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**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
**REGION III**  
841 Chestnut Building  
Philadelphia, Pennsylvania 19107

June 20, 1994

Commander, Atlantic Division  
Naval Facilities Engineering Command  
Environmental Quality Division  
Code: 1823  
Norfolk, Virginia 23511-6287  
Attn: Jim Szykman

**SUBJECT:** Review of Site 1 Focused RI/FS, Allegany Ballistics Laboratory, Rocket Center, West Virginia

Dear Mr. Szykman:

The EPA has reviewed the Site 1 Focused Remedial Investigation Feasibility Study (RI/FS) at the Allegany Ballistics Laboratory (ABL), Rocket Center, West Virginia.

Review comments are divided into major concerns which apply to the document as a whole and specific comments which are linked to a subsection as presented in the planning document.

**GENERAL COMMENTS**

The Sampling Plan is vague. To fully approve the plan, more detail is necessary, including:

- Rationale explaining why some samples will be analyzed for selected chemicals, but not others. If a sound justification is not provided, all samples should be analyzed for VOCs, SVOCs, PEST./PCBs, and inorganics. Without more complete sampling and analysis coverage, or an explanation for not analyzing for selected chemicals, it will be difficult to provide a complete risk assessment to determine that the Navy has not overlooked any human health or ecological risks.
- The figures used to present the proposed locations for sampling various media should all be of the same scale, and should clearly indicate the proposed locations and/or areas to be investigated. Additionally, maps of the proposed sampling locations for soil and soil gas, as well as the proposed seismic lines need to be presented

The results of the Work Plan will not provide a comprehensive understanding of the geology and hydrogeology for Site 1. Water levels should be measured during high- and low- flow periods, or at least over a longer time period. The direction of shallow ground water flow needs to be determined at Site 1, specifically in relation to the solvent disposal pits. A series of three or four piezometers should be installed. The Work Plan states that one of the major fracture orientations is to the northwest. Contaminants from the solvent disposal pits may have migrated through the alluvial aquifer, into the bedrock and along these fractures in a NW direction. There are no wells located in that area to detect the possibility of contamination. Fracture trace analysis may indicate the orientation of some of the fractures, but not the degree of interconnection between them. A pump test should be planned for this site.

The document does not present Conceptual Site Models for Site 1. The models would include clear descriptions of the types of physical conditions or problems expected at Site 1 as well as the potential pathways for exposure to contaminants. Site 1 includes solvent disposal pits, burning pads, and former drum storage pad and burning areas located on a terrace level 10 - 15 feet above the river; and ash landfills and old dump sites located on a younger terrace level 5 - 8 feet above the river. Separate Conceptual Site Models should be presented for the disposal pits, burning pads, and landfills/dumps. Line drawings or figures representing each of these situations would be a good addition to Section 4 of the Work Plan.

The Work Plan should include a separate list of potential contaminants of concern and preliminary remediation goals (PRGs), as recommended by the Risk Assessment Guidance for Superfund, Part B. The purpose of this information is to allow the Feasibility Study to be performed concurrently with the RI and risk assessment.

The document presents a summary of former investigations across the entire Base. The results are presented in text, tables, and on figures. The EPA will accept these presentations as background information for this Phase of the investigation but can not verify that the results, as presented, are valid. The former reports have not been approved and do not contain all the validated data for these results.

There is a gross deficiency of information regarding the seismic survey and ecological impacts survey in the plans.

Ecological characterization has been given minimal attention. The Navy failed to recognize the importance of ecological receptors and extent of contamination. Ecological risk assessment appears to have received only minor consideration.

In general, it is still unclear to the EPA (BTAG) that the plans to carry out ecological characterization, extent of contamination, pathway analysis, and impact and risk assessment have been given the importance deserved. For example, Section 2.2 of the Field Sampling Plan devotes merely one paragraph to sampling operations and the parameters to be included. Attached is a list of parameters EPA recommends for physical characterization of surface water and sediment. Table 2-3 in the Field Sampling Plan offers a cursory list of parameters for surface water and sediment.

From the general description of the site, it is very plausible that surface runoff has carried contamination to the North Branch of the Potomac. This is not to disparage the Navy's efforts to characterize the groundwater pathway, but the surface pathway deserves equal efforts.

The documents do not mention Region III's supplementary risk assessment guidance documents as sources. A copy of this guidance is attached.

Surficial (both soil and water) characterization of extent of contamination does not appear to be sufficiently covered. **Additional sampling and analysis should be considered in two areas identified in the earlier draft RI from CH2M HILL. These two areas identified high TCE concentrations in the soil near soils sampling sites 98 and 113 and sampling sites 102 and 110. At the May 19th meeting it was decided that the surface water/sediment sample for location SD-3 would be moved to the location along the river at the soil sampling sites 102 and 110. The surface water samples should be analyzed for VOCs at this new site as well as at SD-7 and SD-8. An additional surface water/sediment sample (SD-7A) should be taken along the open burn landfill. A phased approach does not appear to have been planned to cover results of initial investigations that would lead logically to cover this concern.**

## **SPECIFIC COMMENTS**

### **Fracture Trace Analysis**

The fractures identified on the photos should be verified in the field. The EPA would appreciate seeing the results of this analysis before the draft RI report is presented.

### **Seismic Survey**

Although some details were provided during the meeting at ABL on 5/19/94, the lack of information regarding objective, type of sources, type of spread, length of spread (related to depth of investigation), and specific tie-in wells is a cause for concern. Many geophysical surveys fail in the field because of poor pre-survey planning regarding such tasks. Poor communication between contractors and their sub-contractors concerning these issues is also top on the list for failure of such surveys to provide needed information.

This is the first important task to be performed; its results will provide the foundation for later studies so it should not be rushed into without appropriate planning. It is recommended that an additional east-west line be run north of the solvent pits and that two north-south "tie" lines be added. A figure, showing the proposed extent of the geophysical survey needs to be provided in the Work Plan.

### **Soil Gas Sampling**

Provide a map of the proposed soil gas sampling locations across the open burn area landfill. This map will indicate the potential coverage provided for soil gas analysis.

### **Focused Soil Investigation**

The use of the direct push technology for soil sampling is fitting for this site. The sampling depths and locations also seem to be appropriate. However, the EPA cautions against compositing any soil samples; the Sampling and Analysis Plan indicates that ash and soil samples will be composited from the inert burn area ash landfill. Compositing samples will only provide an indication that something may be in the sample, not how much. The results can not be used in a risk assessment. Additional soil samples should be planned in areas near the former sampling locations HCS-BG-98 and -113 and -102 and -110.

### **Well Installation and Well Testing**

- Some type of flow logging such as brine tracing or flow meter logging should also be performed, in addition to the noted downhole geophysical methods, before packing off and sampling discrete intervals. These methods will assist in properly identifying the sampling intervals. Please note that in the Sampling and Analysis Plan, geophysical testing of the new wells is not mentioned.
- Bedrock wells on-site should be installed after the DNAPL investigation if there is any inkling that product may occur in the wells (see below).
- There is virtually no information on drilling techniques in either document.

### **DNAPL Investigation**

- Interface probes should be used at wells previously identified as potential DNAPL wells in order to get a feeling for the DNAPL pools, if they exist. The probes should be placed into the wells before purging; DNAPL samples for chemical analysis (see below) should also be taken before purging the well.

### **Groundwater Sampling**

- Monitor Well samples should be analyzed (per CRL directive) for both total and dissolved metals. At the meeting on May 19, 1994 it was discussed that selected wells (1GW1-1GW4, and 1GW10) would be the only wells from which the samples would be analyzed for dissolved metals and that all the remaining samples would be analyzed for both total and dissolved metals. The wells selected for dissolved metals analysis had only been sampled for total metals before and low concentrations were detected.
- If free product is identified, it should be sampled separately with all constituents and their physical properties identified. This is crucial for understanding what treatment options will be available in the FS.
- Water levels should be taken for a year, if possible. All of this data may not be available for the RI report, but it will be important for Design. One round for the RI is not sufficient.
- Once the contaminated area is better delineated, a pump test should be run in the area most likely to be remediated. This will help to assess clean-up times and remediation strategies and can be used in the FS.

### **Investigation Derived Waste**

Although the EPA realizes the intent of the investigation is not to spread highly contaminated materials around the site, it should not be assumed that only materials in the vicinity of wells 1GW-3, -9, and -13 are contaminated. Some type of testing should be performed before disposal of all materials to ensure that their disposal will not cause a hazard. State regs should also be checked regarding this matter. **Additionally, putting cuttings into a well as a means of construction, as implied in the plan, is not an accepted practice for MW installation! Proper construction methods using filter pack, grout, and cement should be used.**

### **Baseline Ecological Risk Assessment**

On p 2-5, some work on the floodplain is described, however, the document fails to complete the topic. The Navy should characterize the floodplain ecologically and attempt to determine whether or not contamination has been transported across it to the river. In addition, the Navy should acknowledge the possibility that depositional areas in the riparian zone may hold unknown quantities of contaminants.

It is noted that the Work Plan designates four surface water sampling stations, but no accompanying text could be found regarding the rationale behind these locations. Furthermore, we could find no description of the kinds of sampling or observations planned for these areas.

Figure 3-8 in the draft Work Plan indicates points where sediment will be sampled, but these are separate from the surface water sampling locations. No rationale is offered regarding why these areas are separated. It is common to collect both samples from the same location. The discussion regarding surface water and sediment on page 4-2 of the Work Plan fails to describe either the parameters or why sampling points are so distant from each other. The second sentence in this paragraph claims that the plans are to cover the needs of the human health risk, the environment, and the FS and further (in the next sentence) claims that sufficient samples "...should be collected" with regard to some general contamination, but specifics are missing. No information is offered regarding methods of determining either water column or benthic organisms.

On the other hand, Task 12: Surface Water Sampling, states that some surface water sampling will coincide with the sediment sampling locations. Again, a rationale should be offered for using this approach.

#### Ecological Recommendations:

- 1) The investigator should plan to carry out systematic ecological characterization for the site's ecological values. It should begin with an effort to identify the various habitats found in the vicinity and should also include a carefully considered plan to sample for contamination in these areas.
- 2) The investigator should plan to carry out an environmental risk assessment using the draft guidelines attached. This approach is partly based upon a phased approach.
- 3) The investigator should plan subsequent phases depending upon findings of the initial sampling and analyses.
- 4) Sampling locations for surface water and sediment should coincide or some explanation offered regarding why or why are not.
- 5) The investigators should either fully explain methods for surface water and sediment characterization or reference appropriate sources. We usually recommend RBP # 3 for stream characterization.
- 6) Surface water samples should be collected at all sediment collecting stations. A rationale as to why these stations have been selected should also be offered.

Also attached to these comments is a separate set of review comment by the Central Regional Laboratory, Quality Assurance Branch. The comments are directed to Quality Assurance of the Sampling and Analysis Plan. Please correct the omissions noted in the Sampling and Analysis Plan and provide a QA/QC plan from the designated laboratory.

If you have any questions concerning any of these comments, please call me (215) 597-2317.

Sincerely,



Bruce W. Beach  
Remedial Project Manager

cc: Paul Leonard, EPA (letter only)  
P. Costello, WV DEP

Attachments

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY  
REGION III  
841 Chestnut Building  
Philadelphia, Pennsylvania 19107

June 20, 1994

Commander, Atlantic Division  
Naval Facilities Engineering Command  
Environmental Quality Division  
Code: 1823  
Norfolk, Virginia 23511-6287  
Attn: Jim Szykman

**SUBJECT:** Ecological Risk Assessment Documents

Dear Mr. Szykman:

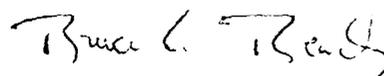
Enclosed please find a set of documents that the Biological Technical Assistance Group (BTAG) proposes as guidance for Ecological Assessment.

The enclosed documents include:

- 1) Risk Assessment Guidance for Superfund, Volume II
- 2) ECO Update, Volume 1, Numbers 1 - 5
- 3) Compendium of ERT Toxicity Testing Procedures
- 4) Classification of Wetlands and Deepwater Habitats of the United States
- 5) Rapid Bioassessment Protocols For Use in Streams and Rivers
- 6) Checklists for Preparing National Environmental Policy Act Documents
- 7) Federal Manual for Identifying and Delineating Jurisdictional Wetlands
- 8) Draft Aquatic Ecological Risk Assessment (AERA) Methodology

If you have any questions concerning these documents, please call me (215) 597-2317.

Sincerely,



Bruce W. Beach  
Remedial Project Manager

cc: Paul Leonard, EPA (letter only)  
P. Costello, WV DEP

## ATTACHMENT I

### SURFACE WATER AND SEDIMENT PARAMETERS

#### CHEMICAL AND PHYSICAL PARAMETERS

These parameters are considered to be the minimum required to characterize the aquatic system. In some cases, others may be required where endangerment is suspected and additional information may shed light on the situation.

#### Surface Water:

##### Field Parameters --

- Temperature
- Dissolved Oxygen
- pH
- Conductivity
- Salinity (for marine and estuarine systems only)
- Flow (width & depth)

##### Laboratory Parameters --

- Total Suspended Solids
- Alkalinity
- Hardness
- BOD, COD TDS, & Non-settleable solids (optional)

#### Sediment:

##### Field Parameters --

- Temperature
- Eh (use EPA method 9045)
- pH
- Conductivity
- Color (Munsell)

##### Laboratory parameters --

- TOC (use EPA method 415.13 combustion methodology: report as % organic matter)
- Grain size (either ASTM hydrometer or emery tube)
- Moisture (report as %) (Routine Analytical Services: RAS)
- Solids (report as %) (RAS)

**ATTACHMENT II**

**ENVIRONMENTAL RISK ASSESSMENT GUIDELINES**

## ENVIRONMENTAL RISK ASSESSMENT GUIDELINES

### EPA III Superfund Technical Support Section

#### Introduction:

Three levels of Environmental Risk Assessment (ERA) are recognized as available to the risk assessor: 1) the screening level; 2) the semi-quantitative level; and 3) the quantitative level. A logical procession from 1 through 3 is assumed and each should be carried out in such a way as to lead logically to the next, more restrictive tier.

The level of ecological characterization carried out at Superfund sites is designed to address the potential for risk regarding types of habitats and species mixes reported in the RI. The screening level risk assessment is not sufficiently detailed to allow the risk assessor to perform anything more detailed than a very general risk assessment. To carry out the more detailed assessment, the assessor needs site-specific toxicological information on representative flora and fauna from all habitats. In addition, backup information such as chronic toxicity studies, tissue residue analyses, and observation of abnormality, etc. are needed.

#### Screening Level:

In the absence of specific studies to provide detailed information, the only approach considered to be protective of the greatest number of species, is the conservative environmental effects quotient (EEQ) approach. In this approach, the most conservative criteria available are derived from a wide variety of sources, applicable to the media. For example, in the aquatic habitat, the chronic ambient water quality criteria are used, where the criterion value is divided into the concentration reported from the remedial investigation.

Comparable criteria are not available for some media. In these cases, a literature search is used to establish a conservative basis. More specifically, the literature search is used to find information relating to organisms of that medium that have been reported as impacted by certain levels of contamination. These are then used to establish ecotoxicological values as the denominator for calculating the ecological toxicological values. The background numbers appearing in other sources (e.g., Shacklette and Boerngen) are used only as guidance for determining reasonable background values, but should not be used in calculating the EEQ. In some rare cases basic ecotoxicological values exceed the background values (e.g., aluminum, iron, and magnesium, due to the prevalence in soil). In these cases, the judgement can be made to drop them from consideration.

The EEQ is derived from dividing the criterion value for a particular medium into the value reported for the medium from investigative reports. For example, in aquatic assessments, the denominator is the ambient water quality criterion, chronic value.

Those EEQ calculations that show a result higher than one (1), are considered to demonstrate a potential risk. Values higher than ten (10) are considered to be of moderately high potential risk and above 100, extreme risk.

Measures such as diversity, abundance, and density as well as interspecies relationships (e.g., predator/prey relationships) are helpful in the risk assessment. Comparison to control or background levels are used in conjunction with this information to determine relative risk.

The uncertainty of the screening level risk assessment is minimized by using the conservative approach joined with the use of the 95% UCL of the reported data. Attached are instructions for deriving the 95% UCL.

#### Semi-quantitative:

In this level of risk assessment, ecological receptors are selected that are representative. They are selected from among the populations considered to be exposed in the habitats and media as well as from the pathways of contaminant transport. The indicator species selected is always more than one and from different classes of organisms and from both the indigenous flora and fauna. Selected species should also come from all contaminated media and pathways insofar as possible. Exposure in some pathways, e.g. groundwater isolated from all ecological receptors, would be exempted.

Exposure routes are selected, based upon both the species selected and the type(s) of contamination as well as the fate and transport picture. Exposure routes include ingestion, respiration, incidental exposure (e.g., physical contact), etc.

Dosage estimates are calculated, assuming 100% exposure to the contamination identified in the medium where the exposure occurs. This should be calculated as the daily dosage, but with the caveat that most if not all contaminants have chronic or long term implications. The factor used should be derived based upon bioconcentration factor, chemical/biochemical mobility, and comparative toxicity of the of the contaminant(s).

The dosage is then divided by the criterion value, e.g., the AWQC-chronic value for aquatic assessments. The calculated results are evaluated just as they are in the screening level.

The organisms studied are surrogates for each medium and habitat and extrapolation is considered possible to other members of the same ecosystem. The safety factor between species of the same class is 10 and between species of different classes is 100.

Uncertainty in this level of risk assessment becomes more important because of the raised level of the use of technical information. While use of the 95% UCL is still used, the basic criteria may be different as background/control data rather than the conservative criteria are brought into use as the denominator for the risk calculations. However, if it is determined that these values are excessively above the literature/criteria values used in the screening level risk assessment, then the lower values should be used. In any case, uncertainty becomes more of a mathematical concern than is the case in the screening level risk assessment.

#### Quantitative Risk Assessment:

This is the most detailed risk assessment. The above methods are formulated to lead to this and all calculations are aimed at meeting the objectives of this level of assessment whether it is completed to this level or not. This level is merely the analyses of information gathered for levels 2 and 3 and supplemented by studies specifically for level 3. Such studies as chronic bioassays (two organisms per medium for each habitat), tissue residues (tissue selected according to the kinds of contaminants identified), and other studies as needed (e.g., ecological succession, fledgling success, etc.).

This level of assessment requires the kinds of studies that constitute the most complete weight of evidence that can be carried out.

The exposure analysis is the most involved spatial and temporal analyses on each ecological component practicable.

The exposure profile involves the most complete spatial and temporal scenarios practicable.

The calculations are based upon as many factors as possible and that can be gathered through acceptable scientific practice.

In sum, this is the most scientifically rigorous assessment of the three. Extrapolation is usually not necessary at this level, but if done it is carried out using the same approach as that used in the semi-quantitative level.

Uncertainty is a large issue in this level of risk assessment.

It involves both qualitative and quantitative analyses of uncertainty and should be as thorough as possible. At this level of risk assessment, uncertainty probably cannot be completed without peer review.

Conclusion:

The screening level risk assessment is based upon a minimum of information and is based upon conservative criteria. It is the art of assessing risk using judgement that the level of protection offered is for 95% of the species found on the site and within the greatest extent of contamination possible.

The semi-quantitative risk assessment narrows the window to specific organisms considered to be representative of the habitats and pathways. It calculates the potential for risk to surrogates and uses safety factors to extrapolate to associated species in each habitat and medium.

The third tier risk assessment involves rigorous scientific disciplines such as toxicological and bioassay studies. The species studied in the toxicological, bio-assay work, etc. are specific to the habitats and media that are reported in the contamination descriptions. All studies are aimed at development of a weight of evidence approach by medium and habitat that can determine the level of potential risk.

This level of risk assessment forms the closest link between the estimate of risk potential and the actual risk that can be expected. The other two steps leading to this level (the screening and the semi-quantitative levels) are more artful and therefore are based upon conservative criteria.

The focus of risk assessment is the potential for risk. Risk need not be proven, but potential for risk is the critical point that risk managers deal with in making decisions.

Suggested Table of Contents For Environmental Risk Assessment:

- |  |                                  |
|--|----------------------------------|
| 1) Problem Definition                            | 6) Risk Characterization         |
| 2) Source Characterization and Exposure Pathways | 7) Interpretation                |
| 3) Exposure Assessment                           | 8) Limitations (Uncertainty)     |
| 4) Ecological Receptor Characterization          | 9) Risk Assessment (Conclusions) |
| 5) Ecological Effects Characterization           | 10) Recommendations              |

# Attachment A: LTA PRESENTATION

It has proven to be beneficial to represent sampling data in a tabular format based on several organizational and statistical parameters. See Attachment 1 for an example format (note that the chemicals of concern are arrayed in an alphabetical arrangement for organic and inorganic compounds).

## Statistical Calculations

The approach for calculating upper 95% confidence levels (UCL) of the mean for the potential contaminants of concern (COC) has three major components:

- . Data reduction to obtain a matrix of maximum contaminant concentrations;
- . Performing statistical calculations on the contaminant data set in raw and log transformed states, assuming the data, if graphed-frequency of occurrence over value, would be characterized as either a Gaussian or skewed (lognormal) distribution; and
- . Determining which UCL value (Gaussian or lognormal-based) to accept by comparing the UCL values to their respective data sets and verifying that the UCL does not exceed the maximum value in its associated data set. If the maximum value is exceeded by the UCL in both cases, then the maximum value of the raw data set is substituted for the calculated UCLs.

The elements of data evaluation tasks which are integral to the generation of a maximum contaminant concentration matrix are presented below. It should be noted that various approaches have been taken for some of the elements itemized below. The approaches discussed represent those that have been utilized by Region III and are felt to be the most applicable to ecological risk assessments.

- . Duplicate Sample Results - Samples collected as duplicates will be consolidated into a single result, using the higher of the two detected values for each parameter.
- . Split Sample Results - When available, analytical results of samples collected as splits by the oversight contractor will be compared to the results obtained by the PRP's contractor. Where the value is higher in the oversight contractor's results, it will be used in place of the PRP's data (i.e., will be considered as a duplicate sample).
- . Non-detects - One-half the sample quantitation limit (SQL) will be used as a proxy concentration for parameters positively identified, but below SQLs, within a particular medium. For example, if vinyl chloride is positively identified in groundwater in at least one location but is not detected in soil, one-half the SQL will be used to calculate the UCL concentration for groundwater; non-detects in soil will be treated as a concentration of zero.

Blank-Affected Results - If contaminants are detected in blank samples, these values must be compared to corresponding environmental sample results (i.e., environmental media samples associated and shipped with blank samples). If the corresponding environmental sample result is less than five times the blank result (ten times for common laboratory contaminants such as acetone, 2-butanone, methylene chloride, toluene, and the phthalate esters), then one-half the SQL is substituted. If greater, the environmental result stands as reported. If the result has been "B" qualified at the laboratory or data validation level, then one-half the SQL is inserted.

Qualified Results - All results associated with qualifiers which imply that a concentration, whether true or estimated, has been detected, are valid for inclusion in the UCL calculation. Exceptions to this are the aforementioned blank-qualified data and rejected data (typically qualified with an "R"). For rejected data no one-half SQL substitution takes place - the rejected data values are eliminated and the data set population is reduced accordingly.

Upon isolating the maximum values for each potential COC at every location, UCL calculation can occur. For every potential COC data set, both UCL formulae are always utilized. The following details the statistical process:

UCL Method # 1: Assumes Gaussian Distribution

If a potential COC data set assumes a Gaussian (normal) distribution, then the following formula is used to calculate the UCL:

$$UCL = \bar{x}_n + t(s_n/\sqrt{n})$$

Where:

$\bar{x}_n$  is the arithmetic mean of the raw data

$s_n$  is the arithmetic standard deviation of the raw data

$t$  is the one-tailed  $t$  statistic value assuming  $n-1$  degrees of freedom (df) and a selected level of significance (95%;  $P < 0.05$ )

$n$  is the population of the data set

sqrt = square root

UCL Method # 2: Assumes Skewed (Lognormal) Distribution

If a data set is assumed to be skewed (unbalanced), then the raw data results must be transformed into logarithmic equivalents. This is accomplished by taking the natural log of each result in the data set and calculating the UCL using the transformed data. The following formula is used to calculate the UCL for a lognormal data set:

$$UCL = e^{(\bar{x}_n + \sqrt{2} \cdot (s_n + B)/\sqrt{n-1})}$$

Where:

$\bar{x}_m$  is the arithmetic mean of the log transformed data

$V$  is the variance of the log transformed data (variance = the square of the standard deviation of the transformed data)

$s_m$  is the standard deviation of the log transformed data

$H$  is the  $H$  statistic, dependent on  $s_m$ , the sample population  $n$ , and a selected level of significance (95%)

$n$  is the population of the data set

sqrt = square root

When the two UCL values have been calculated, a determination is made as to which value best represents the potential COC data set. This is achieved based on the following set of criteria:

- . If one of the two calculated UCLs exceeds the maximum value concentration in the potential COC data set, then the UCL less than the maximum value is used.
- . If both UCL values do not exceed the maximum value concentration in the potential COC data set, then the greater UCL is used.
- . If both UCL values exceed the maximum value concentration in the potential COC data set (frequently occurs when the data set population is four or less), then both UCLs are eliminated and the maximum value concentration is substituted.

Utilization of the approach discussed herein will produce several beneficial effects. First, PRP analytical data will be evaluated and presented in a consistent manner in the Remedial Investigation Reports. Second, subsequent data evaluation for the same site and/or comparisons among sites can be approached in a uniform manner. Third, utilization of this approach by the PRPs will eliminate the need, and subsequent cost, of re-evaluation and manipulation of the data set by EPA or its contractors. This may also make additional resources available for other ecological risk assessment tasks.

**FORMAT FOR DISPLAYING ECOLOGICAL RISK ASSESSMENT DATA**

CHEMICALS OF CONCERN	BACKGROUND CONCENTRATION <sup>1</sup>	CONCENTRATION RANGE		NUMBER OF DETECTS <sup>3</sup>	NUMBER OF SAMPLES <sup>4</sup>	MEAN	95% UCL
(Alphabetical order by parameter category)							

1. Units are ....
2. Minimum/maximum detected concentration above the sample quantitation limit (SQL). Units are ....
3. Number of times constituent was detected above the SQL. Sample results from duplicate and splits were consolidated into a single sample result using the higher detected concentration for each constituent.
4. Number of samples taken and analyzed for the constituent. Sample number varies based on number of usable results.

**ATTACHMENT III**

**REGION III SUPPLEMENTARY RISK ASSESSMENT GUIDANCE**



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**

Region III  
841 Chestnut Street  
Philadelphia, Pennsylvania 19107

March 18, 1994

**SUBJECT:** Region III Supplementary Risk Assessment Guidance for Superfund

**FROM:** Roy L. Smith, Ph.D., Senior Toxicologist  
Technical Support Section (3HW13) *RL Smith*

**TO:** Risk Assessment Guidance Package Addressees

Since 1990, the EPA Region III risk assessors have developed several technical guidance documents clarifying and extending EPA's national risk assessment guidance for Superfund. In the past, the Region has distributed each document as it became final, and afterward provided copies on request. The Region now sees a need for a more formal distribution method.

This new procedure will begin by providing all current Region III risk assessment guidance documents to persons who (1) have Region III mailing addresses, and (2) are now enrolled in our mailing list for the Risk-Based Concentration Table. The documents are attached to this memo. If you are not currently on this mailing list, but would like to be, please fax Anna Poulton (215-597-9890) and give her your name, address, and phone and fax numbers. Please say whether you would like to receive the risk assessment guidance, the Risk-Based Concentration Table, or both. If you are already on the mailing list, you need not respond.

The Region will also use the mailing list to disseminate new guidance documents, and will also periodically distribute fresh copies of the complete guidance package. Of course, we will continue to respond to direct requests for copies at any time. Please make these requests via fax to Anna Poulton.

Each Region III risk assessment guidance document has been reviewed by Regional and Headquarters program personnel and scientists in EPA's Office of Research and Development, and revised in response to comments. Regional Superfund management has concurred with the recommendations, and each document carries the Division Director's signature. The recommendations are now being applied by Region III technical support personnel in writing and reviewing Superfund risk assessments in the Region.

Questions about how the guidance should be applied to particular sites should be referred to the EPA toxicologist working with that site. Please call me at 215-597-6682 with other comments and observations about the distribution process.

Attachments

Region III  
Technical Guidance Manual  
Risk Assessment

## Use of Monte Carlo Simulation in Risk Assessments

EPA Contact: Dr. Roy L. Smith



EPA  
Region III

Hazardous Waste Management Division  
Office of Superfund Programs  
February 1994

EPA's current risk assessment methods express health risks as single numerical values, or "single-point" estimates of risk. This technique provides little information about uncertainty and variability surrounding the risk estimate. Recent EPA guidance (EPA, 1992) recommends developing "multiple descriptors" of risk to provide more complete information to Agency decision-makers and the public. Monte Carlo simulation is a highly effective way to produce these multiple risk descriptors. This document recommends guidelines under which Region III risk assessors may accept the optional use of Monte Carlo simulation to develop multiple descriptors of risk. *The Region will continue to require single-point risk estimates, prepared under current national guidance, in conjunction with optional Monte Carlo simulations.*

### SINGLE RISK ESTIMATES VS. MULTIPLE DESCRIPTORS

EPA designed its human health risk assessment guidance (e.g., EPA, 1991, 1989 and 1988) to produce protective, rather than best, estimates of risk. EPA is aware that true risks are probably less than its estimates, but has chosen a regulatory policy of giving the benefit of uncertainty surrounding the risk assessment to the exposed public.

These protective risk estimates sometimes create difficulty for Agency decision-makers and the public. Site-specific Regional risk assessments usually present risk as a single number, or single-point estimate, accompanied by a qualitative discussion of uncertainty. The public tends to focus on the single-point estimate and to overlook the uncertainty, which may span several orders of magnitude. EPA risk managers, though aware of the uncertainty, must still justify their decision to either accept or reduce the single-point risk. If the risk is close to the maximum acceptable level, it is likely that different assumptions would have produced a different risk number, leading to a different decision. In this way, single-point risk assessment methods place the risk assessor in an inappropriate risk management role.

Recent EPA guidance on risk characterization (EPA 1992) discusses this problem in depth, and recommends the use of multiple risk descriptors in addition to protective single-point risk estimates. Inclusion of these additional risk descriptors provide the public with more complete information on the likelihood of various risk levels, and risk managers will choose multiple risk-based cleanup goals from which to choose. This guidance mentions Monte Carlo simulation as an effective source of multiple risk descriptors.

### MONTE CARLO SIMULATION

Monte Carlo simulation is a statistical technique by which a quantity is calculated repeatedly, using randomly selected "what-if" scenarios for each calculation. Though the simulation process is internally complex, commercial computer software performs the calculations as a single operation, presenting results in simple graphs and tables. These results approximate the full range of possible outcomes, and the likelihood of each. When Monte Carlo simulation is applied to risk assessment, risk appears as a frequency distribution graph similar to the familiar bell-shaped curve, which non-statisticians can understand intuitively.

Monte Carlo simulation also has important limitations, which have restrained EPA from accepting it as a preferred risk assessment tool:

1. Available software cannot distinguish between variability and uncertainty. Some factors, such as body weight and tap water ingestion, show well-described differences among individuals. These differences are called "variability". Other factors, such as frequency and duration of trespassing, are simply unknown. This lack of knowledge is called "uncertainty". Current Monte Carlo software treats uncertainty as if it were variability, which may produce misleading results.
2. Ignoring correlations among exposure variables can bias Monte Carlo calculations. However, information on possible correlations is seldom available.
3. Exposure factors developed from short-term studies with large populations may not accurately represent long-term conditions in small populations.
4. The tails of Monte Carlo risk distributions, which are of greatest regulatory interest, are very sensitive to the shape of the input distributions.

Because of these limitations, Region III does not recommend Monte Carlo simulation as the sole, or even primary, risk assessment method. Nevertheless, Monte Carlo simulation is clearly superior to the qualitative procedures currently used to analyze uncertainty and variability. For baseline risk assessments at NPL sites, Region III recommends that uncertainty and variability surrounding single-point risk estimates rely on multiple descriptors of risk (EPA, 1992). Monte Carlo simulation will be an acceptable method for developing these multiple descriptors.

The following example (from Smith, in press) illustrates the advantages of Monte Carlo simulation in risk assessment:

At a Superfund site in Region III, volatile organic compounds migrated to residential wells. The single-point RME estimate of lifetime cancer risk to exposed residents, based on ingestion of tap water and inhalation while showering, was  $1.14 \times 10^{-3}$ .

Figure 1 shows the output of a PC-based Monte Carlo simulation program for the risk assessment. Each exposure parameter was entered as a frequency distribution (i.e., a "bell-shaped" curve showing the range of possible values, and the likelihood of each)

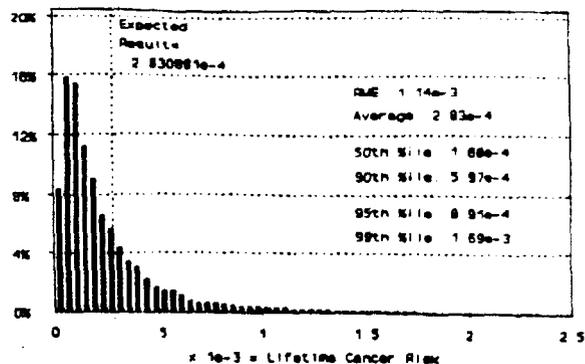


Fig 1. Probability distribution of upper bound lifetime cancer risk.

rather than as a single number. Carcinogenic potency slopes were entered as fixed values rather than frequency distributions, so the variability in risk was due entirely to the exposure assumptions.

Risk was calculated 5000 times, with each calculation based on a different randomly-selected exposure scenario. The figure lists the RME, average, and four percentiles of risk, and shows the entire risk distribution. The RME risk estimate fell between the 95th and 99th percentiles in this example, appropriately protective as intended. This figure clearly provides more complete risk information than the single numerical RME estimate.

#### GUIDELINES FOR USING MONTE CARLO SIMULATION

Region III risk assessors believe that Monte Carlo simulation requires more development before it can serve as the primary risk assessment method, for reasons described above. However, the technique has clear advantages over the qualitative analyses of uncertainty and variability currently in use. Region III will accept Monte Carlo simulations submitted as uncertainty/variability analyses in risk assessments, under the following guidelines:

1. Include only human receptors. This guidance excludes environmental receptors.
2. Submit a work plan for EPA review before doing the Monte Carlo simulation, to ensure the work will be acceptable to EPA. The workplan should describe the software to be used, the exposure routes and models, and input probability distributions and their sources. EPA expects that peer-reviewed literature and site-specific data will be used whenever possible. Use professional judgment only as a last resort, and only in the form of triangular or uniform distributions. Describe how correlations among input variables will be handled.

3. Include only exposure variables in the Monte Carlo simulation. Enter reference doses and carcinogenic slope factors as single numbers, except for specific contaminants for which the EPA Office of Research and Development has already approved frequency distributions.
4. Include only significant exposure scenarios and contaminants in the Monte Carlo simulation. First, calculate RME risks for all exposure routes under current guidance. Select exposure routes for which RME risk exceeds either  $1e-6$  cancer risk or a non-carcinogenic hazard index of 1. Include only contaminants which contribute 1% or more of the total RME risk or hazard index.
5. Use Monte Carlo simulation only to analyze uncertainty and variability, as a "multiple descriptor" of risk. Include standard RME risk estimates in all graphs and tables of Monte Carlo results. Generate deterministic risks using current EPA national guidance (EPA 1992, 1991, 1989, and 1988).
6. Include graphs and tables showing and describing each input distribution, distributions of risk for each exposure route, and distributions of total risk (summed across exposure pathways and age groups, as appropriate under current guidance).

Region III will not accept Monte Carlo simulations which are not approved beforehand, or do not adhere to these guidelines.

#### SUMMARY

Region III will accept Monte Carlo simulations that conform to the guidelines in this document, as part of baseline human health risk assessments. The most important guideline is that all risk assessments must include single-point RME risk estimates prepared under current EPA national guidance. The Region will accept Monte Carlo simulation only as an optional addition to, not a substitute for, current risk assessment methods.

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Region III  
Technical Guidance Manual  
Risk Assessment

# Exposure Point Concentrations In Groundwater

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November 1991

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)

## 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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*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.*

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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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## **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.

#### **RISK ASSESSMENT**

##### **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, UCL<sub>95</sub> (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

$$\bar{x} = e^{\bar{t}}$$

4. Obtain the  $UCL_{95}$  using the expression

$$UCL_{95} = e^{\bar{x} + \frac{d^2}{2} \frac{H}{\sqrt{n}}} \quad (\text{Land, 1971, 1975})$$

where:

$\bar{x}$  = arithmetic mean of log transformed data

$d^2$  = variance of log transformed data

$H$  = Tabular H statistic, depends on geometric  $\sigma$ ,  $n$ , 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

$$UCL_{95} = X_a + \left( \frac{t \sigma}{\sqrt{n}} \right)$$

where

$X_a$  = arithmetic mean of the raw data

$\sigma$  = 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-detected data and obtain a maximum likelihood estimate of the detected data (Gilbert, 1987).

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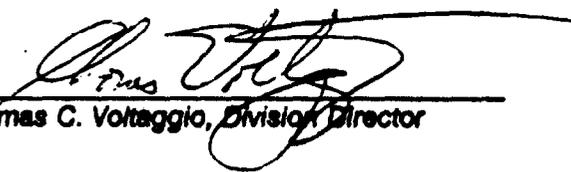
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## Chemical Concentration Data Near The Detection Limit

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November 1991

*Risk assessments often inappropriately report and handle data near the limits of detection. Common errors include (1) omission of detection limits, (2) failure to define detection limits which are reported, and (3) unjustified treatment of non-detects as zero. This guidance is intended to improve the quality and consistency of handling data near the detection limit in risk assessments done in Region III. (EPA/903/8-91/001)*

### REPORTING DETECTION LIMITS

The practice of omitting information on detection limits from risk assessments is inappropriate, both technically and ethically, because it conceals important uncertainties about potential levels of undetected risk. For example, failure to detect TCE in drinking water at a detection limit of 50 parts per billion (PPB) does not establish acceptable levels of health risk; failure to detect TCE at 0.05 ppb does. If risk assessors neglect to consider detection limits for analytical data, they may overlook serious health threats. Furthermore, detection limits should appear both in data summary tables in the body of the risk assessment, and in tables of raw data in appendices.

In a generic sense, there are two types of analytical lower limits: detection limits and quantitation limits. The detection limit is the lowest concentration that can reliably be distinguished from zero, but is below the level which is quantifiable with acceptable precision. At the detection limit, the analyte is proven to be present, but the reported concentration is an estimate. The

quantitation limit is the lowest concentration which can be not only detected, but also quantified with a specified degree of precision. At the quantitation limit, the analyte is both proven present and measured reliably. The quantitation limit is always greater than the detection limit, usually by a factor of about three.

### NON-DETECTION v. ZERO CONCENTRATION

The routine assumption that site-related contaminants, if undetected, are absent from samples is often unduly optimistic. Some frequently-encountered carcinogens (e.g., vinyl chloride and tetrachloroethene in drinking water, beryllium in soil) are significant potential health risks at levels below detection limits. Risk assessors should use professional judgment, augmented by the decision path described below, to decide if hazardous contaminants should be assumed present at levels below the detection limit.

Detection limit is the lowest concentration that can be distinguished from zero, but is below the level which is quantifiable with acceptable precision.

The quantitation limit is the lowest concentration which can be not only detected, but also quantified with a specified degree of precision.

## EXISTING GUIDANCE

Section 5.4 of the EPA Risk Assessment Guidance for Superfund (USEPA, 1989) IA recommends that all data qualifiers should be reported in the exposure assessment, and that their implications be considered before the data are used for risk assessment. Section 6.5.1 suggests use of models when monitoring data are restricted by the limit of quantitation, and Section 5.3.1 contains guidance for re-analyzing samples and determining which data should be treated qualitatively.

EPA's Guidance for Data Useability in Risk Assessment (USEPA, 1990) Section 3.3.4, subdivides generic detection limits and quantitation limits, describing six different lower analytical limits. Section 4.2 of DURA describes a strategy for selecting appropriate analytical methods, which includes consideration of risk at the detection limit.

- (1) The instrument detection limit (IDL) is three times the standard deviation of seven replicate analyses at the lowest concentration of a laboratory standard that is statistically different from a blank.
- (2) The method detection limit (MDL) is three times the standard deviation of seven replicate spiked samples handled as environmental samples.
- (3) The sample quantitation limit (SQL) is the method detection limit corrected for sample dilution and other sample-specific adjustments.
- (4) The contract required detection limit (CRDL) is the sample quantitation limit which CLP laboratories are required to maintain for inorganic analytes.
- (5) The contract required quantitation limit (CRQL) is the sample quantitation limit which CLP laboratories must maintain for organic analytes.
- (6) The limit of quantitation (LOQ) is the level above

which analytes may be quantified with a specified precision, often +/- 30%. This precision is usually assumed to occur at ten times the standard deviation measured for the instrument detection limit.

Even with an optimum sample and analysis plan, risk assessors still confront situations where significant risks can occur below the detection limit. Neither RAGS nor DURA presents a procedure for assessing risks from undetected, but potentially present compounds, nor do they suggest a specific reporting format for detection limits. This Region III guidance document addresses these gaps in national risk assessment guidance. It is intended to augment, not replace, national guidance.

## RECOMMENDED METHODOLOGY

### A. Reporting Detection Limits

Risk assessments should include analytical limits in all data tables, including summary tables. One of the following should be reported for all undetected analytes, in order of preference:

Sample Quantitation Limit  
Contract Required Detection Limit (or CRQL)  
Limit of Quantitation (as described in DURA)

Each data table in the risk assessment should clearly describe which limits are reported, and define them.

Risk assessments should use the format shown below for all data tables. Undetected analytes should be reported as the detection limit (i.e., either the SQL, CRDL/CRQL, or LOQ, in that order) with the code "U". Analytes detected above the detection limit, but below the quantitation limit, should be reported as an estimated concentration with the code "J".

---

Compound	Concentration in Sample (Code)		
	Sample Number		
	123	456	789
Trichloroethene	0.1(U)	15	0.8(J)
Vinyl Chloride	0.2(U)	0.2(U)	2.2
Tetrachloroethene	5.5	3.1(J)	0.1(U)

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Non-detects are reported as the sample quantitation limit, defined as three times the standard deviation of seven replicate spiked samples handled as environmental samples, corrected for sample dilution and other sample-specific adjustments.

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## Non-Detection v. Zero Concentration

Risk assessors have the following methods to choose from, for handling data below the detection limit:

1. **Non-detects handled as detection limits** - In this highly conservative approach, all non-detects are assigned the value of the detection limit, the largest concentration of analyte that could be present but not detected. This method always produces a mean concentration which is biased high, which is inconsistent with Region III's policy of using best science in risk assessments.
2. **Non-detects reported as zero** - This is the best-case approach, in which all undetected chemicals are assumed absent. This method should be used only for specific chemicals which the risk assessor has determined are not likely to be present, using the decision path below.
3. **Non-detects reported as half the detection limit** - This approach assumes that on the average all values between the detection limit and zero could be present, and that the average value of non-detects could be as low as half the detection limit. This method (or method four, below) should be used for chemicals which the risk assessor has determined may be present below the detection limit, using the decision path below.
4. **Statistical estimates of concentrations below the detection limit** - Use of statistical methods to estimate concentrations below the detection limit is technically superior to method three above, but also requires considerably more effort and expertise than the three simpler methods. Also, these statistical methods are effective only for data sets having a high proportion of detects (typically, greater than 50%). Therefore, statistical predictions of concentrations below the detection limit, as described by Gilbert (1987) and reviewed by Helsel (1990), are recommended only for compounds which significantly impact the risk assessment and for which data are adequate.

### C. Decision Path for Handling Data Near the Detection Limit (DL)

Summarizing the discussion above, method one (non-detects = DL) consistently overestimates concentrations below the detection limit, and should not be used. Risk assessors should use the following decision path to select among method two (non-detects

= 0), method three (non-detects = DL/2), and method four (specialized statistics) to achieve the least biased estimate of reasonable maximum exposure.

The choice of method should be based on scientific judgment about whether: (1) the undetected substance poses a significant health risk at the detection limit, (2) the undetected substance might reasonably be present in that sample, (3) the treatment of non-detects will impact the risk estimates, and (4) the database is sufficient to support statistical analysis. The decision path below, followed by examples of appropriate selections, is recommended:

1. **Is the compound present at a hazardous concentration in any site-related sample?**

If no, assume non-detects are zero; if yes, continue.  
(Note that if the compound is not present in any sample at a hazardous level (e.g.,  $10^{-6}$  risk or a hazard quotient of 1), it probably should be dropped from the risk assessment.)

2. **Was the sample taken down-gradient of (or, if no gradient exists, adjacent to) a detectable concentration of the chemical?**

If no, assume non-detects are zero; if yes, continue.

3. **Do the chemical's physical-chemical characteristics (e.g., water solubility, octanol-water partitioning, vapor pressure, Henry's law constant, biodegradability, etc.), permit it reasonably to be present in the sample? Are other site-related compounds with similar characteristics present in the sample?**

If no (to both questions), assume non-detects are zero; if yes (to either question), continue.

4. **Does the assumption that non-detects equal DL/2 significantly impact route-specific quantitative risk estimates?**

If no, assume non-detects equal DL/2; if yes, consider using statistical methods to estimate concentrations below the detection limit for that exposure route, assuming data quality permits.

## EXAMPLES

1. TCE is present in groundwater on site at 500 µg/l, a potentially hazardous concentration. Elevated TCE concentrations are measured upgradient of a residential well, but TCE is not detected in the residential well itself. Other site-related chlorinated VOCs are detected in the residential well. The detection limit for TCE was 5 µg/l (equivalent to  $5 \times 10^{-6}$  risk under the exposure scenario in the risk assessment).

### Decision Path

Step 1 - continue

Step 2 - continue

Step 3 - continue

Step 4 - assume non-detects are DL/2. If multiple well samples are available, and TCE is detected in some, consider using specialized statistical methods.

2. Chromium is present in on-site soils at 10,000 mg/kg, a potentially hazardous concentration under direct contact exposure. Chromium is not detected in an adjacent off-site soil sample, although other site-related metals are. The detection limit for chromium in soil is 0.1 mg/kg, well below a hazardous concentration under the exposure scenario in the risk assessment.

### Decision Path

Step 1 - continue

Step 2 - continue

Step 3 - continue

Step 4 - assume non-detects are DL/2; using specialized statistics is unnecessary because the risk assessment would not change appreciably.

3. PCBs are not detected in 20 on-site soil samples. There is no history of PCB disposal at the site, and PCBs were not detected in any other medium.

### Decision Path

Step 1 - assume non-detects are zero.

4. Vinyl chloride, a site-related contaminant, is measured in surface water downstream of the site boundary at 10 µg/l, a hazardous concentration for a resident receptor. Five hundred meters upstream of the site, vinyl chloride is not detected at a DL of 0.1 µg/l.

### Decision Path

Step 1 - continue

Step 2 - assume upgradient non-detects equal zero.

5. 2,3,7,8-TCDD is detected in an unfiltered monitoring well sample at 5 ng/l, a potentially hazardous concentration. The next downgradient well has no detectable TCDD. Pentachlorophenol, also detected in the first well, is not detected in the second.

### Decision Path

Step 1 - continue

Step 2 - continue

Step 3 - assume non-detects of both TCDD and PCP equal zero because of low mobility in groundwater.

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For additional information, contact (215) 597-6682.

Approved by:

  
Thomas C. Voltaggio, Division Director

**ATTACHMENT IV**

**CRL QA/QC COMMENTS**

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY



REGION III  
CENTRAL REGIONAL LABORATORY  
201 DEFENSE HIGHWAY  
SUITE 200  
ANNAPOLIS, MARYLAND 21401

QUALITY  
ASSURANCE  
BRANCH

DATE: June 9, 1994

SUBJECT: Allegany Ballistics Laboratory Draft Sampling and Analysis  
Plan (FY94125)

FROM: E.J. Clugston, Engineer  
Program Support Section (3ES32)

TO: Bruce Beach, RPM  
VA/WV Federal Facility Section (3HW71)

THRU: Cynthia C. Metzger, Chief *CCM*  
Program Support Section (3ES32)

We have reviewed the Allegany Ballistics Laboratory Draft Sampling and Analysis Plan, based on QAMS 005/80, general technical adequacy, and appropriate Agency guidance.

We find the information presented is generally acceptable; however, there are numerous omissions. Therefore, we are recommending conditional approval until complete information is supplied.

In addition, we must have a QA/QC Plan from the designated laboratory.

If you have any questions, please call me at (410) 573-6845.



Environmental Protection Agency  
Region III

Revision No.: 4  
Date: 1/3/91  
Page: 1 of 16

Quality Assurance Project Plan Review

Site Name: Allegany Ballistics Lab  
Document Title(s): Draft Sampling and Analysis Plan

Account No: TYP036N4B  
Document Number: FY94125

Requester Name: Bruce W. Beach  
Title: RPM

Mail Code: 3HW71  
Phone No.: 215-597-2317

Plan Prepared by: CH2M Hill

Date Received: May 24, 1994

Date Requested by:

Program:	..X..CERCLA	.....REMOVAL	.....Fund-Lead
	.....RCRA	.....REMedial	.....ENF-Lead
	.....Other (Specify)	.....SI	.....State-Lead

Primary

	Y	N
Does Plan provide sufficient documentation - enough information so reviewer (and others) knows what will be done, by whom, etc?	.....	.....
Has document been correctly applied (comply with applicable regulation or guidance)?	.....	.....
Does document accomplish what it is supposed to?	.....	.....

Major Deficiencies were found in the following elements:

...Title page	...QA Objectives	...Analytical Proc.	...Prev. Main.
...Table of Contents	...Sampling Proc.	...Data Reduction	...Data SOPs
...Project Descrip.	...Sample Custody	...Internal QC Ck.	...Corr. Action
..X..Org. and Resp.	..X..Calib. Proced.	...Audits	...QA Reporting

See the attached for discussion of comments relative to all elements.

Conclusion/Recommendation:

Approval	.....
Resubmission	.....
Conditional	..X..

QA Reviewer: E.J. Clugston

Data Review Complete: June 9, 1994

Identification

IA IU NI NA

I) Title page

Does page include:

- |  |        |       |        |       |
|--|--------|-------|--------|-------|
| 1 - Title of project?  | ...X.. | ..... | .....  | ..... |
| 2 - Name(s) of principal investigators and affiliates shown? | .....  | ..... | ..(1). | ..... |
| 3 - Appropriate approval lines at bottom?                    | .....  | ..... | ..(1). | ..... |
| 4 - Plan prepared in document control format?                | .....  | ..... | ..(1). | ..... |

II) Table of Contents

Does Table include:

- |  |        |       |        |       |
|--|--------|-------|--------|-------|
| 1 - List of all Plan required elements and appropriate page numbers? | ...X.. | ..... | .....  | ..... |
| 2 - Include distribution list?                                       | .....  | ..... | ..(1). | ..... |
| 3 - Include list of Appendices?                                      | ...X.. | ..... | .....  | ..... |

IA = Included & Acceptable  
IU = Included & Unacceptable  
NI = Not included  
NA = Not applicable

Comments:

- (1) QAMS 005/80, the regulations for preparing QA/QC plans, requires approval lines at bottom of Title page. Also required is that the Plan be prepared in document control format and a distribution list.

III) Project Description

IA IU NI NA

Are the following addressed (or referenced),  
consistently presented, technically correct?

1 - Statement of general objectives (purpose)?	...X..	.....	.....	.....
2 - Dates for start and completion of project and sampling activities (schedule)?	...X..	.....	.....	.....
3 - Overview of project's scope (activities)?	...X..	.....	.....	.....
4 - Specific objectives for this phase of work?	...X..	.....	.....	.....
5 - Background information?	...X..	.....	.....	.....
5a - Description of site?	...X..	.....	.....	.....
5b - Site History (operational, legal, remedial efforts)?	...X..	.....	.....	.....
6 - Brief statement of intended data uses?	...X..	.....	.....	.....
*7 - Description of sampling network design and rationale?	...X..	.....	.....	.....
7a - Design of overall monitoring systems?	...X..	.....	.....	.....
7b - Specific location of sampling sites?	...X..	.....	.....	.....
7c - Justification of overall design?	...X..	.....	.....	.....
Sample matrices?	...X..	.....	.....	.....
- Sample locations?	...X..	.....	.....	.....
*10 - Parameters to be measured?	...X..	.....	.....	.....
*11 - Frequency of collection?	...X..	.....	.....	.....
*12 - Field and lab measurements?	...X..	.....	.....	.....
13 - Procedures for groundwater sample preparation, or other similar fractions/sub-groups specified and included in parameter definition?	...X..	.....	.....	.....
14 - Type of sample(s) (grab, composite, etc.)?	...X..	.....	.....	.....
15 - Are data needs relative to data uses addressed? (Will the data answer specific objectives?)	...X..	.....	.....	.....

\*Depending on the Program and/or project, information related to sampling may be discussed under Project Description (Section III) or Sampling Procedures (Section VI) in the QAPjP or in a separate Field Sampling Plan - the questions apply regardless of format.

Comments:

IV) Project Organization

	IA	IU	NI	NA
1 - Does the Plan identify key people responsible for:				
1a - Overall QA/QC?	...X..	.....	.....	.....
1b - Sampling operations and sampling QC?	...X..	.....	.....	.....
1c - Laboratory analyses and laboratory QC?	...X..	.....	.....	.....
1d - Data processing and data processing QC?	.....	.....	..(1).	.....
1e - Data review oversight?	.....	.....	..(1).	.....
1f - Performance and System Audits? (Lab and Field)	.....	.....	..(1).	.....
2 - Does the QAPjP define who performs:				
2a - Data review?	.....	.....	..(1).	.....
2b - Review and confirmation of any tentatively identified organic compounds?	.....	.....	..(1).	.....
2c - If CLP, preparation and final review of SAS requests?	.....	.....	..(1).	.....
3 - Are phone numbers and addresses included?	.....	.....	..(2).	.....
4 - Is line authority for all referenced organizations explained or demonstrated by including an organizational chart(s)?	...X..	.....	.....	.....
4a - Are contractors and subcontractors included in organizational chart?	...X..	.....	.....	.....
5 - Are personnel qualifications included? training? Experience? Resumes?	.....	.....	..(3).	.....
6 - Is the organizational structure appropriate to accomplish the QA objectives of the project?	.....	.....	..(4).	.....

Comments:

- (1) Please supply this information.
- (2) Phone numbers expedite communications.
- (3) A brief bio of principal staff members should be given.
- (4) Unknown without additional information.

V) QA Objectives (DQOs)

	IA	IU	NI	NA
1 - Is there a statement of intended data usage?	...X..	.....	.....	.....
2 - Are the terms and definitions for precision, accuracy, representativeness, comparability, and completeness properly used and expressed (i.e. QA/QC concepts and theories are understood and properly implemented and followed throughout the plan)?	...X..	.....	.....	.....
3 - Are Data Quality Objectives (DQOs) quantitatively stated for precision and accuracy (bias)?	...X..	.....	.....	.....
3a - Have the following been defined for each matrix and parameter?				
1) Level of QA effort (frequency of QC, etc.)?	...X..	.....	.....	.....
2) Accuracy (matrix spikes, surrogate spikes, reference samples, etc.)?	...X..	.....	.....	.....
3) Precision (replicate samples)?	...X..	.....	.....	.....
4) Sensitivity or MDL?	...X..	.....	.....	.....
5) Statistical reporting units?	...X..	.....	.....	.....
3b - Are quantitative limits established for each?	...X..	.....	.....	.....
3c - Are field and lab both covered?	.....	.....	..(1).	.....
3d - Are QA objectives presented in a table format?	...X..	.....	.....	.....
3e - Is it clear that a distinction has been defined for "total" system variability and bias and not just looking at the laboratory?	...X..	.....	.....	.....
3f - Are objectives/requirements properly expressed (e.g., not confused with capabilities)?	...X..	.....	.....	.....
4 - If appropriate, are completeness objectives quantitatively stated?	...X..	.....	.....	.....
5 - Are representativeness and comparability appropriately addressed?	...X..	.....	.....	.....
6 - Are the interrelationships (and differences) between study design (number of samples needed), analytical procedures, internal QC, and data assessment reflected in the DQOs?	...X..	.....	.....	.....

Comments:

- (1) Only the field is covered, not the laboratory.

VI) Sampling Procedures (see also Section III)

	IA	IU	NI	NA
1 - Does the Plan:				
1a - Provide specific guidance for all field work?	...X..	.....	.....	.....
1b - Provide a mechanism for planning and approving site activities?	...X..	.....	.....	.....
1c - Ensure that sampling activities are limited to those that are necessary and sufficient?	...X..	.....	.....	.....
1d - Provide a common point of reference for all parties to ensure comparability and compatibility between all activities performed at the site?	...X..	.....	.....	.....
2 - Are the following elements included?				
2a - Investigation objectives?	...X..	.....	.....	.....
2b - Site background?	...X..	.....	.....	.....
2c - Analysis of existing data?	...X..	.....	.....	.....
2d - Analytes of interest?	...X..	.....	.....	.....
2e - Sample types?	...X..	.....	.....	.....
2f - Map of locations to be sampled?	...X..	.....	.....	.....
2g - Sample locations and frequency?	...X..	.....	.....	.....
2h - Technique or guideline used to select sites?	...X..	.....	.....	.....
2i - Specific sample collection methods?	...X..	.....	.....	.....
2j - Description of sampling devices?	...X..	.....	.....	.....
2k - Containers (type and source)?	...X..	.....	.....	.....
2l - Preservatives (type and source)?	...X..	.....	.....	.....
2m - Procedures for preservation?	...X..	.....	.....	.....
2n - Holding times?	...X..	.....	.....	.....
2o - Reagents (type and source)?	...X..	.....	.....	.....
2p - Transport and storage?	...X..	.....	.....	.....
2q - Preparation of sampling equipment before and during sampling) and containers?	...X..	.....	.....	.....
2r - Blanks?	...X..	.....	.....	.....
2s - Filtering procedures, if applicable?	...X..	.....	.....	.....
2t - Record-keeping requirements?	...X..	.....	.....	.....
2u - Coordination with laboratory?	...X..	.....	.....	.....

Comments:

VII) Sample Custody

1 - Sample Collection: Does the plan address:

1a - Field custody procedures?

1) Transfer of custody and shipment?

2) Receipt of samples?

3) Lab custody procedures?

1b - Does Plan include examples of forms, tags, labels, records, etc.?

1c - Does Plan address evidentiary considerations?

2 - Do field documentation procedures:

2a - Document source of reagents or supplies?

2b - Include procedures/forms for recording the exact location and specific considerations associated with sample acquisition?

2c - Document specific preservation method?

2d - Include labels containing all necessary information?

2e - Include form to track custody?

3 - Do lab custody procedures:

3a - Identify sample custodian?

3b - Provide for custody record within the lab?

3c - Specify procedures for sample handling, storage, disbursement for analysis, and disposal?

4 - Does the Plan address final evidence files?

	IA	IU	NI	NA
1a - Field custody procedures?	...X..	.....	.....	.....
1) Transfer of custody and shipment?	...X..	.....	.....	.....
2) Receipt of samples?	...X..	.....	.....	.....
3) Lab custody procedures?	...X..	.....	.....	.....
1b - Does Plan include examples of forms, tags, labels, records, etc.?	...X..	.....	.....	.....
1c - Does Plan address evidentiary considerations?	...X..	.....	.....	.....
2 - Do field documentation procedures:				
2a - Document source of reagents or supplies?	...X..	.....	.....	.....
2b - Include procedures/forms for recording the exact location and specific considerations associated with sample acquisition?	...X..	.....	.....	.....
2c - Document specific preservation method?	...X..	.....	.....	.....
2d - Include labels containing all necessary information?	.....	.....	..(1).	.....
2e - Include form to track custody?	.....	.....	..(1).	.....
3 - Do lab custody procedures:				
3a - Identify sample custodian?	.....	.....	..(2).	.....
3b - Provide for custody record within the lab?	.....	.....	..(2).	.....
3c - Specify procedures for sample handling, storage, disbursement for analysis, and disposal?	.....	.....	..(2).	.....
4 - Does the Plan address final evidence files?	.....	.....	..(2).	.....

Comments:

(1) Please supply this information.

(2) No information is given in regard to the laboratory. We assume a separate QA/QC plan will be submitted.

VIII) Calibration Procedures and Frequency

IA IU NI NA

1 - For the Field

- |  |        |       |       |       |
|--|--------|-------|-------|-------|
| 1a - Does Plan include methods/procedures to assure field equipment are functioning optimally?                 | ...X.. | ..... | ..... | ..... |
| 1b - Is schedule/frequency of above included?  | ...X.. | ..... | ..... | ..... |
| 1c - Are equipment logbooks required to record usage, maintenance, calibration, and repair?                    | ...X.. | ..... | ..... | ..... |
| 1d - Does Plan include calibration standards or reagents to be used, their source and traceability procedures? | ...X.. | ..... | ..... | ..... |
| 1e - Does Plan include documentation requirements for calibration:   |        |       |       |       |
| 1) Date(s) of calibration?   | ...X.. | ..... | ..... | ..... |
| 2) Identification of standards used?   | ...X.. | ..... | ..... | ..... |
| 3) Personnel performing calibration?   | ...X.. | ..... | ..... | ..... |
| 4) Results of calibration (raw data and summary statistics)?   | ...X.. | ..... | ..... | ..... |
| 5) Corrective actions taken?   | ...X.. | ..... | ..... | ..... |

- Laboratory

- |  |       |       |        |       |
|--|-------|-------|--------|-------|
| 2a - Does Plan include methods/procedures to assure lab equipment are functioning optimally?       | ..... | ..... | ..(1). | ..... |
| 2b - Is schedule/frequency of above included?  | ..... | ..... | ..(1). | ..... |
| 2c - Are equipment logbooks required to record usage, maintenance, calibration, and repair?        | ..... | ..... | ..(1). | ..... |
| 2d - Does Plan include calibration standards to be used, their source and traceability procedures? | ..... | ..... | ..(1). | ..... |
| 2e - Does Plan include calibration documentation requirements:                                     |       |       |        |       |
| 1) Date(s) of calibration?   | ..... | ..... | ..(1). | ..... |
| 2) Identification of standards used?   | ..... | ..... | ..(1). | ..... |
| 3) Personnel performing calibration?   | ..... | ..... | ..(1). | ..... |
| 4) Results of calibration (raw data and summary statistics)?                                       | ..... | ..... | ..(1). | ..... |
| 5) Corrective actions taken?   | ..... | ..... | ..(1). | ..... |
| 2f - Are calibration procedures applicable to analytical methods chosen?                           | ..... | ..... | ..(1). | ..... |
| 2g - Are all analytes included in calibration standards?   | ..... | ..... | ..(1). | ..... |

Comments:

- (1) Laboratory must submit a QA/QC Plan.

IX) Analytical Procedures

	IA	IU	NI	NA
1 - Are all analytical procedures documented or written as SOPs and included in full or by reference for all parameters?	...X..	.....	.....	.....
1a - Are all procedural steps and options described?	...X..	.....	.....	.....
2 - Are the criteria of method selection included (e.g., in order to obtain a particular DQO)?	...X..	.....	.....	.....
3 - If method choice is governed by regulatory requirement (e.g., NPDES, SDWA, RCRA), have the appropriate methods been chosen?	...X..	.....	.....	.....
4 - Are the following included?				
4a - Designated laboratory name?	...X..	.....	.....	.....
4b - Description of laboratory facilities?	.....	.....	..(1).	.....
4c - Description of laboratory equipment and supplies?	.....	.....	..(1).	.....
4d - Laboratory credentials?	.....	.....	..(1).	.....
5 - Do the methods include specific QC requirements (type, frequency, acceptance, etc.)?	...X..	.....	.....	.....
6 - Are the analytical procedures approved, or equivalent to EPA procedures?	...X..	.....	.....	.....
7 - Are analytical costs included?	.....	.....	.....	...X..
7a - Are costs reasonable to meet objectives?	.....	.....	.....	...X..

Comments:

(1) No lab information has been given. We assume it will be submitted later.

X) Data Reduction, Validation and Reporting

IA IU NI NA

Reduction

- |   |        |       |       |       |
|---|--------|-------|-------|-------|
| 1 - Are units specified for all determinations?   | ...X.. | ..... | ..... | ..... |
| 2 - Are equations/procedures used to calculate concentrations included or referenced?         | ...X.. | ..... | ..... | ..... |
| 3 - Are the types of records to be maintained, described, including how and where stored?     | ...X.. | ..... | ..... | ..... |
| 4 - Are procedures included for transfer of data to forms, reports, etc.?                     | ...X.. | ..... | ..... | ..... |
| 5 - Are procedures for proofing (transcription errors) and cross-calculation checks included? | ...X.. | ..... | ..... | ..... |
| 6 - Are procedures for handling blank results described?                                      | ...X.. | ..... | ..... | ..... |

Validation

- |   |        |       |       |        |
|---|--------|-------|-------|--------|
| 1 - Are functions and scope specifically defined?   | ...X.. | ..... | ..... | .....  |
| 2 - Are techniques presented and summarized?  | ...X.. | ..... | ..... | .....  |
| 3 - Are criteria used to accept or reject data described in a uniform and consistent manner?<br>(See also Section XI)             | ...X.. | ..... | ..... | .....  |
| 4 - If CLP, does the Plan include provision for data review using the functional guidelines and qualified review personnel, etc.? | .....  | ..... | ..... | ...X.. |

Reporting

- |  |        |       |        |       |
|--|--------|-------|--------|-------|
| 1 - Is the flow or reporting scheme from collection of raw data through document storage included? | ...X.. | ..... | .....  | ..... |
| 2 - Are requirements for recordkeeping in field and lab notebooks described?                       | ...X.. | ..... | .....  | ..... |
| 3 - Are the key individuals who will handle or report data identified?                             | ...X.. | ..... | .....  | ..... |
| 4 - Are examples of forms and reports included?  | .....  | ..... | ..(1). | ..... |
| 5 - Does the Plan describe exactly what will be reported (e.g., QC results, etc.)?                 | .....  | ..... | ..(1). | ..... |

Comments:

- (1) These should be included.

XI) Internal QC Checks

	IA	IU	NI	NA
1 - Does Plan describe procedures for both field and lab?	...X..	.....	.....	.....
2 - Are the protocols used (spikes, surrogates, blanks, etc.) described for each parameter and matrix?	...X..	.....	.....	.....
3 - Are field and lab acceptance or control limits specified for each?	.....	.....	..(1).	.....
4 - Is the frequency of the checks described?	...X..	.....	.....	.....
5 - Is the system measuring total error/variability and not just sampling/lab error/variability?	...X..	.....	.....	.....
6 - Are the procedures described for internal QC checks consistent with the procedures used to assess precision and accuracy (Section XIV)?	...X..	.....	.....	.....

Comments:

**XII) Performance and System Audits**

	IA	IU	NI	NA
1 - Are audits addressed:				
1a - For field activities (sample collection, analyses, etc.)?	...X..	.....	.....	.....
1b - For lab activities?	...X..	.....	.....	.....
2 - Does the Plan identify who will conduct the audit(s)				
2a - for field activities?	...X..	.....	.....	.....
2b - for lab activities?	...X..	.....	.....	.....
3 - Does the Plan describe what protocol will be used for audits?				
3a - for field activities?	...X..	.....	.....	.....
3b - for lab activities?	...X..	.....	.....	.....
4 - Are acceptance criteria defined?				
4a - for field activities?	.....	.....	..(1).	.....
4b - for lab activities?	.....	.....	..(1).	.....
5 - Does the Plan describe distribution of audit reports?	.....	.....	..(1).	.....
6 - Is a schedule of audits included?	.....	.....	..(1).	.....
7 - Are quality control samples scheduled?	...X..	.....	.....	.....

Comments:

This information must be supplied.

XIII) Preventive Maintenance

IA IU NI NA

1 - Does the Plan include a maintenance schedule to minimize downtime?

1a - for field activities?

1b - for lab activities?

-2 - Is a spare parts list available?

3 - Is a source of spare parts identified?

4 - Is the source of repair described?

...X..	.....	.....	.....
...X..	.....	.....	.....
...X..	.....	.....	.....
...X..	.....	.....	.....
...X..	.....	.....	.....

Comments:

XIV) Specific SOPs Used to Assess Data Precision,  
Accuracy, Representativeness and Completeness

IA IU NI NA

1 - Relative to the objectives in Section V, does the Plan include protocols for monitoring whether requirements were met?

..... ..(1) .....

2 - Does the Plan include the equations used to calculate precision, accuracy (bias), and completeness?

..... ..(1) .....

3 - Does the Plan describe the methods used to gather information for precision and accuracy (bias) calculations?

..... ..(1) .....

4 - Are statistical procedures used documented?

..... ..(1) .....

Comments:

(1) This data must be submitted.

XV) Corrective Action for Out-of-Control Situations

1 - Does the Plan include a scheme to:

1a - Identify defects?

1b - Trace defects to source?

1c - Plan and implement correction?

1d - Document results of process?

1e - Document where documents are kept?

2 - Does the Plan include predetermined limits for data acceptability beyond which corrective action is required?

3 - Are procedures for corrective action (who initiates, who approves) included?

4 - Is feedback from performance audits (lab and field) addressed?

	IA	IU	NI	NA
1a - Identify defects?	...X..	.....	.....	.....
1b - Trace defects to source?	...X..	.....	.....	.....
1c - Plan and implement correction?	...X..	.....	.....	.....
1d - Document results of process?	...X..	.....	.....	.....
1e - Document where documents are kept?	.....	.....	..(1).	.....
2 - Does the Plan include predetermined limits for data acceptability beyond which corrective action is required?	.....	.....	..(1).	.....
3 - Are procedures for corrective action (who initiates, who approves) included?	...X..	.....	.....	.....
4 - Is feedback from performance audits (lab and field) addressed?	...X..	.....	.....	.....

Comments:

XVI) QA Reporting Procedures to Management

	IA	IU	NI	NA
1 - Does the Plan specify the type and frequency of reporting?	...X..	.....	.....	.....
2 - Do the reports address:				
2a - Status of project (time table)?	...X..	.....	.....	.....
2b - Results of performance and system audits?	...X..	.....	.....	.....
2c - Data quality assessment?	...X..	.....	.....	.....
2d - Significant QA problems and proposed corrective action?	...X..	.....	.....	.....
2e - Changes in the QAPjP?	...X..	.....	.....	.....
3 - Final Summary Report and distribution?	...X..	.....	.....	.....
3a - Final storage and security of data files?	.....	.....	..(1).	.....

Comments:

(1) Please identify storage location.