR's preferred approach for determining EPCs with ISM data.
- Section 3.4 discusses several additional considerations when working with ISM data.

Additional Information: ISM Nomenclature

ISM is a form of non-discrete or "infinite element" environmental sampling. In site documents, health assessors may see different terms used to describe this type of sampling. Those terms may include "incremental sampling" (or "IS") and "*MULTI INCREMENT®* sampling" (a registered trademark of EnviroStat, Inc.).

3.1 ISM and Common Applications

The statistical basis for ISM is attributed to Pierre Gy, who used the term "incremental sample" to describe a method for obtaining representative samples from heterogenous media [ITRC 2020]. His pioneering work was driven by the highly variable distribution of minerals within rock formations and has paved the way for the current focus on understanding the source and types of sampling errors inherent of environmental data. He identified numerous different sampling errors (e.g., fundamental sampling error, group and segregation error) and ways to eliminate or minimize them to ensure representative data and correct sampling (i.e., "sample correctness" or sampling in such a way so that all particles have the same probability of being included in the sample). Health assessors are directed to other references for further information on Gy's theory of sampling [USEPA 1999; Pitard 2019]. A high-level summary of this theory is included in chapter two of ITRC 2020.

Key Point: Exposure Unit vs. Decision Unit

An exposure unit is a geographically defined area where a person has contact with an environmental medium (e.g., soil, surface water, groundwater, air, biota); and, over time, the person is assumed to move at random throughout the exposure unit (or contact the environmental medium at random). Exposure units may be small if a person only accesses limited areas or large if activity patterns result in exposure over a large area.

ISM samples are designed to provide representative contaminant concentrations over a specific volume of soil. Several agencies use the term "decision unit" to refer to the smallest volume of soil for which a decision will be made with ISM data. The boundaries of decision units can be based on human health exposure areas, ecological exposure areas, source areas, and more. An ISM decision unit may not always align with the exposure unit.

This guidance largely refers to exposure units, but health assessors should be aware that SAPs and DQOs may use the term decision unit.

In brief, the goal of ISM (and Gy's theory of sampling) is to obtain and analyze a sample that contains analytes in the same proportion as soil throughout the given decision unit or exposure unit (see the blue text box to the right). To achieve this, many equal mass increments (e.g., 50) are collected in an unbiased manner across a certain area and combined to form a single sample with minimum bulk sample mass requirements (e.g., one to two kilograms) for

laboratory analysis. Another key element of ISM is that replicate samples (ideally two, each with the same coverage and representativeness as the original sample) are collected. Replicate samples are typically collected in a subset of the exposure units/decisions units for a given program (e.g., 10%) and used to evaluate the overall precision of the sampling method. Some programs may collect replicates at every exposure unit, but this is not always the case nor a requirement of ISM. Replicate ISM data are helpful to understand analytic error and the overall representativeness of the data, both of which are important factors not routinely addressed in other sampling schemes (e.g., discrete sampling).

Use of ISM techniques requires rigorous systematic planning, sample collection, and laboratory processing to ensure correct sampling and representativeness. Here is how it works:

- *Systematic planning.* Sampling design is a key component of ISM and, whenever feasible, health assessors should participate in planning discussions for ISM programs when the data are going to be used for health assessments. Health assessors can provide valuable information for designating exposure units for sample collection, developing data quality objectives (DQOs), and determining how samples should be collected, processed, and analyzed at the laboratory. This can also help ensure that reasonable detection limits are achieved, relative to the decisions and calculations required as part of the PHA. For example, if anticipated detection limits are near ATSDR CVs, then sufficient samples should be collected to conduct more robust statistics with technical support of the ADS group. Ideally, health assessors could also assist in the collection of ISM samples, in order to fully understand the sampling methodology employed and to identify potential sample collection errors before submittal to a laboratory for processing and analysis.

Additional Information: DQOs

The DQO process is used to develop performance and acceptance criteria (i.e., DQOs) that clarify study objectives, define the appropriate type of data, and specify tolerable levels of potential decision errors that will be used as the basis for establishing the quality and quantity of data needed to support decisions (USEPA 2006). DQOs are developed with careful consideration of data precision, accuracy, completeness, and representativeness. Broadly speaking, a sampling program's DQOs could help answer the following types of questions:

- What is the purpose of the data collection?
- What sampling method should be used to collect, ship, and store the sample?
- What analytical method will achieve the purpose of the project?
- What level of quality assurance (QA) and quality control (QC) is needed?

At a very high level, an ISM sampling and analysis plans (SAP) should include 1) a conceptual site model, 2) a clear understanding of the objectives and questions being asked as part of the investigation, and 3) data needs and a sampling and analysis approach. In general, DQOs for an ISM program should specify the sample mass that should be collected to obtain the desired degree of precision; the number of increments that should be collected to adequately represent the area and exposure pathways being evaluated; and other relevant data expectations (e.g., the number of field/laboratory replicates, acceptable variability among field replicates, laboratory reporting limits). ITRC provides guidance for defining some of these parameters when developing DQOs for ISM programs [ITRC 2020]. For additional information on DQOs, refer to Chapter 5 of *PHAGM* and the following EPA resources:

- USEPA 2006. Guidance on systematic planning using the data quality objective process. EPA QA/G-5. Available at: https://www.epa.gov/sites/production/files/2015-06/documents/g4-final.pdf.
- USEPA 2000. Guidance for data quality assessment. Practical methods for data analysis. EPA QA/G-9, QA00 update. Available at: https://www.epa.gov/sites/production/files/2015-06/documents/g9-final.pdf.

- *Sample Collection.* ISM samples are prepared by collecting multiple increments from a defined volume of soil and physically combining them into a single sample for analysis. In the case of soil, the field team typically collects at least 50 increments of uniform mass soil from an exposure unit and combines them into a single one- or two-gallon sealable plastic bag or bucket. The combined increments are then sent to the laboratory as a single sample.[4] Additional ISM field samples (i.e., field replicates) are typically collected concurrently within the exposure unit in order to quantify the total precision of the data, assess uncertainty, and ensure a reliable estimate of the average concentration. This is commonly done by marking the initial ISM sample increment locations with a flag and then collecting additional ISM field samples at a pre-determined distance in the same direction from each of the original increment locations. In most applications, triplicates are collected (i.e., one parent sample and two replicates).

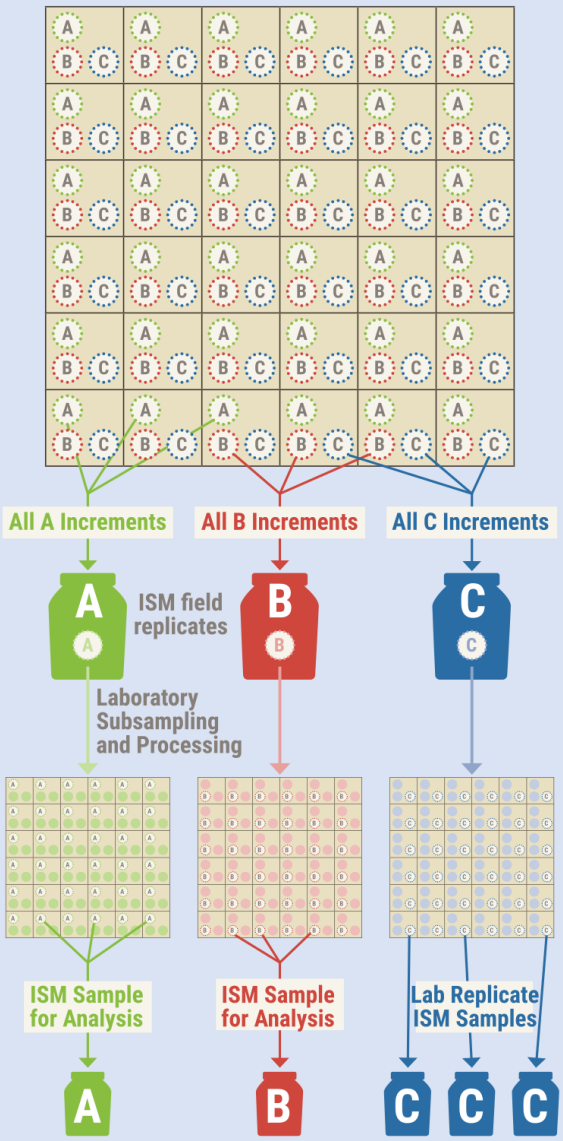
  Many possible sampling designs can be applied for ISM sample collection, each with the goal of yielding unbiased estimates of average concentrations. Systematic random sampling, as shown in the blue text box on the next page, is a common and reliable method. Under this design, the position of the first ISM increment collection point is randomly selected, and the remaining ISM increment collection points are determined by a sampling grid based off this first point. If field duplicates or triplicates are collected, the same grid pattern is used, but based on a new randomly selected starting point. Health assessors can refer to ITRC's guidance for details on the various other ISM sampling schemes [ITRC 2020].

- *Laboratory processing and analysis.* Once the ISM samples are received by the laboratory, the laboratory air dries the samples (if moist)[5], sieves the samples to the targeted particle size and, if required to address the investigation objectives, grinds the samples. A representative subsample is then hand collected from each ISM field sample, by first spreading the sample into a thin layer in a pan and then collecting and combining 30 to 50 small increments with appropriate laboratory sub sampling tools and techniques so as not to bias selection of size fragments. The subsample is then analyzed for selected chemicals.

  Ideally, the project team will have also designated at least one field replicate for separation into laboratory replicates, which can be used to evaluate the potential error generated by laboratory processing, subsampling, and analysis. Under this approach, subsamples are collected from the processed primary sample and independently tested. Laboratory replicates are analyzed to evaluate the precision of the laboratory's subsampling procedure [HDOH 2016].

[4] When ISM samples are collected for VOC analyses, smaller increments are collected (i.e., typically resulting in a total mass of five to ten grams) into a half- or one-liter small mouthed amber glass bottle containing methanol. This different approach for VOCs is used to minimize the amounts of contaminants that evaporate from the sample between the field and the laboratory.
[5] In order to facilitate disaggregation and sieving, moist samples may need to be air-dried in the laboratory. However, this is only appropriate for chemical stable analytes that are unlikely to volatilize during extended air exposure (ITRC 2020).

Key Point: Summary of ISM Sampling and Analysis



The exposure unit is identified and the sampling plan is developed to ensure that multiple increments are collected in a consistent manner, across the entire area. An example of a systematic random sampling plan is shown to the left. In this plan, three ISM field replicates are to be collected across the decision area following the illustrated grid pattern.

Increment samples are collected and combined into three field replicate ISM samples. In this case, a sampler would collect equal volume increments at all A locations and then combine these increments into a single ISM sample. This process is repeated for all B and then C sampling locations.

An aliquot for analysis is collected from each ISM field sample by the laboratory. The ISM field sample is spread out and a subsample is generated following the same process as in the field, but on a much smaller scale. For select ISM field samples, the laboratory will collect multiple subsamples (i.e., laboratory replicates), in order to quantify laboratory error.

The three ISM samples, and any collected laboratory replicates, are analyzed. In this plan, three laboratory replicates were collected from ISM Field Sample C.

Figures were recreated from ITRC, 2020.

3.2 Guidance for Reviewing ISM Data

In all cases, health assessors should critically review ISM data before using it to estimate EPCs. The goal of this review is to ensure that (1) samples were collected and analyzed properly and (2) sample data are adequately representative of the exposure scenarios being investigated. The following should be considered:

- *Data quality objectives (DQOs).* Sampling protocols and sampling reports should clearly state the program's DQOs, which health assessors should review to understand why sampling occurred

and what sampling intended to accomplish. That said, not every sampling report will include DQOs. Sampling reports issued prior to EPA's guidance may not refer to DQOs. Similarly, more recent sampling not conducted under an EPA program and not required to follow EPA's guidance may not refer to DQOs. Even if sampling reports do not refer to DQOs, they should include "purpose statements" or similar language explaining why sampling was conducted.

As a first step, health assessors should read and understand DQOs, along with SAP and quality assurance project plan (QAPP) documentation. As described above, these plans and DQOs should document the area under investigation, sample collection methods (e.g., the number of increments that will be collected, sampling locations, sampling design), and laboratory procedures (e.g., detection limits). Regardless of the sampling objectives, health assessors should use all available documentation to understand the reasons why the environmental data were collected and determine what those data represent. This could be documented through a formal DQO process, or it could be ascertained through other documentation and speaking with the sampling organization, using EPA 2006 as a guide. The main objective of this effort will be to understand if the DQOs of the original data collection allow for the sampling data to be used in the PHA. As part of this process, the health assessor will also need to determine if the data are representative of exposures in an exposure unit. In some cases, the data simply might not be applicable to the PHA.

If ISM data meet the DQOs and the DQOs are compatible with the objectives of the PHA, then the data are considered usable for the PHA. If analytical results are approaching screening values, health assessors should place additional emphasis on meeting the pre-defined DQOs. If the data do not meet the DQOs or DQOs are unavailable, health assessors should generally not use the data for the PHA.

In some scenarios, health assessors may consider using the data (even in the absence of DQOs) with appropriate documentation of any related uncertainties or limitations. One of these scenarios could be when evaluating past exposures, which ATSDR does on a routine basis as part of its mandate. When this is the case, health assessors should be transparent about the limitations of the data. If conclusions/recommendations are sensitive to imprecisions, health assessors should note that data are lacking to make a health determination.

- *Exposure units.* Exposure units are defined by areas that people access (or contact) at random and may differ for acute, intermediate, and chronic exposure scenarios. Health assessors should evaluate the size and shape of the exposure unit, the conceptual site model, incremental sampling locations, and any other available site-specific information to ensure that ISM data represent average exposures within the exposure unit. Health assessors should also evaluate whether increments were collected in a non-biased manner throughout the exposure unit.

  Designating a specific depth for sample collection and then ensuring increments were collected evenly across the full depth of targeted soil is equally as important. This normally requires the use of a sampling tube or similar coring device. Scoops and trowels can collect wedge-shaped increments that bias the sample to the upper part of the exposure unit and underrepresent deeper areas. To the extent possible, health assessors should confirm that samples were collected at depth that is consistent with ATSDR's preferred depth of soil sampling. ITRC and

HDOH guidance include recommendations for a variety of sampling tools depending on the nature of the soil being tested [ITRC 2020; HDOH 2016].

- *Sample collection.* Health assessors should critically review sample collection procedures to ensure that they are consistent with DQOs and SAPs. In particular, health assessors should consider the number of increments and total mass of an ISM sample, as well as the sampling tools used. Where a high degree of heterogeneity in contaminant concentrations is anticipated, a greater number of increments and larger sample mass may be necessary. Highly variable discrete sample data previously collected within a targeted area are often an indication of significant heterogeneity and the need to include a larger number of increments in the sample. Whenever possible, health assessors should review the site history and any previous environmental sampling data to determine whether contaminant concentrations are homogeneously dispersed across the exposure unit. The number of increments to be collected, the sampling depth, and the targeted bulk sample mass should be specified in the SAP or DQOs.

  Some guidance has indicated that a minimum of 30 increments is required to address distributional heterogeneity within a targeted area [ITRC 2020]. However, in many cases, a greater number of increments per sample will be required (ideally at least 50 to 100). For example, 30 increments of soil collected across a quarter acre commercial property with several small areas of elevated contamination levels (i.e., "hotspots") may not accurately characterize average exposures. In this case, additional increments may be needed to provide a better estimate of the true mean. Field studies conducted by the State of Hawaii suggest that at least 50 increments per sample are necessary to represent contaminants sorbed to soil particles [HDOH 2016]. Sites impacted with lead, PCBs, and other contaminants that might be present in their pure state in the soil typically require a larger number of increments per sample to generate representative data (75 increments or more). Generally speaking, the number of increments is tied to distributional heterogeneity and not the size of the exposure area.

  Adequate sample mass is another critical component of ISM. For the individual increments, it is important that each increment has an equal mass. Ideally, the minimum mass and/or volume of individual increments should have been calculated prior to sampling (e.g., as part of the DQO process) to allow for the selection of appropriate collection tools. For the total ISM sample, a minimum bulk mass of one to two kilograms is typically required to overcome error associated with compositional heterogeneity and error in increment collection. Larger sample masses (e.g., two to three kilograms) might be required for cases where the contaminant is present as "hotspots" or as "nuggets" within the sampled material (e.g., lead paint chips).

  Health assessors should also consider whether appropriate sampling tools were used. Chapter 4 of ITRC's guidance provides detailed explanations of these tools as well as additional information on the other points discussed above [ITRC 2020].

- *Laboratory processing and analysis.* As described in Section 2.2, the laboratory must follow specific processing procedures for ISM samples. Laboratory processing involves sieving, grinding (if required), and collecting representative subsamples of ISM field duplicates or triplicates. While this processing can be performed in the field, it is more commonly completed in a controlled laboratory setting.

Health assessors should review sample processing procedures to ensure that samples were properly air dried, sieved (for particle size selection – e.g., less than two millimeters), and ground (for particle size reduction – e.g., when evaluating contaminants adhered to larger particles) to achieve uniform particle sizes, if appropriate.

Requirements for laboratory processing should be described in DQOs and SAPs. Additional details on these procedures is provided in Section 5 of ITRC's guidance [ITRC 2020].

Analytical Results: Finally, health assessors should confirm that samples were analyzed for the specified contaminants and review the data for any anomalies (e.g., rejected results). Once health assessors have determined that the ISM data reasonably represent the average concentration of a targeted contaminant for the specified exposure unit and that the laboratory provided all of the necessary data, health assessors should evaluate results from ISM replicates collected in the field, and if necessary – ISM replicates collected by the laboratory. These replicates can provide valuable insight into the results' precision or reproducibility.

- As described above, field replicates consist of separate ISM samples collected and processed from the same exposure unit. They are typically collected in a subset of the exposure units/decisions units for a given program (e.g., 10%), though some programs may collect replicates at every exposure unit. In situations where ISM field triplicates have been collected, health assessors should evaluate data precision by calculating the relative standard deviation (RSD) of the triplicate results collected from within the same exposure unit.[6] A minimum of three field replicates is required for this calculation. These calculations provide a way to check the overall precision of the sampling method used, including the number of increment samples and bulk sample mass, as well laboratory processing and testing.

  The RSD is calculated as the ratio of the standard deviation of the ISM field replicates to the mean of the ISM field replicates, as shown in Equation 1 below.

  Equation 1. Relative Standard Deviation

  $$RSD = \frac{ISM\ Replicate\ Standard\ Deviation}{ISM\ Replicate\ Mean}$$

  Acceptable RSDs should be specified in the DQOs and health assessors should review RSDs against the DQOs as part of the initial data evaluation step. When DQOs are not available, health assessors should use their judgment to evaluate RSDs following the general guidelines below.

  In general, a high RSD (i.e., a value greater than 0.5) suggests poor precision and potential error. When RSDs are in this range, health assessors should generally not rely on the ISM data to calculate EPCs or to make decisions regarding risk. In these cases, the poor precision among the ISM field triplicates may result in unreliable estimates of mean exposures from the ISM data. When this occurs, health assessors can review the laboratory report to identify the sources of error that contributed to the unacceptable variability among the ISM field replicates. High variability between replicate laboratory subsamples normally suggests subsampling errors.

[6] The RSD is a crude measure of the precision of the ISM results (i.e., whether or not results can be reproduced) and not the accuracy of the ISM results (i.e., whether or not results are biased).

Grinding of samples and/or testing of a large subsample mass can help to alleviate this problem, assuming that the original subsamples were properly collected (i.e., prepared with at least 30 increments, collected using a flat-bottomed and sided tool, etc.). Low variability between laboratory subsample replicate data yet a high RSD for the field samples suggests an error in sample collection in the field. This could include an inadequate number of increments in the sample, an inadequate total sample mass, or improper increment collection methods (e.g., non-systematic random grid, improper tools).

If sample collection error is likely to be the main cause of high variability between replicates, then recollecting samples using a greater number of increments and an increased sample mass should be considered. In some cases, this will not be practical due to time and cost constraints and the lack of obvious improvements to the original sampling method. When this occurs, health assessors should note data gaps and limitations in the PHA. They may also consult with the ADS group for help conducting a more detailed review of the ISM data in context with the safety margins built into applicable CVs and target risks.

Key Steps for Initial Review of ISM Soil Data

Verify that the goals of the sampling program are consistent with the PHA

- Are the objectives of the sampling program consistent with the PHA?
- Are the boundaries of sample collection consistent with the exposure unit?
- Is the sample collection depth consistent with ATSDR's preferred soil sampling depth?
- If DQOs were specified, were they met?

Verify field sampling protocols

- Were a sufficient number of increment samples collected (ideally at least 50)?
- Was an equal size mass collected for each increment sample?
- Were increment samples collected throughout the exposure unit at a consistent depth and in an unbiased manner?
- Was the final ISM sample of an appropriate bulk mass (ideally one to two kilograms)?
- Were a sufficient number of field replicates collected (ideally two from within the same exposure unit and from at least 10% of the exposure units)?

Verify sample processing techniques at the laboratory

- Were the samples air-dried to facilitate disaggregation/sieving, if appropriate?
- Were the samples properly sieved to exclude larger particles, if necessary?
- Were the samples properly ground up/milled to reduce the particle size, if appropriate?
- Were the samples properly digested to target certain contaminants, if necessary?
- Were representative subsamples collected at the laboratory?

Review analytical results

- Were results provided for all of the samples collected and analytes requested?
- Were all QA/QC milestones met?
- Is variability among ISM field replicates (as characterized by the RSD) acceptable, if applicable (i.e., if replicates were collected)?

Additional information on field sampling and laboratory processing is provided in ITRC 2020 and HDOH 2016.

3.3 Guidance for Estimating EPCs with ISM Data

This section walks health assessors through ATSDR's preferred approach for determining EPCs for acute (1-14 days), intermediate (15-364 days), and chronic (365 days and longer) exposure durations with ISM data. Once health assessors have confirmed that ISM samples were correctly collected in the field and processed in the laboratory (Section 3.2), health assessors may use ISM data to calculate EPCs using the methods described below. ATSDR recommends arithmetic means as EPCs for ISM data.

- *Intermediate or chronic exposures*. Procedures to determine EPCs based on the number of field replicates are described below. The same procedures can be used to determine acute EPCs, if the health assessor has decided that the data are appropriate for that purpose.

  - *Single primary ISM sample.* If a single ISM field sample is collected from an exposure unit and no replicate data are available, results from the ISM sample may be used as the EPC as long as you have confirmed sample correctness and representativeness. Health assessors should note in the PHA: "EPCs are based on a single ISM sample. Although the sample appears to have been properly collected, processed, and tested consistent with the general principles of the theory of sampling, field triplicates were not collected, and therefore, we cannot confirm that the sampling program has achieved the designed precision."

  - *Primary ISM sample and one field replicate (i.e., duplicates).* If one ISM field replicate is collected from a given exposure unit, the average of the ISM primary sample and field replicate results should be used as the EPC. Health assessors should note in the PHA: "EPCs are based on one ISM field sample and one replicate. Although the sample appears to have been properly collected, processed, and tested consistent with the general principles of the theory of sampling, field triplicates were not collected and we therefore cannot confirm that the sampling program has achieved the designed precision."

  - *Primary ISM sample and two field replicates (i.e., triplicates).* If two ISM field replicates are collected from an exposure unit, the average of the ISM primary sample and the two ISM field replicates should be used as the EPC, as long as the RSD for the triplicates is less than 0.5.

    When RSDs exceed 0.5, EPCs should generally not be calculated from the ISM data. However, the 0.5 cutoff should be interpreted as more of a guideline than a rule. For example, high RSDs might be unavoidable as concentrations approach laboratory detection

Additional Information: EPCs for ISM Data

The statistical underpinning of ISM sampling methodology, based on Gy's theory of sampling for infinite element media, allows direct estimation of the mean concentration of the contaminant for the targeted exposure area and replaces the use of statistical tests traditionally applied to discrete sample data (e.g., 95 percent upper confidence limits of the arithmetic mean [95UCLs]). When there are multiple ISM field replicates collected in an exposure unit, a 95UCL could in theory be calculated, however, this is generally only warranted when there is significant variability between individual sample data. In these cases, many sampling statisticians trained in Gy's sampling theory would simply conclude that the exposure area should be retested using larger samples collected from a greater number of increment points in lieu of relying on a 95UCL based on highly variable ISM data.

limits. In these cases, health assessors may also consider interpreting RSDs in context with health CVs. For example, a high RSD may indicate low precision, but if the average of ISM replicate results are far below health comparison values, the data may still be appropriate for estimating EPCs and evaluating risk in the PHA. Health assessors must use their best judgment in these cases and consult with the ADS group, as needed.

Acute exposures. As explained in Section 3.2, ISM samples are collected to generate a single value that represents average concentrations over a given volume of soil. In some cases, ISM data may be appropriate for evaluating acute exposures. This will often only be the case when the exposure unit is specifically defined to evaluate the acute scenario and increments are collected in an unbiased manner throughout that exposure unit.[7] If an exposure unit was not specifically designed for evaluating acute exposures, health assessors must use their professional judgment to determine whether ISM data are appropriate to evaluate acute exposures. Procedures to determine appropriate acute EPCs are based on contaminant variability and expected human activities in the exposure unit, as summarized below.

- *Contamination is not expected to be highly variable in the exposure unit.* Health assessors can use the ISM data to estimate acute EPCs following the procedures described above.
- *Contamination is expected to be variable in the exposure unit.* Health assessors should determine whether any expected human activity patterns could result in people spending a majority of their time at one particular area of the exposure unit.
    - *People are not expected to spend more time in any one area of the exposure unit.* Health assessors can use the ISM data to estimate acute EPCs following the procedures described above for intermediate or chronic exposures. For example, ISM data would be appropriate for estimating acute exposures in a schoolyard if children are expected to spend an equal amount of time in all areas of the schoolyard and if increments were collected in an unbiased manner across the area.
    - *People are expected to spend more time in a particular area of the exposure unit.* Health assessors should not use the ISM data to estimate acute EPCs in this case. Returning to the example above, if the schoolyard with variable contamination levels contained a small play area that children preferentially access over acute durations (e.g., a sandbox or swing set area that is devoid of grass), an ISM sample collected across the entire schoolyard would likely not accurately reflect short-term high-intensity exposures in those smaller play areas. In this case, health assessors could redefine the exposure unit for acute exposures and apply the ISM sampling approach to that smaller area.

      If that is not an option, health assessors can use a "rule of thumb" approach to make crude estimates of "high-end" concentrations with the available data. These estimates should only be used to help determine whether to recommend additional

[7] During the DQO process, it is important to first define the volume of soil that you are interested in and then design a sampling strategy that represents those volumes. ISM can be used to collect small volumes of soil in an exposure unit representative of acute exposures. Alternatively, you can define individual areas within a larger exposure unit where acute exposure may be of concern (e.g., play areas, gardens) and sample those areas separately.

sampling; this method should not be used to calculate an EPC and evaluate risk.

Health assessors can estimate "high-end" concentrations by multiplying the measured concentration from the ISM sample by the number of increments captured in the sample [Patil et al. 2011].[8] If the estimated "high-end" concentration is well below the acute CV, then further sampling may not be warranted, and the data gap and associated limitations should be discussed in the PHA. Conversely, if the estimated "high-end" concentration is near or above the acute CV, the health assessor may recommend additional sampling (e.g., discrete sampling) in the areas that people access. Note that when ISM data suggest reason for concern regarding acute exposures (e.g., the "high-end" concentration is an order of magnitude higher than the CV), health assessors should consider taking immediate health-protective actions and not wait for additional sample data.

When acute exposures are of concern and only ISM data are available, health assessors can use this "rule of thumb" to determine whether additional sampling is warranted to fully evaluate acute exposures. Decisions should be discussed with the ADS group.

Health assessors should contact their ADS group with any questions about the appropriateness of ISM data for evaluating acute exposures and whether additional sampling should be recommended.

[8] As an example, consider an ISM sample, composed of 30 increments collected within a one-acre community park, with a resulting contaminant concentration of 5.5 mg/kg. Assuming the ISM sample was collected properly, one could conclude that the mean concentration of the contaminant in the park is 5.5 mg/kg. If residents preferentially access a small area within this park over an acute time frame, that result may over- or under-estimate actual acute exposures for that area. In this example, multiplying the measured concentration (i.e., 5.5 mg/kg) by the number of increments included in the ISM sample (i.e., 30) can provide a crude estimate of "high-end" concentrations within the park (i.e., 165 mg/kg).

Key Point: Process for Determining EPCs for ISM Data

The following steps outline the overall process of determining EPCs for ISM data.

1. Evaluate DQOs (when possible) and whether the samples were collected properly in the field and processed and subsampled properly in the laboratory. If the ISM samples adequately represent the exposure unit and were collected and analyzed correctly, proceed to Step 2. If the ISM sample collection method is deemed to have been inadequate, then reject the data and request additional sample collection. Consult with your ADS group for further direction.
2. Evaluate the precision of ISM field replicates. If there are fewer than two field replicates, proceed to Step 3. Note that collection of a single replicate sample is generally not recommended (a minimum of two replicates is recommended).
    - RSD $\geq$ 0.5: Assess overall data quality in terms of the sampling method used, comparisons to CVs, and other lines of evidence to support use or rejection of the data. Present rationale for including or excluding the ISM data in the PHA.
    - RSD < 0.5: Use the ISM triplicate data to determine the EPC. Proceed to Step 3.
3. Determine the EPC based on the number of ISM field replicates.
    - One primary ISM field sample: Use results from the single ISM sample as the EPC and note any uncertainties in the limitations section of the PHA.
    - Primary ISM field sample and one or more field replicates: Use the average of ISM replicate results as the EPC. For this calculation, substitute non-detect observations with a value equal to the full laboratory reporting limit, if necessary.

3.4 Additional Considerations for Incremental Sampling Data

While ATSDR developed this guidance to apply to a broad range of site-specific scenarios, some ISM data sets will present unique challenges for determining EPCs. In general, health assessors should consult with their ADS group when they encounter any site-specific scenarios or other circumstances not covered by the general practice presented earlier in this section. Two additional considerations when working with ISM data are described below.

- *Comparing or combining ISM data with discrete sampling data.* Health assessors may encounter site-specific data that includes both ISM and discrete sampling results from the same exposure unit. For example, ISM samples may be collected across a large commercial property to evaluate average concentrations and discrete samples may be collected from certain areas that the property owner believes are unique relative to the rest of the site (e.g., "hotspots"). In this case, it is not statistically appropriate to combine results collected from the two methods into a single dataset for the purposes of determining EPCs. This would weight discrete samples more heavily in the dataset, and the resulting concentration might be biased toward the average of the discrete samples. The ISM data should be used to estimate the mean concentration in the exposure unit. The discrete data might be useful for characterizing "hot spot" contamination levels for acute exposures.
- *Multiple ISM samples collected in a single exposure unit.* If multiple ISM samples are collected within different areas of a given exposure unit, for example to optimize the efficiency of anticipated remediation, then health assessors should contact their ADS group on appropriate area-weighted methods to combine the data. A simple example for how this might be done with composite data is provided in Appendix C for illustrative purposes. Note that this does not apply to multiple ISM field replicates collected within the same area of an exposure unit.

4.0 GUIDANCE RECOMMENDATIONS FOR COMPOSITE SAMPLE DATA

This section presents ATSDR's preferred approach for determining EPCs with composite sample data, as follows:

- Section 4.1 provides background information on composite sampling.
- Section 4.2 lists important considerations for health assessors when evaluating composite sample data for PHA purposes.
- Section 4.3 outlines ATSDR's preferred approach for determining EPCs with composite sample data.
- Section 4.4 lists several additional considerations when working with composite sample data.

4.1 Composite Samples and Common Applications

This sampling technique involves combining multiple discrete/grab environmental samples (e.g., soil, sediment, biota) into a single sample for the purpose of analytical efficiency. The resultant concentration is meant to represent contaminant concentrations for the area and volume of material from which the combined grab samples were collected.

To produce a meaningful estimate of the mean, composite samples are collected following a specific sampling design. The sample protocol typically directs where individual grab samples are collected for a composite sample. Typically for soil, sample collection is conducted by gridding off a defined area and then collecting several grab samples of equal volume and in the case of soil, from the same depth interval within each area of that grid. Grab samples from each grid are combined (e.g., in a bowl or a sealable plastic bag) and thoroughly mixed. An aliquot of this mixture is then collected for laboratory analysis, as illustrated in the blue text box below.

To better understand this sample design, picture a five-acre commercial property that has been divided into ten half-acre plots using this grid approach. One sampling strategy for surface soil would involve collecting a composite sample in each of the half-acre plots; and perhaps each composite sample would be comprised of five grab samples. In this case, 10 composite samples would be sent to the laboratory for analysis, rather than 50 grab samples. The use of compositing in this example would therefore reduce the cost associated with analyzing a large set of samples and results could be averaged to obtain a reasonable estimate of mean concentrations across the commercial property. Other compositing methodologies are described elsewhere [EPA 1995].

Key Point: Summary of Composite Sampling and Analysis

Individual samples are collected in the field.

All A Samples

Grab samples are combined and mixed to form a single composite sample.

Sample for Analysis

A subset of the mixture is collected and sent to the laboratory for analysis.

Figure was recreated from USEPA, 1995.

Composite sample data may be appropriate to estimate mean concentrations for a PHA when there is known or expected to be low variability in contaminant concentrations throughout a defined volume of soil. However, composite sample results are often not based on enough increments/sample mass to be meaningful in the same way as ISM data.

4.2 Guidance for Reviewing Composite Sample Data

Health assessors should thoroughly review SAPs and DQOs, where available, before using composite sample data for health assessment purposes. Several issues that health assessors should consider when working with these types of data for soil are listed below. Any additional questions on composite sample data should be addressed by the ADS group.

- *Data quality objectives (DQOs).* Similar to ISM data, health assessors should begin by reviewing DQO and SAPs, if available. As explained in Section 3.2, not every sampling report will include DQOs though they should include "'purpose statements" or similar language explaining why sampling was conducted. Health assessors should review this information to critically evaluate whether the data are appropriate for quantitative use in the PHA.[9] For this, health assessors should use all available documentation to understand the reasons why the environmental data were collected and determine what those data represent.

  DQOs should specify the amount of mass that should be collected to obtain the desired degree of precision; the number of samples that should be collected to adequately represent the exposure unit area, exposure pathways, and exposure duration being evaluated; and other relevant data expectations. If the composite sample meets the DQOs, then the data should be evaluated further for the PHA process. If DQOs are not available, the health assessor must use their best judgement to determine whether data are appropriate to use in the PHA. If necessary,

[9] When data do not meet the criteria for quantitative use, health assessors may consider including a qualitative evaluation of the data to support the overall conclusions of the PHA.

health assessors may consider requesting additional sampling or consulting with the ADS group on this point.

- *Exposure units.* Composite samples are only appropriate for estimating EPCs when they represent the exposure unit under investigation. Health assessors should therefore review the SAP and use their judgment to determine whether the area covered by a composite sample aligns with the exposure unit. If the area represented by a composite sample aligns with the exposure unit, the data can be used to determine EPCs. If any of the grab samples were collected outside the boundaries of the exposure unit, the health assessor must decide whether the data are representative of conditions within the exposure unit. This can be done by considering contaminant concentration patterns across the site and expected exposure patterns. For example, if a composite sample was composed of ten grab samples and two were collected five feet outside the boundaries of an exposure unit for a single residential property, the composite sample may still be appropriate to determine EPCs, especially for sites where contamination levels have limited spatial variability. If, on the other hand, two of the grab samples within a composite were collected further outside of the property and in a highly contaminated area where people are not expected to go (e.g., an area that has recently been fenced off, a known waste disposal site), results may not reflect actual exposures.
- *Sample collection*. Health assessors should use their judgment to determine whether composite samples were collected appropriately. This requires considering the sampling design (e.g., grid sampling design), the number of grab samples collected to create each composite, and the expected variability in contaminant concentrations across the area under investigation. Health assessors should use all available site-specific information (e.g., site plan, site history) to confirm that the sampling plan provides justification for the number of grab samples per composite. Sites with higher degrees of spatial variability require more grab samples to ensure that results adequately represent average conditions than sites with less variable contamination (e.g., floodplain soil contamination).
- *Processing.* Health assessors should review field and laboratory reports to ensure that the composite samples were adequately mixed and that processing of the composite, whether in the field or the laboratory, did not result in any loss of the contamination. This is particularly important when volatile organic compounds (VOCs) are measured from composite samples as these chemicals can evaporate upon mixing of the samples.

While this guidance largely focuses on evaluating and calculating EPCs with soil sample data, health assessors should be aware of several specific considerations when reviewing data from biota composite samples prior to calculating EPCs. In addition to consistency with DQOs, health assessors should ensure that the following criteria are met:

- Each composite sample should consist of a minimum of five specimens.
- Each specimen in a composite sample should be approximately the same size.
- The composite sample should only consist of the edible portions of the biota.
- Each composite sample should be comprised of a single species.

Note that ATSDR is currently developing guidance for collecting and evaluating biota sample data. Until that guidance is available, health assessors should consult the ADS group with any questions regarding the appropriateness of calculating EPCs for biota composite data.

4.3 Guidance for Estimating EPCs with Composite Sample Data

This section walks health assessors through ATSDR's preferred approach for determining EPCs for acute, intermediate, and chronic (365 days and longer) exposure durations with composite soil data.

- *Intermediate or chronic exposures.* ATSDR's guidance depends on the number of composite samples available in the exposure units:
    - *Single composite sample.* If a single composite sample is collected from a given exposure unit and the health assessor has judged that the sample accurately represents the area, then the health assessor should use the sampling result as the EPC. However, health assessors should carefully review underlying information and determine how confident they are that the composite sample represents intermediate and/or chronic exposures. Any uncertainties should be acknowledged in the PHA. In this case, health assessors should specifically note: "Sampling data were limited and ATSDR is applying some level of professional judgement in evaluating the data." If health assessors think that additional sampling is warranted to increase confidence in EPCs or if results are near corresponding CVs, they should consult with their ADS group. In all cases, health assessors should be transparent about the limitations of the sampling data when drawing conclusions in a PHA.

      As an example, consider a residential development that was built on former agricultural lands where residents are concerned about exposure to a pesticide in soils. The health assessor learned that this pesticide was applied by aircraft (i.e., "crop-dusters") and contamination levels are therefore expected to be relatively constant across individual properties. In this case, a composite sample comprised of five grabs of surface soil from a single property may be judged sufficient for characterizing the property-wide pesticide contamination levels. Therefore, if the laboratory reported a concentration of 5.5 mg/kg for the pesticide, then this value should be used as the EPC. The health assessor would acknowledge any uncertainties associated with this value in the PHA.

      As a different example, consider the same scenario, except the residential property is one where the property owner has found a few empty pesticide containers buried in topsoil at different places in the yard. In this case, the health assessor should be concerned about the potential for pesticide "hotspots" not being captured or represented in the composite sample. The health assessor might determine that the results do not adequately characterize contamination levels and recommend further sampling to address this data gap.

    - *Multiple composite samples.* If more than one composite sample is collected from a given exposure unit, health assessors should follow this guidance:
        - *Composites representing unequal size areas.* If composite samples were collected across unequal size areas of the exposure unit, a weighted mean

should be used as the EPC. In these calculations, weights should be equal to the percentage of the exposure unit represented by each composite sample. For example, weighted means would be required if two composites were collected from areas that each represented 25 percent of the exposure unit and a third composite was collected from an area that represented 50 percent of the exposure unit. Examples of weighted mean calculations are presented in Appendix C.

- *Composites representing equal size areas.* If composite samples represent equal size areas of the exposure unit, an arithmetic mean should be used as the EPC. For example, if four composites were collected across equal size areas within an exposure unit and reported at concentrations of 5.5, 6.2, 7.5, and 8.1 mg/kg, the arithmetic mean of these four results (6.8 mg/kg) should be used as the EPC.

When EPCs are based on a limited number of composite samples or composite samples are based on a small number of grabs, health assessors may consider including the following caveat when discussing results in the PHA, "EPCs are based on a limited number of composite samples and the potential for actual exposures to be underestimated or overestimated cannot be quantified or dismissed."

- *Acute exposures.* Similar to ISM data, ATSDR does not recommend using composite sample data to evaluate acute exposures, except in certain circumstances. As explained in Section 4.1, composite samples are collected to generate a single value that represents average concentrations for a given volume of soil. Only in some cases may these data reflect acute exposures. This is limited to when composite sample data are collected across an exposure unit that was specifically designed to evaluate acute exposures.

  The same approach presented in Section 3.3 for ISM should be considered before using composite sample data to determine an acute EPC. Health assessors must use their judgment when determining whether composite sample data are appropriate to evaluate acute exposures and should contact their ADS group for additional guidance if there is any uncertainty.

Note that the criteria outlined above is specific to soil. When calculating EPCs for biota sample data, a minimum of three composite samples should be collected for each species of interest. Additionally, EPCs for one species should be not extrapolated to another species. For example, an EPC calculated from trout composite data should not be used to characterize contamination for a population of bass.

4.4 Additional Considerations for Composite Sample Data

Health assessors may encounter site-specific data that are collected via various different methods (e.g., discrete, composite, ISM). For example, composite soil samples may be collected across a large residential property to evaluate average concentrations while discrete soil samples may be collected from certain areas that the property owner believes are unique relative to the remainder of the property (e.g., "hotspots"). In this case, it is not statistically appropriate to combine results collected from the two methods into a single dataset. This would weight discrete samples more heavily in the dataset, and the resulting concentration might be biased toward the mean of the discrete samples.

Similarly, composite samples might be collected in the same area as ISM samples. Health assessors should consult with the ADS group for additional guidance when working with such data sets.

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Appendix A. Glossary

Arithmetic Mean: For environmental sampling, the arithmetic mean is the average of a set of sampling results. It is calculated by adding the measured concentrations from individual samples together and dividing the sum by the number of samples.

Censored Data: A term commonly used to describe data sets including non-detect observations.

Composite Sample: A collection of grab samples that are combined into a single sample.

Compositional Error: Heterogeneity resulting from the unique physical and chemical composition of individual particles of soil within a volume of soil.

Compositional heterogeneity: Heterogeneity resulting from variable contaminant concentrations between the particles that make up a given volume of soil.

Data quality objective: Quantitative and qualitative measures used to ensure that the quality of the data is sufficient to achieve the project goals. Operational DQOs could be for elements such as where to conduct sampling and the number of sampling locations, while technical DQOs could refer to elements such as measurement completeness, accuracy, and precision.

Decision Unit: The smallest volume of soil (or other media) for which a decision will be made.

Detection Limit: For environmental sampling, detection limits (often referred to as method detection limits) are thresholds below which measured concentrations are not significantly different from a blank signal, at a specified level of probability. Measurements above detection limits are evidence of a nonzero signal at a given probability, confirming that the analyte of interest is present in the sample.

Discrete sample: An individual environmental sample from a single point and time within a targeted area and volume of the subject media that is independent of other samples.

Distributional Heterogeneity: Heterogeneity resulting from the way that soil particles, with unique size and contaminant mass, are distributed within a volume of soil.

Environmental Sample: A collected quantity of air, water, soil, food, or other media in which contamination levels are measured, whether directly in the field or at a laboratory.

Exposure Point Concentration: The representative contaminant concentration within an exposure unit or area in an exposure pathway to which people are exposed for acute, intermediate, or chronic durations during the past, present, or future.

Exposure Unit: A geographically defined area where a person is expected to contact environmental contamination on a routine daily basis.

Grab Sample: An individual sample collected at one location and at one point in time.

Heterogeneity: Occurs when all individual items within a population (e.g., particles within a given volume of soil) are not identical with respect to a specific characteristic of interest (e.g., a mass of contaminant).

Homogeneity: Occurs when all individual items within a population are identical with respect to a characteristic of interest.

Increment: A portion of a volume of soil (e.g., an exposure unit) that is collected and combined with other increments from the same volume of soil to form an ISM sample.

Infinite Element Media: Media composed of elements that cannot be individually identified nor individually selected at random.

ISM sample: A sample prepared by the collection and combination of equal mass increments of soil collected from a targeted exposure area and volume of soil, which is combined, processed, subsampled, and analyzed to directly represent the mean contaminant concentrations for that area and volume of soil.

Non-discrete sample: Sample obtained from methods that are considerably different than discrete sampling in that multiple samples are taken and then combined to minimize sampling errors associated with the heterogeneous nature of soil.

Relative Standard Deviation: Calculated as the standard deviation divided by the arithmetic mean and used to represent precision among ISM field or laboratory replicates, if needed.

Appendix B. Example EPC Calculations for ISM Data

This appendix demonstrates ATSDR's preferred approach for calculating EPCs with ISM data, following the process outlined in Section 3.3. If sample correctness and representativeness are confirmed, the ISM data can be used to estimate an EPC. When triplicate samples are available (i.e., one original and at least two ISM field replicates have been collected for a given exposure unit) and the maximum result from those triplicates exceeds applicable CVs, arithmetic means should be used as the EPCs. Note that although the example shown here is for soil sampling, the methods apply to other media (e.g., sediment). In addition, the process outlined in this appendix is used to determine EPCs for chronic and intermediate exposures. ATSDR generally does not recommend the use of ISM data to evaluate acute exposures, except in certain circumstances (see Section 3.3).

In this example, a surface soil sampling program collected one ISM field sample and two ISM field replicates at a residential property and analyzed the samples for hexavalent chromium. Each ISM field replicate consisted of 50 equal mass increments of soil. The increments were combined in the field and sent to the laboratory for subsampling, processing, and analysis. Results for the three ISM field replicates are shown below.[10]

ISM Field Replicate Results

ISM Field Replicate	Hexavalent Chromium Concentration (mg/kg)
1	100.6
2	99.0
3	134.2

Step One: Review the site history, SAP, and DQOs, when available, to confirm that the ISM field replicates were collected and processed properly and that the ISM data adequately represent the exposure unit (see Section 3.2).

In this example, the health assessor judged that all key elements of the field sampling program (e.g., number of increments, location of increments, collection procedures) and laboratory analysis (e.g., drying, sieving, subsampling) were conducted properly. The health assessor concluded that the data are appropriate for use in the PHA and for calculating an EPC. Note that in this example, the maximum ISM field replicate result is greater than the applicable ATSDR CV.

Step 2: Evaluate the precision of ISM field replicates by calculating the RSD (Section 3.3).

In this example, the health assessor calculated an RSD of 0.18 from the hexavalent chromium concentrations reported for the three ISM field replicates. Based on the low RSD (i.e., less than 0.5) and information gathered from Step 1, the health assessor concluded that there are no major concerns regarding the precision of the ISM replicates and proceeded to calculating an EPC.

Step Three: Determine the intermediate/chronic EPC (Section 3.3).

In this example, there is one primary ISM field sample and two ISM field replicates. The health assessor used the arithmetic mean of the results as the EPC, which is equal to 111.3 mg/kg.

[10] Consistent with the ISM approach, health assessors should assume that the laboratory collected replicate samples from a single field ISM to evaluate laboratory precision. These data are not needed to calculate EPCs and not shown in this example.

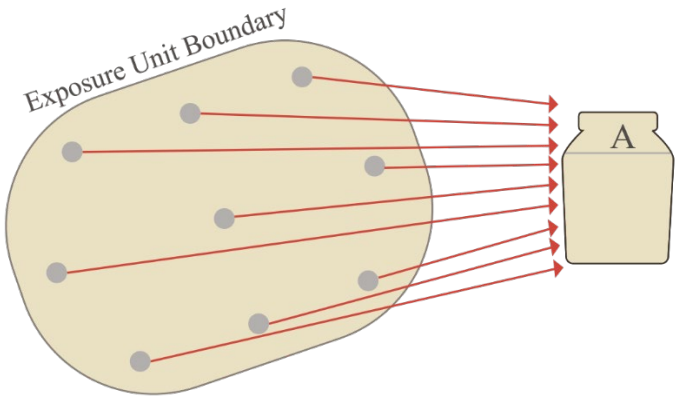
Appendix C. Example EPC Calculations for Composite Sample Data

This appendix demonstrates ATSDR's preferred approach for determining EPCs with composite data for chronic and intermediate soil exposures, following the process outlined in Section 4.3. As described in that section, health assessors may encounter two scenarios when working with composite sample data: an exposure unit with a single composite sample or an exposure unit with multiple composite samples. This appendix outlines the process of determining EPCs for both scenarios, assuming the composite data have already been vetted and deemed appropriate for this purpose.

Although the examples shown here are for soil sampling, the methods apply to other media (e.g., sediment, biota). In addition, the process outlined in this appendix is used to determine EPCs for chronic and intermediate exposures. ATSDR generally does not recommend the use of composite sample data to evaluate acute exposures, except in certain circumstances (see Section 4.3).

Example 1. EPCs for a Single Composite Sample Collected Within an Exposure Unit

This example considers a single composite surface soil sample composed of nine distinct grab samples that were collected across an exposure unit within a small community park (see illustration below). The laboratory reported an arsenic concentration of 42.0 mg/kg for the composite sample.



Step One: Review the site history, SAP, and DQOs, when available, to confirm that the composite sample was collected properly and that the composite sample data adequately represent the exposure unit.

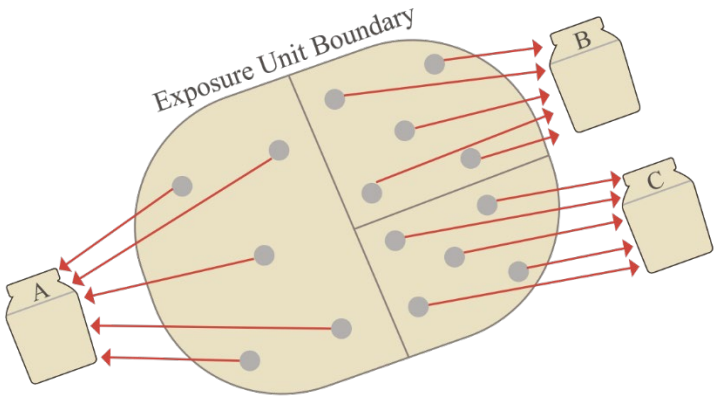
> *In this example, the health assessor judged that the composite sample was properly collected in the field. The nine grab samples that were combined to form the single composite sample were collected across a single exposure unit at equal depth and with similar mass. The health assessor concluded that the data are appropriate for calculating an EPC.*

Step Two: Determine the intermediate/chronic EPC (Section 4.3).

> *In this example, the health assessor used the reported concentration of 42.0 mg/kg as the EPC and documented the sampling procedure and the following note in the PHA: "Sampling data were limited and ATSDR is applying some level of professional judgement in evaluating the data."*

Example 2. EPCs for Multiple Composite Samples Collected Within an Exposure Unit

This example considers the same exposure unit as shown in Example 1, except three composite samples were collected in three different areas of the exposure unit, each composed of five distinct grab samples (see illustration below).



The laboratory reported the following results:

Composite Sample Results

Composite Sample	Arsenic Concentration (mg/kg)
A	45.0
B	90.4
C	72.2

Step One: Review the site history, SAP, and DQOs, when available, to confirm that the composite sample was collected properly and that the composite sample data adequately represent the exposure unit.

> *In this example, the health assessor judged that the composite samples were properly collected in the field. The health assessor noted that the areas represented by the three composite samples were not of equal size and shape: composite sample A represents a larger area of the exposure unit than composite samples B and C. For purposes of illustration, composite sample A represents approximately 50 percent of the exposure unit, and composite samples B and C each represent roughly 25 percent of the exposure unit. The health assessor factored these distinct size areas into their EPC calculations, as shown below.*

Step Two: Determine the intermediate/chronic EPC (Section 4.3).

A weighted average is calculated by weighting the individual observations by a factor of interest—in this case, the area represented by the composite sample. As a result, composite sample results representing

a larger portion of the exposure unit contribute more to the mean value than those representing a smaller portion of the exposure unit. Weighted means should be calculated using Equation 2.[11]

Equation 2. Weighted Mean Calculation for Composite Samples

$$\textbf{\textit{Weighted Mean}} = \sum_{i=1}^{n} (C_i \times w_i)$$

Where:

C_i = the reported concentration for the composite sample.

w_i = the weight for the composite sample (i.e., the percentage of the exposure unit represented by the composite sample).

In this example, the weighted mean was calculated as follows:

$$\text{Weighted Mean} = (45.0\ \text{mg/kg} \times 0.50) + (90.4\ \text{mg/kg} \times 0.25) + (72.2\ \text{mg/kg} \times 0.25) = 63.2\ \text{mg/kg}$$

In this example, the health assessor used the weighted mean of results from the three composite samples as the EPC (i.e., 63.2 mg/kg). The health assessor documented the individual composite sampling results and the procedure used to calculate this EPC in the PHA. They also included the following caveat, "Sampling data were limited and ATSDR is applying some level of professional judgement in evaluating the data."

[11] In this example, all composite sample results were reported as detected concentrations. Non-detect results should conservatively be entered into weighted mean calculations as the value of the full laboratory reporting limit when working with composite sample data. In this example, if the laboratory reported a non-detect result with a reporting limit of 0.05 mg/kg, health assessors should use 0.05 mg/kg in the weighted mean calculations.