Risk Management Procedure For The Derivation and Use Of Soil Exposure Point Concentrations For Unrestricted Use Determinations

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I. INTRODUCTION

The Colorado Department of Public Health and Environment, Hazardous Materials and Waste Management Division (the Division) has a preference for evaluating soil sample analytical data to demonstrate that a no further action to unrestricted use (NFA) determination is appropriate for a Solid Waste Management Unit (SWMU) or other area of soil contamination (collectively referred to as SWMU in this document). The preferred method involves a straightforward point by point comparison of the concentration of each hazardous constituent detected in a soil sample (factoring in cumulative risk of multiple contaminants) to either the site-specific Division approved background values or soil screening/soil cleanup levels (found in the most current version of the Colorado Soil Evaluation Values, Table 1, henceforth referred to as the CSEV Table). If the point-by-point comparisons show that all of the constituents detected at a SWMU are below their respective residential/unrestricted use levels and soil concentrations protective of groundwater (collectively referred to as NFA cleanup levels), then an NFA determination is typically justified.

The point-by-point evaluation is quick and easy to implement, but may also be overly conservative because it assumes that a receptor will remain in contact with the soil at a specific sample location throughout their lifetime. As a result, the point-by-point evaluation method for soil sample data often shows that even at sites with minor releases, the concentration of one or two constituents in the soil at a SWMU exceed their respective NFA cleanup levels. At this point, the facility should evaluate the magnitude and extent of the soil contamination exceeding the NFA cleanup levels and determine whether it is cost effective to simply excavate the impacted soil and dispose of it off-site, or treat to below NFA cleanup levels. The facility may determine that the excavation or treatment of the entire area of soil impacted above NFA cleanup levels is not feasible (e.g., due to a large volume of impacted soil, depth of contamination, high disposal costs, and/or site-specific concerns).

The purpose of this document is to provide general guidance for an approach that a facility may wish to use to further evaluate soil analytical data for a SWMU to determine if remediation of a release will be necessary. There are numerous guidance documents and references available providing detailed “how to” information about the topics discussed in this document, some of which are referenced at the end of this document.

This procedure is intended for use by those facilities (small to mid-size facilities, and/or larger facilities with multiple small to mid-size investigation areas) that may not have the resources to access high level risk assessment expertise. Larger facilities are likely to have risk assessment expertise available and may have developed site-specific methods for evaluating data that are more favorable to the site-specific situation than what is offered in this risk management procedure. This document is not intended to limit a facility’s right to perform a site-specific risk assessment using site-specific information, nor is it meant to prohibit larger sites from applying the procedure discussed herein. However, facilities should be aware that as more site-specific information is incorporated into the evaluation of the soil data, more Division input and approval will be required. For example, if a facility wishes to employ a residential exposure area that is larger or smaller than the 0.5 acres suggested in this document, the facility’s proposal will need to be pre-approved by the Division.

This document is also specific to evaluation of soil analytical data as it relates to potential human health risk. It does not take into account potential ecological risk or the potential for cross-media contamination of ground water from soil contamination. If there is a potential for extensive soil or sediment contamination in an area of current or future significant ecological habitat, ecological risk may become a driver for remediation and a site-specific ecological risk evaluation will be required.

Any proposal to use the process outlined in this guidance document will need to be pre-approved by the Division. Any decision to employ this method should be brought to the attention of the Division at the earliest available opportunity so that agreement can be reached on the methods used to collect and evaluate the data to ensure that when work plans are submitted for review and implemented, the sample results are more likely to be accepted and any continuing debate is about remedial decisions, not methodology or data adequacy.

II. DERIVATION OF THE EXPOSURE POINT CONCENTRATION

The Division recognizes that for some SWMUs the remediation of hazardous constituents based solely on a point-by-point comparison to NFA cleanup levels may be too conservative for the actual human health risk created by the release. An example would be a release that has resulted in soil contamination at a SWMU at concentrations slightly exceeding, perhaps by 10 percent, the NFA cleanup levels in a number of isolated spots over a large area. In these cases, the facility may wish to evaluate the soil contamination over a wider area to determine if the level of contamination in an area represents an unacceptable threat to human health. In risk assessment terms, the level of contamination that a person may be exposed to over a given area (i.e., exposure unit[1] or area) is called the "exposure point concentration" (EPC). This concentration is a conservative estimate of the average chemical concentration in an environmental medium and is calculated for each individual exposure area within a site. The intent of this guidance is to describe the activities necessary to appropriately derive an EPC and how to apply the EPC to support an NFA determination using cleanup levels found in the CSEV Table at a SWMU (both with or without remediation).

Because the true mean concentration of a chemical within an exposure area cannot be calculated with certainty from a limited set of measurements, the U.S. Environmental Protection Agency (U.S. EPA) recommends that the 95th percent upper confidence limit (95UCL) of the arithmetic mean concentration be used as the EPC in calculating exposure and risk (U.S. EPA 2002b). There are some statistical methods where the calculated 95UCL is higher than the highest measured value. In this case the maximum value is used as the EPC instead of the 95UCL (U.S. EPA 2002b). The exception to this statement is that when evaluating lead concentrations in soil, the arithmetic mean of data within an exposure area is generally used as the EPC.

[1] An exposure unit is the geographical area in which individual receptors randomly move and contact a contaminated soil during the relevant period of the exposure duration

The successful derivation of a valid EPC requires the following:

- a complete characterization of the vertical and horizontal extent of the contamination released from a SWMU;
- the specification of the receptor exposure area and exposure depth; and
- collection of a statistically valid data set for each proposed receptor exposure area.

A. Complete Characterization of the Release

The Division requires that the vertical and horizontal extent of a release of hazardous waste or hazardous constituents be completely delineated prior to evaluating the potential human health risk due to the release or the need for further action at a SWMU. The NFA cleanup levels from the CSEV Table are typically used as the criteria for contaminant delineation, but other criteria (e.g., field screening methods) may be employed if developed in conjunction with Division staff. Development of an appropriate sampling plan for investigation of a release is critical to delineating the extent of contamination. The sampling plan should allow for the collection of enough sample points in an initial round of sampling to ensure complete characterization. Alternatively, the sampling plan must include the criteria and methodology that will be used to completely characterize extent of contamination during a "phased" investigation.

The initial design of the sampling plan may depend in part on the anticipated size of the contaminated soil area and/or the nature of the release itself. For most facilities, the source of soil contamination is likely a release from a discrete unit or area where constituent concentrations are highest close to the source and gradually decrease with distance from the unit. In this case, once this initial condition is confirmed, a relatively high density of soil samples may be collected close to the source, with step out soil samples collected further from the source during subsequent rounds to bound the "footprint" of contamination.

For SWMUs where soil contamination is anticipated to be spread fairly uniformly over a large area (e.g., the bottom of an old surface impoundment), it would be appropriate to develop a soil sampling plan to collect a statistically valid data set for the SWMU. To reduce costs, the statistically valid data set for the SWMU could be established over two sampling events. To determine the risk drivers for the unit, the initial sampling event could consist of a random sampling grid across the unit with analysis for the entire range of analytes potentially related to the SWMU. The subsequent sampling event can focus on the collection of a statistically valid data set for each individual exposure area within the SWMU for those constituents found to exceed NFA cleanup levels.

B. Receptor Exposure Area

The Division believes that an exposure area for residential/unrestricted use NFA determinations should have a maximum areal extent of 0.5 acres, which is intended to represent a typical residential lot. At some smaller sites, an EPC can be established for a SWMU with a smaller areal extent (i.e., $1/8^{th}$ of an acre based on U.S. EPA RAGs guidance). The 0.5 acre residential exposure area is consistent with U.S. EPA soil screening guidance (U.S. EPA 1996,

Section 2.3.2). For SWMUs greater than 0.5 acres in areal extent, derivation of multiple exposure point concentrations will generally be required. When possible, each exposure area should be a grid square roughly 150 feet on a side. Alternate grid shapes may be appropriate depending on the actual configuration of the SWMU and/or release area. An attempt should be made to center one of the exposure area grids over the area of highest contamination to represent the worst-case exposure scenario. If there are multiple "hot spots" of contamination within the SWMU, the facility may wish to contact the Division for assistance in designing the exposure area grid.

There are actually two depth intervals that must be evaluated when deriving an EPC for a residential/unrestricted use exposure area. The first depth interval is from 0– 2 inches (0.0 - 0.167 foot). This "surface soil" interval represents what a resident would normally be exposed to if the exposure area was already in residential use, or would be used "as is" in the future for residential development. If site-specific circumstances appear to support the use of an alternate surface soil depth interval, the facility should contact the Division for input and approval. The second depth interval to be evaluated is from 0 - 12 feet and represents the depth to which soil would likely be disturbed and redistributed during basement excavation for residential development. It may not be necessary to evaluate the 0 – 12 foot depth interval if the type and location of the release, supported by the characterization data, indicate that only surface or shallow soil have been impacted. Although these two depth intervals are customarily used, it may be useful to use different depth intervals (e.g., 0 – 1 foot interval) depending on the source of contamination, exposure scenario, etc.

For large SWMUs with multiple exposure area grids, it may not always be necessary to derive an EPC for every area and depth. Assuming that the full extent of contamination has been delineated, it is likely that there will be exposure areas where a point-by-point evaluation indicates the concentration of all hazardous constituents are below their respective residential/unrestricted use NFA cleanup levels at all sample locations (factoring in the cumulative risk of chemicals for cancer and non-cancer risks). These areas would not likely require further evaluation.

C. Statistically Valid Data Set

The collection of a statistically valid data set for each proposed receptor exposure area is key to the derivation of an appropriate EPC. The Division requires a minimum of 12 valid sample results, with a minimum of eight (8) detectable results, to derive an EPC. The following guidance documents can be used when planning a soil investigation to ensure the appropriate level of data is obtained. In general, the data sets used for derivation of an EPC should meet or exceed the criteria for determining the number of samples needed as specified in the U.S. EPA: Guidance for Data Usability in Risk Assessment (Part A) (U.S. EPA 1992a). Consideration should also be given to using U.S. EPA's Systematic Planning Using the Data Quality Objectives Process (U.S. EPA 2006) for designing a plan to collect data of sufficient quality and quantity to support the goals of the study. The *Visual Sample Plan* software available from EPA at http://vsp.pnnl.gov/ is useful in taking into account different standard deviation and population distributions in calculating the number of samples needed to achieve specific confidence requirements in a sample population.

If the soil analytical data were collected prior to attempting to use the EPC methods described in this document, the above referenced guidance documents can be used to decide if the existing data is adequate. If the existing data are not adequate, it is suggested that additional data collection occur prior to proceeding with derivation of the EPC.

D. Derivation of the EPC

As noted above, the EPC is a conservative estimate of the average chemical concentration in an environmental medium. Because of the uncertainty associated with estimating the true average concentration at a site, the 95UCL of the arithmetic mean concentration is used for this variable. The EPC should be calculated in accordance with the U.S. EPA guidance document titled "Calculating Upper Confidence Limits for Exposure Point Concentrations at Hazardous Waste Sites" (U.S. EPA 2002b),or other more current documents. The latest version of U.S. EPA's ProUCL statistical software package for analysis of environmental data sets with and without nondetect (ND) observations may be found at http://www.epa.gov/osp/hstl/tsc/software.htm. ProUCL is a comprehensive statistical software package with statistical methods and graphical tools to address many environmental sampling and statistical issues.

In brief, the data set should first be evaluated through exploratory analysis to determine the best distributional assumption for the data set. Distributions can be analyzed using a variety of methods, many of which are described in Gilbert (1987) and U.S. EPA (2000). The recommended method will vary based on sample size, level of data censoring, etc. ProUCL software includes statistical methods to address various environmental issues for both full data sets without NDs and for data sets with NDs.

Based on the results of the data distribution testing, one of the following approaches can be used to calculate the 95UCL for the arithmetic mean of the data set:

- Use the Sharpiro-Wilk test for normality;
- If the data are normally distributed, use the approach based on the Student's *t* -statistic;
- If the data are lognormally distributed, use the Land method based on the *H*-statistic;
- If the data are neither normally or lognormally distributed, there are distribution-free or nonparametric methods available. These methods are further described in U.S. EPA (2002) and include an approach based on the Chebyshev inequality and an approach based on the bootstrap resampling procedure.

If the 95UCL calculated using the methods described above results in a value that exceeds the maximum detected concentration in the data set, or the data set results cannot be approximated by a smooth continuous function, then the maximum concentration in the data set should be used to represent the EPC. Please note that if the most recent version of ProUCL is used, the 95UCL should never exceed the maximum value in the data set.

As noted above, the calculation of an EPC requires a minimum of 12 valid samples results, with at least eight (8) detectable results. The more samples collected, the better the estimate of the 95UCL on the mean. Data sets with 12 to 30 samples are preferred. For sample sets with 12 or fewer valid samples, the maximum detected concentration provides the EPC (U.S. EPA, 1992b).

Some data sets developed during the characterization of releases from a SWMU will have sample results with contaminant concentrations much higher than the data set as a whole. There are a variety of statistical tests available for determining if a measured value is an outlier that should not be included within a statistical data set. However, for the purposes of calculating an EPC, the outlier value should be incorporated if the outlier consists of a hazardous constituent that is likely related to a release from the SWMU.

Alternatively, the facility could assume that the outlier represents a "hot spot" of contamination that will be remediated regardless of whether the overall EPC is above acceptable risk levels. In this case, the facility can derive an EPC for the area that will be excavated without incorporating the outlier value(s). In order to ensure that the entire "hot spot" is actually removed, and to ensure the removal of the outlier value(s) is complete, the facility will have to conduct additional pre-characterization samples to bound the area of excavation, or excavate the hot spot based on visual or other criteria and then collect confirmation samples. Once the hot spot has been removed, the outlier sample result(s) that constituted the hot spot can be replaced in the EPC calculation with a background or average concentration value to represent the "clean" fill that will be placed in the excavated area or the concentration that will remain after soil treatment. Additional approaches for addressing potential outliers can be found in U.S. EPA 2000.

III. USE OF THE EXPOSURE POINT CONCENTRATION

A. For Evaluating Whether the Release Requires Remediation

Once the EPC for each constituent in an exposure area is derived, there are several ways in which it can be used to evaluate whether the releases from a SWMU warrant further action.

First, if there is reason to believe that the concentration of the constituent in question is elevated due to naturally-occurring concentrations or a non-site, non-release related anthropogenic source, a background concentration for that constituent can be established and then compared to the EPC. The Division will accept background concentrations for a constituent developed in accordance with the technical guidance for the latest version of U.S. EPA's ProUCL statistical software package. At this time the document is titled "ProUCL Version 4.1.00 Technical Guide (Draft) (U.S. EPA 2010). The Division will also consider accepting background concentrations calculated using other appropriate pre-approved methods. Please note that Division and U.S. EPA policy is to calculate background/anthropogenic values using the 95UCL. The EPC for each constituent at each exposure area can be compared directly to the background concentration to determine whether remediation is required as long as background concentration was determined according to an approved method. The use of the 95th percent

upper tolerance limit (UTL) for calculating background values for comparison to an EPC is specifically proscribed, but individual sample points can be compared to the UTL for screening or to identify potential "hot" spots.

The second way to determine whether remediation is required is to directly compare the EPC for each constituent at each exposure area to the NFA cleanup levels, factoring in the cumulative risk posed by multiple contaminants for both cancer and noncancer risk, as per the Division's Corrective Action Guidance Document (CDPHE 2002). This can be accomplished by the facility with little or no input from the Division.

The third way to use the EPC is as a direct input into site- (or SWMU-) specific risk assessment algorithms, particularly if site-specific potential exposure pathways (e.g., food chain pathways, vapor intrusion) are not included in CSEV Table values or NFA cleanup levels in use at the site. The intent of the site-specific risk assessment would be to replace the conservative generic exposure risk input parameters with available, verified, site-specific information to determine the actual risk level posed by the release. The actual risk levels are then evaluated to determine whether the releases from the SWMU warrant further action. The methodology and input parameters to a unit-, or site-specific risk assessment should be discussed with the Division prior to implementation.

B. For Guiding Remediation of the Release

The EPC will often be one of the criteria for determining the type and magnitude of the remediation effort for a release. For example, for an area of widespread, relatively uniform contamination, the facility may wish to simply excavate or treat an entire exposure area where the EPC exceeds acceptable human health risk levels. In this case, the excavation/treatment would continue to the identified boundary of the impacted exposure area. Confirmation soil sampling will be required in this instance.

Alternatively, if the contamination within an exposure area exists in relatively discreet "hot spots," the facility may be required to excavate/treat the hot spots, replace the hot spot soil with clean soil, and then recalculate an EPC for the area. This process can continue until the EPC is at or below the cleanup goal established for the SWMU. Additional information on applying this approach can be found in the U.S. EPA guidance document titled "Draft Guidance on Surface Soil Cleanup at Hazardous Waste Sites: Implementing Cleanup Levels (U.S. EPA 2002a).

When using the second approach, deciding on the initial size of the hot spot excavation is not as straightforward as it may first appear. One method is to extrapolate the concentration gradient between the hot spot and surrounding data points using standard isocontouring methods. The initial excavation could then be planned to encompass the isoconcentration contour for the highest concentration that can be plugged into the EPC calculation (as a single data point) and still be at or below the acceptable human health risk level. A key component of this type of remediation is the collection of confirmation soil samples to ensure that the hot spots are completely removed. Note that confirmation soil sampling can be performed pre - or post – excavation/treatment, depending on the circumstances.

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