BEFORE THE DEPARTMENT OF ENVIRONMENTAL QUALITY
OF THE STATE OF MONTANA

In the matter of the amendment of ARM 17.55.109 pertaining to incorporation by reference	)))	NOTICE OF AMENDMENT (CECRA)

TO: All Concerned Persons

1. On March 13, 2014, the Department of Environmental Quality published MAR Notice No. 17-357 regarding a notice of proposed amendment (no public hearing contemplated) of the above-stated rule at page 436, 2014 Montana Administrative Register, Issue Number 5.

2. The department has amended the rule as proposed, but with the following changes, stricken matter interlined, new matter underlined:

17.55.109 INCORPORATION BY REFERENCE (1) through (3) remain as proposed.

(4) The references adopted in (1)(c) through (1)(f) are to be used as screening levels. When the department uses screening levels referenced in (1)(d) and (1)(e) rather than site-specific data to make a listing decision under ARM 17.55.108, it shall use the higher applicable screening level provided for in (1)(d) or (1)(e). ~~and t~~The department's use of these screening levels for purposes of ARM 17.55.108(1) does not establish these levels as cleanup standards.

(5) remains as proposed.

3. The following comments were received and appear with the department's responses:

COMMENT NO. 1: The background concentrations should be published in the amendment rather than incorporating the document by reference.

RESPONSE: The Montana Administrative Procedure Act provides for incorporation by reference of publications and the format used in this rulemaking is standard for agency rulemaking as well as with the way the existing rule was adopted. The background study containing Table 4-4, which identifies the background concentrations, is available on the department's web site and the table would be difficult to publish legibly on an ARM page, because of the number of columns in the table.

COMMENT NO. 2: The proposed amendment should incorporate the entire background study report, as it contains important information regarding sample collection procedures and data evaluation processes.

RESPONSE: The background study containing Table 4-4, which identifies the background concentrations, is available on the department's web site. The department does not agree that it is necessary to include the entire study in the incorporation rule, as the department is not adopting sample collection procedures

and data evaluation processes, but only the background values themselves. This is consistent with the way the other publications already incorporated by reference are adopted.

COMMENT NO. 3: One commenter noted that the proposed amendment was not developed with representation of a stakeholder group. Another commenter requested that the department enlist a stakeholder group to discuss the rule and, if the department moved forward without consultation with the stakeholder group, requested a hearing on the rules prior to adoption.

RESPONSE: Following receipt of these comments, the department convened a stakeholder group meeting and discussed the proposed rule amendment. The department and stakeholders had a productive dialogue and no one voiced any objection to the department proceeding to adopt the proposed amendment. As the requested consultation meeting was held, the department is not holding a hearing on the proposed rule amendment.

COMMENT NO. 4: The study to establish statewide background concentrations was not developed with input from the regulated communities and it may not be appropriate to establish these concentrations due to differing geology, land use, and population density across the state.

RESPONSE: The department, through its retained consultant, conducted the background study with the goal of identifying generic Montana-specific background concentrations of inorganic constituents in surface soil that could be used for initial screening of sites. The department does not agree that the study required the input from the regulated community, as conducting the study is within the department's expertise and is part of the department's administration of CECRA. In the absence of the background study, EPA regional screening levels, which in many cases provide levels far below the Montana-specific background levels contained in Table 4-4, would be used for screening inorganic constituents. Therefore, there is a benefit to the regulated community in the event that sites which may have exceedances of regional screening levels do not exceed the background levels, thus avoiding listing on the CECRA priority list.

COMMENT NO. 5: The preference for locally derived background data should be included in the proposed amendment.

RESPONSE: The requirement to consider site-specific background data when available is already provided for in ARM 17.55.108(5).

COMMENT NO. 6: The data set used to derive the background values should be made available via the department's web site in spreadsheet format.

RESPONSE: The department will place the spreadsheet containing the data on the web site as requested.

COMMENT NO. 7: Background values should not be established based on the fines fraction data set since fines fraction is not a standard soil analytical procedure.

RESPONSE: The standard soil analytical procedure for lead is analysis of the fine (<250 µm or 60-mesh sieved) fraction, because the smaller particles are more likely to be inadvertently ingested and more likely to adhere to the skin (EPA Superfund Lead-Contaminated Residential Sites Handbook, August 2003). The department designed the background study to include a comparison of bulk versus fine fractions to determine whether it is appropriate to analyze the sieved portion of samples for all metals, rather than only sieved samples for lead analysis. A statistical analysis of the study results revealed a prevalence of higher concentrations of metals in the fine fraction than in the bulk fraction. Therefore, it is appropriately protective for the department to base the background values on the fine fraction and to compare those values to sieved sample concentrations.

COMMENT NO. 8: The sample interval used in the background study (zero to six inches) is not consistent with the Tier 1 Surface Soil Risk-based Screening Levels which used a zero to two-foot interval. Therefore, the background values are not applicable to the appropriate surface soil interval.

RESPONSE: Because of the way the undisturbed sample locations were chosen in the background study, the composition of the soil from six to twenty-four inches is not expected to differ from the sampled interval of zero to six inches. If a potential site exhibited different characteristics, the option for site-specific background data collection is provided for in ARM 17.55.108(5).

COMMENT NO. 9: Composite samples were not properly homogenized in the field. The samples were placed in a Ziploc bag and should have been mixed in a stainless steel bowl using stainless steel utensils.

RESPONSE: The department is not aware of information that indicates compositing samples in a stainless steel bowl is any better than the use of a Ziploc bag, nor that there is any requirement to do so.

COMMENT NO. 10: Field duplicates were collected as splits of the regular composite soil sample, which only evaluates the precision of the analytical laboratory and not the entire data collection program.

RESPONSE: Field duplicate samples are designed to monitor overall sampling and analytical precision. Soil field duplicates are typically collected by collecting a grab or composite sample, homogenizing the sample, and splitting the sample into two equal aliquot parts. Since both the parent sample and the duplicate sample are collected in exactly the same manner, this method evaluates both sampling and analytical precision. Given the heterogeneity of soils, this method is preferable to collocated samples. EPA Region IX [Sampling and Analysis Plan (Field Sampling Plan and Quality Assurance Project Plan) With Guidance, March 1997], the EPA Environmental Response Team (Standard Operating Procedure Six Quality Assurance/Quality Control Samples, February 1992), and the state of New Jersey (Field Sampling Procedures Manual, August 2005) all recommend homogenization of field duplicate soil samples.

COMMENT NO. 11: Two surface soil samples per county are not sufficient to allow a statistical evaluation of constituent concentrations at the county level. The

sample program did not evaluate population distribution, land use, or other factors that might logically be used to select a sample distribution.

RESPONSE: The sampling design provides for complete geographic coverage of the state with 112 total samples (excluding quality control samples). This data set is adequate for evaluation of statewide background concentrations. Areas of the state where inorganic concentrations have been more influenced by population, land use, or other factors may be evaluated using site-specific background concentrations.

COMMENT NO. 12: It may not be appropriate to combine the data sets across the state given the different land-forms throughout the state. Additional statistical evaluation is needed to determine if a statewide background concentration is statistically appropriate.

RESPONSE: The background study is based upon an evaluation of background inorganic concentrations across the state. Without the use of this state-specific level for screening purposes, the department would use the regional screening levels, which, in many cases, are more conservative and could result in the listing of sites unnecessarily. The department agrees that the use of site-specific background for screening is appropriate, if such data exists, and ARM 17.55.108(5) provides for this.

COMMENT NO. 13: The statistical value used as the background value was the 95 percent upper tolerance limit (UTL) with 90 percent coverage. A coverage rate of at least 95 percent or higher should be used to minimize the possibility of characterizing clean sites as being contaminated. EPA's ProUCL software guidance implies that 95 percent confidence UTL with 95 percent coverage is typical for calculating a background value. ProUCL provides the upper simultaneous limit (USL) which could be considered for use as it would not be subject to false positives. Sites with soil concentrations that exceed the USL of 95 percent should not be considered contaminated.

RESPONSE: The department chose to evaluate the background study data using a UTL with a 95 percent confidence limit with 90th percentile coverage based upon federal and state guidance and on the need to be appropriately protective of human health while providing a realistic characterization of naturally occurring inorganics in soil. Nearly every background inorganic compound data set was lognormally distributed, which precluded the selection of a statistic that would include a larger portion of the population. The EPA Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities Unified Guidance (EPA 2009) cautions that "UTLs based upon lognormal distributions are typically higher…than other parametric or nonparametric UTLs." It is the department's responsibility to be appropriately conservative and protective of human health in its screening process. Therefore, it is more important that the department avoid false negatives than false positives.

COMMENT NO. 14: The use of the 95 percent UTL with 95 percent coverage would not modify the current arsenic action limit of 40 mg/kg. Also, lowering the action level could reopen sites with concentrations below the current arsenic action

limit, but higher than the proposed background level. If the proposed background values were based on the 95 percent UTL with 95 percent coverage, the department would not need to expend resources to reevaluate sites for potential reopening.

RESPONSE: Please see Response to Comment No. 13 regarding use of the 95 percent UTL with 95 percent coverage. Also, the department does not anticipate reopening or reevaluating sites that have already been closed based solely upon the change in the arsenic screening level.

COMMENT NO. 15: ProUCL recommends that a point-by-point comparison of individual samples be used only for a small number of site observations due to the likelihood of generating false positive errors with larger sample numbers. For example, collection of only seven samples from a clean site would result in a greater than 50 percent probability that at least one sample would exceed the background value. This could result in false positive results, requiring unwarranted additional investigation. The background values will routinely falsely identify clean sites as being contaminated and place unwarranted demands on department and responsible party resources.

RESPONSE: The department intends that point-by-point comparisons to the background levels be the first step in the screening process, with site-specific background analysis and/or other statistical analyses available as appropriate. The EPA ProUCL Version 5.0.00 Technical Guide (EPA 2013) cited by the commenters actually states on page 20 that this is appropriate. Specifically, the guidance provides that, "A site observation exceeding a background UTL may lead to the conclusion that the constituent is present at the site at levels greater than the background concentrations level." Page 21 of the guidance further states that point-by-point comparisons are useful to "1) screen and identify the contaminants/ constituents of potential concern (COPCs), 2) identify the potentially polluted site areas of concern (AOCs), or 3) continue or stop remediation or excavation at an onsite area of concern." These are exactly the types of decisions for which the department proposes to use the UTLs. Statistically, there is 95 percent confidence that only 10 percent of any number of samples collected from a population that truly represents background would exceed the department's background values. EPA's caution regarding point-by-point comparisons and background values relates to the need to evaluate realistic exposures in areas large enough to have more than six samples, not that additional point-by-point comparisons may change the probability of exceedance. The commenters appear to be incorrectly applying the increase in probability of exceeding any one of a set of criteria for multiple parameters every time a new parameter is added to the criteria with the probability of collecting additional samples or an entire new data set.

COMMENT NO. 16: If used, the background values in Table 4-4 should be rounded to the number of significant digits reported in the underlying data set.

RESPONSE: When the department developed the Montana Tier 1 Risk-based Corrective Action Guidance for Petroleum Releases, it rounded the screening level values to the nearest significant digit in the summary tables, which has resulted in confusion for users and a reliance on the non-rounded values presented in the

master tables. The department did not want to create this same type of confusion in the background study and, therefore, did not round the values.

COMMENT NO. 17: Screening levels identified in ARM 17.55.109 are often used as de facto cleanup levels, so the background values need to be statistically sound, applicable across diverse geological settings, and focus on constituents that present a potential threat. This could also affect sites where Phase II environmental site assessments are being conducted, as the background values will be used for determining a recognized environmental condition at a site, which could depress property values and hinder development.

RESPONSE: ARM 17.55.109(4) provides that the referenced documents are to be used as screening levels and that they are not cleanup standards. Screening levels serve as a baseline tool to assess whether there is a need for further evaluation. Some parties may choose to use screening levels as cleanup levels in order to save the time and expense of calculating site-specific cleanup levels, but that practice is not mandated by the department. In addition, collection of site-specific background samples is also available and can be used in a Phase II environmental site assessment to ensure that a site is not improperly characterized as having a recognized environmental condition. This addresses the commenter's concern regarding property values and development.

COMMENT NO. 18: The proposed background values are based on the 90th percentile of the background data set and exceedance rates are expected to be approximately 10 percent. Samples collected from counties in mineralized regions have a greater probability of a false positive. The department should consider using other background values for specific geological types associated with mineralized areas.

RESPONSE: While mineralized regions may have higher concentrations of inorganics, it is not appropriate to allow non-mineralized portions of the state to be contaminated to levels that represent mineralized areas. Rather, the background values are meant to represent the state as a whole, while still allowing the collection of site-specific background data for sites in mineralized areas as provided for in ARM 17.55.108(5).

COMMENT NO. 19: The background study avoided mineralized areas by not collecting samples within 1/2 mile of known abandoned mine sites. Avoiding mineralized areas imparts a low bias to the sample results and inadequately addresses regional variations in inorganic constituent concentrations.

RESPONSE: The department collected samples from every county in the state and the data sets included outliers that are representative of the more mineralized portions of the state. The department included all outliers in its calculation of the background values so that the generic statewide background concentrations would be representative of all areas of the state. In addition, the opportunity to collect site-specific background data is provided for in ARM 17.55.108(5).

COMMENT NO. 20: Table 4-4 includes constituents with a proposed background value less than the corresponding EPA regional screening level. It is not clear why exceeding a background value for these constituents would result in a determination of a potential imminent or substantial threat. The department should clarify that either the background value or regional screening level, whichever is higher, is used and also focus on the receptor group that may be an issue.

RESPONSE: When using the screening levels to screen a site, the department will generally use the higher of the EPA regional screening level or the background level found in Table 4-4. For example, the EPA regional screening level for cobalt is 2.3 milligrams per kilogram (mg/kg) and the background level in Table 4-4 is 10 mg/kg. Typically, the department would use 10 mg/kg for screening. The exception to this would be when there is site-specific background data available that is lower than the Table 4-4 background levels. In that instance, the site-specific data could be used as provided for in ARM 17.55.108(5) in place of the Table 4-4 background levels. The department has added this clarification to the rule. Receptors are already considered in listing decisions; see ARM 17.55.108(5).

COMMENT NO. 21: The background study lists nine other states for which background soil concentrations have been calculated and only one utilizes a 90th percentile as the basis for calculating a background value. Other states utilize a more statistically robust method to better control the false positive error rate. The department could propose that a statistical test be conducted on the data instead of setting an overly conservative background value.

RESPONSE: The department anticipates that other options may be considered if site observations exceed the UTL for a particular compound. For mineralized areas, the option of obtaining site-specific background samples is available. In addition, the department anticipates allowing more rigorous statistical analyses to compare site populations to background data sets to determine if the site concentrations are protective or to determine if there is a statistical difference between site concentrations and background. These statistical analyses may include hypothesis testing where appropriate.

COMMENT NO. 22: ProUCL provides the USL, which could be considered for use as it would not be subject to false positives. Sites with soil concentrations that exceed the USL of 95 percent should not be considered contaminated.

RESPONSE: The ProUCL guidance provides the following caution in several locations: "Caution: To provide a proper balance between false positives and false negatives, the upper limits described above, especially a 95 percent USL (USL95) should be used only when the background data set represents a single environmental population without outliers (observations not belonging to background). Inclusion of multiple populations and/or outliers tends to yield elevated values of USLs (and also of UPLs and UTLs) which can result in a high number (and not necessarily high percentage) of undesirable false negatives, especially for data sets of larger sizes (e.g., n > 30)." (emphasis added). The data sets include outliers but, since there were no problems associated with the data, the department had no reason to discard these outliers that are representative of mineralized areas of the state. Based on the guidance, the department utilized the UTL to avoid false

negatives in the initial screening of sites for listing on the CECRA priority list.

Reviewed by: DEPARTMENT OF ENVIRONMENTAL QUALITY

/s/ John F. North By: */s/ Tracy Stone-Manning*
JOHN F. NORTH TRACY STONE-MANNING, DIRECTOR
Rule Reviewer

Certified to the Secretary of State, August 25, 2014.