

**Region III
Technical Guidance Manual
Risk Assessment**

Exposure Point Concentrations In Groundwater

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The EPA method of risk assessment uses long term or chronic exposure as a basis for determining the excess cancer risk at a Superfund site. Oftentimes, the risk from exposure to contaminated groundwater is inappropriately calculated from the single highest confirmed concentration found in a groundwater well. This approach is mathematically and conceptually indefensible since a single measurement cannot represent the contamination in an entire plume at a Superfund site. Instead, a sufficient database is required to effectively represent site risk during a lifetime of exposure. The larger database serves to reduce the uncertainty inherent in risk analysis, and the Remedial Project Manager is provided with a more scientifically sound risk evaluation on which to trigger a remedial decision. While this approach applies to most Superfund sites, factors such as calculation method, well placement and use of the historical database attain particular importance at sites where groundwater contamination is not clearly established. This guidance is intended to improve the quality and consistency of deriving exposure point concentrations in groundwater in risk assessments performed in Region III. (EPA/903/8-91/002)

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COMMUNICATION

In accordance with our longstanding policy of involving scientists at the early stages of the RI/FS process, this Guidance document stresses communication. Clear lines of contact both between the technical support staff and the risk manager as well as among the technical personnel are essential to the process. The Guidance outlines a sampling strategy, including both spatial and temporal collection and handling of groundwater data. This strategy promotes a coherent technical approach to the RI/FS process, initiating the proper experimental design and correct data usage. Hence, the risk manager is provided with a justifiable risk conclusion based on sound

scientific methodology.

The risk associated with groundwater usage at a site is generally calculated by combining the pollutants' concentrations in the aquifer of concern along with site-specific exposure parameters. This result is then combined with chemical specific exposure factors to obtain the final risk value. The approach assumes that the pollutants' concentration is linearly related to risk, thus, changes in concentration may have a significant influence on the risk analysis for the site. A clear understanding of this relationship and its potential impact on the final risk value underscores the requirement for a conceptually correct derivation of the exposure point concentration.

WELL PLACEMENT

During the scoping meeting, the toxicologist may present the guidelines for risk analysis from contamination in groundwater. These may include selecting the location of groundwater wells and proposing analytical methods of sampling for suspected contaminants. The choice of groundwater wells is of prime importance in determining the appropriate concentrations of pollutants in the aquifer of concern. Placement of wells in both the horizontal and vertical planes should be considered. In general, both horizontal and vertical placement of groundwater monitoring wells should be designed so that monitoring well data can be extrapolated to future residential well usage. Consultation with the hydrogeologist is required to outline any hydrological and/or geological concerns which may impact the subsequent well selection.

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A. Horizontal Well Placement

Hydrogeologists may locate wells for a variety of purposes, yet toxicologists primarily utilize water quality data to assess the potential risks to human health. Since toxicologists usually do not direct well placement, the body of data obtained for hydrogeological objectives may be used by the toxicologist for a different purpose.

For example, groundwater wells may be located by the hydrogeologist purposely to identify the fringe of contamination. On the other hand, the toxicologist requires information concerning the reasonable maximum concentration of pollutants in the aquifer of concern. In this case, the ideal placement of wells for risk purposes is near the apparent center of the plume. The choice of wells may be different for on site and off site scenarios or if multiple sources are present.

B. Vertical Well Placement

The aquifer of interest should provide sufficient water for residential use. In some cases, monitoring well data from two independent aquifers may be combined if each aquifer cannot supply enough water individually. If the aquifer is not currently used as a drinking water source, consider the likelihood of its future use as a drinking water source. For example, monitoring well data from a perched aquifer is not appropriate for risk assessment because it usually does not provide sufficient water for residential use. In any case, the appropriateness of spatial placement may depend on hydrogeological factors. Thus, consultation with a hydrogeologist is required to outline potential problems.

Identification of wells should be such that the toxicologist may combine water quality data from several wells in order to achieve a reasonable maximum estimate of groundwater contamination. Those wells which meet the criteria discussed above may be grouped for spatial analysis. Temporal analysis may be achieved by multiple sampling of the chosen wells.

It is important to recognize that the combined data from multiple well sampling should belong to the same statistical data population data, i.e. the apparent center of the plume.

C. Well Construction

Once the well locations have been determined, the hydrogeologist should be consulted to determine the adequacy of well construction. The problems identified with well construction may also influence the choice of data to be used by the risk assessor.

Although both filtered and unfiltered data should be collected (USEPA, 1990b), the data is evaluated on a well by well basis by the risk assessor for its potential use in extrapolating monitoring well data to a residential well scenario. Generally, unfiltered data is preferred, however, if there is an obvious discrepancy in the levels of inorganics, or if secondary MCLs are exceeded, filtered data may be selected for use in the risk assessment. This issue is addressed more fully in a separate Region III guidance document which is currently in draft form (USEPA, 1991b).

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The **appropriateness of spatial placement** in both horizontal and vertical planes may depend on hydrogeological factors.

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RISK ASSESSMENT

HISTORICAL DATABASE

During the scoping phase, the complete historical database should be thoroughly examined. If the historical data demonstrate clear trends, the toxicologist should incorporate relevant site-specific information into the risk calculation. Site-specific information should also be considered in determining the confidence assigned to the trend direction. In addition, the historical database should be evaluated for landmark actions, such as emergency removal or remedial action prior to the RI/FS. Use of the historical database should include consideration of potential inconsistencies in analytical methods, data validation protocols and QA/QC practices which may have changed with time (USEPA, 1990c).

If the available information is inadequate to substantiate the risk assessment, additional sampling events should be performed for each well identified for risk assessment purposes. The sampling events should be spaced such that an independent sample population is obtained. The selected time interval should be acceptable to all members of the investigation team.

As data is collected, the results should be reviewed for trends. The number of sampling rounds should be sufficient to yield a database with clear trends. The sampling effort may be a continual process, such that the RI/FS process is not delayed. In this respect, information obtained from ongoing sampling efforts may be submitted as addendums to the Remedial Investigation report.

DATA QUALITY OBJECTIVE

A high data quality objective is recommended. Depending on site conditions, analysis of samples using SAS procedures may be warranted. For example, EPA method 500 series for drinking water, which have lower detection limits for some contaminants, can provide greater sensitivity for assessing contaminant concentrations. Thus, a clearer evaluation of the relevance of contaminants detected at concentrations below the detection limit may be attained. In some cases, this approach may eliminate the need to apply the "0.5 times the detection limit" rule (USEPA, 1989). In addition, and if logistics permit, provisions should be made for reanalysis of rejected or estimated samples within their holding times.

A. Current Scenarios

The current, on site risk should be based on the most reliable database obtained during the entire site investigation which may include studies other than the RI/FS. The data to be included in the calculation consists of useable, water quality data obtained from repeated sampling of the wells identified for risk assessment purposes as well as useable historical information. Treatment of non-detects is considered in a separate Region III guidance document (USEPA, 1991a). The reasonable maximum concentration of pollutants in the aquifer can be calculated as the upper 95th percent confidence limit of the arithmetic mean, UCL₉₅ (See Highlights). If the database is sufficient, a preliminary conservative risk assessment may be performed following the Phase I investigation. Current off site risk may be assessed using water quality data from a set of wells independent of those identified for on site risk (possibly residential wells).

B. Future Scenarios

Future risk may be estimated using the results of a fate and transport groundwater modelling effort. Consultation with the hydrogeologist is recommended to determine the appropriate modelling approach. If the hydrogeologist determines that groundwater modelling is not appropriate due to site specific conditions, current monitoring well data may be used to assess future risk.

HIGHLIGHT #1: LOGNORMAL DISTRIBUTION

The following calculations are used to determine the UCL-95 for the useable groundwater dataset.

1. Identify the frequency distribution of the sample population. A lognormal distribution can be characterized as having no zero values and the relative percentage of data points greater than or less than the mean is not equal. The W test by Shapiro and Wilk may be used to test the distribution type (Gilbert, 1987).

According to Dean, 1981, most environmental datasets are skewed lognormally and the data can be assumed to be lognormally distributed. Note that this assumption is supported only by a large dataset and may not necessarily apply to small datasets available at Superfund sites.

2. If the sample frequency distribution is lognormal, transform the detected data to logarithmic equivalents using the expression

$$t = \ln(x)$$

where:

x = raw groundwater data

t = transformed data

3. Obtain an estimate of the arithmetic mean of the transformed data, if desired, using the expression

$$O = \exp(O_g + F^2/2)$$

4. Obtain the UCL-95 using the expression

$$UCL-95 = \exp(O_g + F^2/2 + FH / (n-1)^{0.5})$$

(Land, 1971, 1975)

where:

O_g = arithmetic mean of log transformed data

F^2 = variance of log transformed data

H = Tabular H statistic, depends on geometric

F, n, and selected degree of probability

(Gilbert, 1987).

n = sample size

5. If the UCL-95 is greater than the maximum value, use the W test to examine the sample population for normality.

HIGHLIGHT #2: NORMAL DISTRIBUTION

The following calculations are used to determine the UCL-95 for the useable groundwater dataset.

1. Identify the frequency distribution of the sample population as outlined in highlight #1.

2. Calculate the UCL-95 using the following expression

$$UCL-95 = x_a + t(F/n^{0.5})$$

where

x_a = arithmetic mean of the raw data

F = arithmetic standard deviation of the raw data

t = Tabular t statistic, depends on degree of freedom (df = n-1) and selected degree of probability (one tailed @ $p < 0.05$).

n = sample size

3. If it is determined that the sample population is neither lognormally distributed nor normally distributed, omit the non-detect data and obtain a maximum likelihood estimate of the detect data (Gilbert, 1987).

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For additional information, (215) 597-6626.

Approved by: _____
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