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Department of Conservation & Natural Resources
DIVISION OF ENVIRONMENTAL PROTECTION

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Re: **BMI Plant Sites and Common Areas Projects, Henderson, Nevada**
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 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,

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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* (NDEP, 2009a) with additional clarification provided in the March 19, 2009 *Supplemental Guidance on Data Validation* (NDEP, 2009b). 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 (US EPA, 2008). 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 (US EPA, 1999; US EPA, 2004) 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 (US EPA, 2004), this factor is 10X (see Table 4, page 17 for example). The 2008 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 (US EPA, 2010) 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.

NDEP Considerations

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 NDEP believes that background and risk-based decisions should be based on all of the data and not complicated datum-specific rules that result in unnecessary censoring that can introduce 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:
 - c. The sample contains some percentage of native analyte.

For Case 1, the original USEPA NFG (US EPA, 1999; US EPA, 2004) in most cases recommends censoring the sample result 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, a 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 (US EPA, 1999; US EPA, 2004), 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, and is often less than one half of the PQL. 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 (US EPA, 1999; US EPA, 2004) 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 data 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).

To accommodate these changes to NDEP guidance for blank contamination, additional reason codes need to be developed to accommodate blank contamination issues that address cases of:

3. No effect from blank contamination,
4. Potential effect on site data (e.g., high bias), and
5. Background data effect (e.g., effect of high bias on background comparisons).

Please note that these issues will be addressed via revisions to the NDEP's EDD guidance document under separate cover.

This is the required approach for organic, inorganic, and radionuclide measurement data: blank contamination must not be used alone to censor sample data.

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 background comparisons and on the HHRA. Also, the data used for HHRA will need to address all compounds associated

with blank contamination issues and needs to be first discussed in the Data Usability (DU) section of the HHRA and then interpreted in the Uncertainty Analysis.

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. However, NDEP is requiring that previously validated data that are impacted by blank contamination be discussed in the Uncertainty Analysis section of any report that uses such data so that 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 requirements 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] 1) exceed background, 2) do not exceed background, or 3) cannot be determined. Outcome 3 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.

6. Reasoning behind Recommended change in Qualifying Data

Censoring results in loss of data and information. In cases where data quality indicators indicate severe bias, such as low spike recoveries, censoring is often justified. However 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* before a complete understanding is gained of how the data will be used. By not censoring during the data validation step, 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. Additionally, 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.

Lastly, there is an additional reason for not continuing to censor data due to blank contamination that 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 inspire improvement.

7. 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 and 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, respectively. 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, respectively. 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. Please note that NDEP requires that radionuclide data must not be censored for statistical analysis.

8. 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 by applying a qualifier 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 with dilution factors, different matrices (soil versus water), or sample weights and volumes recognized.

9. 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