



Permit



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Mr. Dave Cobrain
Hazardous Waste Bureau
2905 Rodeo Park Dr. E/Bldg 1
Santa Fe, NM 87505

RE: References for Sections 11.10.3 through 11.10.6 of the Draft Los Alamos National Laboratory Hazardous Waste Permit

Mr. Cobrain:

Attached please find references justifying the content of Sections 11.10.3 through 11.10.6 of the Draft Hazardous Waste Permit for Los Alamos National Laboratory.

The references for Section 11.10.3, Chemical Analyses, are more generalized than for the other sections and as such, a single reference list has been provided that covers all requirements. More detailed references are provided for the other sections.

If you or any of your staff have questions, please contact me at (801) 451-2864 or via email at paigewalton@msn.com.

Thank you,

Paige Walton
AQS Senior Scientist and Project Lead

Enclosures

cc: Joel Workman, AQS (electronic)

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11.10.3 Chemical Analyses

References:

EPA 1986. US Environmental Protection Agency, "Test Methods for Evaluating Solid Waste – Physical/Chemical Methods," EPA/SW-846, 3rd Edition (1986) through update IV (January 2008)

EPA 2001: US Environmental Protection Agency, "EPA Requirements for Quality Assurance Project Plans," EPA QA/R-5, EPA/240/B-01/003, Washington, D.C. (March 2001).

EPA 2004. US Environmental Protection Agency, "Contract Laboratory Program National Functional Guidelines for Inorganic Data Review," OSWER 9240.1-45, EPA 540-R-04-004 (October 2004)

EPA 2008. US Environmental Protection Agency, "Contract Laboratory Program National Functional Guidelines for Superfund Organic Methods Data Review," EPA-540-R-08-01 (June 2008)

NELAC 2003. National Environmental Laboratory Accreditation Conference (NELAC), "Environmental Laboratory Accreditation Standard, EPA/600/R-04/003 (July 2003)

NMED 2009. New Mexico Environmental Department, DOE Oversight Bureau, "Quality Assurance Project Plan for Environmental Monitoring Programs," (April 2009)

11.10.4 Site-Specific Human Health Risk Assessment

The Permittees shall prepare a Human Health Risk Assessment Report in support of corrective action, and, if necessary, for closure in accordance with Permit Part 9. Should the Permittees be unable to meet the cleanup levels in Permit Section 11.4.2, they shall conduct a site-specific risk assessment in accordance with current and acceptable EPA, Regional EPA, and Department guidance and methodology (as updated). If the Department determines that a human health risk assessment work plan is necessary, The Permittees shall submit to the Department for its review and approval a workplan that includes, at a minimum, the site-specific exposure assumptions and any additional sampling needed to support the risk assessment. The Permittees shall prepare a Human Health Risk Assessment Report in support of corrective action, and, if necessary, for closure in accordance with Permit Part 9.

11.10.4.1 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: (NMED 2009, USEPA Region 8, USEPA 1989, and USEPA 2008)

- (1) identification of suspected sources;
- (2) identification of contaminants;
- (3) identification of contaminant releases;
- (4) identification of transport mechanisms;
- (5) identification of affected media;
- (6) identification of land use scenarios;
- (7) identification of potential receptors under current land use scenario;
- (8) identification of potential receptors under future land use scenario; and
- (9) 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.

References:

NMED 2009. Technical Background Document for development of Soil Screening Levels, Volume I: Soil Screening Guidance Technical Background Document.

<http://www.nmenv.state.nm.us/hwb/guidance.html>

USEPA Region 8. Site Conceptual Model. http://www.epa.gov/region8/r8risk/hh_scm.html

USEPA 1989. Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part A). http://www.epa.gov/oswer/riskassessment/ragsa/pdf/rags-vol1-pta_complete.pdf

USEPA (Region 6) 2008. Corrective Action Strategy, November. http://www.epa.gov/region6/6pd/rcra_c/pd-o/cas_final08.pdf

11.10.4.1.i Exposure Pathways

The identification of exposure pathways shall include of 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 (USEPA 1989). An evaluation of the potential for contaminants to migrate from soil to groundwater shall also be provided (NMED 2009 and USEPA 2009). 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 (USEPA 1989).

References:

NMED 2009. Technical Background Document for development of Soil Screening Levels, Volume I: Soil Screening Guidance Technical Background Document.

<http://www.nmenv.state.nm.us/hwb/guidance.html>

USEPA 1989. Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part A). http://www.epa.gov/oswer/riskassessment/ragsa/pdf/rags-vol1-pta_complete.pdf

EPA Region 6 2009: Regional Screening Levels Users Guide (EPA Region 6) http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/usersguide.htm

11.10.4.1.ii 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 (USEPA 1992 and USEPA 1996). The evaluation of data shall also include a comparison of detection limits with appropriate and current risk-based screening levels, if MDLs are inconsistent and do not achieve the requirements of Permit Section 11.10.3 (Chemical Analyses). Current EPA methodology for handling non-detects and replicates in the risk assessment shall be applied. (Gilbert 1987, USEPA 1996, and USEPA 2009)

References:

Gilbert, R.O. 1987. Statistical Methods for Environmental Pollution Monitoring. Van Nostrand Reinhold Co., New York.

USEPA 1996. Data Validation Guidance, Parts I-IV. <http://www.epa.gov/ne/oeme/index.html>

USEPA 2009. Statistical Software ProUCL 4.0 for Environmental Applications for Data Sets with and without Nondetect Observations. <http://www.epa.gov/esd/tsc/software.htm>

11.10.4.1.iii Constituents of Potential Concern

Appropriate EPA and/or the Department 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 (NMED 2009, USEPA 1989a, USEPA 1989b and USEPA 1994):

- (1) site attribution analysis;
- (2) essential nutrients; and/or
- (3) risk-based toxicity screen.

Unless sufficient evidence and special circumstances can be provided by the Permittees, all detected organics not attributable to field or laboratory contamination shall be retained and treated as site-related chemicals (USEPA 1989a).

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 (NMED 2009, USEPA 1989a, USEPA 1989b, USEPA 2002, and USEPA 1994):

- (4) comparison of maximum detected site concentrations to a background reference value (e.g., upper tolerance limit, UTL);
- (5) 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);. If the sampling size is not sufficient to perform statistical analysis, a comparison of the maximum site concentration to the maximum background concentrations shall be used;
- (6) conduct a graphical analysis of site data and background data (e.g., histograms and/or box and whisker plots);
- (7) conduct a geochemical analysis of site data to a background reference chemical; and/or
- (8) 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.

References:

NMED 2009. Technical Background Document for development of Soil Screening Levels, Volume I: Soil Screening Guidance Technical Background Document.
<http://www.nmenv.state.nm.us/hwb/guidance.html>

USEPA 1989a. Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part A). http://www.epa.gov/oswer/riskassessment/ragsa/pdf/rags-vol1-pta_complete.pdf

USEPA 1989b. Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities.
<http://www.hanford.gov/dqo/project/level5/statanal.pdf>

USEPA 2002. Guidance for Comparing Background and Chemical Concentrations in Soil at CERCLA Sites. EPA 540-R-01-003.
<http://www.epa.gov/oswer/riskassessment/pdf/background.pdf>

USEPA (Region 8) 1994. Evaluating and Identifying Contaminants of Concern for Human Health. http://www.epa.gov/region8/r8risk/pdf/r8_ra03-cocs.pdf

11.10.4.1.iv Exposure Point Concentrations

The Permittees 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. Current EPA methodology for handling non-detects and replicates in the risk assessment shall be applied. EPA recommends a 95% or greater estimate of the upper confidence limit (UCL \geq 95% UCL) on the arithmetic mean be used as an EPC for chronic exposures. If conditions are

identified where acute exposures must be evaluated, the maximum detected site concentration shall be used as the EPC. (NMED 2009, USEPA 1989, USEPA 2002a, and USEPA 2008)

The EPCs shall be determined using statistical analyses that are data distribution and size dependent. EPA and/or the Department accepted guidance and methodologies shall be used, such as the ProUCL software (USEPA 2009).

EPCs shall be calculated for soil, groundwater, surface water, sediment, and biota (NMED 2009, USEPA 1989, USEPA 2002a, and USEPA 2008).

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 Department methodology, based upon the volatilization factor or particulate emission factor. Indoor air concentrations shall be determined using EPA and Department accepted approaches, such as the EPA recommended Johnson and Ettinger model. (USEPA 1991 and USEPA 2002b)

References:

NMED 2009. Technical Background Document for development of Soil Screening Levels, Volume 1: Soil Screening Guidance Technical Background Document.
<http://www.nmenv.state.nm.us/hwb/guidance.html>

USEPA 1989. Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part A). http://www.epa.gov/oswer/riskassessment/ragsa/pdf/rags-vol1-pta_complete.pdf

USEPA 1991. Johnson and Ettinger Model for Subsurface Vapor Intrusion into Buildings.
http://www.epa.gov/oswer/riskassessment/airmodel/johnson_ettinger.htm

USEPA 2002a. Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites. OSWER 9285.6-10.
<http://www.epa.gov/oswer/riskassessment/pdf/ucl.pdf>

USEPA 2002b. OSWER Draft Guidance for Evaluating the Vapor Intrusion to Indoor Air Pathway from Groundwater and Soils (Subsurface Vapor Intrusion Guidance).
<http://epa.gov/osw/hazard/correctiveaction/eis/vapor.htm>

USEPA 2009. Statistical Software ProUCL 4.0 for Environmental Applications for Data Sets with and without Nondetect Observations. <http://www.epa.gov/esd/tsc/software.htm>

11.10.4.1.v Toxicity Assessment

The Permittees 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. (NMED 2009, USEPA 1989, and USEPA 2009)

References:

NMED 2009. Technical Background Document for development of Soil Screening Levels, Volume I: Soil Screening Guidance Technical Background Document.
<http://www.nmenv.state.nm.us/hwb/guidance.html>

USEPA 1989. Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part A). http://www.epa.gov/oswer/riskassessment/ragsa/pdf/rags-vol1-pta_complete.pdf

EPA Region 6 2009: Regional Screening Levels Users Guide (EPA Region 6)
http://www.epa.gov/reg3hwmd/risk/human/rb-concentration_table/usersguide.htm

11.10.4.1.vi Risk Characterization

The Permittees 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 for all media and pathways shall be determined. (NMED 2009 and USEPA 1989)

For those chemicals 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. (NMED 2009 and USEPA 1989)

References:

NMED 2009. Technical Background Document for development of Soil Screening Levels, Volume I: Soil Screening Guidance Technical Background Document.
<http://www.nmenv.state.nm.us/hwb/guidance.html>

USEPA 1989. Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part A). http://www.epa.gov/oswer/riskassessment/ragsa/pdf/rags-vol1-pta_complete.pdf

11.10.4.1.vii Uncertainties

The Permittees 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. (USEPA 1989)

References:

USEPA 1989. Risk Assessment Guidance for Superfund Volume I: Human Health Evaluation Manual (Part A). http://www.epa.gov/oswer/riskassessment/ragsa/pdf/rags-vol1-pta_complete.pdf

11.10.5 Site-Specific Ecological Risk Assessment Methods

If the screening level ecological risk assessment indicates unacceptable risk, then the Permittees shall conduct a site-specific ecological risk assessment. If the Department determines that an ecological risk assessment work plan is necessary, the Permittees shall submit to the Department for its review and approval a work plan that includes, at a minimum, the site-specific exposure assumptions and any additional sampling needed to support the risk assessment. In addition, the Permittees shall prepare a site-specific Ecological Risk Assessment Report in support of corrective action, and, if necessary, for closure in accordance with Permit Part 9 (*Closure*). The assessment shall be conducted using EPA and/or the Department approved guidance and methodologies. The ecological risk assessment shall follow the same methodologies outlined above in the human health risk assessment for determining constituent of potential ecological concern (COPEC) and data quality assurance. (NMED 2009 and 2008)

References:

NMED 2009. Technical Background Document for development of Soil Screening Levels, Volume II: Tier 1 Screening-Level Ecological Risk Assessment. <http://www.nmenv.state.nm.us/hwb/guidance.html>

NMED 2008. Guidance for Assessing Ecological Risks Posed by Chemicals: Screening-Level Ecological Risk Assessment, 2008. <http://www.nmenv.state.nm.us/hwb/guidance.html>

11.10.6 Determination of Background

The Permittees shall determine an appropriate background data set for inorganic constituents at the site. The Permittees shall determine whether one or more background data sets are appropriate depending on soil types 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. A 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 Permittees shall provide summary statistics for background metals concentrations in each medium of concern and include the following information:

- (1) number of detects;
- (2) total number of samples;
- (3) frequency of detection;
- (4) minimum detected concentration;
- (5) maximum detected concentration;

- (6) minimum sample quantitation limit (SQL);
- (7) maximum SQL;
- (8) arithmetic mean;
- (9) median;
- (10) standard deviation; and
- (11) coefficient of variation.

The Permittees shall determine the 95% upper tolerance limit (UTL) for each metal using a distribution-based statistical method.

References:

NMED 2009. Technical Background Document for development of Soil Screening Levels, Volume I: Soil Screening Guidance Technical Background Document.
<http://www.nmenv.state.nm.us/hwb/guidance.html>

Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites
<http://www.epa.gov/oswer/riskassessment/pdf/background.pdf>

Role of Background in the CERCLA Cleanup Program
http://www.epa.gov/oswer/riskassessment/pdf/bkgpol_jan01.pdf

USEPA 2009. Statistical Software ProUCL 4.0 for Environmental Applications for Data Sets with and without Nondetect Observations.
<http://www.epa.gov/esd/tsc/software.htm>

11.10.6.1 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 the subject media (e.g., 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 Permit Section 11.10.4.1.iii and current EPA and/or the Department accepted guidance. The site attribution analyses shall consist of a statistical comparison of the background data set to the site data set, if sufficient samples are available, 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 Permittees shall include that metal as a site contaminant.

References:

NMED 2009. Technical Background Document for development of Soil Screening Levels, Volume I: Soil Screening Guidance Technical Background Document.
ftp://ftp.nmenv.state.nm.us/hwbdocs/HWB/guidance_docs/NMED_June_2006_SSG.pdf

Guidance for Comparing Background and Chemical Concentrations in Soil for CERCLA Sites ***<http://www.epa.gov/oswer/riskassessment/pdf/background.pdf>***

Role of Background in the CERCLA Cleanup Program
http://www.epa.gov/oswer/riskassessment/pdf/bkgpol_jan01.pdf

USEPA 2009. Statistical Software ProUCL 4.0 for Environmental Applications for Data Sets with and without Nondetect Observations. ***<http://www.epa.gov/esd/tsc/software.htm>***