NEVADA DIVISION OF ENVIRONMENTAL PROTECTION
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STATE OF NEVADA

Department of Conservation & Natural Resources

DIVISION OF ENVIRONMENTAL PROTECTION

Brian Sandoval, Governor
Leo M. Drozdoff, P.E., Director
Colleen Cripps, Ph.D., Administrator

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Mark Paris
Basic Remediation Company
875 West Warm Springs Road
Henderson, NV 89011

Curt Richards
Olin Corporation
3855 North Ocoee Street, Suite 200
Cleveland, TN 37312

Jay Steinberg
NV Environmental Trust
35 East Wacker Drive, Suite 1550
Chicago, IL 60601

Joe Kelly
Montrose Chemical Corp of CA
600 Ericksen Ave NE, Suite 380
Bainbridge Island, WA 98110

Brian Spiller
Stauffer Management Co LLC
1800 Concord Pike
Wilmington, DE 19850-6438

Craig Wilkinson
Titanium Metals Corporation
PO Box 2128
Henderson, NV 89009

Re: **BMI Plant Sites and Common Areas Projects, Henderson, Nevada**
Revised Guidance on Qualifying Data due to Blank Contamination for the BMI Complex and Common Areas

Dear Messrs.:

All of the parties listed above shall be referred to as "the Companies" for the purposes of this letter. Attachment A of this letter provides revised guidance regarding the censoring of data due to blank contamination and should be utilized in the review and reporting of censored data. Please note that Attachment A is also posted on NDEP's website at http://ndep.nv.gov/bmi/technical.htm under "Data Validation."

Please contact the undersigned with any questions at sharbour@ndep.nv.gov or 775-687-9332.

Sincerely,

Shannon Harbour, P.E.
Supervisor, Special Projects Branch
Bureau of Corrective Actions
NDEP-Carson City Office
Fax: 775-687-8335

SH:s

ec: Jim Najima, Bureau of Corrective Actions, NDEP
Greg Lovato, Bureau of Corrective Actions, NDEP
William Knight, Bureau of Corrective Actions, NDEP
Michael Friend, Bureau of Corrective Actions, NDEP
Joe McGinley, McGinley & Associates

Brian Rakvica, McGinley and Associates
Brian Giroux, McGinley and Associates
Paul Black, Neptune and Company, Inc.
Kelly Black, Neptune and Company, Inc.
Dave Gratson, Neptune and Company, Inc.
Paul Hackenberry, Hackenberry and Associates
Kurt Fehling, The Fehling Group
Teri Copeland
Joanne Otani
Julie Panko, Chemrisk
Stephen Tyahla, U.S. EPA, Region 9, RCRA Corrective Action Office
Brenda Pohlmann, City of Henderson
Barry Conaty, Holland & Hart LLP
Ranajit Sahu, BRC
Lee Farris, BRC
Mark Jones, ERM
Alan Delorme, ENVIRON
Mark Travers, ENVIRON
Craig Wilkinson, TIMET
Kirk Stowers, Broadbent & Associates
Victoria Tyson, Tyson Contracting
Ed Modiano, de maximis
Lynne Preslo, GeoEco
Andrew Barnes, Geosyntec
George Crouse, Syngenta Crop Protection, Inc.
Nick Pogoncheff, PES Environmental
Lee Erickson, Stauffer Management Company
Curt Richards, Olin Corporation
Paul Sundberg, Montrose Chemical Corporation
Joe Kelly, Montrose Chemical Corporation of CA
Jeff Gibson, AMPAC
Jeanette Daniels, AMPAC

cc: David Sadoff, AIG Consultants, Inc., 121 Spear Street, 3rd Floor, San Francisco, CA 94105
Leslie Hill, U.S. Department of Justice, PO Box 23896, Washington, DC 20026-3986
Rick Kellogg, Basic Remediation Company, 2001 Kirby Drive, Suite 500, Houston, TX 77019
Robert Infelise, Cox Castle Nicholson, 555 California Street, 10th Floor, San Francisco, CA 94104-1513
Michael Ford, Polsinelli Shughart, Security Title Plaza, 3636 N. Central Avenue, Suite 1200, Phoenix, AZ 85012
Lee Erickson, Stauffer Management Company, P.O. Box 18890, Golden, CO 80402

Attachment A

Guidance on Qualifying Data due to Blank Contamination for the BMI Complex and Common Areas

1. Purpose

The purpose of this NDEP guidance document is to define rules for interpreting the effects of blank contamination on the reporting of sample concentrations. Previous to this NDEP guidance, NDEP rules for interpreting blank contamination were based on the USEPA National Functional Guidelines (NFG). Changes to the USEPA NFG for organic chemicals have led NDEP to reconsider how the effects of blank contamination should be interpreted. This NDEP guidance document first provides some background information that explains the evolution of USEPA and NDEP guidance, specifies new rules for interpreting blank contamination, and provides some examples of the types of data problems or issues that have been observed in datasets previously submitted for the BMI Complex and Common Areas.

2. Background

USEPA National Function Guidelines

Previous NDEP guidance specific to qualifying data due to blank contamination is found in the February 26, 2009 *Supplemental Guidance on Data Validation* (1) with additional clarification provided in the March 19, 2009 *Supplemental Guidance on Data Validation* (2). The February and March 2009 supplements were established by NDEP because of an updated version of the USEPA NFG for Superfund Organic Methods Data Review (3). The 2008 guidance from USEPA included a new algorithm for qualifying volatile organic chemical (VOC) results based on blank contamination, and the NDEP guidance extended this approach to semi-VOCs (SVOCs).

Historically the USEPA NFGs (4, 5) have defined a factor (e.g., 5X, 10X) that is used to determine whether sample results that are associated with blank contamination should be censored (reported as non-detects). Briefly the USEPA NFG rules report a sample result as detected if the sample concentration is greater than the blank concentration by some factor. Otherwise the result is reported as not detected. For some inorganic chemicals (5) this factor is 10X (see Table 4, page 17 for example). The 2008 (3) USEPA NFGs for Organic Methods Data Review revised this methodology for VOCs, eliminating the 5X and 10X rule, hence simplifying the rules for qualifying concentration data that are associated with blank contamination. However, the latest USEPA NFG for Inorganic Superfund Data Review (6) continues to use a complicated set of algorithms and multiplication factor rules to determine detection status of a sample concentration when there is blank contamination.

The USEPA NFGs indicate use of two sensitivity indicators, a method detection limit (MDL) and a contract required quantitation limit (CRQL). The CRQL is analogous to the practical quantitation limit (PQL), and the MDL is analogous to the sample quantitation limit (SQL) for the purposes of this NDEP guidance. The USEPA NFG rules depend upon the type of blank, and the concentrations of both blanks and samples compared to the associated MDL (SQL) and

CRQL (PQL). The multiplication factor (e.g., 5X, 10X) is used as described above, and if the sample result is reported as non-detect because of blank contamination, then it is reported at the CRQL (PQL), regardless of the actual concentration result.

<u>NDEP Considerations</u>

NDEP understands that the relative uncertainty around an analyte concentration is greater below the PQL, but does not believe using a single datum approach to decision-making, which is the basis of the USEPA NFG rules, is appropriate for the types of decisions encountered at the BMI Complex and Common Areas. Instead, background and risk-based decisions should be made based on all of the data, and complicated datum-specific rules that result in unnecessary censoring is inappropriate and can introduces bias into subsequent background comparisons and risk assessment.

NDEP considers two conditions that need to be considered when evaluating a single sample result (datum) for detection of an analyte in the presence of blank contamination. These conditions assume the blank and sample concentrations are both greater than the MDL/SQL (otherwise reporting of the sample result as a detect or as a non-detect at the SQL is clear) with:

1. One or more associated Blanks > Sample. The possible reasons are:
   a. The sample contains NO (significant) native analyte.
   b. The sample contains some percentage of native analyte.
2. The Sample > all associated Blanks. The possible reason is:
   a. The sample contains some percentage of native analyte.

For Case 1, the original USEPA NFG (4, 5) recommends censoring the sample result, in most cases at the CRQL (PQL). The presumption is that the majority, if not all, of the analyte in the native sample is from blank contamination. For a single datum such a simple and conservative decision might be reasonable, but NDEP does not regard this as reasonable in the context of data from a collection of samples. For the NDEP BMI Complex and Common Areas work, this sample result is rarely considered separately, but is used to understand the distribution of analyte concentration for background comparisons, comparison with applicable risk-based metrics, and estimation of exposure point concentrations. Following the original USEPA NFG (4, 5), the typical action is to censor at the PQL or perhaps at some multiple of this level (e.g. one half the PQL). This results in a biased distribution, which is often a high bias because most blank contamination is less than any PQL, <u>and is often less than one half of the PQL</u>. If instead, the sample concentration is reported, with an associated qualifier and reason code that explains the effect of blank contamination, then background and risk-based decisions can be made with better information. The reported concentration, the SQL and information about the associated blank contamination would be provided.

For Case 2, the original USEPA NFG (4, 5) also recommends censoring the sample result, unless the sample value is greater than the PQL with sufficient difference between the blank and sample values. The logic is that the sample value contains some amount of contamination, and is therefore only usable if there is sufficient confidence (some factor is used) that the native amount is (significantly) greater than the blank amount. If the sample result is less than the PQL, then the result can be censored at the PQL. Similar to Case 1, if the sample value as reported by the laboratory is reported with an associated qualifier and reason code, then more complete information is provided for decision-making.

There are a few other considerations that are important when considering the effect of potential blank contamination. For example, blank concentrations need to be compared to sample concentrations on an equal basis. If dilution factors, different matrices (soil versus water), or sample weights and volumes complicate the comparison, the comparison will need to be performed on the raw data (e.g. counts, areas). In addition, it is recognized that some analytical techniques have a sensitivity that will pick up a fairly static level of background signal. These techniques include High Resolution Mass Spectrometry (e.g. HR/GC of PCB congeners, and dioxin/furans) and ICP-MS. This static background is not the typical laboratory contaminant case such as phthalates or methylene chloride. In most cases these static levels are much less than important risk-based metrics. However, there are cases where laboratories have prevalent contamination that is observed in blank samples, and that can significantly impact sample data reporting and subsequent background comparisons and risk assessment. Examples in the NDEP BMI Complex and Common Areas include formaldehyde and in some instances metals using ICP-AES.

3. Requirements

All environmental concentration data collected from native samples that have associated blanks should be reviewed to identify if the native samples might have been contaminated. Sample data that are associated with blank contamination should not be censored for this quality control issue. However, during data validation the data should be qualified with an appropriate qualifier (e.g. J-flag, B-flag) and further characterized with an appropriate reason code and discussion if necessary. In cases where the same data are censored or rejected due to other quality assurance and control issues, this should be clear in the validation reports and electronic data deliverables (EDDs).

This is the required approach for organic, inorganic, and radionuclide measurement data. That is blank contamination must not be used alone to censor sample data. When blank contamination is associated with data, a qualifier and reason code should be applied in the data set (e.g. EDD). The potential impact of blank contamination should be discussed in the Uncertainty Analysis of the subsequent human health risk assessment (HHRA) report (or similar report). This should include a discussion of the potential impact of blank contamination on site date (e.g. high bias), background comparisons, and the HHRA. Also, the data used for HHRA will need to address all compounds associated with blank contamination issues. This needs to be first discussed in the Data Usability (DU) section of the HHRA and interpreted in the Uncertainty Analysis. These issues will be addressed via revisions to the NDEP's EDD guidance document.

These requirements apply to all new data reported for the BMI Complex and Common Areas. However, NDEP acknowledges that previously reported data have not followed these new NDEP requirements for reporting of data associated with blank contamination, and that some reports have been reviewed and approved based on previous requirements. NDEP does not require that historical data be subjected to the requirements specified here, but instead that previously validated data that are impacted by blank contamination will be discussed in the Uncertainty Analysis section of any report that uses such data. In so doing, a semi-quantitative comparison of the potential differences between approaches taken previously and the requirements specified herein will be described and explained in the Uncertainty Analysis section of any report that uses such data. The requirements specified herein will be applied to all data collected after June 2011.

NDEP further notes that the impact of addressing blank contamination issues following the requirement specified herein, or previous practice, are likely to be observed in background comparisons as well as risk assessment. A potential issue for background comparisons concerns censoring limits for reported data. This is particularly of concern because the background data were evaluated and reported using previous requirements for blank contamination. There are three possible outcomes – site concentrations for a chemical (metal or radionuclide) exceed background, do not exceed background, or cannot be determined. The latter outcome occurs if there are many non-detects in the data, and the SQLs for site and background data are different. In this case, the outcome of the background comparisons should be reported as not determined, and the chemical in question should be carried through to the HHRA.

4. Reasoning behind Recommended change in Qualifying Data

Censoring results in loss of data and therefore information. In cases where data quality indicators indicate sever bias, such as low spike recoveries, censoring is often justified. But in the case of blank contamination, the data should not be censored solely for this reason during data validation. Following the original USEPA NFGs (4, 5), censoring is performed *a priori*. This is before a complete understanding is gained of how the data will be used. By not censoring during the data validation step, but understanding the influence of blank contamination and including this information in the data usability evaluation, the full complement of data are still used and available for the decision making.

In many instances the approach taken when blank contamination is evident may have little influence on the ultimate decision(s). This is common when the concentrations of most samples are significantly greater than or less than any risk-based level of interest. Also, blank contamination is often insignificant with respect to the risk-based decisions that will be made. The most critical cases to consider are when the sensitivity of the analytical method is near background concentration levels or a risk-based comparison level (i.e., NDEP BCLs), and the blank contamination and sample concentrations are near the SQLs. For these cases, the full data set needs careful consideration to support a reasonable risk-based decision.

Many types of blank may be associated with a set of samples, including field, laboratory (calibration, preparation). It is impossible to associate a particular blank with a particular sample and it is possible that even though there is contamination of the blanks, this is not true for the samples. Recoveries of laboratory control spikes are one way to assess this. If the recovery is very close to the expected recovery, or even on the low side, any contamination in the blanks may not necessarily be associated with samples. USEPA guidance has always recommended comparing sample values against the highest blank in cases where more than one blank is associated with the sample. Since blank levels often change with time (continuing calibration blanks can show this) a more likely scenario is that blank contamination of samples is somewhat random.

There is an additional reason for not continuing to censor data due to blank contamination. This issue involves the relationship between the Companies and the commercial laboratories. When there are examples of blank contamination that are unexpected, the typical approach is to just censor the results and continue with the project. This provides no incentive for the laboratory to improve their operations. By not censoring the data, and considering the sample concentration data in the context of risk-based decisions, the impact of these laboratory practices will become more apparent and hopefully improved upon.

5. Example Data Sets

Results from a number of BMI Complex and Common Areas projects were reviewed to show instances where blank censoring has resulted in data sets that were impacted by blank censoring. In most instances the effect is to bias the data set high, since the censored level is greater than the sample reported (actual) value. In several cases large numbers of data were censored well above the original reported levels. Data from the BRC Mohawk Sub-Area Soil Investigation (Datasets 52, 52a, 52b) are provided as examples below.

Results from 83 samples collected at the Mohawk site for antimony were all adjusted to due blank contamination. The mean and median values of the actual reported samples (unadjusted) were 0.33 and 0.31 mg/kg respectively. In most cases the values were adjusted up to the quantitation limit of 1 mg/kg, in some cases higher. The resulting mean and median values are 1.33 and 1 respectively. This resulting shift in the distribution to these much higher central values impacts the comparison of this data set to background values. Data from the 2010 Background Soil Compilation Report, Table 2 shows both the censored (non-detect) data (mean and median values of 0.33 and 0.24 respectively) and detect data (mean and median values of 0.199 and 0.175 respectively) are below these adjusted Mohawk mean and median values.

For boron, the Mohawk uncensored mean and median values are 7.35 and 7.05 respectively with the censored values at 34.4 and 21.75. These censored values are well above the background levels for boron where the mean and median values in the detected data set are 7.85 and 6.6. Similar examples can be shown for mercury, thallium, molybdenum, and selenium.

In both cases, background comparisons might fail (suggest site concentrations are greater than background) because of censoring due to blank contamination, when, in fact, the background comparisons would not fail if blank contamination is addressed using the requirements specified herein.

Other more general concerns include uranium-235. U-235 exists naturally at very low activity concentrations compared with activity concentrations for other uranium isotopes of interest and compared to analytical sensitivity. However, following past practice, if there is blank contamination for U-235 sample results, then the result might be censored at a PQL, which is often around 1 pCi/g. This is much greater than the concentration levels in background samples, and can result in incorrect conclusions that uranium activity concentrations exceed background. Note also that NDEP requires that radionuclide data must not be censored for statistical analysis.

6. Required Changes

NDEP is recommending that instead of censoring any data due to blank contamination at the data validation step, the Companies should follow the same approach taken by the laboratories. That is, a qualifier should be applied to the associated data along with sufficient information to understand the level of contamination relative to that found in the samples. These data will therefore be assigned a qualifier with an associated reason code indicating blank contamination is associated with the results. These data will be carried through to the data usability and analysis process. By using a single common approach across all data sets where contamination is recognized but data are not censored during data validation, data comparability is more likely.

The impact of the blank contamination will be evaluated in the data usability analysis and considered within the context of any decisions in the Uncertainty Analysis sections of data or risk-based reports. Contamination will need to be considered on an equal basis and dilution factors, different matrices (soil versus water), or sample weights and volumes recognized.

7. References

(NDEP, 2009a) NDEP. (February 26, 2009). Supplemental Guidance on Data Validation. Available at http://ndep.nv.gov/bmi/technical.htm#data.

(NDEP, 2009b) NDEP. (March 19, 2009). Supplemental Guidance on Data Validation. Available at http://ndep.nv.gov/bmi/technical.htm#data.

(US EPA, 1999) US EPA. (October 1999) National Functional Guidelines for Organic Data Review. EPA 540-R-99-008.

(US EPA, 2004) US EPA. (October 2004). National Functional Guidelines for Inorganic Data Review. EPA 540-R-04-004.

(US EPA, 2008) US EPA. (June 2008). National Functional Guidelines (NFG) for Superfund Organic Methods Data Review. EPA- 540-R-08-01. Available at http://epa.gov/superfund/programs/clp/guidance.htm

(US EPA, 2010) US EPA. (January 2010). National Functional Guidance for Inorganic Superfund Data Review. EPA-540-R-10-011