

General



560 Golden Gate Blvd, Suite 130
Golden, CO 80401
ENTERED
(303) 763-7188
(303) 763-8889 FAX
www.techlawinc.com

November 7, 2005

Mr. David Cobrain
State of New Mexico Environment Department
Hazardous Waste Bureau
2905 Rodeo Park Drive East
Building One
Santa Fe, New Mexico 87505-6303



Reference: Work Assignment No. 06110.290.0002; State of New Mexico Environment Department, Santa Fe, New Mexico; Human Health and Ecological Risk Assessment Support; Draft generic permit language for risk assessments and determination of background concentrations, Task 2 deliverable.

Dear Mr. Cobrain:

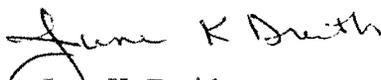
Enclosed please find the deliverable for the above-referenced work assignment. The deliverable consists of draft generic permit language for human health and ecological risk assessments as well as determination of background concentrations.

The text was drafted to be sufficiently specific so a facility would know the type of required information, but generic enough to allow for changes in EPA and/or State guidance. Please review the attached deliverable and if you have any questions or comments, we can modify the document accordingly.

The document is formatted in Word. The deliverable was emailed to you on November 7, 2005 at dave.cobrain@state.nm.us. A hard (paper) copy of the letter will be sent to you via mail.

If you have any questions, please call me at (303) 763-7188 or Ms. Paige Walton at (801) 451-2978.

Sincerely,


June K. Dreith
Program Manager

Enclosure

cc: Paige Walton, TechLaw



TASK 2 DELIVERABLE

**DRAFT GENERIC PERMIT LANGUAGE FOR RISK ASSESSMENTS AND
DETERMINATION OF BACKGROUND CONCENTRATIONS**

Human Health and Ecological Risk Assessment Support

Submitted by:

**TechLaw, Inc.
560 Golden Ridge Road
Suite 130
Golden, CO 80401-9532**

Submitted to:

**Mr. David Cobrain
State of New Mexico Environment Department
Hazardous Waste Bureau
2905 Rodeo Park Drive East
Building One
Santa Fe, New Mexico 87505**

In response to:

Work Assignment No. 06110.290

November 7, 2005

DRAFT GENERIC PERMIT LANGUAGE FOR RISK ASSESSMENTS AND DETERMINATION OF BACKGROUND CONCENTRATIONS

HUMAN HEALTH AND ECOLOGICAL RISK ASSESSMENTS

The Permittee shall prepare human health and ecological risk assessment report for determination of clean closure, risk-based closure, and/or in support of corrective action. Risk assessments shall be conducted in accordance with current and acceptable United States Environmental Agency (EPA), Regional EPA, and State of New Mexico guidance and methodology.

1. HUMAN HEALTH RISK ASSESSMENT METHODS

A risk assessment may be required for human receptors that are potentially exposed to site-related chemicals in environmental media. The risk assessment shall contain a conceptual site model (CSM), which shall aid in understanding and describing each site. The CSM shall address the following components:

- Identification of suspected sources,
- Identification of contaminants,
- Identification of contaminant releases,
- Identification of transport mechanisms,
- Identification of affected media,
- Identification of land use scenarios,
- Identification of potential receptors under current land use scenario,
- Identification of potential receptors under future land use scenario, and
- Identification of potential routes of exposure.

Potential human receptors under current and/or future land use scenarios may include residential, industrial, construction, and recreational. Other special receptors may be required on a site-specific basis.

1.1 Exposure Pathways

The identification of exposure pathways shall include a discussion of all potential pathways and justify whether the pathways are complete. Pathways that shall be considered include soil, groundwater, air, surface water, sediment, and biota. An evaluation of the potential for contaminants to migrate from soil to groundwater shall also be provided. The risk assessment shall also address exposure mechanisms for each exposure pathway, including ingestion, inhalation, dermal, and inhalation of volatile organic compounds volatilized from soil and/or groundwater.

1.2 Data Quality Assurance

The risk assessment shall include an evaluation of analytical data and the usability of the data in the assessment. Data validation shall be conducted in accordance with current EPA guidelines. The evaluation of data shall also include a comparison of detection limits with appropriate and current risk-based screening levels. Current EPA methodology for handling non-detects and replicates in the risk assessment shall be applied.

1.3 Constituents of Potential Concern

Appropriate EPA and/or State guidance shall be used to identify constituents of potential concern (COPCs). With the exception of chemicals attributed to field or laboratory contamination, all analytes detected in sampled media (i.e., soil, air, surface water, groundwater, biota, and/or sediment) shall be retained or eliminated as COPCs using one or more of the following processes:

- Site attribution analysis,
- Essential nutrients, and/or
- Risk-based toxicity screen.

Unless sufficient evidence and special circumstances can be provided by the Permittee, all detected organics not attributable to field or laboratory contamination shall be retained and treated as site-related chemicals.

Inorganics detected in site media shall be compared to an appropriate background data set to determine if concentrations are present at levels significantly above background. The site attribution analysis may consist of a tiered approach as follows:

- Comparison of maximum detected site concentrations to a background reference value (e.g., upper tolerance limit, UTL);
- If the site maximum exceeds the background reference value, and sample size is sufficient, statistically compare the site data set to the background data set using appropriate statistical analyses (e.g., Wilcoxon Rank Sum Test);
- Conduct a graphical analysis of site data and background data (e.g., histograms and/or box and whisker plots);
- Conduct a geochemical analysis of site data to a background reference chemical; and/or
- Evaluate essential nutrients and compare to recommended daily allowances and/or upper intake limits.

All inorganics for which the site attribution analyses indicate are present above natural background shall be retained as COPCs for the risk assessments.

1.4 Risk-Based Toxicity Screen

The Permittee may conduct a risk-based screening assessment to identify the COPCs that are likely to contribute significantly to risks calculated for each exposure scenario and exposure medium in order to focus the risk assessment on those chemicals that contribute the greatest significance to overall risk. The risk-based screening assessment shall consist of the comparison of the maximum detected site concentration to an appropriate risk-based screening level (e.g., New Mexico Soil Screening Levels or EPA Region 6 Soil Screening Levels). Chemicals for which the maximum detected site concentrations exceed the respective risk-based screening levels shall be retained for further risk analysis.

1.5 Exposure Point Concentrations

The Permittee shall determine exposure point concentrations (EPCs) that are representative of the concentrations of chemicals in each given medium to which a receptor may be exposed. EPA recommends a 95% estimate of the upper confidence limit (95% UCL) on the arithmetic mean be used as an EPC for chronic exposures. For acute exposures, the maximum detected site concentration shall be used as the EPC.

The EPCs shall be determined using statistical analyses that are data distribution and size dependent. EPA and/or State accepted guidance and methodologies shall be used, such as the ProUCL software.

EPCs shall be calculated for soil, groundwater, surface water, sediment, and biota.

EPA does not recommend estimating intakes for the air inhalation pathway, but rather compares estimated volatile/particulate air concentrations adjusted for exposure frequencies, duration, and time. For inhalation of volatiles/particulates from soil, EPCs shall be determined based upon the current EPA and/or State methodology, based upon the volatilization factor or particulate emission factor. Indoor air concentrations shall be determined using EPA and State accepted approaches, such as the EPA-recommended Johnson and Ettinger model.

1.6 Exposure Assumptions

The Permittee shall use EPA and/or State approved exposure assumptions. Exposure assumptions may be based upon site-specific data.

1.7 Toxicity Assessment

The Permittee shall use the most recently available toxicity factors to calculate carcinogenic and noncarcinogenic risks/hazards based upon the currently acceptable hierarchy of sources for toxicity data. Generally, the approved hierarchy is as follows:

- EPA's Integrated Risk Information System (IRIS),
- Provisional EPA National Center for Environmental Assessment (NCEA),
- Agency for Toxic Substances and Disease Registry (ASTDR), and
- Other EPA publications (such as the Health Effects Assessment Summary Tables (HEAST), Water Quality Criteria, and Health Advisories).

1.8 Toxicity Assessment

The Permittee shall quantitatively estimate the potential for carcinogenic (risk) and noncarcinogenic (hazard) effects for all chemicals with toxicity data and provide a discussion of uncertainties associated with the risk assessment. Cumulative effects for risk and hazard shall be determined.

For those chemical without toxicity data, appropriate surrogate data may be applied. If surrogate toxicity data are not available, risks/hazards shall be qualitatively addressed in the uncertainties section of the report.

1.9 Uncertainties

The Permittee shall provide an uncertainties section that discusses all assumptions, professional judgments, and data which may result in uncertainties in the final estimates of risk and hazard. The uncertainties shall also discuss whether risks/hazards may have been under or overestimated due to the assumptions made in the assessment.

2. ECOLOGICAL RISK ASSESSMENT METHODS

An ecological risk assessment may be required for receptors that are potentially exposed to site-related chemicals in environmental media. The ecological risk assessment process shall consist of a scoping assessment, a screening-level assessment, and if warranted, a site-specific assessment. Based upon the results of the scoping assessment, the Permittee shall demonstrate whether additional analyses are warranted. If the scoping assessment indicates that there is potential for ecological hazard, a screening-level ecological risk assessment shall be conducted. Based upon the results of the screening assessment, a site-specific ecological risk assessment may or may not be necessary.

2.1 Scoping Assessment

In order to assess whether ecological hazards are a concern at the site, the Permittee shall conduct a scoping assessment. The New Mexico Environment Department's "Site Assessment Checklist" and/or other current EPA and/or State guidance shall be used for conducting the scoping assessment. The site assessment checklist and/or scoping report shall contain the following information:

- Scope and intent,
- Specific site information (including site location and site characterization),
- Findings of a site investigation (including habitat and exposure pathway evaluation),
- Identification of ecological receptors of potential concern, and
- Preliminary conceptual site exposure model (including complete exposure pathways).

If the scoping assessment indicates that there are any rare, threatened, or endangered species or otherwise protected species use the property, and/or there are any species which are considered a

recreational or a commercial resource, and/or plants or animal species use the affected property for habitat or foraging and could come into contact with site contaminants, then the Permittee shall conduct a screening level ecological risk assessment.

2.2 Screening Level Ecological Risk Assessment

The screening level ecological risk assessment shall be conducted in accordance with current EPA and/or State approved methodologies. The Permittee shall establish ecologically based screening levels (EBSL) calculated using dietary exposure models and toxicity reference values (TRVs). The screening level hazard quotient shall be calculated for each constituent of potential ecological concern (COPEC) in each media using the maximum detected site concentration and the calculated EBSL. The assessment of overall risk shall include cumulative risk if more than one COPEC is present at a site.

2.3 Site-specific Ecological Risk Assessment

If the screening level ecological risk assessment indicates unacceptable risk, then the Permittee shall conduct a site-specific ecological risk assessment. The assessment shall be conducted using EPA and/or State approved guidance and methodologies. The ecological risk assessment shall follow the same methodologies outlined above in the human health risk assessment for determining COPEC and data quality assurance.

DRAFT GENERIC PERMIT LANGUAGE FOR RISK ASSESSMENTS AND DETERMINATION OF BACKGROUND CONCENTRATIONS

DETERMINATION OF BACKGROUND

The Permittee shall determine an appropriate background data set for inorganic constituents at the site. The Permittee shall determine whether one or more background data sets are appropriate depending on soil type and geology at the site. Background concentrations for groundwater shall be collected from upgradient wells. The background data set shall be representative of natural conditions unaffected by site activities and shall be statistically defensible. Sufficient number of background samples shall be collected for use in the risk assessment, including conducting site attribution analyses and comparison of data sets.

The Permittee shall provide summary statistics for background metals concentrations in each medium of concern and include the following information:

- Number of detects,
- Total number of samples,
- Frequency of detection,
- Minimum detected concentration,
- Maximum detected concentration,
- Minimum sample quantitation limit (SQL),
- Maximum SQL,
- Arithmetic mean,
- Median,
- Standard deviation, and
- Coefficient of variation.

The Permittee shall determine the 95% upper tolerance limit (UTL) for each metal using statistical methods that are distribution based.

Comparing Site Data to Background

The 95% UTL for each metal shall be used as the background reference value for use in screening assessments and determining whether metals are present in soil/groundwater/surface water/sediment due to site activities. The site maximum detected concentration shall be compared to the 95% UTL for each metal. If the site maximum detected concentration is greater than the background reference value, then additional site attribution analyses shall be conducted.

Site attribution analyses shall be conducted in accordance with current EPA and/or State accepted guidance. The site attribution analyses shall consist of a statistical comparison of the background dataset to the site data set, using distribution based tests such as the Wilcoxon Rank Sum Test.

If the results of the site attribution analyses indicate that the metal is present at the site above naturally occurring levels, then the Permittee shall include that metal as a site contaminant.