STATE OF NEVADA
Department of Conservation & Natural Resources
DIVISION OF ENVIRONMENTAL PROTECTION
Jim Gibbons, Governor
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NEVADA DIVISION OF ENVIRONMENTAL PROTECTION
protecting the future for generations

April 13, 2009

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Re. **BMI Plant Sites and Common Areas Projects, Henderson, Nevada**
Supplemental Guidance on Data Validation

Dear Sirs and Madam:

All of the parties listed above shall be referred to as "the Companies" for the purposes of this letter. The Nevada Division of Environmental Protection (NDEP) provides supplemental guidance on data validation in Attachment A.

Please contact me with any questions (tel: 702-486-2850 x247; e-mail: brakvica@ndep.nv.gov).

Sincerely,

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Attachment A

NDEP Data Verification and Validation Requirements – Supplement April, 2009

This supplemental guidance combines all previous data verification and validation guidance associated with the BMI Complex and Common Areas work and also incorporates recent United States Environmental Protection Agency (USEPA) guidance into a single document. This document supersedes the prior NDEP guidance: May 3, 2006, *Guidance on Data Validation Procedures* (1), and February 23, 2007, *Additional Guidance on Data Validation Procedures* (2). It also incorporates the *Supplemental Guidance on Data Validation* (3), dated February 26 and March 19, 2009.

The new guidance that is incorporated here is based on the USEPA document, *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use* (4), OSWER January, 2009. This new USEPA guidance is being incorporated into the verification and validation steps at the BMI Complex and Common Areas because it provides a consistent set of terms for each stage of data validation (DV). The prior BMI Complex and Common Areas DV guidance used terms based on the DRAFT *EPA Region 9 Superfund Data Evaluation/Validation Guidance* (5). This guidance has never been finalized since the 2001 draft.

New Guidance for Data Validation:

There are many terms used in verifying and validating environmental data that have an historical origin that are imprecise and in some cases outdated. These terms may be generally understood but no longer have a current reference point. The USEPA Guidance (1) incorporates terminology correlated with verification and validation steps that provide transparency and consistency in the DV process. For example, the new guidance categorizes DV Stages based upon sample specific and instrument specific quality control (QC). It provides explicit details as to what needs to be reported and what is to be validated at each Stage. There are differences between the analytical methods in the USEPA Contract Laboratory Program (CLP) Program (from which this new USEPA Guidance is derived) and the methods used at the BMI Complex and Common Areas (e.g. Resource Conservation and Recovery Act (RCRA) based), however, there is sufficient overlap such that the DV language is applicable to the BMI Complex and Common Areas methods and the use of the Stages language in this new USEPA guidance will be valuable to the BMI Complex and Common Areas quality assurance (QA) program.

This guidance does not propose any significant revisions with how data are validated, but we request use of the terminology in this new USEPA Guidance (4) as a common lexicon of terms to be used by the Companies when reporting validated data. Additional details are provided below describing how to use this new guidance for data collected at the BMI Complex and Common Areas.

We request that the Companies begin using the following Stages terminology in their Data Validation Summary Reports (DVSR) and electronic data deliverables (EDD) reports (where applicable):

Stages and Processes Used to Verify and Validate Lab Analytical Data:

Stage 1: Verification and validation based only on completeness and compliance of sample receipt conditions, sample characteristics, and basic analytical results

Stage 2A: Verification and validation based on completeness and compliance checks of sample receipt conditions and ONLY sample-related QC results

Stage 2B: Verification and validation based on completeness and compliance checks of sample receipt conditions and BOTH sample-related and instrument-related QC results

Stage 3: A verification and validation based on completeness and compliance checks of sample receipt conditions, both sample-related and instrument-related QC results, AND recalculation checks against the laboratory reported results

Stage 4: A verification and validation based on completeness and compliance checks of sample receipt conditions, both sample-related and instrument-related QC results, recalculation checks, AND the review of actual instrument outputs

The recommended minimum baseline checks that are to be followed for each stage of analytical data are shown in Appendix A of the USEPA Guidance. Using this new language, all data collected at the BMI Complex and Common Areas should be validated at least to Stage 2B . Also, items of particular note found in Appendix A of the USEPA Guidance (4) are identified below.

The QC acceptance criteria that are to be used in evaluation of the data will come from the NDEP Guidance [e.g. *Supplemental Guidance on Data Validation* (3)] along with Companies Work Plans, Quality Assurance Project Plans (QAPPs), standard operating procedures (SOPs), or Laboratory established criteria as described in the analytical methods. The origin of these criteria should be clearly documented in the data validation summary report (DVSR). For example, the DVSR should cite the document (e.g. SOP) that describes the specific acceptance criteria for continuing calibration.

For Requested Reporting Limits discussion in Section 1.1(5) of Appendix A of the USEPA Guidance (1). The Companies should ensure that the reporting limits are consistent with the NDEP Guidance *Detection Limits and Data Report* (December 3, 2008).

In addition, at least 10% of all data within a DVSR should be validated to Stage 4. Our 2006 guidance (1) on DV indicated this is calculated based on the number of data packages validated within a DVSR. To clarify, the criterion to use is calculated based on the total number of samples times the total number of analytical suites [e.g. semi-volatile organic compounds (SVOCs), radionuclides, organochlorine (OC) Pesticides]. If at least 10% of the samples with a similar number of analytical suites are chosen, this criterion is achieved.

This Updated Guidance is consistent with the NDEP's May 3, 2006 Guidance:

The requirement that all sample results be validated to Stage 2B and at least 10% are to be validated to Stage 4 is consistent with our prior guidance. Note that Stage 2B includes, among others items, the check of initial and continuing calibration information. Our guidance does not require 100% of this to be validated. Consistent with the previous guidance only a random check of 10-20% is required. The USEPA guidance uses the term Deuterated Monitoring Compound (DMC), which is analogous to a

surrogate compound as applied in most instances under the methods used at the BMI Complex and Common Areas. Also note that providing the reports specified in Stage 4 (instrument reports) in an electronic format for all results is requested to minimize the length of the DVSR hard copy reports.

At least 10% of all data are to be validated to Stage 4. Consistent with our previous guidance, only 10-20% of these samples need to have the recalculation checks (described in Stage 3 of the new USEPA guidance), and 5% of those samples should have the integration and mass spectrum match comparisons (described in Stage 4 of the new guidance). When calculating the percentage of data that need to be validated for recalculation and integration or mass spectrum matches, the algorithm is also based on the number of samples times the number of analytical suites. To meet this, choose a group of samples with a similar number of analytical suites and validate the appropriate percentage. The Companies are also encouraged to select data based upon historical results where a historically higher number of qualified data were observed.

This Updated Guidance is consistent with the NDEP's February 23, 2007 Guidance:

Validated data are to be provided in a summary report (hard copy and electronic format) along with a database (EDD) and laboratory reports (electronic format, include Chain-of-Custodies) for all samples validated. All laboratory reports should include a Case Narrative and other required reporting items consistent with the Nevada Laboratory Certification program. Any third party validation that was used to prepare the summary report should also be provided in electronic format. The database supplied with the summary report should only include the results that were validated (i.e., do not include historical data) and should also follow the *Guidance on Uniform Electronic Data Deliverables* (6). The data should also include the QC results (blanks, spikes, surrogates, etc) and other information desired by the Companies in separate database table(s). The EDD should specify the Stage of validation for each record in the validation level field. Please note that the revised EDD format is being developed by the NDEP based upon comments from the Companies. The revised EDD format will address this issue.

The following information is requested with the data validation summary reports:

- An Introduction with Purpose/Objective/Process. The report should describe the matrices sampled, along with the applicable sampling techniques or a reference to the exact work plan where this information can be found.
- Complete descriptions of the sensitivity indicator terms (sample quantitation limit (SQL), practical quantitation limit (PQL), quantitation limit (QL), etc.,) used in the report and EDD. See additional information on this topic in the NDEP *Guidance on Detection Limits and Data Reporting* (7), dated December 3, 2008.

- Details on the applicable samples and sample delivery group (SDG) identification numbers (IDs), that correspond to locations and sampling time, analyses performed (analytical suites), stage of validation performed (e.g.: 2B, 4). Any non-typical sampling or sample handling that was performed should be described (e.g. filtering).
- A data validation qualifier definition
- Reason codes that link results in the database to specific qualifier logic
- Data validation findings for each parameter based on the level of review. When non-conformances are identified they should be linked to the appropriate sample(s) and SDG.

When professional judgment is used to arrive at a decision, the logic should be clearly described. Please justify decisions (use of professional judgment) that don't follow the typical data validation algorithms.

- Evaluation of the Precision, Accuracy, Reproducibility, Comparability, Completeness, and Sensitivity (PARCCS) parameters
- Conclusions/Recommendations
- References
- The DVSRs should include tables that specify when a non-conformance has been identified during the data validation process. Providing these tables in both hardcopy and electronic (ideally in a spreadsheet or database format) will facilitate review of the DVSR and subsequent usability evaluation. These tables should be categorized by issue, for example, those samples qualified due to Laboratory Control Sample exceedances should be within the same table. Each table should specify the sample, SDG/lab package, the analyte(s), the data quality indicator and objective (e.g., % Recovery, Limits of 85-115%), the sample result(s) and the data validation qualifier(s). Both the qualifier based on this non-conformance issue and the overall qualifier applied to this datum should be provided to help understand the qualifiers supplied in the QC database table and EDD. This information is necessary to both properly evaluate the DVSR and will also facilitate data usability investigations. Each data quality indication, for example, percent recovery, percent difference, precision (relative percent difference (RPD)), area (for internal standards), raw level of blank value that is used to compare with analyte levels in the native samples, cooler temperature, holding time days and exceedance should be captured in these tables.

References

1) NDEP *Guidance on Data Validation Procedures*. May 3, 2006.
2) NDEP *Additional Guidance on Data Validation Procedures*. February 23, 2007,
3) NDEP *Supplemental Guidance on Data Validation*. February 26 and March 19, 2009
4) USEPA *Guidance for Labeling Externally Validated Laboratory Analytical Data for Superfund Use*, OSWER January, 2009. EPA 540-R-08-005.
5) USEPA *Region 9 Superfund Data Evaluation/Validation Guidance* (DRAFT). December 2001. R9QA/006.1.
6) NDEP *Guidance on Uniform Electronic Data Deliverables*. February 27, 2009 (revision pending).
7) NDEP *Guidance on Detection Limits and Data Reporting.* December 3, 2008.