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EPA SUPERFUND POLICY ON USING AVERAGES



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Supplemental Guidance to RAGS: Calculating the Concentration Term

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The overarching mandate of the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) is to protect human health and the environment from current and potential threats posed by uncontrolled releases of hazardous substances. To help meet this mandate, the U.S. Environmental Protection Agency's (EPA's) Office of Emergency and Remedial Response has developed a human health risk assessment process as part of its remedial response program. This process is described in *Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual (RAGS/HHEM)*. Part A of RAGS/HHEM addresses the baseline risk assessment, and describes a general approach for estimating exposure to individuals from hazardous substance releases at Superfund sites.

This bulletin explains the concentration term in the exposure/intake equation to remedial project managers (RPMs), risk assessors, statisticians, and other personnel. This bulletin presents the general intake equation as presented in RAGS/HHEM Part A, discusses basic concepts concerning the concentration term, describes generally how to calculate the concentration term, presents examples to illustrate several important points, and, lastly, identifies where to get additional help.

THE CONCENTRATION TERM

How is the concentration term used?

RAGS/HHEM Part A presents the Superfund risk assessment process in four "steps": (1) data collection and evaluation; (2) exposure assessment; (3) toxicity assessment; and (4) risk characterization. The concentration term is calculated for use in the exposure assessment step. Highlight 1 presents the general equation Superfund uses for calculating exposure, and illustrates that the concentration term (C) is one of several parameters needed to estimate contaminant intake for an individual.

For Superfund assessments, the concentration term (C) in the intake equation is an estimate of the arithmetic average concentration for a contaminant based on a set of site sampling results. Because of the uncertainty associated with estimating the true average concentration at a site, the 95 percent upper confidence limit (UCL) of the arithmetic mean should be used for this variable. The 95 percent UCL provides reasonable confidence that the true site average will not be underestimated.

Why use an average value for the concentration term?

An estimate of average concentration is used because:

Supplemental Guidance to RAGS is a bulletin series on risk assessment of Superfund sites. These bulletins serve as supplements to *Risk Assessment Guidance for Superfund: Volume 1 - Human Health Evaluation Manual*. The information presented is intended as guidance to EPA and other government employees. It does not constitute rulemaking by the Agency, and may not be relied on to create a substantive or procedural right enforceable by any other person. The Government may take action that is at variance with these bulletins.

Highlight 1
**GENERAL EQUATION FOR ESTIMATING EXPOSURE
TO A SITE CONTAMINANT**

$$I = C \times \frac{CR \times EFD}{BW} \times \frac{1}{AT}$$

where:

- I = intake (i.e., the quantitative measure of exposure in RAGS/HHEM)
- C = contaminant concentration
- CR = contact (intake) rate
- EFD = exposure frequency and duration
- BW = body weight
- AT = averaging time

- (1) carcinogenic and chronic noncarcinogenic toxicity criteria¹ are based on lifetime average exposures; and
- (2) average concentration is most representative of the concentration that would be contacted at a site over time.

For example, if you assume that an exposed individual moves randomly across an exposure area, then the spatially averaged soil concentration can be used to estimate the true average concentration contacted over time. In this example, the average concentration contacted over time would equal the spatially averaged concentration over the exposure area. While an individual may not actually exhibit a truly random pattern of movement across an exposure area, the assumption of equal time spent in different parts of the area is a simple but reasonable approach.

When should an average concentration be used?

The two types of exposure estimates now being required for Superfund risk assessments, a reasonable maximum exposure (RME) and an average, should both use an average concentration. To be protective, the overall estimate of intake (see Highlight 1) used as a basis for action at

¹ When acute toxicity is of most concern, a long-term average concentration generally should not be used for risk assessment purposes, as the focus should be to estimate short-term, peak concentrations.

Superfund sites should be an estimate in the high end of the intake/dose distribution. One high-end option is the RME used in the Superfund program. The RME, which is defined as the highest exposure that could reasonably be expected to occur for a given exposure pathway at a site, is intended to account for both uncertainty in the contaminant concentration and variability in exposure parameters (e.g., exposure frequency, averaging time). For comparative purposes, Agency guidance (U.S. EPA, *Guidance on Risk Characterization for Risk Managers and Risk Assessors*, February 26, 1992) states that an average estimate of exposure also should be presented in risk assessments. For decision-making purposes in the Superfund program, however, RME is used to estimate risk.²

Why use an estimate of the arithmetic mean rather than the geometric mean?

The choice of the arithmetic mean concentration as the appropriate measure for estimating exposure derives from the need to estimate an individual's long-term average exposure. Most Agency health criteria are based on the long-term average daily dose, which is simply the sum of all daily doses divided by the total number of days in the averaging period. This is the definition of an arithmetic mean. The

² For additional information on RME, see RAGS/HHEM Part A and the National Oil and Hazardous Substances Pollution Contingency Plan (NCP), 55 *Federal Register* 8710, March 8, 1990.

arithmetic mean is appropriate regardless of the pattern of daily exposures over time or the type of statistical distribution that might best describe the sampling data. The geometric mean of a set of sampling results, however, bears no logical connection to the cumulative intake that would result from long-term contact with site contaminants, and it may differ appreciably from — and be much lower than — the arithmetic mean. Although the geometric mean is a convenient parameter for describing central tendencies of lognormal distributions, it is not an appropriate basis for estimating the concentration term used in Superfund exposure assessments. The following simple example may help clarify the difference between the arithmetic and geometric mean when used for an exposure assessment:

Assume the daily exposure for a trespasser subject to random exposure at a site is 1.0, 0.01, 1.0, 0.01, 1.0, 0.01, 1.0, and 0.01 units/day over an 8-day period. Given these values, the cumulative exposure is simply their summation, or 4.04 units. Dividing this by 8 days of exposure results in an arithmetic mean of 0.505 units/day. This is the value we would want to use in a risk assessment for this individual, not the geometric mean of 0.1 units/day. Viewed another way, multiplication of the geometric mean by the number of days equals 0.8 units, considerably lower than the known cumulative exposure of 4.04 units.

UCL AS AN ESTIMATE OF THE AVERAGE CONCENTRATION

What is a 95 percent UCL?

The 95 percent UCL of a mean is defined as a value that, when calculated repeatedly for randomly drawn subsets of site data, equals or exceeds the true mean 95 percent of the time. Although the 95 percent UCL of the mean provides a conservative estimate of the average (or mean) concentration, it should not be confused with a 95th percentile of site concentration data (as shown in Highlight 2).

Why use the UCL as the average concentration?

Statistical confidence limits are the classical tool for addressing uncertainties of a distribution average. The 95 percent UCL of the arithmetic

mean concentration is used as the average concentration because it is not possible to know the true mean. The 95 percent UCL therefore accounts for uncertainties due to limited sampling data at Superfund sites. As sampling data become less limited at a site, uncertainties decrease, the UCL moves closer to the true mean, and exposure evaluations using either the mean or the UCL produce similar results. This concept is illustrated in Highlight 2.

Should a value other than the 95 percent UCL be used for the concentration?

A value other than the 95 percent UCL can be used provided the risk assessor can document that high coverage of the true population mean occurs (i.e., the value equals or exceeds the true population mean with high probability). For exposure areas with limited amounts of data or extreme variability in measured or modeled data, the UCL can be greater than the highest measured or modeled concentration. In these cases, if additional data cannot practicably be obtained, the highest measured or modeled value could be used as the concentration term. Note, however, that the true mean still may be higher than this maximum value (i.e., the 95 percent UCL indicates a higher mean is possible), especially if the most contaminated portion of the site has not been sampled.

CALCULATING THE UCL

How many samples are necessary to calculate the 95 percent UCL?

Sampling data from Superfund sites have shown that data sets with fewer than 10 samples per exposure area provide poor estimates of the mean concentration (i.e., there is a large difference between the sample mean and the 95 percent UCL), while data sets with 10 to 20 samples per exposure area provide somewhat better estimates of the mean, and data sets with 20 to 30 samples provide fairly consistent estimates of the mean (i.e., the 95 percent UCL is close to the sample mean). Remember that, in general, the UCL approaches the true mean as more samples are included in the calculation.

Should the data be transformed?

EPA's experience shows that most large or "complete" environmental contaminant data sets

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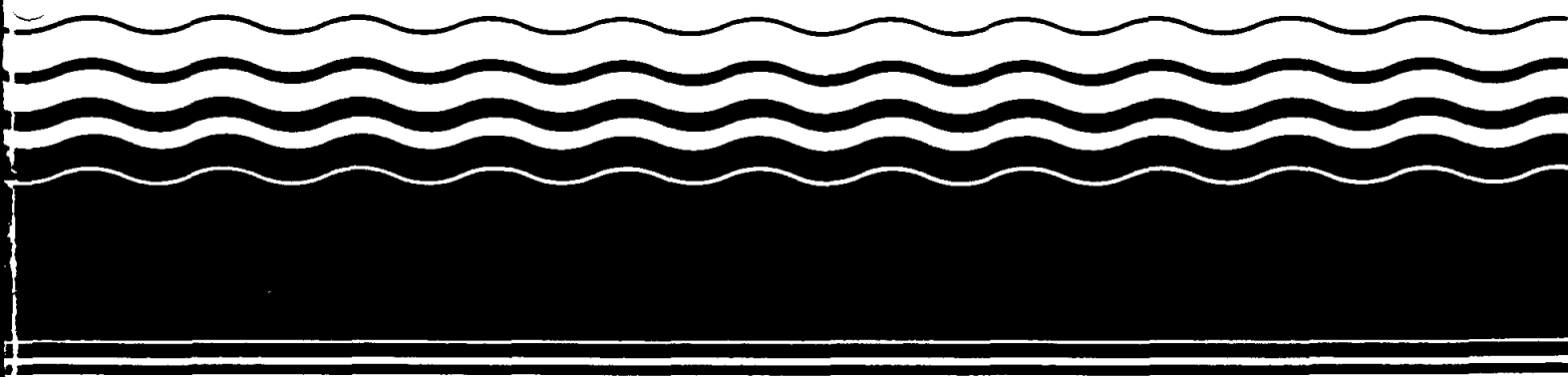
EPA 540/1-89.002
December 1989

Superfund



Risk Assessment Guidance for Superfund Volume I Human Health Evaluation Manual (Part A)

Interim Final



DEFINITIONS FOR CHAPTER 6

Absorbed Dose. The amount of a substance penetrating the exchange boundaries of an organism after contact. Absorbed dose is calculated from the intake and the absorption efficiency. It usually is expressed as mass of a substance absorbed into the body per unit body weight per unit time (e.g., mg/kg-day).

Administered Dose. The mass of a substance given to an organism and in contact with an exchange boundary (e.g., gastrointestinal tract) per unit body weight per unit time (e.g., mg/kg-day).

Applied Dose. The amount of a substance given to an organism, especially through dermal contact.

Chronic Daily Intake (CDI). Exposure expressed as mass of a substance contacted per unit body weight per unit time, averaged over a long period of time (as a Superfund program guideline, seven years to a lifetime).

Contact Rate. Amount of medium (e.g., ground water, soil) contacted per unit time or event (e.g. liters of water ingested per day).

Exposure. Contact of an organism with a chemical or physical agent. Exposure is quantified as the amount of the agent available at the exchange boundaries of the organism (e.g., skin, lungs, gut) and available for absorption.

Exposure Assessment. The determination or estimation (qualitative or quantitative) of the magnitude, frequency, duration, and route of exposure.

Exposure Event. An incident of contact with a chemical or physical agent. An exposure event can be defined by time (e.g., day, hour) or by the incident (e.g., eating a single meal of contaminated fish).

Exposure Pathway. The course a chemical or physical agent takes from a source to an exposed organism. An exposure pathway describes a unique mechanism by which an individual or population is exposed to chemicals or physical agents at or originating from a site. Each exposure pathway includes a source or release from a source, an exposure point, and an exposure route. If the exposure point differs from the source, a transport/exposure medium (e.g., air) or media (in cases of intermedia transfer) also is included.

Exposure Point. A location of potential contact between an organism and a chemical or physical agent.

Exposure Route. The way a chemical or physical agent comes in contact with an organism (i.e., by ingestion, inhalation, dermal contact).

Intake. A measure of exposure expressed as the mass of a substance in contact with the exchange boundary per unit body weight per unit time (e.g., mg chemical/kg-day). Also termed the normalized exposure rate; equivalent to administered dose.

▶ **Lifetime Average Daily Intake.** Exposure expressed as mass of a substance contacted per unit body weight per unit time, averaged over a lifetime.

Subchronic Daily Intake (SDI). Exposure expressed as mass of a substance contacted per unit body weight per unit time, averaged over a portion of a lifetime (as a Superfund program guideline, two weeks to seven years).

validated and the chemicals of potential concern have been selected (see Chapter 5, Section 5.3.3). The exposure assessment proceeds with the following steps.

Step 1 -- Characterization of exposure setting (Section 6.2). In this step, the assessor characterizes the exposure setting with respect to the general physical characteristics of the site and the characteristics of the populations on and near the site. Basic site

characteristics such as climate, vegetation, ground-water hydrology, and the presence and location of surface water are identified in this step. Populations also are identified and are described with respect to those characteristics that influence exposure, such as location relative to the site, activity patterns, and the presence of sensitive subpopulations. This step considers the characteristics of the current population, as well as those of any

the highest exposure that is reasonably expected to occur at a site. RMEs are estimated for individual pathways. If a population is exposed via more than one pathway, the combination of exposures across pathways also must represent an RME.

Estimates of the reasonable maximum exposure necessarily involve the use of professional judgment. This chapter provides guidance for determining the RME at a site and identifies some exposure variable values appropriate for use in this determination. The specific values identified should be regarded as general recommendations, and could change based on site-specific information and the particular needs of the EPA remedial project manager (RPM). Therefore, these recommendations should be used in conjunction with input from the RPM responsible for the site.

In the past, exposures generally were estimated for an average and an upper-bound exposure case, instead of a single exposure case (for both current and future land use) as recommended here. The advantage of the two case approach is that the resulting range of exposures provides some measure of the uncertainty surrounding these estimates. The disadvantage of this approach is that the upper-bound estimate of exposure may be above the range of possible exposures, whereas the average estimate is lower than exposures potentially experienced by much of the population. The intent of the RME is to estimate a conservative exposure case (i.e., well above the average case) that is still within the range of possible exposures. Uncertainty is still evaluated under this approach. However, instead of combining many sources of uncertainty into average and upper-bound exposure estimates, the variation in individual exposure variables is used to evaluate uncertainty (See Section 6.8). In this way, the variables contributing most to uncertainty in the exposure estimate are more easily identified.

6.2 STEP 1: CHARACTERIZATION OF EXPOSURE SETTING

The first step in evaluating exposure at Superfund sites is to characterize the site with respect to its physical characteristics as well as those of the human populations on and near the site. The output of this step is a qualitative evaluation of the site and surrounding populations with respect to those characteristics that influence exposure. All information gathered during this step will support the identification of exposure pathways in Step 2. In addition, the information on the potentially exposed populations will be used in Step 3 to determine the values of some intake variables.

6.2.1 CHARACTERIZE PHYSICAL SETTING

Characterize the exposure setting with respect to the general physical characteristics of the site. Important site characteristics include the following:

- climate (e.g., temperature, precipitation);
- meteorology (e.g., wind speed and direction);
- geologic setting (e.g., location and characterization of underlying strata);
- vegetation (e.g., unvegetated, forested, grassy);
- soil type (e.g., sandy, organic, acid, basic);
- ground-water hydrology (e.g., depth, direction and type of flow); and
- location and description of surface water (e.g., type, flow rates, salinity).

Sources of this information include site descriptions and data from the preliminary assessment (PA), site inspection (SI), and remedial investigation (RI) reports. Other sources include county soil surveys, wetlands maps, aerial

and also is useful as documentation of the exposure pathway analysis. Exhibit 6-8 provides a sample format for presenting this information.

6.4 STEP 3: QUANTIFICATION OF EXPOSURE: GENERAL CONSIDERATIONS

The next step in the exposure assessment process is to quantify the magnitude, frequency and duration of exposure for the populations and exposure pathways selected for quantitative evaluation. This step is most often conducted in two stages: first, exposure concentrations are estimated, then, pathway-specific intakes are quantified. The specific methodology for calculating exposure concentrations and pathway-specific exposures are presented in Sections 6.5 and 6.6, respectively. This section describes some of the basic concepts behind these processes.

6.4.1 QUANTIFYING THE REASONABLE MAXIMUM EXPOSURE

Exposure is defined as the contact of an organism with a chemical or physical agent. If exposure occurs over time, the total exposure can be divided by a time period of interest to obtain an average exposure rate per unit time. This average exposure rate also can be expressed as a function of body weight. For the purposes of this manual, exposure normalized for time and body weight is termed "intake", and is expressed in units of mg chemical/kg body weight-day.

Exhibit 6-9 presents a generic equation for calculating chemical intakes and defines the intake variables. There are three categories of variables that are used to estimate intake:

- (1) chemical-related variable -- exposure concentration;
- (2) variables that describe the exposed population -- contact rate, exposure frequency and duration, and body weight; and
- (3) assessment-determined variable -- averaging time.

Each intake variable in the equation has a range of values. For Superfund exposure assessments, intake variable values for a given pathway should be selected so that the combination of all intake variables results in an estimate of the reasonable maximum exposure for that pathway. As defined previously, the reasonable maximum exposure (RME) is the maximum exposure that is reasonably expected to occur at a site. Under this approach, some intake variables may not be at their individual maximum values but when in combination with other variables will result in estimates of the RME. Some recommendations for determining the values of the individual intake variables are discussed below. These recommendations are based on EPA's determination of what would result in an estimate of the RME. As discussed previously, a determination of "reasonable" cannot be based solely on quantitative information, but also requires the use of professional judgment. Accordingly, the recommendations below are based on a combination of quantitative information and professional judgment. These are general recommendations, however, and could change based on site-specific information or the particular needs of the risk manager. Consult with the RPM before varying from these recommendations.

Exposure concentration. The concentration term in the intake equation is the arithmetic average of the concentration that is contacted over the exposure period. Although this concentration does not reflect the maximum concentration that could be contacted at any one time, it is regarded as a reasonable estimate of the concentration likely to be contacted over time. This is because in most situations, assuming long-term contact with the maximum concentration is not reasonable. (For exceptions to this generalization, see discussion of hot spots in Section 6.5.3.)

Because of the uncertainty associated with any estimate of exposure concentration, the upper confidence limit (i.e., the 95 percent upper confidence limit) on the arithmetic average will be used for this variable. There are standard statistical methods which can be used to calculate the upper confidence limit on the arithmetic mean. Gilbert (1987, particularly sections 11.6 and 13.2) discusses methods that can be applied to data that are distributed normally or log normally. Kriging is another method that

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Draft Soil Screening Level Guidance

Office of Emergency and Remedial Response
Hazardous Site Control Division

Quick Reference Fact Sheet

NOTICE: This document is draft and should only be used in the context of demonstration pilots being overseen by the U.S. EPA. The methods used to support the approach discussed herein will undergo rigorous technical review and public comment before this document is finalized along with SSLs for approximately 60 additional chemicals in the summer of 1994.

BACKGROUND

On June 19, 1991, the U.S. Environmental Protection Agency's (EPA's) Administrator charged the Office of Solid Waste and Emergency Response (OSWER) with conducting a 30-day study to outline options for accelerating the rate of cleanups at National Priority List (NPL) sites. The study found that the current investigation/remedy selection process takes over 3 years to complete because each site is treated as a unique problem, requiring the preparation of site-specific risk assessments, cleanup levels, and technical solutions. The study proposed that standardizing the remedial planning and remedy selection process would significantly reduce the time it takes to start cleanups and would improve consistency across the Regions. One of the specific proposals was for OSWER to "examine the means to develop standards or guidelines for contaminated soils."

On June 23, 1993, EPA announced the development of Soil Trigger Levels as one of the Administrative Improvements to the Superfund program. This fact sheet presents Soil Screening Levels (SSLs) (formerly known as trigger levels) for 30 chemicals and represents OSWER's first step toward standardizing the evaluation and cleanup of contaminated soils under the Comprehensive Environmental Response Compensation and Liability Act (CERCLA).

An SSL is a chemical concentration in soil that represents a level of contamination above which there is sufficient concern to warrant further site-specific study. Concentrations in soil above this screening level would not automatically designate a site as "dirty," nor trigger a response action. However, they suggest that a further evaluation of the potential risks that may be posed by site contaminants is appropriate. Generally, if contaminant concentrations in soil fall below the screening level and the site meets specific residential use conditions, no further study or action is warranted for that area under CERCLA (Superfund). However, some States have developed screening numbers that are more stringent than those presented in this fact sheet, and therefore further study may be warranted under State programs.

PURPOSE OF SSLs

The primary purpose of the SSLs is to accelerate decision-making concerning contaminated soils. Initial applications will focus remedial investigations by eliminating from further study site areas that do not warrant further study under CERCLA. In fostering prompt identification of the contaminants and exposure areas of concern, the SSLs may also help simplify or accelerate the baseline risk assessment and may serve as Preliminary Remediation Goals (PRGs) under specified conditions. EPA will explore other potential applications as it proceeds to refine and expand this guidance. Such applications may include removal response actions, site assessment/NPL listing, voluntary cleanups, and Resource Conservation and Recovery Act (RCRA) Corrective Actions.

ATTRIBUTES OF SSLs

The 30 SSLs presented in this document have been developed using residential land use human exposure assumptions and considering three pathways of exposure to the contaminants (see Figure 1):

- ingestion of soil
- inhalation of volatiles and fugitive dusts
- migration of contaminants through soil to an underlying potable aquifer.

These pathways have proven to be the most common routes of human exposure to contaminants in the residential setting at hazardous waste sites evaluated by EPA. Also, substantial efforts have been made to model these particular pathways.

Other routes/pathways may contribute significantly to the risk posed by exposure to specific contaminants (e.g., dermal exposure or exposure via food chain contamination). OSWER will continue to seek consensus on the appropriate methods required to quantify additional routes/pathways generically. The results of these efforts may be included in the final guidance.

Depending on site-specific conditions. At some sites, this may be the entire site; at others, this may be only a portion of the site. For the purposes of this guidance, the Agency believes that the size of a typical residential lot (1/4 acre) is an appropriate averaging area for the most conservative case (i.e., residential land use). For large sites that could be divided into many areas equivalent to the size of a residential lot, the number of samples needed to characterize the site becomes quite high. This, coupled with the costs of analytical services for each sample, could make the sampling costs onerous. Therefore, OERR recommends following guidance for measuring soil contaminant levels at NPL sites.

Sample Pattern

A grid pattern such as a triangular or square/rectangular grid is recommended to establish sample locations for each exposure area (U.S. EPA, 1987). Biased sampling must also be used in areas of suspected contamination or stained soils and must be evaluated separately from the samples obtained by systematic sampling.

Number of Samples

As mentioned, it is necessary to balance the need to achieve statistical confidence in determining a meaningful arithmetic mean concentration of contaminants in each exposure area with the cost of obtaining the 20 to 30 samples recommended by ORD. Compositing of discrete samples is an option since EPA is interested in determining the arithmetic mean of the contaminant concentration(s). Twenty discrete samples can be composited down to four or five composite samples, while maintaining confidence that the area average is not grossly underestimated. Compositing may mask contaminant levels that are slightly higher than the SSL, but areas of high contamination will still be detected. Compositing is both a reasonable approach and an efficient use of resources, since Superfund is interested in average exposure over time. However, none of the composite samples should exceed the prescribed SSL for any contaminant. For volatile organic compounds (VOCs), compositing is not appropriate (U.S. EPA, 1989a, 1992a). Therefore, OERR advocates that 10 discrete samples should be taken per exposure area for VOCs, and no sample can exceed the Screening Level(s). Both the discrete VOC samples and the composites must be analyzed by Contract Laboratory Program (CLP) (or equivalent) methods. (NOTE: Seven of the 30 contaminant SSLs for the groundwater migration pathway at a DAF of 10 are below CLP RAS or CLP-equivalent detection limits. For these contaminants, special analytical services should be requested for recalibration of the instruments. For example, to measure low levels of VOCs, the gas chromatograph/mass spectrometer (GC/MS) can be recalibrated to detect at 1, 2, 5, 10, and 25 ppb.

Use of Field Methods

Where available and appropriate, field methods (soil gas surveys, immunoassays, X-ray fluorescence) can be used.

Again, for compounds other than VOCs, compositing samples is acceptable as long as it is consistent with the field methodology. If any sample concentration exceeds an SSL, further site study is required. In addition, 10% to 20% of field samples must be sent to a CLP (or equivalent) laboratory for confirmatory analysis (U.S. EPA, 1992a). Please note that field methods must be capable of achieving appropriate detection limits for most groundwater SSLs.

Depth

When measuring soil levels at the surface for the inhalation and ingestion pathways, samples should be taken at a depth of 6 inches. Additional sampling beyond 6 inches may be appropriate, depending on the contaminant's mobility, to account for geographic differences in construction practices where soil disturbances are reasonably expected. For example, in the Northeast, the ground may be excavated to 15 feet before laying the foundation and constructing the basement of a home. Excavated overburden is commonly used as fill material around the property so that contaminants that were at depth are now near the surface. Thus, it is important to be cognizant of construction practices in the area.

For the groundwater pathway, the entire soil column, from the surface to the top of the aquifer, should be sampled. For the evaluation of vertical stratification, samples should not be averaged over depth (i.e., the soil core should not be composited over depth), but rather individual samples should be evaluated at appropriate depth intervals. One soil core per exposure area may be sufficient. However, where dense nonaqueous phase liquids (DNAPLs) are suspected, soil cores may be taken more frequently.

Sampling for Background Contamination

For metals, background sampling is necessary to be certain that OSWER is not defining levels below background as of regulatory concern. If a statistical comparison of background concentration and site samples indicates that background metals concentrations are significantly above the SSLs, use of the SSLs will be of limited value, as discussed earlier.

Additional Sampling Needed for Groundwater Tier 2

To use groundwater Tier 2, site-specific soil characteristics must be determined by sampling. Parameters to measure include bulk density, porosity, organic carbon content, and water content.

Geostatistics

For large areas where the data are not widely scattered, geostatistical approaches, such as kriging, can be used to estimate sample concentration trends across the exposure area (U.S. EPA, 1989a).