Report of the Lead Workgroup to the Cleanup Standards Scientific Advisory Board

July 27, 2022

1. INTRODUCTION

The Cleanup Standards Scientific Advisory Board ("CSSAB", or "Board") to the Pennsylvania Department of Environmental Protection ("PADEP", or "Department") unanimously submitted a memo entitled, "*Memorandum - Consideration for the Application of the IEUBK Model and ALM for the Development of Soil Direct Contact Values for Lead within the Act 2 Program"* to the Department on September 17, 2020 ("Memo").

The Memo expressed the CSSAB's support for the Department's decision to replace the two models currently being used to calculate direct contact soil numeric values ("NVs") for lead for residential and nonresidential land use with the Integrated Exposure Uptake Biokinetic ("IEUBK") Model (version 1.1) (residential) and the Adult Lead Model ("ALM") (nonresidential), both developed and supported by the United States Environmental Protection Agency ("EPA").

The Memo also indicated that the Department should consider the use of the average as an additional attainment demonstration option for lead in soil under the Statewide health standard ("SHS") of the Land Recycling and Environmental Remediation Standards Act ("Act 2"). Specifically, the final paragraph of the Memo states:

> *"Based on this analysis of attainment demonstration alternatives, use of the average lead concentration should be considered as an additional option for the attainment demonstration so that the attainment "toolbox" includes a mechanism that meshes with the input criteria in the IEUBK model and ALM. By the same token, persons wishing to use the two existing attainment tests could do so consistent with what is currently provided for in the regulations implementing Act 2."*

In the August 11, 2021 meeting of the CSSAB, the Department requested that a lead workgroup be assembled to evaluate the use of the average as an attainment test for lead in soil. Subsequently, the Lead Workgroup ("Workgroup") was assembled in September 2021.

The Workgroup subsequently developed two interim work products, a draft white paper that provided extensive background information on the scientific factors associated with lead in soil in Pennsylvania and its regulation by PADEP (Attachment A) and an analysis of datasets from actual soil lead remediation sites in the Commonwealth (Attachment B). The white paper was developed to support deliberations of the Workgroup. As such, its purpose was to present the science and other facts underlying the development of Act 2 NVs and medium-specific concentrations ("MSCs") for lead in soil, without expressing opinions or providing conclusions and recommendations. Portions of the white paper are included in this report. The purpose of the dataset evaluation was to examine the relationship of the proposed average attainment test to the two existing tests (the 75%/10X ad hoc rule and the 95% Upper Confidence Limit on the Mean ("95% UCL")).

This *Report* presents two additional results of the Workgroup's deliberations:

- The recommendations of the Workgroup regarding the addition of an average attainment test based on the average soil lead concentration from site-specific sampling results, and
- Suggested draft regulatory language to incorporate the average soil lead concentration based on site-specific attainment sampling results as an additional attainment test in 25 Pa. Code Chapter 250. Administration of the Land Recycling Program.

2. UNIQUE TREATMENT OF LEAD FOR THE DIRECT CONTACT SOIL EXPOSURE PATHWAY

Beginning with the language of Act 2 of 1995 (Act 2) and continuing with the development of draft regulations in 1996 and the final regulations in 1997, it was understood that soil direct contact numeric values ("NVs") for lead would be calculated differently from NVs for other regulated substances. It is acknowledged that lead effects on developing children is an important consideration and that alternate mechanisms to address this issue would be needed.

2.1. Statutory Language

Section 303 of Act 2, which addresses factors used in calculating direct contact NVs to be applied in developing MSCs in soil, states:

> ***Section 303. Statewide health standard.***
>
> *(c) Additional factors. -- When establishing a medium-specific concentration, …. the medium-specific concentration for the ingestion of groundwater, inhalation of soils, ingestion and inhalation of volatiles and particulates shall be calculated by the department using valid scientific methods,* ***reasonable exposure pathway assumptions and exposure factors for residential and nonresidential land use which are no more stringent than the standard default exposure factors established by EPA based on the following levels of risk:***
>
> *(1) For a regulated substance which is a carcinogen, the medium-specific concentration is the concentration which represents an excess upper bound lifetime cancer target risk of between 1 in 10,000 and 1 in 1,000,000.*
>
> ***(2) For a regulated substance which is a systemic toxicant, the medium-specific concentration is the concentration to which human populations could be exposed by direct ingestion or inhalation on a daily basis without appreciable risk of deleterious effects for the exposed population.*** **(**Emphasis added)

2.2. Development of Numeric Values for Lead Compared to Other Systemic Toxicants

The text of the current Chapter 250 regulations governing the calculation of NVs for direct contact to lead in soil as a systemic toxicant describe the approach taken, unchanged from those published in 1997, and currently enumerated in § 250.306(e), as follows:

> *(e) The residential ingestion numeric value for lead in soil was developed using the Uptake Biokinetic (UBK) Model for Lead (version 0.4) developed by the EPA (U.S. Environmental Protection Agency. (1990). Uptake Biokinetic (UBK) Model for Lead (version 0.4). U.S. EPA/ECAO. August 1990, in lieu of the algorithms presented in subsections (a) and (b). Default input values are identified in Appendix A, Table 7. Because the UBK model is applicable only to children, the nonresidential ingestion numeric value was calculated according to the method developed by the Society for Environmental Geochemistry and Health (Wixson, B. G. (1991)).*

The Society for Environmental Geochemistry and Health (SEGH) Task Force Approach to the Assessment of Lead in Soil. Trace Substances in Environmental Health. (11-20)

There are two essential differences between the approach in these regulations for developing lead NVs and the approach taken for developing NVs for other systemic toxicants regulated under Act 2. These differences are identified and explained below.

2.2.1. Toxicity Values versus Public Health Policy Goals

The first step in implementing Act 2 Section 303(c) during the promulgation of the original Chapter 250 regulations was to identify toxicity values available from authoritative sources for each regulated substance relative to carcinogenicity and systemic effects. Under Act 2 Section 303(c)(1) those values could include an Oral Cancer Slope Factor ("CSF_O") for the ingestion exposure route and an Inhalation Unit Risk ("IUR") for the inhalation exposure route. Similarly, under Act 2 Section 303(c)(2) the toxicity values could include an Oral Reference Dose ("RfD_O") for the ingestion exposure route and an Inhalation Reference Concentration ("RfCi") for the inhalation exposure route. For each regulated substance, any number, or none of these values might have been available.

When the final Chapter 250 regulations were published in 1997, none of these toxicity values existed for lead and lead compounds from an authoritative source.

In the absence of toxicity values for lead, other methods were needed to calculate NVs for direct contact to lead in soil, which led to the adoption of the two methods in § 250.306(e). As shown in Chapter 250, Appendix A, Table 7, both methods specify a Target Blood Lead Level ("TBLL") as the goal limiting the value of the corresponding NV. The UBK model assumes a default TBLL for children of 10 micrograms per deciliter ("ug/dL"), derived by EPA in the early 1990s from the Centers for Disease Control and Prevention's ("CDC") 1991 level of concern for lead poisoning prevention in children. The SEGH algorithm assumes a TBLL for adult receptors of 20 ug/dL. Both models are characterized as generating ingestion NVs and no inhalation NVs are calculated.

This unique approach to calculating NVs for direct contact to lead in soil will persist when the UBK Model is replaced by the IEUBK Model and the SEGH algorithm is replaced by the ALM. However, the TBLLs will change and no longer be referenced to the CDC's 10 ug/dL level of concern and the SEGH TBLL of 20 ug/dL.

The 10 ug/dL Level of Concern from 1991 applied by EPA as the TBLL in the UBK Model (version 0.4) was replaced as a CDC policy goal by a value of 5 ug/dL and renamed a Blood Lead Reference Value ("BLRV") in 2012, as described in a CDC Morbidity and Mortality Weekly Report dated October 28, 2021[1], as follows:

> *In 2012, CDC introduced the population-based blood lead reference value (BLRV) to identify children exposed to more lead than most other children in the United States…. The BLRV is based on the 97.5th percentile of the blood lead distribution in U.S. children aged 1–5 years from National Health and Nutrition Examination Survey (NHANES)[2]*

[1] https://www.cdc.gov/mmwr/volumes/70/wr/mm7043a4.htm

[2] NHANES - About the National Health and Nutrition Examination Survey (cdc.gov)

data… The initial BLRV of 5 µg/dL, established in 2012, was based on data from the 2007–2008 and 2009–2010 NHANES cycles. In 2012, CDC's former Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) recommended the establishment of the BLRV and proposed it be set at 5 µg/dL (5). This recommendation was based on the weight of evidence indicating that the adverse health effects of BLLs <10 µg/dL in children included neurologic, cardiovascular, immunologic, and endocrine effects. ACCLPP further recommended that the BLRV be updated every 4 years based on the 97.5th percentile of BLLs for children aged 1–5 years across the two most recent combined NHANES cycles for which data are available.

In October 2021, a Workgroup member contacted Jill Ryer-Powder, Ph.D., MNSP, DABT, Chair of CDC's BLRV Workgroup, and a member of its Lead Exposure and Prevention Advisory Council ("LEPAC") regarding the status of her workgroup's efforts to update the CDC's BLRV. In her email response to that inquiry on October 5, 2021, Dr. Ryer-Powder stated the following:

Please note that the BLRV is not a health-based number – rather it represents a value based on the 97.5th percentile of blood lead level (BLL) concentrations for US children aged 1 to 5 years. The BLRV is neither a clinical reference level defining an acceptable range of blood lead levels in children nor is it a health-based toxicity threshold; rather it is a policy tool that helps identify the children in the upper end of the population blood lead distribution in order to target prevention efforts and evaluate their effectiveness. ***This is important to understand when setting a standard for "acceptable" concentrations of lead in soil.*** (Emphasis added)

It is notable that, in publishing the IEUBK Model version 2.0 and its User's Guide in May 2021, nine years after the CDC adopted the BLRV of 5 ug/dL, the EPA's TBLL of 5 ug/dL was adopted as the default value with no apparent reference to the actions taken by the CDC in 2012 and no mention of the ACCLPP's January 2012 report recommending those actions.

Since the original promulgation of the Chapter 250 regulations, the California EPA ("CA EPA") has developed CSF_O and IUR values for lead. As CA EPA is an acceptable source for toxicity values under Chapter 250, these two values are currently listed for lead in Chapter 250, Appendix A, Table 5B. However, the residential, direct contact NV calculated using these toxicity values is reportedly greater than 2000 mg/kg. This NV for carcinogenic effects is therefore at least four times greater than the current 500 mg/kg systemic toxicant NV listed in Chapter 250, Appendix A, Table 4, and could not be selected as the residential, direct contact NV. This calculated NV for carcinogenic effects is also at least ten times higher than the Department's proposed residential, direct contact NV of 200 mg/kg, which was derived in accordance with the procedure discussed below in Section 3.

The reference doses and concentrations used to develop the NVs for substances other than lead are health-based toxicity values and the TBLLs used to develop the direct contact NVs for lead in soil are intrinsically related to a level of concern or BLRV adopted by CDC as public health policy tools. This lack of equivalence and the absence of a valid reference dose or concentration for lead prevent a determination of which of these factors would provide a more protective basis for calculating direct contact soil NVs, and by extension MSCs.

2.2.2. Single Medium Pathway Versus Multimedia Pathways

When direct contact NVs for ingestion of soil are calculated for a regulated substance other than lead, the toxicity values used in those calculations are related solely to the intake of soil containing that substance. As the following excerpt from the IEUBK Model version 2.0 User's Guide states, that is not the case for lead when using the IEUBK Model:

> *Exposure can be thought of as the contact with a chemical or other agent, which may result in the absorption or exchange across boundaries of an organism, such as the gut, lungs, and skin. The results from the exposure component of the IEUBK model are estimated intake rates for the quantities of Pb* [lead]*inhaled or ingested from environmental media. The media addressed by the IEUBK model include soil, house dust, drinking water, air, and food. Paint is usually addressed in terms of its contribution to the measured concentration of Pb in soil or house dust.*[3] (Pages 16-17)

It should be noted, however, that the model defaults do not include a contribution from lead-based paint to lead in soil or house dust, but it can be added as an alternate source. The media addressed do include maternal blood.

Section 7, Table 5 and Figure 6 from Attachment A provide a discussion of the effect of running the IEUBK Model with all media included as their default values and alternative runs for "soil and dust only" and "soil only". The "soil only" model run, otherwise at the same default settings used by the Department to generate the proposed 200 mg/kg NV, results in an alternate calculated NV of 686 mg/kg. This value is more than three times higher than the proposed NV and approximately one-third of the calculated carcinogenic effects NV of >2000 mg/kg.

Although the absence of a valid reference dose or concentration for lead and the lack of equivalence between the toxicity values used to set NVs for other regulated substances and the public health policy tools used for lead still make it uncertain which methodology provides the absolute greater protection, the use of the multimedia pathway approach in the IEUBK Model instead of focusing only on lead in soil unquestionably shifts the resultant NV in a more conservative direction.

3. CURRENT NV AND MSC VALUES AND PADEP PROPOSED REVISIONS

3.1. Soil Numeric Values and Medium-Specific Concentrations for Lead: 1997 - Present

Based on the output from the UBK Model and SEGH algorithm, the residential NV for direct contact to lead in soil is 500 mg/kg and the NV for nonresidential land use is 1000 mg/kg. However, in accordance with Section 250.308, the soil-to-groundwater NV for lead was calculated to be 450 mg/kg. Section 250.305 requires, in effect, that the lowest of these three numbers, i.e., 450 mg/kg, becomes the MSC for both the residential and nonresidential land use scenarios. Exceptions to this rule occur when either equivalency or buffer distance is used to attain the soil-to-groundwater NV, or the NV derived from using the Synthetic Precipitation Leaching Procedure ("SPLP") test to attain the soil-to-groundwater NV

[3] User's Guide for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) Version 2 (epa.gov)

is greater than the applicable residential or nonresidential direct contact NV, leading to the direct contact NV being the MSC.

3.2. Proposed Revisions

In the August 2021 CSSAB meeting, the Department proposed updating the models used to calculate NVs for direct contact to lead in soil for both residential and nonresidential land use. As shown in Table 1, the Department proposes to replace the UBK Model with the IEUBK Model (version 2.0) for residential land use and the SEGH algorithm with the ALM for nonresidential land use.

Table 1: Proposed Changes in Models, NVs for Direct Contact to Lead in Soil and MSCs

Land Use	Current Model	Proposed Model	Current TBLL (ug/dL)	Proposed TBLL (ug/dL)	Current DC* NV (mg/kg)	Proposed DC* NV (mg/kg)	Soil-to-GW NV** (mg/kg)	Current MSC*** (mg/kg)	Proposed MSC (mg/kg)
Residential	UBK	IEUBK	10	5	500	200	450	450	200
Nonresidential	SEGH	ALM	20	5	1,000	1050	450	450	450***

*DC: Direct contact **No change will occur in this NV ***In the absence of exceptions noted above

Table 1 also shows the Department's proposal would lower the TBLL from 10 ug/dL and 20 ug/dL for residential and nonresidential land use, respectively, to a consistent 5 ug/dL. The selection of this TBLL is based on the default value included in the IEUBK Model version 2.0 released by EPA in May 2021. The Department's proposal also assumes a 5% probability of exceedance cutoff for both models. As the table shows, adoption of the IEUBK Model v. 2.0 will lower the residential NV from 500 mg/kg to 200 mg/kg. However, the use of the ALM together with the 5 ug/dL TBLL will result in a small increase in the nonresidential NV from 1000 mg/kg to 1050 mg/kg.

Importantly, the table shows the soil-to-groundwater NV of 450 mg/kg will not change. As noted above, because this NV is currently lower than either of the direct contact NVs, the soil-to-groundwater NV is currently the MSC for both land uses. In the absence of any of the infrequent exceptions noted above, this will still be the case for the nonresidential land use scenario. However, with the adoption of 200 mg/kg for the residential scenario NV, that value will then be lower than the soil-to-groundwater NV, making it the applicable MSC for residential sites. For this reason, the focus of the remainder of this analysis is on the IEUBK Model v. 2.0.

4. IEUBK MODEL V. 2.0

This discussion of the IEUBK Model (version 2.0) relies in part on excerpts from the User's Guide[4] with page numbers referenced for each one.

The IEUBK Model is used in two principal ways: Preliminary Remediation Goal ("PRG")[5] Mode and Risk Assessment Mode. The principal model inputs and calculations are the same for both modes of using

[4] User's Guide for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) Version 2 (epa.gov)

[5] *The PRG is the average concentration of a chemical in an exposure area that will yield the specified target risk in an individual who is exposed at random within the exposure area.* Calculating Preliminary Remediation Goals (PRGs) | US EPA

the model, i.e., a TBLL and a probability of exceedance cutoff. The difference between these two modes is the variable for which a value is being sought.

4.1. Selection of TBLL and Probability of Exceedance Cutoff

The first decisions to be made in applying the IEUBK Model are to select the TBLL (or, Blood Lead Level of Concern, or cutoff) and the probability of exceedance cutoff. As noted above, the Department's current proposal is to select 5% as the probability of exceedance cutoff and to lower the TBLL from the current 10 ug/dL to 5 ug/dL. Selection of the 5 ug/dL TBLL is based on EPA's adoption of the latter as the default in the IEUBK Model v. 2.0 in May 2021, as shown in the following excerpt from the IEUBK Model v.2.0 User's Guide:

TABLE 2-2. Default Values for the IEUBK Model Parameters

Parameter	***Default Value***	***Units***
Blood Pb level of concern, or cutoff	*5*	*µg/dL*

(Page 31)

4.2. Preliminary Remediation Goal Mode

The model is run in PRG Mode (or Find Mode) to calculate the soil concentration that would result in a user-specified probability of exceedance cutoff not being exceeded for a user-specified TBLL. Running the model in Find Mode using the same default input parameters, a "Change Cutoff" of 5 ug/dL, and a "Probability of Exceeding Cutoff" of 5%, the model generates a "Soil and/or Dust Concentration" of 200 ppm or mg/kg. This is the mode in which the Department would have run the model to generate a PRG of 200 mg/kg that is the basis for the proposed NV/MSC for residential direct contact to lead in soil of 200 mg/kg.

4.3. Risk Assessment Mode

The model is run in Risk Assessment Mode (or Run Mode) to calculate a geometric mean ("GM") blood lead ("PbB") concentration and the associated probability of exceedance of a user-specified TBLL, as summarized in the following excerpt from the User's Guide:

> *The IEUBK model is used to assess risk and support environmental cleanup decisions at residential sites. The model is not intended to predict the geometric mean (GM) PbB* [blood lead] *for a given child. Instead, IEUBK allows the user to estimate, for a hypothetical child or population of similarly exposed children, a plausible distribution of PbB concentrations centered on a GM PbB concentration (see Hogan et al., 1998 for additional discussion). The GM PbB is predicted from available information about the child's or children's exposure to Pb. From this distribution, the model estimates the probability that a child's or a population of children's PbB concentration will exceed a* ***target PbB level****.* [i.e., Target Blood Lead Level (TBLL)] *(*Page 13) (Emphasis added)

The default values listed in the User's Guide include the following entries for soil and dust:

TABLE 2-2. Default Values for the IEUBK Model Parameters

DATA ENTRY FOR SOIL/DUST (constant over time)		
Concentration (starting values to be modified using appropriate site data):		
soil	*200*	*µg/g*
dust	*150*	*µg/g*

(Page 29) (Emphasis added)

The entry for soil of 200 ug/g reflects the PRG calculated above based on no change in the standard model defaults or inputs. Therefore, using the model defaults for all input parameters (including an "outdoor soil lead concentration" of 200 ug/g or mg/kg), in Run Mode, the model generates a probability distribution graph showing a 4.979% probability (effectively 5%) of exceeding a PbB concentration of 5 ug/dL. This is the mode in which the model is run to demonstrate an input concentration is predicted to satisfy the 5% probability of exceedance cutoff for the selected TBLL of 5 ug/dL.

The bold text in this excerpt indicates that these starting values can be modified "using appropriate site data". This is what is done in Risk Assessment Mode. Absent any other changes in the defaults or inputs, it is clear only values entered that are equal to or less than 200 ug/g (200 mg/kg) will generate an acceptable probability of exceedance value of 5% or less. Thus, the question is, what value representing "appropriate site data" is meant to be entered to perform this test? That question is answered in the following excerpts from the User's Guide:

> *2.0 Loading and Starting the Model*
>
> *2.3 Detailed Descriptions of Input Options*
>
> *2.3.4 Soil/Dust Data*
>
> *2.3.4.2 Lead in Soil*
>
> *The TRW[6] recommends replacing the default constant soil value (200 µg/g) (or variable values)* ***with site-specific data representative of the average soil Pb concentration for the exposure scenario.*** (Page 36) (Emphasis added)
>
> *2.3.4.2.1 Developing a Soil Lead Concentration (PbS)*
>
> ***The PbS should be the arithmetic mean of the concentration of Pb in the soil that a child is likely to be exposed to.*** *Unless there is site-specific information to the contrary, the child is usually assumed to have an equal chance of contacting soil throughout the decision unit (DU); therefore, in most cases, the PbS would be the arithmetic mean concentration of Pb in soil of the DU. The method for estimating the arithmetic mean depends on how the soil samples were collected. Typically, the simple average of the concentrations measured in each of the samples is appropriate (the sum of the sample concentrations divided by the number of samples).* ***The arithmetic average is appropriate when samples were collected using incremental composite sampling, when samples were collected using simple random sampling, and systematic sampling approaches that result in sample locations that were evenly spaced within the DU.*** (pages 36 and 37) (Emphasis added)

[6] EPA's Technical Review Workgroup for Metals and Asbestos Lead Committee

The Workgroup has considered the use of the 95% UCL as an alternative soil concentration instead of the average value in Risk Assessment Mode. The use of a UCL is addressed in the IEUBK Model v.2.0 User's Guide section 2.3.4.2.1 as follows:

> *There will be some uncertainty in the estimate of the PbS due to the variability of Pb concentration in the DU soil. Theoretically, the distribution of PbB concentration that is predicted by the IEUBK model accounts for the uncertainty in the PbS (Section 2.3.8). In some cases, a risk assessor may choose to use an upper confidence limit (UCL) on the arithmetic mean PbS to account for the uncertainty in the estimate (EPA, 2007); however, this is less common for site lead risk assessment.* (Page 38)

On balance, the excerpts referenced above for running the model in this mode clearly favor using the average concentration of site data as the soil input concentration. They also establish that the model accounts for uncertainty in soil lead concentrations without the need to use a UCL to address this source of uncertainty.

5. USE OF THE IEUBK MODEL AT LRP SITES

Under the SHS, when the direct contact soil NV determined by the IEUBK Model run in PRG mode is the MSC, this concentration is first applied to the results of site characterization sampling to construct, by interpolation, a surface that circumscribes the volume of soil that exceeds the MSC. That volume of soil then becomes the soil that must be remediated. For lead, that typically means excavation and removal from the property, although other in situ approaches may be used, after which attainment sampling is performed on the walls and bottom of the excavation. Presently, only the ad hoc 75%/10X test and the 95% UCL test found in § 250.707. Statistical tests. (b)(1)(i) and (ii), respectively, may be applied to demonstrating attainment.

The use of the average of site-specific data for concentrations of lead in soil has been accepted by PADEP as the IEUBK Model input in Risk Assessment Mode under the SSS to demonstrate an acceptable risk level for direct contact to lead in soil by children ages 1-5 years. In this mode, the model output is the calculated probability of exceeding a user-specified TBLL (i.e., 5 ug/dL) to be compared to a user-specified probability of exceedance cutoff (i.e., 5%).

In essence this approach is identical to the model calculations used to generate the SHS MSC. The permitted use of the model in this manner under the SSS is on its own an acknowledgment by the Department that the average is an appropriate attainment test for direct contact to lead in soil. Any concern over allowing the use of the average attainment test under the SHS must, therefore, stem from a sense that the application of the average attainment test under the SHS would somehow generate a less conservative outcome than its use under the SSS.

However, there is an essential difference between the potential outcomes generated using the IEUBK Model under the SHS versus the SSS that could weigh against such concerns. As noted above, under the SHS, the volume of soil exceeding the MSC based on characterization sampling must be identified, remediated and post-remediation attainment samples collected. The results of attainment sampling could still include some concentrations exceeding the MSC and yet pass one of the existing attainment tests or the proposed average test. Nonetheless, there will have been an effort made to remediate all soil identified by site characterization as contaminated above the MSC.

By contrast, under the SSS, a baseline risk assessment can be performed prior to any remediation to determine if an unacceptable risk exists at the site. Based on Workgroup discussions, that risk assessment can be based on characterization data. If the average of those soil concentrations is less than 200 mg/kg, then the model will indicate an acceptable probability of exceedance and any soil exhibiting concentrations greater than 200 mg/kg can remain in place. Only if this risk calculation results in an unacceptable outcome would the remediation of soil with concentrations greater than 200 mg/kg be necessary, but then only to the extent required to achieve an acceptable probability of exceedance.

While there are additional protections provided under the SSS, they are either not available under the SHS or not necessary. These additional protections are primarily engineering and institutional controls, or consideration of cumulative effects in risk calculations, either across exposure pathways or regulated substances having the same impact as lead in children ages 1-5 years old. However, cumulative effects across regulated substances do not come into consideration because lead is unique among all regulated substances in terms of how risks are assessed with respect to an affected organ. On the other hand, there would seem to be not only an advantage under the SHS in terms of permanence and reduction in toxicity, mobility, or volume, but also the same consideration of cumulative effects across exposure pathways in that the same multimedia modeling methodology is applied under both the SHS and the SSS.

Therefore, to the extent that attainment of the SHS based on the average of attainment sampling results would more consistently remediate soil identified during characterization as exceeding 200 mg/kg, and the same multimedia modeling applies under both standards, cleanups under the SHS cannot rightfully be considered less conservative than those done under the SSS. It follows that allowing the use of an average attainment test under the SHS would not produce a less conservative or protective outcome than the current use of that test under the SSS.

6. COMPARATIVE EVALUATION OF ATTAINMENT TESTS

As part of the Workgroup's evaluation of the appropriateness of adding the average as an attainment test for direct contact to lead in soil, datasets were solicited from the PADEP and any Workgroup members who would provide them. In all, data were received for six Act 2 sites that have received relief from liability for releases of lead to soil. After reviewing the data, it was determined that data from four sites could be used in the evaluation. However, one of those four provided sufficient data to permit the evaluation of datasets from six separate units and one additional dataset created by combining attainment data from all six units. Therefore, a total of ten datasets were examined for the relationship of the three attainment tests to each other. An eleventh dataset was created by combining the full attainment dataset with the characterization data from that same site. The purpose of examining this large dataset is discussed later in this section.

6.1. Description of the Datasets and Graphs

Table 2 presents a summary of dataset and site characteristics and attainment test values for each site. The data were provided to the Workgroup as report tables in pdf format and were entered into Excel manually. Only two of the datasets included non-detect ("ND") values, 5 of 33 results at <0.25 mg/kg for Site 2 and 2 of 14 results at <0.5 mg/kg for Site 4, Unit HE-3. These latter two would also become 2 of 74 results in the Site 4, All Attainment dataset. Since the assumed value for any of the seven ND results

would have little effect on the determination of any of the three attainment test values, they were entered at the limit included in the pdf tables.

The 95% UCL values were determined by entering the datasets (including ND values) into the EPA's ProUCL software. The 95% UCL statistics suggested by the software program were selected. The listing of 95% UCL values in Table 2 includes a key that identifies which UCL statistic was suggested by ProUCL for each dataset. Output from the ProUCL software is included in Attachment B.

Attachment B also presents graphs of all datasets listed in Table 2. These graphs plot lead concentration on the y-axis versus the rank percentile of each sampling result in ascending order from 0% to 100% on the x-axis. Each graph also shows three color-coded horizontal lines - each one corresponding to one of the attainment test values listed in Table 2. As listed in Table 2, the datasets are from sites with a variety of land uses and geology. The number of samples in each dataset ranges from 8 to 74. Except for Site 5, the data were generated from post-excavation attainment sampling. The Site 5 dataset is comprised of 16 characterization samples collected to demonstrate attainment of the SSS by entering the average of these data in the IEUBK Model and running it in Risk Assessment Mode to show an acceptable risk based on a <5% probability of exceedance of the selected TBLL. This example was retained to show that simply comparing this same average concentration to the SHS MSC would have demonstrated the same outcome.

These 10 datasets also exhibit a variety of data distributions, including normal (3), lognormal (1) and gamma (6). Despite the variability of characteristics associated with these sites and datasets, this is nonetheless a limited sampling of the full range of conditions that might exist at sites with lead contamination in soils subject to the requirements of the LRP.

Table 2: Dataset Characteristics and Attainment Test Value Comparisons										
Dataset	**Site Use**	**Geology**	**Sample Type**	**Nbr (n)**	**MSC (mg/kg)**	**Data Distribution[1]**	**Maximum (mg/kg)**	**Average Value (mg/kg)**	**75%/10X Value[1] (mg/kg)**	**95%UCL Value[2] (mg/kg)**
Site 2	Wire Burn	Shale Fill	Attnmt.	33	450	Gamma	1024	**203**	280	AG **330**
Site 3	Scrap Yard	Alluvial Sediments	Attnmt.	53	1000	Lognormal	5897	**836**	961	H**2099** LN**1129** HN**2609**
Site 5	Orchard	Mixed Fill	Charac.[3]	16	500	Gamma	1050	**324**	471	AG**547**
Site 4, HE-1	Leaded Glass Manufacturing	Limestone Residuum	Attnmt.	8	450 NE[4]	Gamma	275	61.9	**38.4**	AG**180**
Site 4, HE-2			Attnmt.	16	450 NE[4]	Normal	392	**152**	**207**	ST203
Site 4, HE-3			Attnmt.	14	450 NE[4]	Gamma	279	67.1	**56.4**	AG**173**
Site 4, HE-4			Attnmt.	12	450 NE[4]	Normal	327	**137**	195	ST**196**
Site 4, HE-5			Attnmt.	12	450 NE[4]	Gamma	356	**101**	135	AG**255**
Site 4, HE-6			Attnmt.	12	450 NE[4]	Normal	353	**82.3**	99.4	ST**133**
Site 4, All. Attnmt.			Attnmt.	74	450 NE[4]	Gamma	392	**104**	**149**	AG132

Abbreviations: Nbr: Number; MSC: Medium Specific Concentration; mg/kg: milligrams per kilogram; Attnmt.: Attainment; Charac.: Characterization

Color coding: **292** Highest attainment test value; **203** Lowest attainment test value

Footnotes:

[1] Actual result in the dataset that is closest to, without exceeding, the 75th percentile

[2] From USEPA's ProUCL (See Attachment B)

[3] Although the data from this site is from characterization, it has been included in this analysis because the average of these data was used with the IEUBK Model to demonstrate attainment of the SSS.

[4] NE: No Exceedances, i.e., remediation proceeded until none of the results exceeded the MSC

Key to ProUCL 95% UCL Values:

AG: 95% Adjusted Gamma UCL (use when n<50)

H: 95% H-UCL; Disclaimer- *ProUCL computes and outputs H-statistic based UCLs for historical reasons only. H-statistic often results in unstable (both high and low) values of UCL95 as shown in examples in the Technical Guide. It is therefore recommended to avoid the use of H-statistic based 95% UCLs. Use of nonparametric methods are preferred to compute UCL95 for skewed data sets which do not follow a gamma distribution.*

LN: Lowest ProUCL nonparametric 95% UCL – ProUCL did not suggest this value

HN: Highest ProUCL nonparametric 95% UCL – ProUCL did not suggest this value

ST: 95% Student's-t UCL

6.2. Comparison of Attainment Test Results

The purpose of analyzing these datasets has been to examine the relative concentrations of the average, 75%/10X and 95% UCL tests for each of them. The expectation has been that the average concentration would be the lowest of the three and the 75%/10x and 95% UCL would be consistently higher and reasonably close to each other.

Concentrations for each of these attainment values have been color coded in Table 2 to show which of them is the lowest and highest for each of the ten datasets. For eight of the datasets, the average concentration is, as expected, the lowest of the three. For the other two, the 75%/10X concentration is the lowest. However, the difference between 75%/10X value and the average value in each case is not so great (38.4 mg/kg vs 61.9 mg/kg and 56.4 mg/kg vs 67.1 mg/kg).

Table 2 also shows the 95% UCL concentration to be the highest of the three concentrations for eight of the ten datasets. For one of these, Site 3, there are three 95% UCL values listed. The first one is the suggested statistic, but the key to ProUCL values indicates that a nonparametric 95% UCL should be used. ProUCL lists many nonparametric options, none of which is identified as preferred. For this reason, the lowest and highest nonparametric values are also listed for Site 3. The lowest of these is 1129 mg/kg, which is not nearly so much higher than the 961 mg/kg 75%/10X value as the suggested value of 2099 mg/kg.

For the other two sites, the 75%/10X concentration is the highest. For one of these, Site 4, HE-2, the difference is insignificant (207 mg/kg vs 203 mg/kg) and for the other, Site 4, All Attainment, the difference is only slightly more significant (149 mg/kg vs 132 mg/kg).

These relationships can also be viewed on the graphs in Attachment B, along with the ProUCL printouts.

Finally, an eleventh dataset was created by combining the seventy-four attainment samples from Site 4 with the eighty-eight characterization samples from that site. The resultant dataset has 162 samples ranging from <0.5 mg/kg to 24, 900 mg/kg. The average was 998 mg/kg, which, as will be shown, is why it was examined. Although it is obviously not a true attainment sample dataset, nonetheless, all the results exist on one property. It was therefore used to address one of the Department's concerns that the average of a large dataset might be used to successfully demonstrate attainment with many of the samples exceeding the MSC by more than ten times. In the case of this dataset, if the MSC were the current nonresidential direct contact NV of 1000 mg/kg, the average of 998 mg/kg would demonstrate attainment and the maximum value of 24,900 mg/kg would be nearly twenty-five times the MSC. Only two other results in this dataset exceed ten times the MSC. Discussion of this example focused on the need to examine possible limitations that could accompany the regulatory provisions of the average attainment test. Such a solution is identified in the recommendations at the end of this report.

7. SUMMARY

This section provides a summary of the key points made in the report that are supportive of the Workgroup rationale supporting the appropriateness of the average attainment test.

Summary Point #1: Lead is unique among regulated substances that are systemic toxicants for two reasons:

- There are no systemic toxicity values available for lead to calculate NVs, therefore, lead NVs are calculated using models based on a public health policy tool (the TBLL). Were there an acceptable systemic toxicity value for lead, it would be possible to compare the lead MSC using the standard methodology applied to all other systemic toxicants to the model-generated MSC to assess which methodology provides the more conservative results. That is not possible since there is no reference dose or concentration available for lead and the methodology for calculating lead NVs/MSCs is unique among all other systemic toxicants.
- The models used to calculate lead NVs are multimedia models that include inputs of lead not just from contaminated soil, but also from air, drinking water, house dust, food and maternal blood. This is not the case with other regulated substances for which only inputs from soil are considered. The use of this multimedia pathway approach instead of focusing only on lead in soil unquestionably shifts the resultant NVs in a more conservative direction. Were that modeling to be done with only the soil input, the model-calculated residential direct contact MSC would be 686 mg/kg, not 200 mg/kg. (There is no suggestion in this report that the multimedia approach in these models be changed.)

Given this unique methodology for calculating NVs for direct contact to lead in soil, it is appropriate to consider attainment criteria recommended for use with these models. (see Section 2)

Summary Point #2: While allowing for the use of an Upper Confidence Limit (UCL) EPA provides a recommendation and instructions to use the average concentration of lead in soil with the IEUBK Model as the soil lead concentration (PbS) input. This recommendation and instructions are documented in the following excerpts from the IEUBK Model User's Guide[7] (See Section 4):

- *2.3.4.2 Lead in Soil*
  The TRW[8] recommends replacing the default constant soil value (200 µg/g) (or variable values) with site-specific data representative of the average soil Pb concentration for the exposure scenario. (Page 36)

- *2.3.4.2.1 Developing a Soil Lead Concentration (PbS)*
  The PbS should be the arithmetic mean of the concentration of Pb in the soil that a child is likely to be exposed to. ….in most cases, the PbS would be the arithmetic mean concentration of Pb in soil of the DU. ….Typically, the simple average of the concentrations measured in each of the samples is appropriate…. The arithmetic average is appropriate when samples were collected using incremental composite sampling, when samples were collected using simple random sampling, and systematic sampling approaches that result in sample locations that were evenly spaced within the DU. (pages 36 and 37)

Summary Point #3: This use of the average of site-specific data for concentrations of lead in soil has been accepted by PADEP as the IEUBK Model input in Risk Assessment Mode under the SSS to demonstrate an acceptable risk level for direct contact to lead in soil by children ages 1-5 years. In this

[7] User's Guide for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) Version 2 (epa.gov)
[8] EPA's Technical Review Workgroup Lead Committee

mode, the model output is the calculated probability of exceeding a user-specified TBLL (i.e., 5 ug/dL) to be compared to a user-specified probability of exceedance cutoff (i.e., 5%).

Summary Point #4: Use of the average attainment test if permitted under the SHS would be no less conservative or protective than its use under the SSS, as currently permitted by the Department. This is due primarily to a preference for remediation remedies under the SHS and the inclusion of cumulative effects across the same multimedia exposure pathways addressed under the SSS. The latter is unique to lead among regulated substances. (see Section 5)

- Based on the collection of characterization data with values above and below the MSC, the SHS would require the remediation of all soil exceeding the MSC before any attainment testing is performed.
- The SHS therefore includes a preference for permanent remedial actions that results in a reduction of toxicity, mobility and volume.
- By applying multimedia models to the calculation of NVs for lead, the MSC under the SHS includes cumulative effects across exposure pathways not otherwise included for other systemic toxicants making it uniquely equivalent to the SSS for lead in that respect.

Summary Point # 5: The evaluation of three attainment tests applied across ten datasets shows a relationship among them that is predominantly what was anticipated, i.e., the preponderance of the results showed the ascending order of these test values to be the average, the 75%/10X ad hoc rule and the 95% UCL of the mean.

- The results for eight of the ten datasets showed the lowest value to be the average; for the other two, the lowest value was for the 75%/10X test.
- Evaluation of an eleventh dataset created to examine the potential need for limitations on high concentrations led to the identification of an existing provision of Chapter 250 that has been considered to address this issue and is referenced in the following recommendations. (see Section 6 and Attachment B).
- As the 95% UCL test value will always be higher than the average test value, adoption of the average as a third attainment test will largely eliminate the use of the 95% UCL test. However, there is no suggestion made in this report that either the 95% UCL test or the 75%/10X test be eliminated for lead.

8. Recommendations

Based on the conclusions enumerated above, the Workgroup recommends that the PADEP adopt an average attainment test, solely for direct contact to lead in soil, at § 250.707(b)(1) as follows:

> *(iv) For sites with a release of lead or lead compounds that has been remediated to attain an MSC for lead based on an ingestion numeric value calculated in accordance with the requirements of § 250.306(e) and Appendix A, Table 7, the arithmetic average of all attainment samples, which shall be randomly collected in a single event from the site, shall be equal to or less than the applicable MSC.*

This recommendation is made with the understanding that the average attainment test will be exempt from the requirements of § 250.707(d) (see Attachment C), and subject to the existing sampling requirements of § 250.703(d), and the existing limitations on high concentrations of § 250.703(c), which read as follows:

> *§ 250.703*
> *(c) Sampling points for demonstration of attainment of soils shall be selected to be random and representative both horizontally and vertically based on a systematic random sampling as set forth in a Department approved reference. If exceedances of a standard occur in a localized area, the Department may require additional characterization and remediation if three or more adjacent samples exceed the standard by more than ten times.*
>
> *(d) For statistical methods under § 250.707(b)(1)(i) and (iv) (relating to statistical tests), the number of sample points required for each distinct area of contamination to demonstrate attainment shall be determined in the following way:*
>
> *(1) For soil volumes equal to or less than 125 cubic yards, at least eight samples.*
> *(2) For soil volumes up to 3,000 cubic yards, at least 12 sample points.*
> *(3) For each additional soil volume of up to 3,000 cubic yards, an additional 12 sample points.*
> *(4) Additional sampling points may be required based on site-specific conditions*

Attachment A: Lead Attainment Subgroup White Paper

1. INTRODUCTION

The Cleanup Standards Scientific Advisory Board (CSSAB, or Board) to the Land Recycling Program (LRP) of the Pennsylvania Department of Environmental Protection (PADEP, or Department) unanimously submitted a memo entitled, "*Memorandum - Consideration for the Application of the IEUBK Model and ALM for the Development of Soil Direct Contact Values for Lead within the Act 2 Program"* to the LRP on September 17, 2020 (Memo).

The Memo expressed the CSSAB's support for the Department's decision to replace the two models currently being used to calculate direct contact soil numeric values (NVs) for residential and nonresidential land use with the Integrated Exposure Uptake Biokinetic (IEUBK) Model (version 1.1) (residential) and the Adult Lead Model (ALM) (nonresidential), both developed and supported by the United States Environmental Protection Agency (EPA).

The Memo also included a recommendation that the Department consider the use of the average as an additional attainment demonstration option for lead in soil under the Statewide health standard. Specifically, the final paragraph of the CSSAB 2020 Memo states:

> *"Based on this analysis of attainment demonstration alternatives, use of the average lead concentration should be considered as an additional option for the attainment demonstration so that the attainment "toolbox" includes a mechanism that meshes with the input criteria in the IEUBK model and ALM. By the same token, persons wishing to use the two existing attainment tests could do so consistent with what is currently provided for in the regulations implementing Act 2."*

In the August 11, 2021 meeting of the CSSAB, the Department requested that a new lead workgroup be assembled to address concerns from members of the LRP staff regarding the use of the average as an attainment test for lead. Subsequently, the 2021 Lead Workgroup was assembled in September 2021. During the first meeting of the workgroup, two subgroups were formed, one to address attainment criteria including use of the average, and one to address follow-on characterization issues as necessary. **In its current form, this white paper has been developed to support deliberations of the Lead Attainment Subgroup. As such, its principal purpose is to present the science and other facts underlying the development of Act 2 NVs and medium-specific concentrations (MSCs) for lead in soil, without expressing opinions or conclusions regarding the appropriateness of using the average as an attainment test. The goal has been to facilitate the subgroup's efforts to accommodate all opinions and arrive at conclusions as a group, not preempt that process. Eventually, some parts of this white paper may be incorporated into a report prepared by the full 2021 Lead Workgroup regarding the use of the average concentration of attainment sampling results as an attainment test, in addition to the two currently available attainment tests.**

In the text that follows, frequent reliance is made on language from published sources. Where this is the case, the borrowed language is shown in italics and a reference or link to the source is provided.

2. UNIQUE TREATMENT OF LEAD FOR THE DIRECT CONTACT SOIL EXPOSURE PATHWAY

Beginning with the language of Act 2 of 1995 and continuing with the development of draft regulations in 1996 and the final regulations in 1997, the stage was set for numeric values (NVs) associated with direct contact with soil containing lead to be calculated differently from NVs for other regulated substances.

2.1. Applicable Statutory Language

The applicable language of Act 2 of 1995 is contained in Section 303, the full text of which is provided in Attachment A. The following excerpt applies to the factors to be used in establishing the direct contact NVs to be applied in the development of Medium-Specific Concentrations (MSCs) for lead in soil:

> ***Act 2 of 1995, Section 303. Statewide health standard.***
>
> *(c) Additional factors. -- When establishing a medium-specific concentration, …. the medium-specific concentration for the ingestion of groundwater, inhalation of soils, ingestion and inhalation of volatiles and particulates shall be calculated by the department using valid scientific methods, reasonable exposure pathway assumptions and exposure factors for residential and nonresidential land use which are no more stringent than the standard default exposure factors established by EPA based on the following levels of risk:*
>
> *(1) For a regulated substance which is a carcinogen, the medium-specific concentration is the concentration which represents an excess upper bound lifetime cancer target risk of between 1 in 10,000 and 1 in 1,000,000.*
>
> *(2) For a regulated substance which is a systemic toxicant, the medium-specific concentration is the concentration to which human populations could be exposed by direct ingestion or inhalation on a daily basis without appreciable risk of deleterious effects for the exposed population.*

2.2. Development of Numeric Values for Lead Compared to Other Systemic Toxicants

The first step in implementing this statutory language in developing the original Chapter 250 regulations was to identify toxicity values available from authoritative sources for each regulated substance relative to carcinogenicity and systemic effects. Under Section 250.303(c)(1) those values could include an Oral Cancer Slope Factor (CSF_O) for the ingestion exposure route and an Inhalation Unit Risk (IUR) for the inhalation exposure route. Similarly, under Section 250.303(c)(2) the toxicity values could include an Oral Reference Dose (RfD_O) for the ingestion exposure route and an Inhalation Reference Concentration (RfCi) for the inhalation exposure route. For each regulated substance, any number, or none of these values might have been available.

When the final Chapter 250 regulations were published in 1997, none of these toxicity values existed for lead and lead compounds from an authoritative source. Since then, the California EPA (CA EPA) has developed CSF_O and IUR values for lead. As CA EPA is an acceptable source for toxicity values under Chapter 250, these two values are listed for lead in Chapter 250, Appendix A, Table 5B. However, NVs calculated using these toxicity values for comparison to the NVs listed in Appendix A, Table 4 are substantially higher than the current NVs in that table, as well as the Department's proposed changes to those NVs.

To provide an understanding of the scientific rationale for the absence of toxicity values for lead, Attachment B provides a detailed accounting of the scientific reasoning associated with the decisions made in 2006 by the New York State Department of Environmental Conservation (NYSDEC) and the New York State Department of Health (NYSDOH) not to adopt toxicity values for lead and lead compounds. In that excerpt, NYSDEC and NYSDOH make the following concluding statements regarding non-cancer and cancer toxicity values:

Text from https://www.dec.ny.gov/docs/remediation_hudson_pdf/techsuppdoc.pdf

> ***Non-Cancer***
> *Many environmental guidelines or standards for lead are based on children as the sensitive population (e.g., CA EPA, 1997; Health Canada, 1992; RIVM, 2001; US EPA, 2000a, 2001; WHO, 1996). The derivations of these guidelines, however, are different from the derivation of guidelines for most contaminants. The guidelines are not based directly on a daily intake of lead from one route of exposure (for example, a reference dose for oral intake or a reference concentration for air intake) but are based on a blood lead level. The blood lead level is typically 10 mcg/dL (micrograms of lead per deciliter of blood), which is the Centers for Disease Control and Prevention (CDC) level of concern for blood lead in young children (ATSDR, 1999; CDC, 1991). In most cases, the guidelines are derived so that the blood levels of almost all children exposed at the guideline would be below 10 mcg/dL. This is the approach taken in the derivation of the SCOs for lead (see Section 5.3.4 Chronic Lead SCOs).* ***Thus, toxicity values (reference dose or reference concentration) for the non-cancer effects of lead are not proposed.*** **[emphasis added]**
> ***Cancer***
> *Only one of the authoritative bodies reviewed, the CA EPA, has derived oral cancer potency factors and inhalation unit risks for inorganic lead compounds (CA EPA, 1992, 1997, 2002, 2004). Most recently, the oral potency factor for lead was restricted to lead acetate, one of the two lead compounds shown to cause cancer via the oral route (CA EPA, 2005). In contrast, the US EPA (2005c) lead database for risk assessment in the Integrated Risk Assessment System, which is the peer-reviewed source for US EPA toxicity values for chemicals, contains the following statement:*
>
> > *Quantifying lead's cancer risk involves many uncertainties, some of which may be unique to lead. Age, health, nutritional state, body burden, and exposure duration influence the absorption, release, and excretion of lead. In addition, current knowledge of lead pharmacokinetics indicates that an estimate derived by standard procedures would not truly describe the potential risk.* ***Thus, the Carcinogen Assessment Group recommends that a numerical estimate not be used.***
> >
> > ***Given the problems associated with extrapolating animal data on lead to humans, animal-based oral cancer potency factors and inhalation unit risks for lead are not proposed.*** **[emphasis added]**

In the absence of toxicity values for lead, other methods were needed to calculate NVs for direct contact to lead in soil. Detailed accounts of the decisions made to identify and apply these methods are provided in relevant excerpts from the preambles to the 1996 draft Chapter 250 regulations and the 1997 final regulations reproduced herein in Attachment C. The following excerpt from the 1996 Preamble presents the basis for selecting the UBK model:

The direct contact soil MSC for lead for residential exposures has been estimated on the basis of protection of 95% of a population of children in the age range of 0 to 84 months. The Uptake Biokinetic (UBK) Model for Lead (version 0.4) was used to make this estimate. Although this model has been updated at least twice since version 0.4, this version was used because it was the version in use at the time the EPA developed its recommended residential lead-in-soil level of 500 mg/kg. Appendix A, Table 6 contains the input values that have been used in the model. The soil lead level from Appendix A, Table 6 (495 ug/g) has been rounded to 500 mg/kg which is the direct contact soil MSC for lead for residential exposures.

Note: A careful reading by Lead Attainment Subgroup members of the three excerpts in Attachments B and C is recommended.

The text of the current Chapter 250 regulations governing the calculation of NVs for direct contact to lead in soil as a systemic toxicant are unchanged from those published in 1997 in § 250.306(e), as follows:

(e) The residential ingestion numeric value for lead in soil was developed using the Uptake Biokinetic (UBK) Model for Lead (version 0.4) developed by the EPA (U.S. Environmental Protection Agency. (1990). Uptake Biokinetic (UBK) Model for Lead (version 0.4). U.S. EPA/ECAO. August 1990, in lieu of the algorithms presented in subsections (a) and (b). Default input values are identified in Appendix A, Table 7. Because the UBK model is applicable only to children, the nonresidential ingestion numeric value was calculated according to the method developed by the Society for Environmental Geochemistry and Health (Wixson, B. G. (1991)). The Society for Environmental Geochemistry and Health (SEGH) Task Force Approach to the Assessment of Lead in Soil. Trace Sub- stances in Environmental Health. (11-20)

As shown in Appendix A, Table 7 (Attachment D) the UBK model assumes a Target Blood Lead Level (TBLL) for children of 10 micrograms per deciliter (ug/dL), derived from the Centers for Disease Control and Prevention's (CDC) 1991 level of concern for lead poisoning prevention in children. However, the SEGH algorithm assumes a TBLL for adult receptors of 20 ug/dL. Both models are characterized as generating ingestion NVs and no inhalation NVs are calculated.

By contrast, the approach for other systemic toxicants regulated under the LRP is first to calculate the NV for substances with an RfD_O using the equations in subsection (a) and the exposure assumptions in subsection (d) of *§ 250.306. Ingestion numeric values* and the NV for substances with an RfCi using the equations in subsection (a) and the exposure assumptions in subsection (d) of *§ 250.307. Inhalation numeric values*. The exposure assumptions used in these calculations include either a substance-specific reference dose or reference concentration, or both. If both toxicity values are available, subsections (c) of both *§ 250.306 and § 250.307* require that NVs for each exposure route are calculated for residential and nonresidential land use. For each substance and land use the NV for direct contact with soil is the lower of the two NVs for ingestion and inhalation from 0-15 ft. below ground surface (BGS) for residential land use and 0-2 ft. BGS for nonresidential land use.

2.3. Soil Numeric Values and Medium-Specific Concentrations for Lead: 1997 - Present

Based on the output from the UBK Model and SEGH algorithm, the residential NV for direct contact to lead in soil is 500 milligrams per kilogram (mg/kg) and the NV for nonresidential land use is 1000 mg/kg. However, in accordance with Section 250.308, the soil-to-groundwater NV for lead was calculated to be 450 mg/kg. Section 250.305 requires, in effect, that the lowest of these three numbers, i.e., 450 mg/kg, becomes the Medium-Specific Concentration (MSC) for both the residential and nonresidential land use scenarios. (Exceptions to this rule occur when either equivalency or buffer distance is used to attain the soil-to-groundwater MSC, or the NV derived from using the Synthetic Precipitation Leaching Procedure (SPLP) test to attain the soil-to-groundwater MSC is greater than the applicable (i.e., residential or nonresidential) direct contact NV, leading to the direct contact NV being the MSC.

3. PROPOSED PADEP NUMERIC VALUE AND MEDIUM-SPECIFIC CONCENTRATION REVISIONS

In the August 2021 CSSAB meeting, the Department proposed updating the models used to calculate NVs for direct contact to lead in soil for both residential and nonresidential land use. As shown in Table 1, the Department proposes to replace the UBK Model with the IEUBK Model (version 2.0) for residential land use and the SEGH algorithm with the Adult Lead Model (ALM) for nonresidential land use.

Table 1: Proposed Changes in Models, NVs for Direct Contact to Lead in Soil and MSCs

Land Use	Current Model	New Model	Current TBLL (ug/dL)	New TBLL (ug/dL)	Current DC* NV (mg/kg)	New DC* NV (mg/kg)	Soil-to-GW NV** (mg/kg)	Current MSC*** (mg/kg)	New MSC (mg/kg)
Residential	UBK	IEUBK	10	5	500	200	450	450	200
Nonresidential	SEGH	ALM	20	5	1,000	1050	450	450	450***

*DC: Direct contact **No change will occur in this NV ***In the absence of exceptions noted above

Table 1 also shows the Department's proposal would lower the TBLL from 10 ug/dL and 20 ug/dL for residential and nonresidential land use, respectively, to a consistent 5 ug/dL. The selection of this TBLL is based on the default value included in the IEUBK Model version 2.0 released by EPA in May 2021. The Department's proposal also assumes a 5% probability of exceedance cutoff for both models. As the table shows, adoption of the IEUBK Model v. 2.0 will lower the residential NV from 500 mg/kg to 200 mg/kg. However, the use of the ALM together with the 5 ug/dL TBLL will result in a small increase in the nonresidential NV from 1000 mg/kg to 1050 mg/kg.

Importantly, the table shows the soil-to-groundwater NV of 450 mg/kg will not change. As noted above, because this NV is currently lower than either of the direct contact NVs, the soil-to-groundwater NV is currently the MSC for both land uses. In the absence of any of the infrequent exceptions noted above, this will still be the case for the nonresidential land use scenario. However, with the adoption of 200 mg/kg for the residential scenario NV, that value will then be lower than the soil-to-groundwater NV, making it the applicable MSC for residential sites.

For this reason and, as a consequence of the proposed residential MSC of 200 mg/kg representing the lowest value for lead in soil proposed to date, the focus of the remainder of this white paper will be on the conservatism of using the IEUBK Model to derive residential direct contact NVs relative to the process used for other substances, the derivation of the TBLL and related CDC Blood Lead Reference Levels (BLRVs), and the significance of naturally occurring background levels of lead in surficial soils of Pennsylvania.

4. CDC GUIDANCE ON BLOOD LEAD LEVELS IN CHILDREN

4.1. History of CDC Criteria for Blood Lead Levels in Children, 1960 - 1991

The italicized text and table in this subsection are excerpted from the Morbidity and Mortality Weekly Report dated October 29, 2021 (the MMWR).

https://www.cdc.gov/mmwr/volumes/70/wr/mm7043a4.htm

See also CDC Updates Blood Lead Reference Value for Children | CDC Online Newsroom | CDC

CDC has been involved in defining the criteria for interpreting BLLs in children since 1971 (Table 1). The criteria for interpreting BLLs in children was revised over time based on new clinical and scientific evidence and improved laboratory technologies.

TABLE 1. Definitions for interpreting children's blood lead levels — United States, 1960–2021

Year	Blood lead level (µg/dL)	Interpretation*
1960	60	NA
1970	40	Undue or increased lead absorption
1975	30	Undue or increased lead absorption
1978	30	Elevated blood lead level
1985	25	Elevated blood lead level
1991	10	Level of concern
2012	5	Reference value
2021	3.5	Reference value

Abbreviation: NA = not available.
* https://stacks.cdc.gov/view/cdc/61820

The 10 ug/dL Level of Concern from 1991 was applied by EPA as the TBLL in the UBK Model (version 0.4) used to calculate the current residential direct contact NV for lead in soil.

4.2. Introduction of the Population-Based Blood Lead Reference Value (BLRV) in 2012

In 2012, CDC introduced the population-based blood lead reference value (BLRV) to identify children exposed to more lead than most other children in the United States…. The BLRV is based on the 97.5th percentile of the blood lead distribution in U.S. children aged 1–5 years from National Health and Nutrition Examination Survey (NHANES) data… [see NHANES - About the National Health and Nutrition Examination Survey (cdc.gov)] *The initial BLRV of 5 µg/dL, established in 2012, was based on data from the 2007–2008 and 2009–2010 NHANES cycles. In 2012, CDC's former Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP) recommended the establishment of the BLRV and proposed it be set at 5 µg/dL (5). This recommendation was based on the weight of evidence indicating that the adverse health effects of BLLs <10 µg/dL in children included neurologic, cardiovascular, immunologic, and endocrine effects. ACCLPP further*

recommended that the BLRV be updated every 4 years based on the 97.5th percentile of BLLs for children aged 1–5 years across the two most recent combined NHANES cycles for which data are available.

4.3. Update to the BLRV in 2021

The Lead Exposure and Prevention Advisory Committee (LEPAC) was established under the Water Infrastructure Improvements for the Nation Act of 2016. The LEPAC is charged with providing advice and guidance to the Secretary of U.S. Department of Health and Human Services (HHS), Director of CDC, and Administrator of Agency for Toxic Substances and Disease Registry on matters related to lead poisoning prevention and surveillance. In 2020, LEPAC charged a BLRV workgroup with providing advice and guidance regarding new scientific knowledge and technological developments to guide the BLRV. During a May 2021 meeting of the LEPAC, the workgroup recommended that the BLRV be updated from 5 µg/dL to 3.5 µg/dL using data derived from the two most recent NHANES cycles (2015–2016 and 2017–2018), and the LEPAC voted unanimously to accept this recommendation (6). Subsequently, the committee submitted a formal recommendation to the HHS Secretary to update the BLRV from 5 µg/dL to 3.5 µg/dL… The HHS Secretary and CDC concur with the recommendation and have developed communication and implementation plans to announce and promote the BLRV update, including to those at greatest risk.

The BLRV is a population-based measurement which indicates that 2.5% of U.S. children aged 1–5 years have BLLs ≥3.5 µg/dL. It is not a health-based standard or a toxicity threshold. The BLRV should be used as a guide to 1) help determine whether medical or environmental follow-up actions should be initiated for an individual child and 2) prioritize communities with the most need for primary prevention of exposure and evaluate the effectiveness of prevention efforts.

The most common sources of lead exposure in the United States are lead-based paint and dust, lead-contaminated soil, and lead in water from lead pipes and plumbing fixtures (1).

Attachment E presents a table of NHANES statistics for the years in question that were reportedly used by LEPAC's BLRV Workgroup to support the update of the BLRV from 5 ug/dL to 3.5 ug/dL. This table shows 97.5th percentile values of BLL of 3.48 ug/dL for two cycles from 2011 – 2014 and 3.44 ug/dL for two cycles from 2015 to 2018.

(**Personal communication**, December 4, 2021, Jill Ryer-Powder, Ph.D., MNSP, DABT, Chair CDC BLRV Workgroup, Member LEPAC)

See also May 2021 presentation to LEPAC by Jill Ryer-Powder, Ph.D., MNSP, DABT, Chair CDC BLRV Workgroup, Member LEPAC: Blood Lead Reference Value: Recommendation to LEPAC (cdc.gov)

A full copy of the BLRV Workgroup's August 10, 2021 report can be found at: https://www.cdc.gov/nceh/lead/docs/lepac/BLRV-recommendation-report-508.pdf

The NHANES datasets are available at: NHANES Questionnaires, Datasets, and Related Documentation (cdc.gov), but they require SAS software to download.

4.4. How does a BLRV Differ from a Reference Dose or Reference Concentration?

In a personal email communication on October 5, 2021, Dr. Ryer-Powder stated the following (emphasis added):

> *Please note that the BLRV is not a health-based number – rather it represents a value based on the 97.5th percentile of blood lead level (BLL) concentrations for US children aged 1 to 5 years. The BLRV is neither a clinical reference level defining an acceptable range of blood lead levels in children nor is it a health-based toxicity threshold; rather it is a policy tool that helps identify the children in the upper end of the population blood lead distribution in order to target prevention efforts and evaluate their effectiveness.* ***This is important to understand when setting a standard for "acceptable" concentrations of lead in soil.*** **[emphasis added]**

For this and other reasons, it's appropriate to examine how the BLRV differs from reference doses and reference concentrations.

4.4.1. Threshold Dose-Response RfD_O and RfCi vs Non-threshold Public Health Policy BLRV

The oral reference dose (RfD_O) and inhalation reference concentration (RfCi), which are toxicity values used to evaluate potential systemic health effects, are estimates (with uncertainty spanning perhaps one or more orders of magnitude) of a daily exposure level for the human population, including sensitive subpopulations, that is likely to be without an appreciable risk of deleterious effects during a lifetime. Thus, the RfD_O and RfCi represent thresholds below which deleterious health effects are unlikely to occur.

RfD_Os and RfCis are derived from laboratory or human studies in which the administered concentration corresponding to the no observed adverse effect level (NOAEL) or lowest observed adverse effect level (LOAEL) for a critical toxic effect is divided by various uncertainty factors (UFs) and a modifying factor (MF). The uncertainty factors generally consist of multiples of 10 (although values less than 10 are sometimes used), with each factor representing a specific area of uncertainty inherent in the extrapolation from the available data. A UF of 10 is used to account for variation in the general population and is intended to protect sensitive subpopulations (e.g., elderly, children). A UF of 10 is used when extrapolating from animals to humans. A UF of 10 is used when a NOAEL derived from a sub-chronic instead of a chronic study is used as the basis for a chronic RfD. A UF of 10 is used when a LOAEL is used instead of a NOAEL. The MF is a value that typically ranges from 0 to 10 to reflect a qualitative professional assessment of additional uncertainties in the critical study and in the entire data base for the chemical not explicitly addressed by the preceding uncertainty factors. Depending on the chemical and available data, the combination of UFs and the MF can impart a margin of safety of several orders of magnitude (e.g., 1,000-fold or more) to the NOAEL or LOAEL. As such, RfD_Os and RfCis are based on dose-response relationships from human or animal studies with potentially high levels of uncertainty.

By contrast, the following excerpt is from the first paragraph of the Executive Summary in the BLRV Workgroup's August 10, 2021 report recommending the change to 3.5 ug/dL (emphasis added):

> ***No safe level of lead exposure has been identified for children.*** *Protecting children from childhood lead poisoning requires the collective work of many partners, including but not limited to a range of federal, state, territorial, and local agencies, as well as homeowners,*

> *landlords, and clinical providers.* ***The CDC blood lead reference value (BLRV), defined as the 97.5th percentile of blood lead level (BLL) concentrations for U.S. children aged 1 to 5 years****, is an important tool guiding the efforts of these stakeholders, but* ***is not a clinical reference level defining an acceptable range of blood lead levels in children, nor is it a health-based toxicity threshold, and it cannot be used to predict the health outcome for any particular child.***
> https://www.cdc.gov/nceh/lead/docs/lepac/BLRV-recommendation-report-508.pdf

Therefore, unlike reference doses and concentrations, the BLRV does not represent a threshold below which deleterious health effects are unlikely. In fact, if there is no safe level of exposure for the sensitive population represented by children ages 1-5, then, in this context, for certain toxicological effects lead is a systemic non-threshold substance. The BLRV is not based on dose-response studies, but rather on population-based statistics without quantitative equivalence to a toxicity threshold.

Lead also has been identified by EPA in IRIS as a B2 – probable carcinogen based on sufficient evidence of carcinogenicity in animals; however, the EPA has not established quantitative estimates (i.e., oral slope factors or inhalation unit risk factors) to define its potency.

4.4.2. Basis for Revising and Updating Values

The progression of BLRVs from 5 ug/dL in 2012 to 3.5 ug/dL in 2021 follows the recommendation made in 2012 by the ACCLPP that the BLRV be updated every four years based on the most recent NHANES data. In fact, that update to 3.5 ug/dL was first recommended in 2017 but was not successfully implemented. As NHANES data are collected and analyzed in future cycles, the following recommendation from the BLRV Workgroup in its August 10, 2021 report ensures that the BLRV will either remain the same or continue to be revised downward following positive progress in controlling children's exposure to lead, but will never be revised upward based on less encouraging results (emphasis added):

> *The Blood Lead Reference Value Workgroup recommends that the LEPAC adopt a revised BLRV of 3.5 µg/dL (based upon most recent NHANES cycles 2015-2018) [8]. The workgroup also recommends that that* [sic] *the LEPAC reaffirm CDC's commitment to regularly analyzing NHANES data to identify the 97.5th percentile and* ***adopt a policy that this analysis may be used to either maintain or lower, but never increase, the reference value in the future.***
>
> ***These recommendations are consistent with the use of a reference value that is not a threshold for toxicity, nor a fine line for determining when actionable steps should/ should not occur.***
> https://www.cdc.gov/nceh/lead/docs/lepac/BLRV-recommendation-report-508.pdf

This is a completely understandable approach for an agency committed to reducing lead exposures in children. However, this is unlike the basis for revising a reference dose or reference concentration upward or downward, which would only occur if additional authoritative dose-response studies showed the need for a higher or lower value due to higher or lower demonstrated toxicity.

5. IEUBK MODEL V. 2.0

This discussion of the IEUBK Model (version 2.0) will rely mostly on excerpts from the user's guide to be found at: User's Guide for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) Version 2 (epa.gov). (See also Tuesday_1400a-Partridge.PDF (clu-in.org) for a helpful EPA presentation on the IEUBK Model.)

The following subsections describe the components of the model, the modes in which it can be run, with related inputs and outputs and identification of examples. Figure 1 of this white paper is after Figure 1-1 of the User's Guide. It depicts the biological structure of the model.

5.1. Exposure Component

Exposure can be thought of as the contact with a chemical or other agent, which may result in the absorption or exchange across boundaries of an organism, such as the gut, lungs, and skin. The results from the exposure component of the IEUBK model are estimated intake rates for the quantities of Pb inhaled or ingested from environmental media. The media addressed by the IEUBK model include soil, house dust, drinking water, air, and food. Paint is usually addressed in terms of its contribution to the measured concentration of Pb in soil or house dust.

It should be noted, however, that the model defaults do not include a contribution from lead-based paint to Pb in soil or house dust, but it can be added as an alternate source. The media addressed do also include maternal blood.

Quantitation of a child's exposure to Pb (µg/day) requires estimation of the concentration of Pb in the environmental media that the child contacts (usually µg/g, µg/m^3, or µg/L), multiplied by a term to describe the child's daily intake of the medium (usually g/day, m^3/day, or L/day). The Exposure Module estimates how much Pb enters a child's body by calculating media-specific Pb intake rates using the following general equation:

*Pb Intake Rate = Media Pb Concentration * Media Intake Rate*

The values used for media Pb concentrations and media intake rates are either derived from site-specific data or standard default values established by the U.S. Environmental Protection Agency (EPA)... The media intake rates are age-specific... The Exposure Module calculates the intake of Pb from each medium for use in the Uptake Module.

5.2. Uptake Component

The uptake component models the processes by which Pb intake (Pb that has entered the child's body through ingestion or inhalation) is transferred to the blood plasma. Uptake (µg/day) is the quantity of Pb absorbed per unit time from portals of entry (gut, lung) into the systemic circulation of blood. Only a fraction of the Pb entering the body through the respiratory or gastrointestinal (GI) tracts is absorbed into the systemic circulation. This absorption fraction (AF) is, by convention, termed bioavailability and integrates uptake processes which involves bioaccessibility and absorption. The IEUBK model allows for different bioavailabilities of Pb from different environmental media and includes for a partial saturation of GI absorption at high levels of Pb intake.

The Uptake Module calculates media-specific Pb uptake rates using the following equation:

*Pb Uptake Rate = Pb Intake Rate * Absorption Factor*

The Pb intake rates are calculated by the Exposure Module, and the absorption factors are typically standard default values established by EPA. The Pb intake rates and absorption factors are both age- and media-specific. Absorption factors reflect the percentage of Pb that enters the bloodstream after intake from a specific environmental medium. The overall Pb uptake value can be obtained by summing the media-specific Pb uptake values.

5.3. Biokinetics Component

The biokinetic module addresses the transfer of absorbed Pb between blood and other body tissues; the elimination of Pb from the body via urine, feces, skin, hair, and nails; and the storage and/or disposition of Pb in the extra-cellular fluid, red blood cells, liver, kidney, spongy bone, compact bone (e.g., femur), and other soft tissue. The total amount of Pb in each body compartment is age dependent and calculated using total Pb uptake derived by the Uptake Module.

The biokinetic component of the IEUBK model is, therefore, a mathematic expression of the movement of absorbed Pb throughout the body over time by physiologic or biochemical processes. This module converts the total Pb uptake rate from the uptake component into an input to the central plasma-extracellular fluid (ECF) compartment. A variety of complex equations are used to calculate compartmental Pb transfer times. Transfer coefficients are used to model movement of Pb between the internal compartments and to the excretion pathways. The quantities are combined with the total Pb uptake rate to continuously recalculate the Pb masses in each of the body compartments and especially the changing concentration of Pb in blood. Thus, based on site-specific environmental exposures input by the user or default values, a [geometric mean] *GM PbB concentration is predicted.*

5.4. Variability: Probability Distribution Module & Probability Density Curve

An important goal of the IEUBK model is to address variability in PbB concentrations among exposed children. Children having contact with the same concentrations of environmental Pb can develop very different PbB concentrations due to differences in behavior, household characteristics, and individual patterns of Pb uptake and biokinetics. The IEUBK model uses a log-normal probability distribution to characterize variability. The biokinetic component output provides a central estimate of PbB concentration, which is taken to be the GM of a lognormal distribution. The geometric standard deviation (GSD) determines the shape (spread) of the lognormal distribution. The recommended default value for this parameter (1.6) was derived from empirical studies with young children where both blood and environmental Pb concentrations were measured (White et al., 1998).

The Probability Distribution Module estimates a plausible distribution of PbB concentrations that is centered on the GM PbB concentration calculated by the Biokinetic Module. From this distribution, the model calculates the probability or risk that a child's PbB concentration will exceed a user-selected PbB level of concern (e.g. 5 µg/dL). In running this portion of the model, the user specifies a PbB level of concern and a GSD. For

most sites, EPA recommends use of the default values for both the GSD and PbB level of concern.

The results generated by the biokinetics component can be displayed by the model in a Probability Density Curve as shown on Figure 2 for the inputs assumed in calculating the proposed NV of 200 mg/kg (i.e., TBLL = 5 ug/dL and probability of exceedance cutoff = 5%).

5.5. Model Inputs and Defaults

2.1 Inputs
IEUBK contains more than 100 input parameters that are initially set to default values. Of these, many may be changed by the user; the remaining internal model parameters are set to fixed default values. The default values represent national averages or plausible central values that were developed based on peer reviewed literature and research. (page 25)

2.3.4.2 Lead in Soil
The TRW recommends replacing the default constant soil value (200 µg/g) [NV calculated by PADEP] *(or variable values) with site-specific data representative of the average soil Pb concentration for the exposure scenario.* (page 36)

2.3.4.2.1 Developing a Soil Lead Concentration (PbS)
The soil lead concentration term (PbS) is the only input parameter of the Model for which a site-specific value is necessary…. A site PbS may reflect the current exposure scenario (i.e., to predict current risk) or (potential) future exposure scenarios; ***for example, a PbS for future exposure scenarios may reflect a preliminary remediation goal.***

The PbS should be the arithmetic mean of the concentration of Pb in the soil that a child is likely to be exposed to. *Unless there is site-specific information to the contrary, the child is usually assumed to have an equal chance of contacting soil throughout the decision unit (DU); therefore, in most cases, the PbS would be the arithmetic mean concentration of Pb in soil of the DU. The method for estimating the arithmetic mean depends on how the soil samples were collected. Typically, the simple average of the concentrations measured in each of the samples is appropriate (the sum of the sample concentrations divided by the number of samples).* ***The arithmetic average is appropriate when samples were collected using incremental composite sampling, when samples were collected using simple random sampling, and systematic sampling approaches that result in sample locations that were evenly spaced within the DU.*** (pages 36 and 37).

Attachment F lists the default values for the IEUBK version 2.0 model parameters. As stated in Section 3, the Department has generated the proposed direct contact soil NV using the default model parameters.

5.5.1. Running the Model

The model is used in two principal ways:

1. to calculate a geometric mean PbB and the associated probability of exceedance of a user-specified PbB (Run Mode or Risk Assessment Mode) or
2. to calculate the soil concentration that would result in a user-specified probability of exceedance of a user-specified PbB (Find Mode or PRG mode).

The model inputs and calculations are the same for both methods of using the model. The difference between these two modes is essentially what variable is being sought. For example, using the model defaults for all input parameters (including an "outdoor soil lead concentration" of 200 ug/g or mg/kg), in Run Mode, the model generates a probability distribution graph showing a 4.979% probability (effectively 5%) of exceeding a PbB of 5ug/dL. This is the mode in which the model is run to demonstrate an input concentration is predicted to satisfy the 5% probability of exceedance cutoff for a selected BLL goal. The following is excerpted from footnote #11 in the CSSAB's 2020 Memo:

> *From the IEUBK User's Guide* [v.1.1] *(section 2.2.4): "The TRW recommends that the soil contribution to dust lead be evaluated by comparing the average or arithmetic mean of soil lead concentrations from a representative area in the child's yard.*
>
> *The IEUBK model can use an upper confidence limit (UCL); however, the interpretation for the model results is somewhat different if a UCL is used. If an arithmetic mean (or average) is used, the model provides a central point estimate for risk of an elevated blood lead level. If a UCL is used, the model result could be interpreted as a more conservative estimate of the risk of an elevated blood lead level."*
> Link no longer available.

The use of a UCL is further addressed in the user's guide for IEUBK model version 2.0 section 2.3.4.2.1 as follows:

> *There will be some uncertainty in the estimate of the PbS due to the variability of Pb concentration in the DU soil. Theoretically, the distribution of PbB concentration that is predicted by the IEUBK model accounts for the uncertainty in the PbS (Section 2.3.8). In some cases, a risk assessor may choose to use an upper confidence limit (UCL) on the arithmetic mean PbS to account for the uncertainty in the estimate (EPA, 2007); however, this is less common for site lead risk assessment. The performance or acceptance criteria should be established in Step 6 of the DQO process (EPA, 2006). These criteria should be used* [to] *determine the required sample size.* (page 38)
> https://semspub.epa.gov/src/document/HQ/400700

Running the model in Find Mode using the same default input parameters, a "Change Cutoff" of 5 ug/dL, and a "Probability of Exceeding Cutoff" of 5%, the model generates a "Soil and/or Dust Concentration" of 200 ppm or mg/kg. This is the manner in which the model was run by the Department to generate a PRG of 200 mg/kg that is the proposed NV/MSC for direct contact to lead in soil.

> *The PRG is the average concentration of a chemical in an exposure area that will yield the specified target risk in an individual who is exposed at random within the exposure area.*
> Calculating Preliminary Remediation Goals (PRGs) | US EPA

5.5.2. Selection of Target Blood Lead Level (TBLL) and Probability of Exceedance Cutoff

The first decision to be made in applying the IEUBK Model is to select the TBLL and the probability of exceedance cutoff. As noted above, the Department's current proposal is to select 5% as the probability of exceedance cutoff and to lower the TBLL from 10 ug/dL to 5 ug/dL based on EPA's adoption of the latter as the default in the IEUBK Model v. 2.0 in May 2021.

6. NATURALLY OCCURRING LEAD IN SURFICIAL SOILS IN PA

With the reduction proposed in the residential direct contact numeric value for lead in soil from 500 mg/kg to 200 mg/kg, it was apparent that the new MSC for lead in soil would fall much closer to the

range of background concentrations for lead in Pennsylvania soils. Geologists on the subgroup identified data available from the United States Geological Survey (USGS) that could provide a basis for examining the relationship between the proposed MSC and background concentrations in surficial soil in PA.

6.1. USGS Background data for lead in surface soils

In 2007, the U.S. Geological Survey initiated a low-density (1 site per 1,600 square kilometers, 4,857 sites) geochemical and mineralogical survey of soils of the conterminous United States as part of the North American Soil Geochemical Landscapes Project. Sampling and analytical protocols were developed at a workshop in 2003, and pilot studies were conducted from 2004 to 2007 to test and refine these recommended protocols. The final sampling protocol for the national-scale survey included, at each site, a sample from a depth of 0 to 5 centimeters, a composite of the soil A horizon, and a deeper sample from the soil C horizon or, if the top of the C horizon was at a depth greater than 1 meter, from a depth of approximately 80–100 centimeters. The <2-millimeter fraction of each sample was analyzed for a suite of 45 major and trace elements by methods that yield the total or near-total elemental content.

USGS Data Series 801: Geochemical and Mineralogical Data for Soils of the Conterminous United States

Attachment G presents a table that contains a full listing of these 75 samples for the 0-5 cm sampling depth. As shown in this table, each sample is characterized by two Land Cover categories that describe its provenance (e.g., Forested Upland / Mixed Forest). The locations of all 75 sampling sites are shown on Figure 3.

6.2. USGS Background Lead in Soil Concentration Statistics from EPA Website

Based on the data listed in Attachment G, the EPA published statistics for the full data listing and the data listing with two outliers excluded (based solely on an outlier screen), both as shown in Table 2. The provenance of the two highest values that EPA excluded was reviewed and both were found to be from upland forest and examination of the sample site location map showed they were not adjacent to highways or industrial areas. Therefore, the decision was made to use the statistics in Table 2 from the full data set for further analysis.

Table 2: Statistics for Naturally-Occurring Concentrations of Lead in Surficial Soils in PA

Geogenic Soil Lead Concentrations (mg/kg): 2007-2010 (All Data)

Number of Samples	Mean	Std Error	95 UCL	Std Dev	Coeff of Variation	Min	Q1	Median	Q3	90th	95th	99th	Max
75	60.2	5.3	68.9	45.6	0.758	14.7	31.8	46.4	69.3	118	153	261	261

Geogenic Soil Lead Concentrations (mg/kg): 2007-2010 (Outliers Excluded)

Number of Samples	Mean	Std Error	95 UCL	Std Dev	Coeff of Variation	Min	Q1	Median	Q3	90th	95th	99th	Max
73	55.0	3.9	61.4	33.2	0.605	14.7	31.8	46.1	66.5	105	132	161	161

About These Tables:

These tables show the overall occurrence of lead in surface samples as described by USGS.

Sources of These Data:

The U.S. Geological Survey provided the soil sampling data. The data display was prepared by U.S. Environmental Protection Agency. USGS Background Soil-Lead Survey: State Data | US EPA

6.3. Potential Effect of Natural Background Lead in Soil on BLLs in Children

Given the frequent cautions that no blood lead level (BLL) is safe, it seemed that lead concentrations in the range of those shown in Attachment G, with the statistics listed in Table 2 might warrant examination for the potential effect of natural background soil concentrations on BLLs. The statistics in Table 2 (All Data) for the mean, 95% UCL of the mean and the 95th percentile were run through the model with all media inputs set at defaults and probability of exceedance cutoff set at 5% to calculate the corresponding BLLs. The results of these calculations are shown in Table 3.

Table 3: Calculated Effect of Natural Background Lead in PA Surface Soils on BLLs in Children

	USGS Background Lead in PA Surface Soils (Top 5 cm) (mg/kg)	IEUBK Model Calculated* BLLs in Children Based on USGS Background Soil Concentration Statistics (ug/dL)
Average	60.2	3.16
95 % Upper Confidence Limit	68.9	3.27
95th Percentile	153	4.38

Notes:
PA – Pennsylvania
BLL - Blood lead level
cm – centimeters
mg/kg - milligrams per kilogram
UCL - upper confidence limit of the mean
IEUBK - Integrated Exposure Uptake Biokinetic model for lead (USEPA, 2021)
ug/dL - micrograms per deciliter
* - BLLs calculated using the "Find" function by varying the "Change Cutoff" value until the calculated "Soil and/or Dust Concentration" was equal to the background soil concentration using a probability of exceedance of 5% and a geometric standard deviation of 1.6 (both defaults).

6.4. Does Act 2 Allow for Setting a Floor on NVs Based on Natural Background?

There has been some discussion within each of the subgroups of setting a floor on the NV for residential direct contact to lead in soil based on sampling programs to establish regional background values. This subsection of Act 2 would appear to preclude that approach independent of the background standard.

> *§ 250.303(d) Relationship to background. -- The concentration of a regulated substance in an environmental medium of concern on a site where the Statewide health standard has been selected shall not be required to meet the Statewide health standard if the Statewide health standard is numerically less than the background standard. In such cases, the background standard shall apply.*

7. ANALYSIS OF EXAMPLES

Four examples have been identified to show a range of values for TBLL or blood lead concentration (BLC) and PRG and the associated GM BLL with all media included at default values (see Table 4). While all four of these examples were calculated by entering the selected BLC and a probability of exceedance cutoff of 5%, the example listed as having a basis of “PRG = EPA RSL” was not designated as such until

the resulting PRG of 400 mg/kg, which is the current RSL, was generated by the model from entering 7.5 ug/dL as the BLC. The basis "PRG = EPA RSL" was then made due to the significance of this PRG as a federal guidance value.

Table 4: Examples of IEUBK Model v.2.0 Results at 5% Probability of Exceedance Cutoff (All Media)			
Basis	**Blood Lead Concentration (ug/dL)**	**Geometric Mean Blood Lead Concentration**	**PRG Soil Concentration (mg/kg)**
PRG if TBLL not changed from 10 ug/dL to 5 ug/dL	10	4.6	611
PRG = EPA RSL*	7.5*	3.5*	400*
PADEP Proposal	5	2.3	200
New CDC BLRV 10/28/21	3.5	1.6	85

*The EPA RSL of 400 mg/kg is not determined using the IEUBK Model v. 2.0. The BLC and GM values shown for this example are those that would be associated with use of the IEUBK Model v. 2.0 to generate a PRG at that same concentration.

Figure 4 shows the progressive change in shape of the four probability density curves corresponding to each of these examples as the BLCs decline.

A second set of values was calculated for these four examples using defaults for soil and dust only and soil only. Table 5 shows the results of those calculations for PRG under each scenario.

Table 5: Examples of IEUBK Model v.2.0 Results at 5% Probability of Exceedance Cutoff (Ltd. Media)			
Basis	**Blood Lead Concentration (ug/dL)**	**PRG Soil Concentration (mg/kg) Soil & Dust Only**	**PRG Soil Concentration (mg/kg) Soil Only**
PRG if TBLL not changed from 10 ug/dL to 5 ug/dL	10	783	1453
PRG Extended from RSL	7.5	571	1059
PADEP Proposal	5	370	686
New CDC BLRV 10/28/21	3.5	254	472

7.1. Based on all model defaults for all media

The all-media results for BLC and PRG in Table 4 have been plotted on Figure 5 together with the all-media values for the background statistics as shown in Table 3. The purpose of this figure is to show the relationship of the proposed 200 mg/kg MSC to the other examples in Table 4 and to naturally-occurring background for lead in surface soils. This figure also shows that the relationship of BLC to PRG is very close to linear.

It's apparent that the new NV of 200 mg/kg will fall much closer to the natural background range and will be lower than the two highest values (269 mg/kg and 239 mg/kg) listed in Attachment G. However, the PRG corresponding to the new BLRV of 3.5 ug/dL (85 mg/kg) would be imbedded within the natural background range, closest to the value of 68.9 mg/kg in Table 3 for the 95% UCL of the mean of the data in Attachment G. It should also be noted that the BLLs in Table 3 of 3.16 to 4.38 ug/dL essentially bracket the new BLRV.

Finally, this figure shows the extension of the relationship of BLL to PRG to an x-axis intercept of 2.35 ug/dL. At that point the model is predicting that at zero contribution from soil, the remaining media at

their default values would account for a BLL of 2.35 ug/dL. Out of a total TBLL of 5 ug/dL that leaves 2.65 ug/dL for the soil contribution.

7.2. Based on model defaults for soil only and soil/dust only

The examples presented in Table 5 have been plotted on Figure 6 for the relationship of BLLs to PRGs together with the examples of this relationship from Table 4 and Figure 5. The purpose of this figure is to show graphically the effects of accounting for other media inputs when calculating a PRG for soil remediation. It's clear from this figure and Table 5 that eliminating these other media and running the model for soil and dust only and soil only has a substantial effect on the resulting PRG. **This is important to the consideration of how the method of calculating the NV for lead compares to the method used to calculate NVs for all other systemic toxicants for which other media inputs are not incorporated.**

It should be noted that Excel trendlines (not shown) for soil and dust only and soil only both intercept the x-axis at the origin, so that the PRG for soil is associated with the entire 5 ug/dL TBLL. This is contrasted with the all-media intercept of 2.35 ug/dL, which leaves only 2.65 ug/dL of the 5 ug/dL TBLL for soil.

8. OTHER SCREENING VALUES AND CLEANUP GOALS

Attachment H presents other screening values and cleanup goals including the EPA's RSL and state criteria for adjacent states Maryland, New York, New Jersey, and Ohio. Maryland is the only one of these states with soil screening values that match the proposed 200 mg/kg and 1050 mg/kg NVs in the current PADEP proposal. It is unknown whether other states are in the process of reviewing and updating their values.

Figure 1: Biological Structure of the IEUBK Model
(After Figure 1-1 of the IEUBK Model, v.2.0 User's Manual)

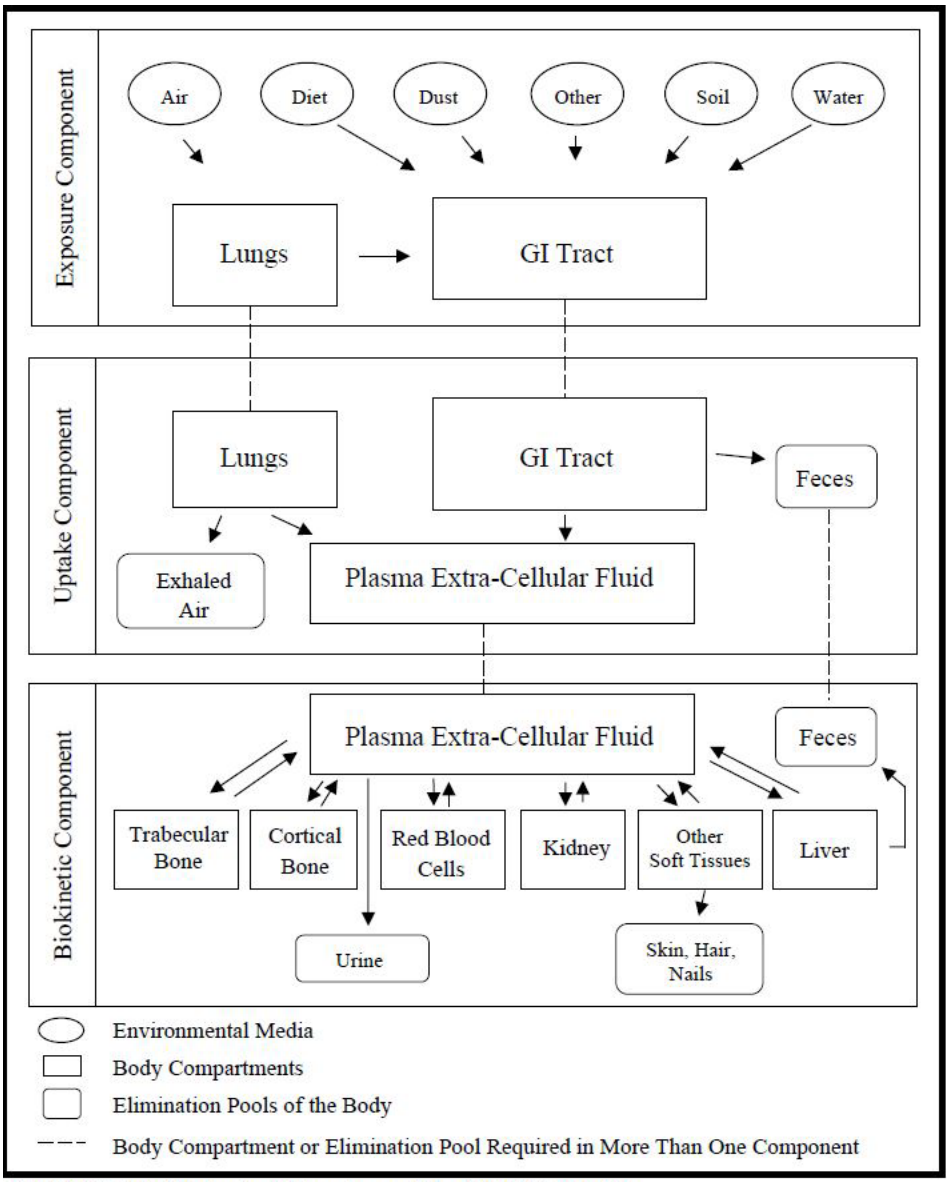
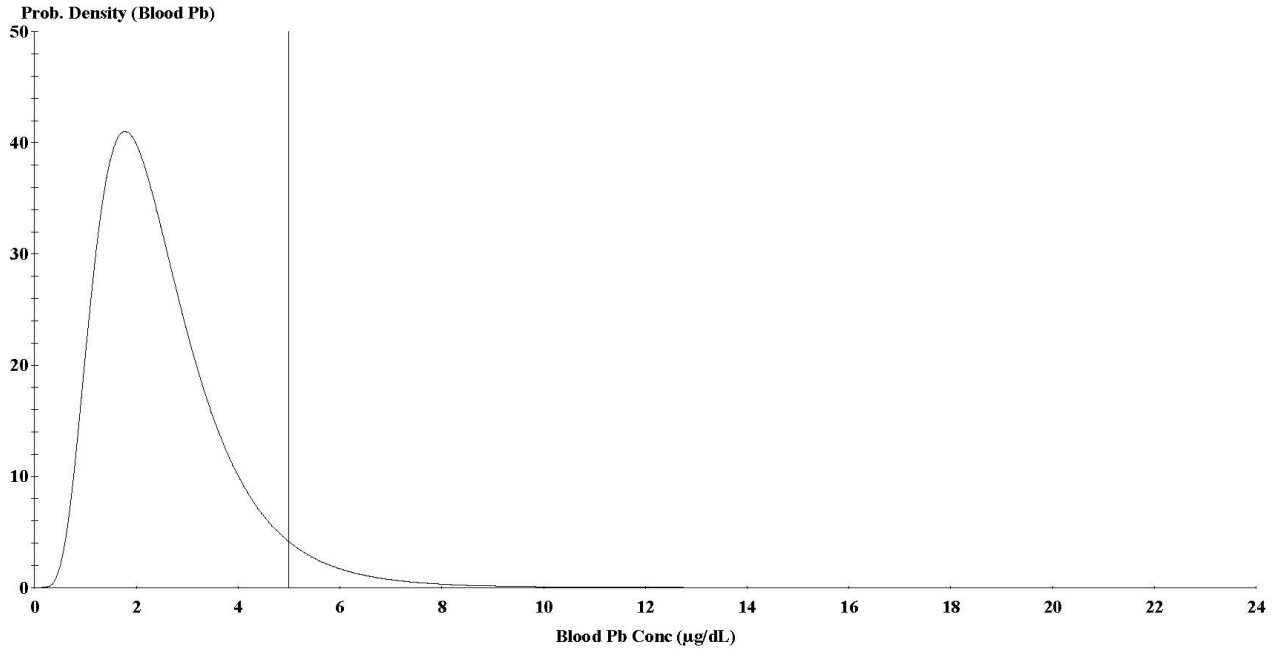


FIGURE 1-1. Biological Structure of the IEUBK Model.

Figure 2: Probability Density Curve, TBLL = 5 ug/dL, Probability of Exceedance Cutoff = 5%



Cutoff = 5.000 µg/dl
Geo Mean = 2.306
GSD = 1.600
% Above = 4.979
% Below = 95.021

Age Range = 12 to 72 months

Run Mode = Research

These IEUBK Model results are valid as long as they were produced with an official, unmodified version of the IEUBK Model with a software certificate.
While IEUBK Model output is generally written with three digits to the right of the decimal point, the true precision of the output is strongly influenced by least precise input values.

Figure 3: USGS Naturally-Occurring Background Lead in Surface Soil in Pennsylvania Sampling Site Location Map

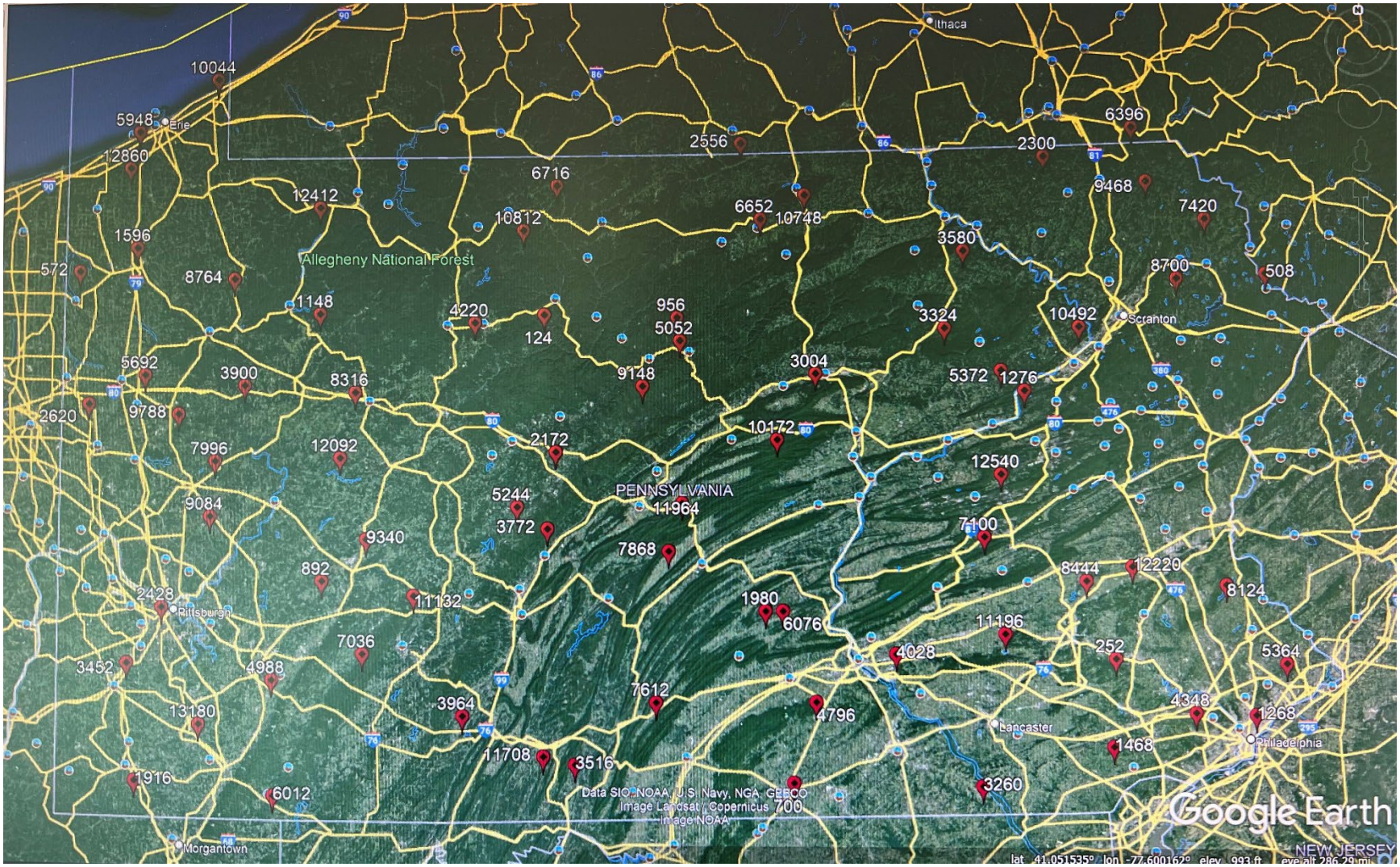


Figure 4: IEUBK v.2.0 Calculated Probability Density Curves

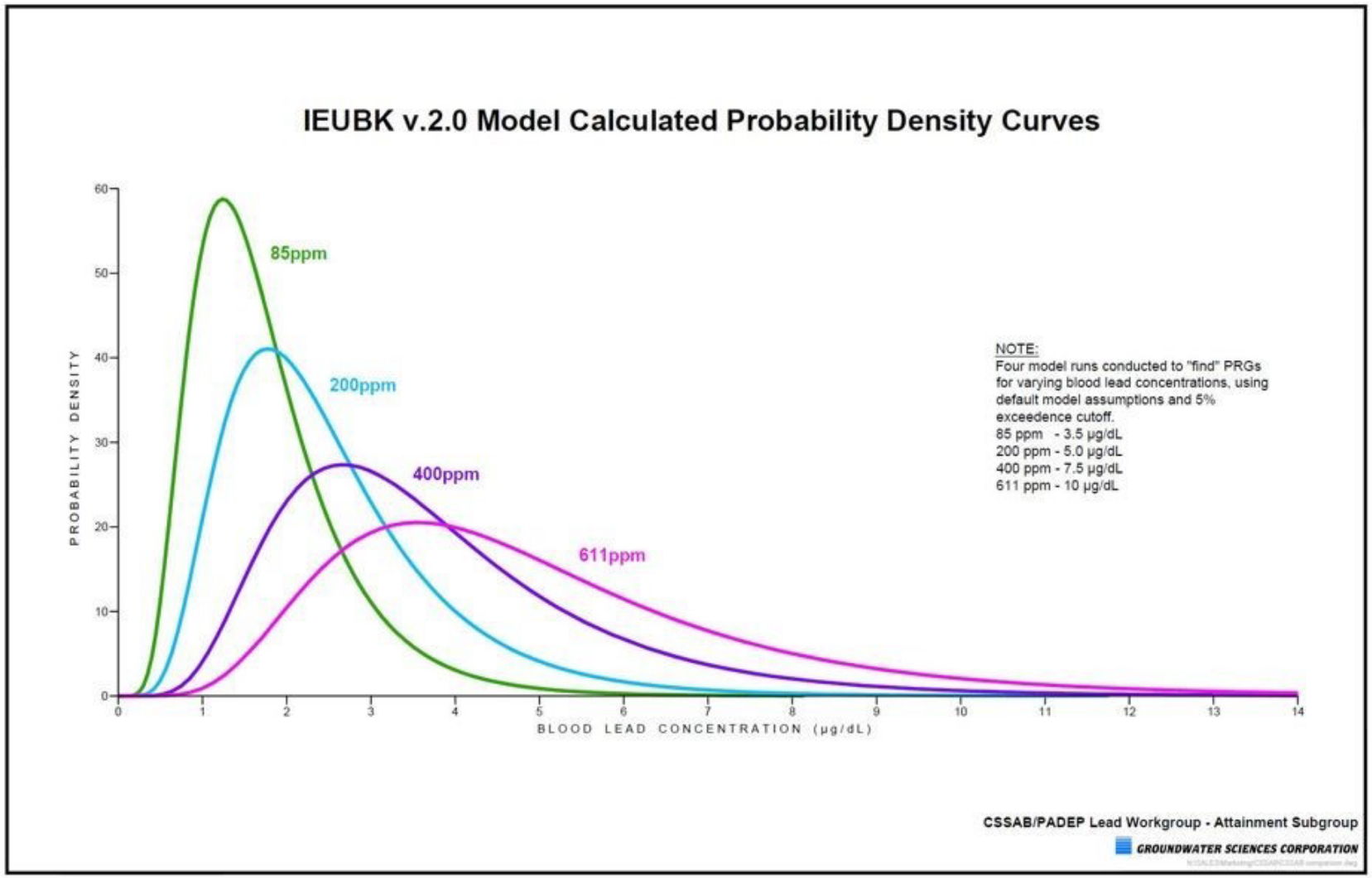


Figure 5: Examples of IEUBK 2.0 PRG Calculations (Default Assumptions) for All Media with Various TBLLs

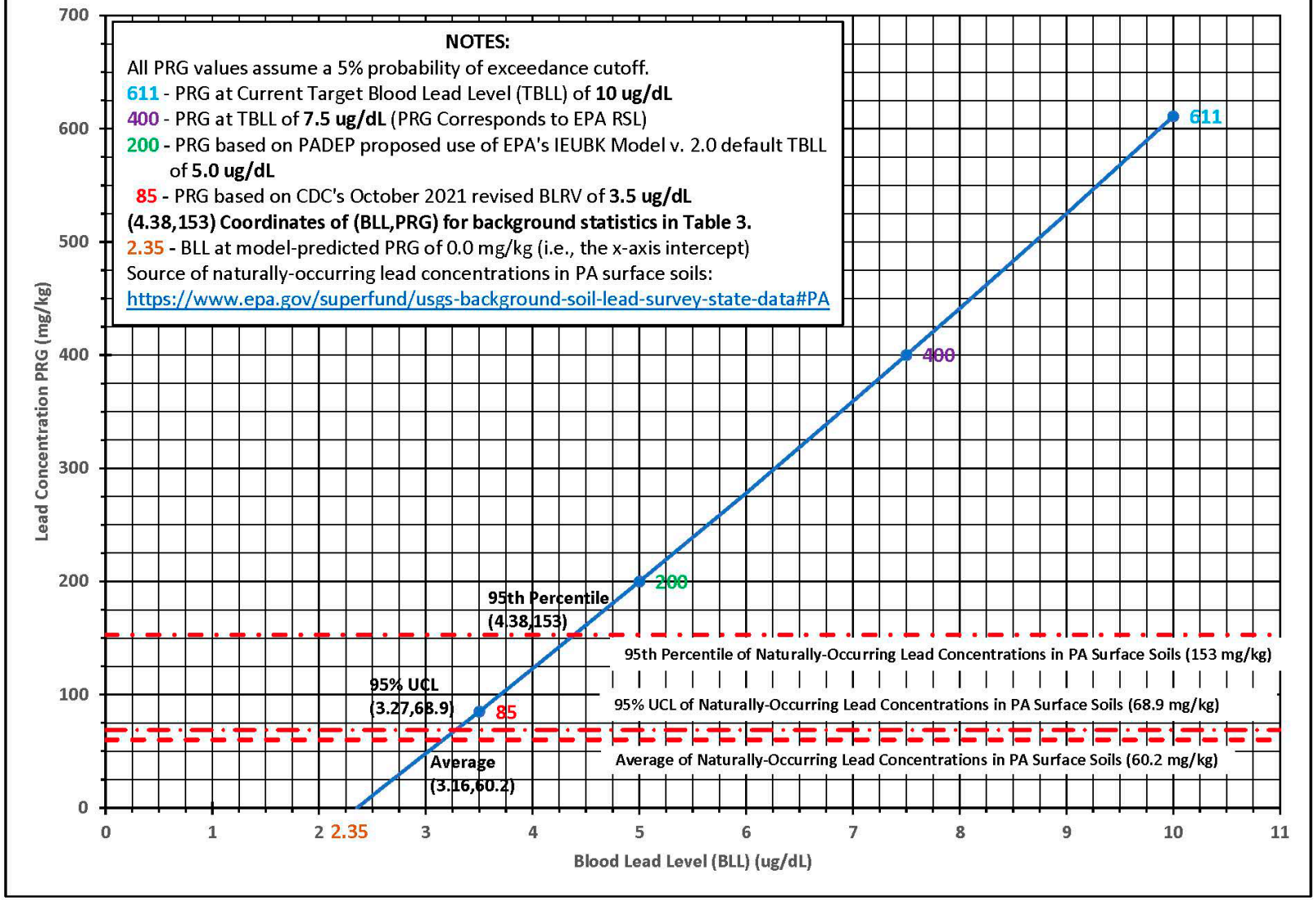
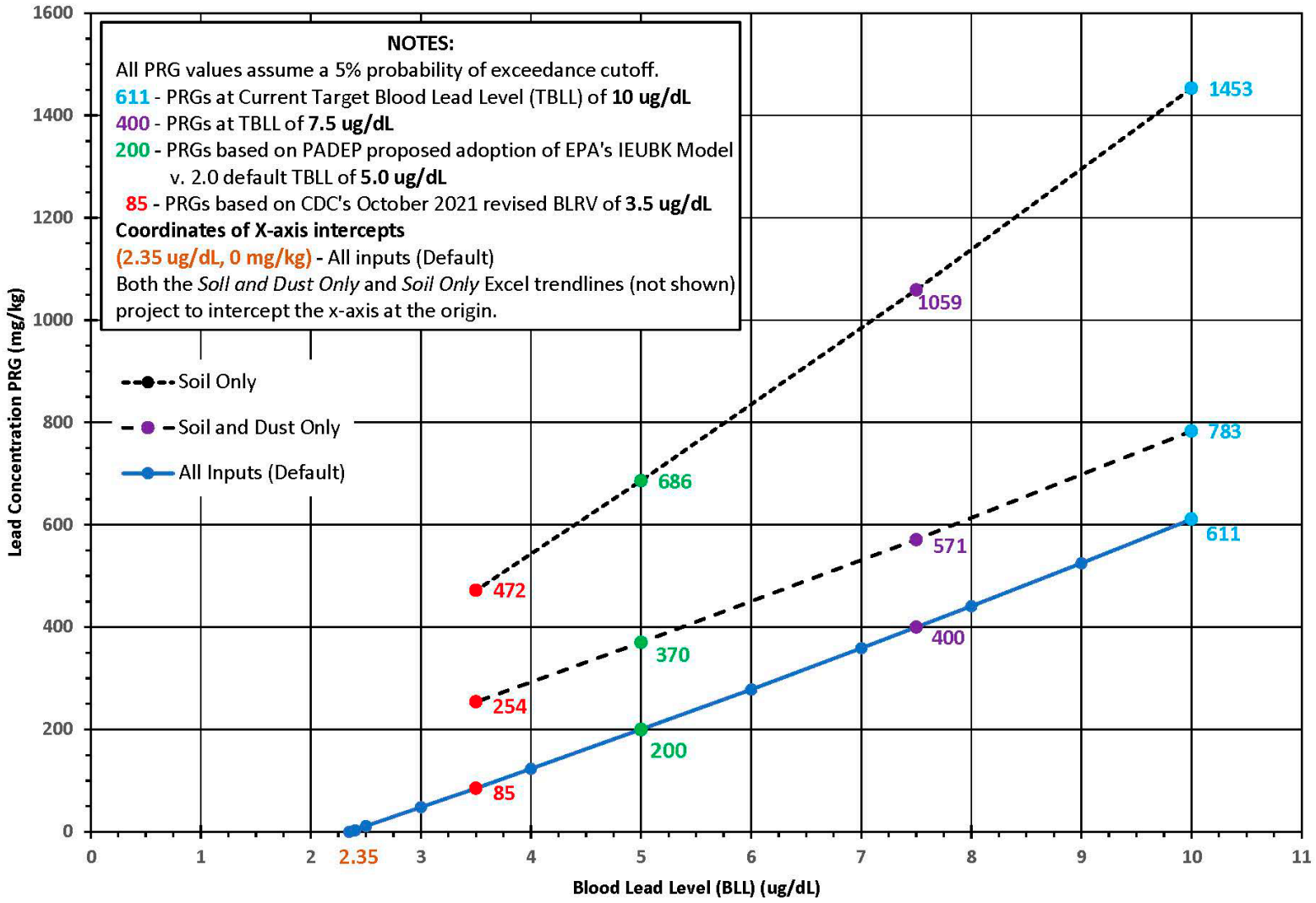


Figure 6: Examples of IEUBK 2.0 PRG Calculations for Selected Combinations of TBLL and Media Inputs



Attachment A: Act 2 of 1995, Section 303 Statewide health standard.

LAND RECYCLING AND ENVIRONMENTAL REMEDIATION STANDARDS ACT Act of May. 19, 1995, P.L. 4, No. 2 ***(Bold text indicates language that may be referenced in the text of this report.)***

Section 303. Statewide health standard.

(a) Standard. -- The Environmental Quality Board shall promulgate Statewide health standards for regulated substances for each environmental medium. The standards shall include any existing numerical residential and nonresidential health-based standards adopted by the department and by the Federal Government by regulation or statute, and health advisory levels. For those health-based standards not already established by regulation or statute, the Environmental Quality Board shall by regulation propose residential and nonresidential standards as medium-specific concentrations within 12 months of the effective date of this act. The Environmental Quality Board shall also promulgate along with the standards the methods used to calculate the standards. Standards adopted under this section shall be no more stringent than those standards adopted by the Federal Government.

(b) Medium-specific concentrations. -- The following requirements shall be used to establish a medium-specific concentration:

(1) Any regulated discharge into surface water occurring during or after attainment of the Statewide health standard shall comply with applicable laws and regulations relating to surface water discharges.

(2) Any regulated emissions to the outdoor air occurring during or after attainment of the Statewide health standard shall comply with applicable laws and regulations relating to emissions into the outdoor air.

(3) The concentration of a regulated substance in groundwater in aquifers used or currently planned to be used for drinking water or for agricultural purposes shall comply with the maximum contaminant level or health advisory level established for drinking water. If the groundwater at the site has naturally occurring background total dissolved solids concentrations greater than 2,500 milligrams per liter, the remediation standard for a regulated substance dissolved in the groundwater may be adjusted by multiplying the medium-specific concentration for groundwater in aquifers by 100. The resulting value becomes the maximum contaminant level for groundwater.

(4) For the residential standard, the concentration of a regulated substance in soil shall not exceed either the direct contact soil medium-specific concentration based on residential exposure factors within a depth of up to 15 feet from the existing ground surface or the soil-to-groundwater pathway numeric value throughout the soil column, the latter to be determined by any one of the following methods:

(i) A value which is 100 times the medium-specific concentration for groundwater.

(ii) A concentration in soil at the site that does not produce a leachate in excess of the medium-specific concentrations for groundwater in the aquifer when subjected to the Synthetic Precipitation Leaching Procedures, Method 1312 of SW 846, Test Methods for Evaluating Solid Waste, promulgated by the United States Environmental Protection Agency.

(iii) A generic value determined not to produce a concentration in groundwater in the aquifer in excess of the medium-specific concentration for groundwater based on a valid, peer-reviewed scientific method which properly accounts for factors affecting the fate, transport and attenuation of the regulated substance throughout the soil column.

(5) For the nonresidential standard, the concentration of a regulated substance in soil shall not exceed either the direct contact soil medium-specific concentration based on nonresidential exposure factors within a depth of up to 15 feet from the existing ground surface using valid scientific methods

reflecting worker exposure or the soil-to-groundwater pathway numeric value determined in accordance with paragraph (4).

(6) Exposure scenarios for medium-specific concentrations for nonresidential conditions shall be established using valid scientific methods reflecting worker exposure.

(c) Additional factors. -- When establishing a medium-specific concentration, other than those established under subsection (b)(1), (2) or (3), the medium-specific concentration for the ingestion of groundwater, inhalation of soils, ingestion and inhalation of volatiles and particulates shall be calculated by the department using valid scientific methods, reasonable exposure pathway assumptions and exposure factors for residential and nonresidential land use which are no more stringent than the standard default exposure factors established by EPA based on the following levels of risk:

(1) For a regulated substance which is a carcinogen, the medium-specific concentration is the concentration which represents an excess upper bound lifetime cancer target risk of between 1 in 10,000 and 1 in 1,000,000.

(2) For a regulated substance which is a systemic toxicant, the medium-specific concentration is the concentration to which human populations could be exposed by direct ingestion or inhalation on a daily basis without appreciable risk of deleterious effects for the exposed population.

(d) Relationship to background. -- The concentration of a regulated substance in an environmental medium of concern on a site where the Statewide health standard has been selected shall not be required to meet the Statewide health standard if the Statewide health standard is numerically less than the background standard. In such cases, the background standard shall apply.

(e) Attainment. -- Final certification that a site or portion of a site meets the Statewide health standard shall be documented in the following manner:

(1) Attainment of cleanup levels shall be demonstrated by collection and analysis of representative samples from the environmental medium of concern, including soils, and groundwater in aquifers at the point of compliance through the application of statistical tests set forth in regulation or, if no regulations have been adopted, in a demonstration of a mathematically valid application of statistical tests. The Department of Environmental Resources shall also recognize those methods of attainment demonstration generally recognized as appropriate for that particular remediation.

(2) A final report that documents attainment of the Statewide health standard shall be submitted to the department which includes the descriptions of procedures and conclusions of the site investigation to characterize the nature, extent, direction, rate of movement of the site and cumulative effects, if any, volume, composition and concentration of contaminants in environmental media, the basis for selecting environmental media of concern, documentation supporting the selection of residential or nonresidential exposure factors, descriptions of removal or treatment procedures performed in remediation, summaries of sampling methodology and analytical results which demonstrate that contaminants have been removed or treated to applicable levels and documentation of compliance with postremediation care requirements if they are needed to maintain the Statewide health standard.

(3) Institutional controls such as fencing and future land use restrictions on a site may not be used to attain the Statewide health standard. Institutional controls may be used to maintain the Statewide health standard after remediation occurs.

(f) Authority reserved. -- If a person fails to demonstrate attainment of the Statewide health standard, the department may require that additional remediation measures be taken in order to meet the health standard, or the person may select to meet the requirements of section 302 or 304.

(g) Deed notice. -- Persons attaining and demonstrating compliance with the Statewide health standard considering residential exposure factors for a regulated substance shall not be subject to the deed acknowledgment requirements of the act of July 7, 1980 (P.L.380, No.97), known as the Solid Waste Management Act, or the act of October 18, 1988 (P.L.756, No.108), known as the Hazardous Sites Cleanup Act. An existing acknowledgment contained in a deed prior to demonstrating compliance with the residential Statewide health standard may be removed. The deed acknowledgment requirements shall apply where nonresidential exposure factors were used to comply with the Statewide health standard.

(h) Notice and review provisions. -- Persons utilizing the Statewide health standard shall comply with the following requirements for notifying the public and the department of planned remediation activities:

(1) Notice of intent to initiate remediation activities shall be made in the following manner:

(i) A notice of intent to remediate a site shall be submitted to the department which provides, to the extent known, a brief description of the location of the site, a listing of the contaminant or contaminants involved, a description of the intended future use of the property for employment opportunities, housing, open space, recreation or other uses and the proposed remediation measures. The department shall publish an acknowledgment noting receipt of the notice of intent in the Pennsylvania Bulletin.

(ii) At the same time a notice of intent to remediate a site is submitted to the department, a copy of the notice shall be provided to the municipality in which the site is located and a summary of the notice of intent shall be published in a newspaper of general circulation serving the area in which the site is located.

(2) Notice of the submission of the final report demonstrating attainment of the Statewide health standard shall be given to the municipality in which the remediation site is located and published in a newspaper of general circulation serving the area and in the Pennsylvania Bulletin.

(3) The department shall review the final report demonstrating attainment of the Statewide health standard within 60 days of its receipt or notify the person submitting the report of substantive deficiencies. If the department does not respond with deficiencies within 60 days, the final report shall be deemed approved.

(4) The notices provided for in paragraphs (1) and (2) are not required to be made or published if the person conducting the remediation submits the final report demonstrating attainment of the Statewide health standard as required by this section within 90 days of the release. If the final report demonstrating attainment is not submitted to the department within 90 days of the release, all notices and procedures required by this section shall apply. This paragraph is only applicable to releases occurring after the effective date of this act.

Attachment B: Excerpts from the Preambles to the 1996 Draft Chapter 250 Regulations and the 1997 Final Chapter 250 Regulations

Excerpt from the 1996 Preamble to Draft Chapter 250 Regs

PENNSYLVANIA BULLETIN, VOL. 26, NO. 33 AUGUST 17, 1996 (Page 3990)

Section 250.305(f) explains the methodology for developing the ingestion numeric value for lead. The types of toxicological data which have been used to develop direct contact soil MSCs for all of the other regulated substances listed in Appendix A, Table 2 do not exist for lead. For example, although lead is classified as a carcinogen, it possesses no cancer slope factor so that a concentration in soil which represents an excess upper bound lifetime cancer target risk of one in 100,000 cannot be estimated. Similarly, even though lead is a systemic toxicant, there are no available oral reference doses from which to develop a threshold effect level for lead. This lack of data makes it necessary to develop direct contact soil MSCs for lead in an alternate manner.

The toxicological endpoints of concern for lead differ between children and adults. Because of this, two separate methods have been used to estimate direct contact soil MSCs for lead—one for residential exposures (based on effects on children) and one for nonresidential exposures (based on effects on adults). The following text describes the methodologies employed in developing both concentrations.

The direct contact soil MSC for lead for residential exposures has been estimated on the basis of protection of 95% of a population of children in the age range of 0 to 84 months. The Uptake Biokinetic (UBK) Model for Lead (version 0.4) was used to make this estimate. Although this model has been updated at least twice since version 0.4, this version was used because it was the version in use at the time the EPA developed its recommended residential lead-in-soil level of 500 mg/kg. Appendix A, Table 6 contains the input values that have been used in the model. The soil lead level from Appendix A, Table 6 (495 ug/g) has been rounded to 500 mg/kg which is the direct contact soil MSC for lead for residential exposures.

Because the UBK Model for Lead applies only to children, it could not be used for the nonresidential exposure scenario. Alternatively, a modeling equation applicable to adult exposures developed by the Society for Environmental Geochemistry and Health (SEGH) was obtained from Wixson (1991).

Excerpt from the Preamble to 1997 Final Chapter 250 Regulations

PENNSYLVANIA BULLETIN, VOL. 27, NO. 33, AUGUST 16, 1997 (Page 4190-4191)

A commentator stated that the Department used invalid models to derive the soil MSC for lead since EPA's IEUBK model has been updated several times and the Department has not used the most updated model. In addition, the Department should adopt a preliminarily promulgated standard by EPA under the Toxic Substances Control Act (TSCA) or adopt a standard not less than 5,000 mg/kg. The final-form regulations are based on two state-of-the-art models for estimation of MSCs for lead in residential and nonresidential soils. Although more recent versions of EPA's IEUBK model have been developed, the use of the most recent version would result in a residential MSC for lead that is lower than the 500 mg/kg level. The TSCA notice in the Federal Register, September 11, 1995, recommends a range of lead concentrations in soil of 400 mg/kg to 5,000 mg/kg. The notice also includes recommendations for interim controls to reduce exposure of children to contaminated soil within that range. Under the final-form regulations, the Statewide health standards fall within the range identified in the EPA notice.

In addition, exceedance of the 500 mg/kg residential soil MSC is not precluded under the site-specific standard. The interim controls identified in the EPA notice could be used under the site-specific standard in conjunction with a lead concentration in soil that is higher than 500 mg/kg.

Attachment C
Excerpt from New York State Brownfield Cleanup Program Development of Soil Cleanup Objectives, Technical Support Document
Prepared By:
New York State Department of Environmental Conservation and New York State Department of Health, September 2006

Toxicity Values for Inorganic Lead

Non-Cancer

Lead and inorganic lead compounds cause a variety of health effects in humans, and can damage the nervous, cardiovascular, gastrointestinal, hematopoietic, and reproductive systems. The database on lead toxicity is unusual because it contains a large amount of data on dose-response relationships in humans (ATSDR, 1999). Consequently, the degree of uncertainty about the noncancer human health effects of lead is relatively low compared to almost all other contaminants (US EPA, 2005c). In most studies, however, the measure of dose is an internal one (most commonly, blood lead level or PbB). In addition, most studies cannot attribute blood lead levels to one single route, pathway, or source of exposures or exposures during a limited, defined time. This is because lead can accumulate in the human body, and blood lead at any given time is dependent on current and past exposures to lead. Current exposures (e.g., food, water, air, and soil) are important because absorbed lead goes into the blood before distributing to other parts of the body. Past exposures are important because the body stores absorbed accumulated lead in bones. The lead in bones can be released into the blood under certain circumstances. Thus, blood lead is considered the most reliable measure of a person's risk of non-cancer health effects from lead.

Experimental studies of the toxicity of lead in animals provide support for observations in humans. Current knowledge of lead pharmacokinetics indicates that toxicity values derived by the application of default risk assessment procedures (e.g., using administered, ingested, or inhaled dose) to animal dose-response data might not accurately estimate the potential risk (US EPA, 2005c). This stems from concerns that an adequate animal model for lead toxicity in humans is not available and because of the difficulty in accounting for pre-existing body burdens of lead (US EPA, 2005c). Moreover, an animal-based analysis would overlook the significant body of toxicological literature on human toxicity and blood lead levels (ATSDR, 1999). Thus, animal data on lead toxicity have not been used by the ATSDR (1999), US EPA (2001, 2005c), or other public health agencies to evaluate the potential human non-cancer health effects of lead exposures. Neither ATSDR (1999), nor the US EPA (2005c), nor other authoritative bodies have proposed or developed a lead reference dose or reference concentration based on animal data.

Public health agencies recognize that the primary population, dose measure, and health concern associated with environmental exposures to lead are children, blood lead levels, and neurotoxicity, respectively (e.g., ATSDR, 1999; FL DEP, 2004; NJ DEP, 2004; MN PCA, 1999; US EPA, 2001; WHO, 1996). Young children are especially vulnerable to the toxic effects of lead for at least two reasons:

(1) Increased Exposures Relative to Adults. Children are likely to be exposed to environmental lead in many more ways than are adults (e.g., more hand-to-mouth activity, more contact with dirt, more mouthing/ingestion of non-food items). Children also have greater food, water, and inhalation rates per unit body weights than do adults. In addition, young children absorb a greater percentage of ingested lead than do adults, and might absorb a greater percentage of inhaled lead than do adults (ATSDR, 1999).

(2) Increased Sensitivity Relative to Adults. For many effects, the lead blood levels that cause toxicity in children are lower than the levels that cause effects in adults, and the effects may be more severe than those in adults (ATSDR, 1999). This suggests that children are more sensitive to the toxic effects of absorbed lead than adults. The toxicological data on the effects of lead on young children support concern for the increased sensitivity of fetuses, neonates, and infants to the toxicological effects of elevated blood lead levels (ATSDR, 1999). Much of the concern over lead exposure in women of child-bearing age stems from concerns that the exposures could lead to elevated blood lead levels in the fetus (US EPA, 2003).

Many environmental guidelines or standards for lead are based on children as the sensitive population (e.g., CA EPA, 1997; Health Canada, 1992; RIVM, 2001; US EPA, 2000a, 2001; WHO, 1996). The derivations of these guidelines, however, are different from the derivation of guidelines for most contaminants. The guidelines are not based directly on a daily intake of lead from one route of exposure (for example, a reference dose for oral intake or a reference concentration for air intake) but are based on a blood lead level. The blood lead level is typically 10 mcg/dL (micrograms of lead per deciliter of blood), which is the Centers for Disease Control and Prevention (CDC) level of concern for blood lead in young children (ATSDR, 1999; CDC, 1991). In most cases, the guidelines are derived so that the blood levels of almost all children exposed at the guideline would be below 10 mcg/dL. This is the approach taken in the derivation of the SCOs for lead (see Section 5.3.4 Chronic Lead SCOs). ***Thus, toxicity values (reference dose or reference concentration) for the non-cancer effects of lead are not proposed.*** **[emphasis added]**

Cancer

The National Toxicology Program (NTP, 2005) classifies lead and lead compounds as "reasonably anticipated to be human carcinogens" based on limited evidence from studies in humans and sufficient evidence from studies in experimental animals. Similarly, the International Agency for Research on Cancer (IARC, 2004) classifies inorganic lead compounds as "probably carcinogenic to humans (Group 2A)" based on limited evidence for the carcinogenicity to humans and sufficient evidence for the carcinogenicity to experimental animals.

According to the NTP (2003, 2005) reviews, lead exposure has been associated with increased risks of lung, stomach, and bladder cancer in human populations. The epidemiological evidence is strongest for lung and stomach cancer. The evidence is not conclusive because most of the studies have limitations. These include poor exposure assessment and failure to control for confounders (other factors that could increase the risk of cancer, including lifestyle factors and concurrent occupational exposure to other carcinogens). In addition, they did not demonstrate relationships between the amount of exposure (e.g., concentration or duration) and the magnitude of cancer risk. Thus, the epidemiological data on lead are inadequate to develop cancer toxicity values (i.e., oral cancer potency factor or inhalation unit risk) for lead.

Long-term exposures to soluble (lead acetate and lead subacetate) or insoluble (lead phosphate, lead chromate) inorganic lead compounds have caused cancer in laboratory animals (NTP, 2003, 2005). Kidney tumors were most frequently associated with lead exposure, but tumors of the brain, hematopoietic system, and lung were reported in some studies. However, only two lead compounds (lead acetate and lead subacetate) have caused cancer in animals after oral exposures. Other lead compounds have caused cancer in animals after subcutaneous injection (lead phosphate or lead chromate), subcutaneous injection followed by intraperitoneal injection (lead phosphate), or intramuscular injection (lead chromate). The possibility that the carcinogenicity of lead chromate is caused by exposure to hexavalent chromium (chromate), which is an animal carcinogen, cannot be excluded. Lead naphthenate

(dermal exposures), lead carbonate (diet), lead arsenate (diet), lead nitrate (drinking water), and metallic lead, as lead powder) (intramuscular or gavage) did not significantly increase tumor incidences in experimental animals. Studies of the carcinogenicity of inhaled lead were not found.

Only one of the authoritative bodies reviewed, the CA EPA, has derived oral cancer potency factors and inhalation unit risks for inorganic lead compounds (CA EPA, 1992, 1997, 2002, 2004). Most recently, the oral potency factor for lead was restricted to lead acetate, one of the two lead compounds shown to cause cancer via the oral route (CA EPA, 2005). In contrast, the US EPA (2005c) lead database for risk assessment in the Integrated Risk Assessment System, which is the peer-reviewed source for US EPA toxicity values for chemicals, contains the following statement:

> *Quantifying lead's cancer risk involves many uncertainties, some of which may be unique to lead. Age, health, nutritional state, body burden, and exposure duration influence the absorption, release, and excretion of lead. In addition, current knowledge of lead pharmacokinetics indicates that an estimate derived by standard procedures would not truly describe the potential risk. Thus, the Carcinogen Assessment Group recommends that a numerical estimate not be used.*

Given the problems associated with extrapolating animal data on lead to humans, animal-based oral cancer potency factors and inhalation unit risks for lead are not proposed. **[emphasis added]**

Attachment D: Chapter 250, Appendix A, Table 7

Table 7
DEFAULT VALUES FOR CALCULATING MEDIUM-SPECIFIC CONCENTRATIONS FOR LEAD

Input Values Used in UBK Model for Lead (for residential exposure scenario)

Geometric Standard Deviation (GSD)	1.42 (default)	Drinking water intake	Model default
Outdoor air lead concentration	0.2 µg/m^3 (default)	Soil lead level	495 µg/g
Indoor air lead concentration (% of outdoor)	30	Indoor dust lead level	495 µg/g
Time spent outdoors	Model default	Soil/dust ingestion weighting factor (%)	45
Ventilation rate	Model default	Paint lead intake	Model default
Lung absorption	Model default	Maternal contribution method	Infant model
Dietary lead intake	Model default	Mother's blood lead at birth	7.5 µg/dL blood (model default)
GI method/bioavailability	Non-linear	Target blood lead level	10 µg/dL blood
Lead concentration in drinking water	4.00 µg/L (default)		

Input Values Used in SEGH Equation (for nonresidential exposure scenario)

Concentration of lead in soil (S)	987 µg/g
Target blood lead level in adults (T)	20 µg/dL blood
Geometric standard deviation of blood lead distribution (G)	1.4
Baseline blood lead level in target population (B)	4 µg/dL blood
Number of standard deviations corresponding to degree of protection required for the target population (n)	1.645 (for 95% of population)
Slope of blood lead to soil lead relationship (δ)	7.5 µg/dL blood per µg/g soil

Attachment E: NHANES Statistics in Support of the BLRV Update from 5 ug/dL to 3.5 ug/dL

Table 1. Sample weighted geometric mean and selected percentiles of blood lead concentrations (in µg/dL) for U.S. children age 1-5 years (NHANES 2011-2018)

NHANES	Sample size	Geometric mean	50th	75th	90th	95th	97.5th
2011-2014 (2 cycles)	1531	0.86 (0.80-0.93)	0.82 (0.75-0.89)	1.21 (1.09-1.32)	1.90 (1.64-2.24)	2.57 (2.26-3.05)	3.48 (2.65-4.29)*
2015-2018 (2 cycles)	1419	0.71 (0.66-0.77)	0.65(0.6-0.71)	1.04(0.94-1.16)	1.66(1.49-1.86)	2.41(1.9-3.01)	3.44(2.68-4.22)†

*n=46 for the sample size in this percentile in NHANES 2011-2014.

†n=42 for the sample size in this percentile in NHANES 2015-2018.

Personal communication December 4, 2021:
Jill Ryer-Powder, Ph.D., MNSP, DABT, Chair CDC BLRV Workgroup, Member LEPAC

Attachment F: Default Values for the IEUBK Model v. 2.0 Parameters

TABLE 2-2. Default Values for the IEUBK Model Parameters

Parameter	Default Value	Units
Indoor air Pb concentration (% of outdoor)	30	%
AIR (by year)		
Air concentration:		
Age =		
0-1 year (0-11 months)	0.10	µg/m^3
1-2 years (12-23 months)	0.10	µg/m^3
2-3 years (24-35 months)	0.10	µg/m^3
3-4 years (36-47 months)	0.10	µg/m^3
4-5 years (48-59 months)	0.10	µg/m^3
5-6 years (60-71 months)	0.10	µg/m^3
6-7 years (72-84 months)	0.10	µg/m^3
Time outdoors:		
Age =		
0-1 year (0-11 months)	1	hours/day
1-2 years (12-23 months)	2	hours/day
2-3 years (24-35 months)	3	hours/day
3-7 years (36-84 months)	4	hours/day
Lung absorption	32	%
DATA ENTRY FOR DIET (by year)		
Dietary Pb intake:		
Age =		
0-1 year (0-11 months)	2.66	µg Pb/day
1-2 years (12-23 months)	5.03	µg Pb/day
2-3 years (24-35 months)	5.21	µg Pb/day
3-4 years (36-47 months)	5.38	µg Pb/day
4-5 years (48-59 months)	5.64	µg Pb/day
5-6 years (60-71 months)	6.04	µg Pb/day
6-7 years (72-84 months)	5.95	µg Pb/day
DATA ENTRY FOR ALTERNATE DIET SOURCES (by food class)		
Concentration:		
home-grown fruits	0	µg Pb/g
home-grown vegetables	0	µg Pb/g
fish from fishing	0	µg Pb/g
game animals from hunting	0	µg Pb/g

TABLE 2-2. Default Values for the IEUBK Model Parameters

Parameter	Default Value	Units
Percent of food class:		
home-grown fruits	0	%
home-grown vegetables	0	%
fish from fishing game	0	%
animals from hunting	0	%
DATA ENTRY FOR DRINKING WATER		
Lead concentration in drinking water	0.9	µg/L
Ingestion rate:		
Age =		
0-1 year (0-11 months)	0.40	L/day
1-2 years (12-23 months)	0.43	L/day
2-3 years (24-35 months)	0.51	L/day
3-4 years (36-47 months)	0.54	L/day
4-5 years (48-59 months)	0.57	L/day
5-6 years (60-71 months)	0.60	L/day
6-7 years (72-84 months)	0.63	L/day
DATA ENTRY FOR ALTERNATE DRINKING WATER SOURCES		
Concentration:		
first-draw water	0.9	µg/L
flushed water	0.9	µg/L
fountain water	0.9	µg/L
Percentage of total intake:		
first-draw water	50	%
flushed water	100 minus first draw and fountain	
fountain water	15	%
DATA ENTRY FOR SOIL/DUST (constant over time)		
Concentration (starting values to be modified using appropriate site data):		
soil	200	µg/g
dust	150	µg/g
Soil/dust ingestion weighting factor (percent soil)	45	%
DATA ENTRY FOR TOTAL SOIL/DUST INGESTION (by year)		
Soil/dust ingestion:		
Age =		
0-1 year (0-11 months)	0.086	g/day
1-2 years (12-23 months)	0.094	g/day
2-3 years (24-35 months)	0.067	g/day
3-4 years (36-47 months)	0.063	g/day
4-5 years (48-59 months)	0.067	g/day
5-6 years (60-71 months)	0.052	g/day
6-7 years (72-84 months)	0.055	g/day
DATA ENTRY FOR SOIL/DUST MULTIPLE SOURCE ANALYSIS (constant over time)		

TABLE 2-2. Default Values for the IEUBK Model Parameters

Parameter	Default Value	Units
Fraction of indoor dust Pb attributable to soil (M_{SD})	0.70	Unitless
Ratio of dust Pb concentration to outdoor air Pb concentration	100	µg Pb/g dust per µg Pb/m^3 air
DATA ENTRY FOR SOIL/DUST MULTIPLE SOURCE ANALYSIS WITH ALTERNATIVE HOUSEHOLD DUST LEAD SOURCES (constant over time)		
Concentration (starting values to be modified using appropriate site data):		
household dust (calculated value)	150	µg/g
secondary occupational dust	1,200	µg/g
school dust	200	µg/g
daycare center dust	200	µg/g
second home	200	µg/g
Percentage:		
household dust (calculated value)	100 minus all other	%
secondary occupational dust	0	%
school dust	0	%
daycare center dust	0	%
second home	0	%
BIOAVAILABILITY DATA ENTRY FOR ALL GUT ABSORPTION PATHWAYS		
Total Pb absorption (at low intake):		
diet	50	%
drinking water	50	%
soil	30	%
dust	30	%
alternate source	0	%
Fraction of total net absorption at low intake rate that is attributable to non-saturable (passive) processes	0.2	unitless
DATA ENTRY FOR ALTERNATE SOURCES (by year)		
Total Pb intake:		
Age =		
0-1 (0-11 months)	0	µg/day
1-2 years (12-23 months)	0	µg/day
2-3 years (24-35 months)	0	µg/day
3-4 years (36-47 months)	0	µg/day
4-5 years (48-59 months)	0	µg/day
5-6 years (60-71 months)	0	µg/day
6-7 years (72-84 months)	0	µg/day
DATA ENTRY MENU FOR MATERNAL-TO-NEWBORN LEAD EXPOSURE		
Mothers blood Pb concentration at childbirth	0.6	µg/dL
DATA ENTRY MENU FOR PLOTTING AND RISK ESTIMATION		
GSD for PbB	1.6	unitless

TABLE 2-2. Default Values for the IEUBK Model Parameters

Parameter	Default Value	Units
Blood Pb level of concern, or cutoff	5	µg/dL

Attachment G: Lead data for samples of surface soils collected from a depth of 0 to 5 centimeters in Pennsylvania USGS Data Series 801: Geochemical and Mineralogical Data for Soils of the Conterminous United States

[LabID, unique identifier assigned by the analytical laboratories; cm, centimeters; mg/kg, milligrams per kilogram]

LabID	SiteID	StateID	Latitude	Longitude	CollDate	LandCover1	LandCover2	Depth cm	Pb mg/kg
C-341158	124	PA	41.3983	-78.2875	06/22/09	Forested Upland	Deciduous Forest	0.5	40.6
C-364423	252	PA	40.1828	-75.7392	09/14/10	Forested Upland	Deciduous Forest	0-5	239
C-341159	508	PA	41.4739	-74.9908	07/16/08	Forested Upland	Mixed Forest	0-5	82.3
C-341160	572	PA	41.542	-80.4467	05/13/09	Forested Upland	Deciduous Forest	0-5	83.6
C-341161	700	PA	39.7893	-77.1831	06/23/09	Planted/Cultivated	Urban/Recreational Grasses	0-5	25.8
C-341163	892	PA	40.4839	-79.2966	06/24/09	Planted/Cultivated	Fallow	0-5	35.6
C-364424	956	PA	41.3857	-77.6786	09/28/10	Forested Upland	Deciduous Forest	0-5	47.5
C-364425	1148	PA	41.4006	-79.3129	09/10/10	Forested Upland	Deciduous Forest	0-5	58.1
C-341164	1268	PA	39.9703	-75.1194	07/30/09	Developed	Commercial/Industrial/Transportation	0-5	142
C-341165	1276	PA	41.1058	-76.1081	07/21/08	Forested Upland	Deciduous Forest	0-5	48.7
C-341166	1468	PA	39.8829	-75.7595	07/29/09	Planted/Cultivated	Pasture/Hay	0-5	37.1
C-364426	1596	PA	41.627	-80.1763	10/20/10	Forested Upland	Deciduous Forest	0-5	78.8
C-364506	1916	PA	39.7878	-80.1488	09/25/10	Forested Upland	Deciduous Forest	0-5	31.2
C-341167	1980	PA	40.3719	-77.2952	06/12/08	Planted/Cultivated	Pasture/Hay	0-5	14.7
C-341168	2172	PA	40.9259	-78.2396	05/29/09	Developed	Commercial/Industrial/Transportation	0-5	42.1
C-341169	2300	PA	41.9029	-75.9864	07/15/08	Forested Upland	Deciduous Forest	0-5	31.7
C-364427	2428	PA	40.3873	-80.0337	11/18/10	Planted/Cultivated	Urban/Recreational Grasses	0-5	37.6
C-364428	2556	PA	41.9762	-77.3733	07/26/10	Planted/Cultivated	Row Crops	0-5	18.3
C-341170	2620	PA	41.0839	-80.3889	05/15/09	Planted/Cultivated	Pasture/Hay	0-5	22.6
C-341172	3004	PA	41.1842	-77.0475	07/21/09	Forested Upland	Deciduous Forest	0-5	24.8
C-341173	3260	PA	39.7638	-76.3469	06/23/09	Forested Upland	Deciduous Forest	0-5	36.8
C-364430	3324	PA	41.3275	-76.4601	07/23/10	Forested Upland	Deciduous Forest	0-5	147
C-364507	3452	PA	40.1927	-80.1908	09/24/09	Forested Upland	Deciduous Forest	0-5	50.0
C-341174	3516	PA	39.8593	-78.1557	05/06/08	Forested Upland	Deciduous Forest	0-5	46.4
C-364431	3580	PA	41.5895	-76.3672	07/23/10	Forested Upland	Deciduous Forest	0-5	66.5
C-341175	3772	PA	40.6618	-78.278	05/22/09	Planted/Cultivated	Fallow	0-5	31.8
C-364432	3900	PA	41.1536	-79.6596	09/08/10	Forested Upland	Deciduous Forest	0-5	69.3
C-341176	3964	PA	40.026	-78.6582	05/06/08	Herbaceous Upland	Grasslands/Herbaceous	0-5	49.3

C-341177	4028	PA	40.2195	-76.7159	05/23/08	Planted/Cultivated	Pasture/Hay	0-5	19.8
C-364433	4220	PA	41.3711	-78.6028	09/07/10	Forested Upland	Deciduous Forest	0-5	98.0
C-341180	4348	PA	39.9869	-75.3877	07/29/09	Planted/Cultivated	Urban/Recreational Grasses	0-5	46.1
C-341181	4796	PA	40.0618	-77.0769	06/23/09	Forested Upland	Deciduous Forest	0-5	25.6
C-341182	4988	PA	40.1427	-79.5235	06/24/09	Planted/Cultivated	Urban/Recreational Grasses	0-5	29.5
C-364434	5052	PA	41.3062	-77.6669	09/29/10	Forested Upland	Deciduous Forest	0-5	85.3
C-341183	5244	PA	40.7378	-78.415	05/29/09	Forested Upland	Deciduous Forest	0-5	75.6
C-341184	5364	PA	40.141	-74.9731	07/28/09	Planted/Cultivated	Urban/Recreational Grasses	0-5	58.2
C-341186	5372	PA	41.1772	-76.2105	07/21/08	Planted/Cultivated	Fallow	0-5	47.3
C-364435	5692	PA	41.1868	-80.1268	10/19/10	Forested Upland	Deciduous Forest	0-5	48.2
C-364436	5948	PA	42.0307	-80.1793	10/20/10	Forested Upland	Deciduous Forest	0-5	46.7
C-341187	6012	PA	39.7459	-79.5134	07/21/09	Forested Upland	Deciduous Forest	0-5	31.3
C-341188	6076	PA	40.3709	-77.217	06/12/08	Forested Upland	Mixed Forest	0-5	126
C-341189	6396	PA	41.9941	-75.5742	07/15/08	Forested Upland	Mixed Forest	0-5	132
C-341190	6652	PA	41.717	-77.2885	07/30/09	Forested Upland	Deciduous Forest	0-5	34.9
C-341191	6716	PA	41.8396	-78.2228	06/23/09	Forested Upland	Deciduous Forest	0-5	38.8
C-341192	7036	PA	40.2364	-79.1097	06/23/09	Forested Upland	Deciduous Forest	0-5	161
C-341193	7100	PA	40.6114	-76.308	04/14/08	Forested Upland	Mixed Forest	0-5	59.1
C-341195	7420	PA	41.67	-75.257	08/12/08	Planted/Cultivated	Pasture/Hay	0-5	30.6
C-341196	7612	PA	40.0674	-77.7925	05/06/08	Forested Upland	Deciduous Forest	0-5	53.0
C-341197	7868	PA	40.5805	-77.7301	06/03/08	Planted/Cultivated	Pasture/Hay	0-5	51.6
C-364508	7996	PA	40.8923	-79.7934	08/20/10	Planted/Cultivated	Pasture/Hay	0-5	26.1
C-341198	8124	PA	40.4182	-75.2308	10/29/09	Planted/Cultivated	Row Crops	0-5	36.4
C-364509	8316	PA	41.1315	-79.1485	08/19/10	Forested Upland	Mixed Forest	0-5	27.2
C-364437	8444	PA	40.4513	-75.8598	09/14/10	Planted/Cultivated	Row Crops	0-5	29.7
C-341201	8700	PA	41.4697	-75.3999	08/12/08	Herbaceous Upland	Grasslands/Herbaceous	0-5	58.0
C-364439	8764	PA	41.5203	-79.715	09/09/10	Forested Upland	Deciduous Forest	0-5	60.7
C-364440	9084	PA	40.7021	-79.8145	10/21/10	Forested Upland	Deciduous Forest	0-5	45.6
C-364441	9148	PA	41.1507	-77.8415	09/29/10	Forested Upland	Deciduous Forest	0-5	40.0
C-341202	9340	PA	40.628	-79.0956	05/05/08	Planted/Cultivated	Urban/Recreational Grasses	0-5	108
C-341203	9468	PA	41.8063	-75.5197	08/12/08	Forested Upland	Deciduous Forest	0-5	33.3
C-364442	9788	PA	41.0529	-79.967	10/19/10	Forested Upland	Deciduous Forest	0-5	84.4
C-364443	10044	PA	42.2138	-79.8115	10/20/10	Forested Upland	Deciduous Forest	0-5	45.3

C-341204	10172	PA	40.9592	-77.228	04/30/08	Forested Upland	Mixed Forest	0-5	261
C-341205	10492	PA	41.317	-75.8531	07/21/08	Developed	Low Intensity Residential	0-5	153
C-341206	10748	PA	41.7954	-77.0847	07/28/09	Planted/Cultivated	Pasture/Hay	0-5	22.1
C-341208	10812	PA	41.6871	-78.3779	06/24/09	Planted/Cultivated	Pasture/Hay	0-5	30.6
C-341209	11132	PA	40.4351	-78.8793	06/25/09	Forested Upland	Deciduous Forest	0-5	105
C-341210	11196	PA	40.2796	-76.2288	07/24/09	Planted/Cultivated	Pasture/Hay	0-5	16.9
C-341211	11708	PA	39.8873	-78.2969	05/06/08	Forested Upland	Deciduous Forest	0-5	33.4
C-341212	11964	PA	40.745	-77.6666	06/03/08	Forested Upland	Deciduous Forest	0-5	58.6
C-364444	12092	PA	40.9064	-79.2162	09/08/10	Planted/Cultivated	Pasture/Hay	0-5	36.9
C-341213	12220	PA	40.4941	-75.6521	10/29/09	Planted/Cultivated	Row Crops	0-5	39.5
C-364445	12412	PA	41.7673	-79.3178	09/09/10	Forested Upland	Deciduous Forest	0-5	80.9
C-341214	12540	PA	40.8231	-76.2252	04/14/08	Forested Upland	Deciduous Forest	0-5	118
C-364446	12860	PA	41.9039	-80.2187	10/27/11	Planted/Cultivated	Pasture/Hay	0-5	37.8
C-364447	13180	PA	39.9869	-79.8567	11/19/10	Planted/Cultivated	Pasture/Hay	0-5	54.0

Attachment H: Other Screening Values and Cleanup Goals

US Environmental Protection Agency
Regional Screening Levels (November 2021)

Resident	Industrial	Protection of Ground Water MCL-based SSL
400	800	14

FAQ #43 - Where did the inorganic lead SL value in the Table come from?

EPA has no consensus RfD or SFO for inorganic lead, so it is not possible to calculate SLs as we have done for other chemicals. EPA considers lead to be a special case because of the difficulty in identifying the classic "threshold" needed to develop an RfD.

EPA therefore evaluates lead exposure by using blood-lead modeling, such as the Integrated Exposure-Uptake Biokinetic Model (IEUBK). The EPA Office of Solid Waste has also released a detailed directive on risk assessment and cleanup of residential soil lead. The directive recommends that soil lead levels less than 400 mg/kg are generally safe for residential use. Above that level, the document suggests collecting data and modeling blood-lead levels with the IEUBK model. For the purposes of screening, therefore, 400 mg/kg is recommended for residential soils. For water, we suggest 15 µg/L (the EPA Action Level in water), and for air, the National Ambient Air Quality Standard of 0.15 µg/m3.

However, caution should be used when both water and soil are being assessed. The IEUBK model shows that if the average soil concentration is 400 mg/kg, an average tap water concentration above 5 µg/L would yield more than a 5% probability of exceeding a 10 µg/L/dL blood-lead level for a typical child. If the average tap water concentration is 15 µg/L, an average soil concentration greater than 250 mg/kg would yield more than a 5% probability of exceeding a 10 µg/L/dL blood-lead level for a typical child.

For more information see Addressing Lead At Superfund Sites.

New York
6 NYCRR Part 375-6.8 Soil Cleanup Objectives (Effective December 14, 2006)

Unrestricted Use Soil Cleanup Objective	Restricted Use Soil Cleanup Objective					
	Protection of Public Health				Protection of Ecological Resources	Protection of Groundwater
	Residential	Restricted-Residential	Commercial	Industrial		
63 [c]	400	400	1,000	3,900	63 [f]	450

c - For constituents where the calculated SCO was lower than the rural soil background concentration, as determined by the Department and Department of Health rural soil survey, the rural soil background concentration is used as the Track 1 SCO value for this use of the site.

f - For constituents where the calculated SCO was lower than the rural soil background concentrations as determined by the Department and Department of Health rural soil survey, the rural soil background concentration is used as the Track 2 SCO value for this use of the site.

New Jersey
NJAC 7:26D - Appendix 1 (Last Amended May 17, 2021)

Soil Remediation Standard Ingestion-Dermal Residential	Soil Remediation Standard Inhalation Residential	Soil Remediation Standard Ingestion-Dermal Nonresidential	Soil Remediation Standard Inhalation Nonresidential	Soil Remediation Standard Migration to Groundwater
400 *	NA +	800 **	NA +	90

* - Standard based on the Integrated Exposure Uptake Biokinetic (IEUBK) model [1994] for lead in children

** - Standard based on the Adult Lead Model (ALM) [1996]

+ - Not applicable because appropriate toxicological information is not available

Note from Appendix 11 - No inhalation-based toxicity factors are available [17]

17 - There is an inhalation toxicity factor available for this contaminant, but it is based on a route-to-route conversion of an oral study. The Department's Site Remediation and Waste Management Program policy does not allow, except where warranted with physiologically-based pharmacokinetic modeling, for the development of soil remediation standards based on route to- route conversion of toxicity factors.

Note that NJAC 7:26D-7.2 states that the Department shall update a remediation standard for soil or indoor air at J.J.A.C. 7:26D Appendix 1 when:

4. The USEPA revises or replaces its Integrated Environmental Uptake Biokinetic (IEUBK) Model and Adult Lead Model (ALM) and input parameters for lead.

Maryland

Department of the Environment Lead (Pb) Soil Screening Update Fact Sheet (Effective July 1, 2020)

Residential Soil Screening Concentration	Commercial Soil Screening Concentration	Industrial Soil Screening Concentration
200	550	1,050

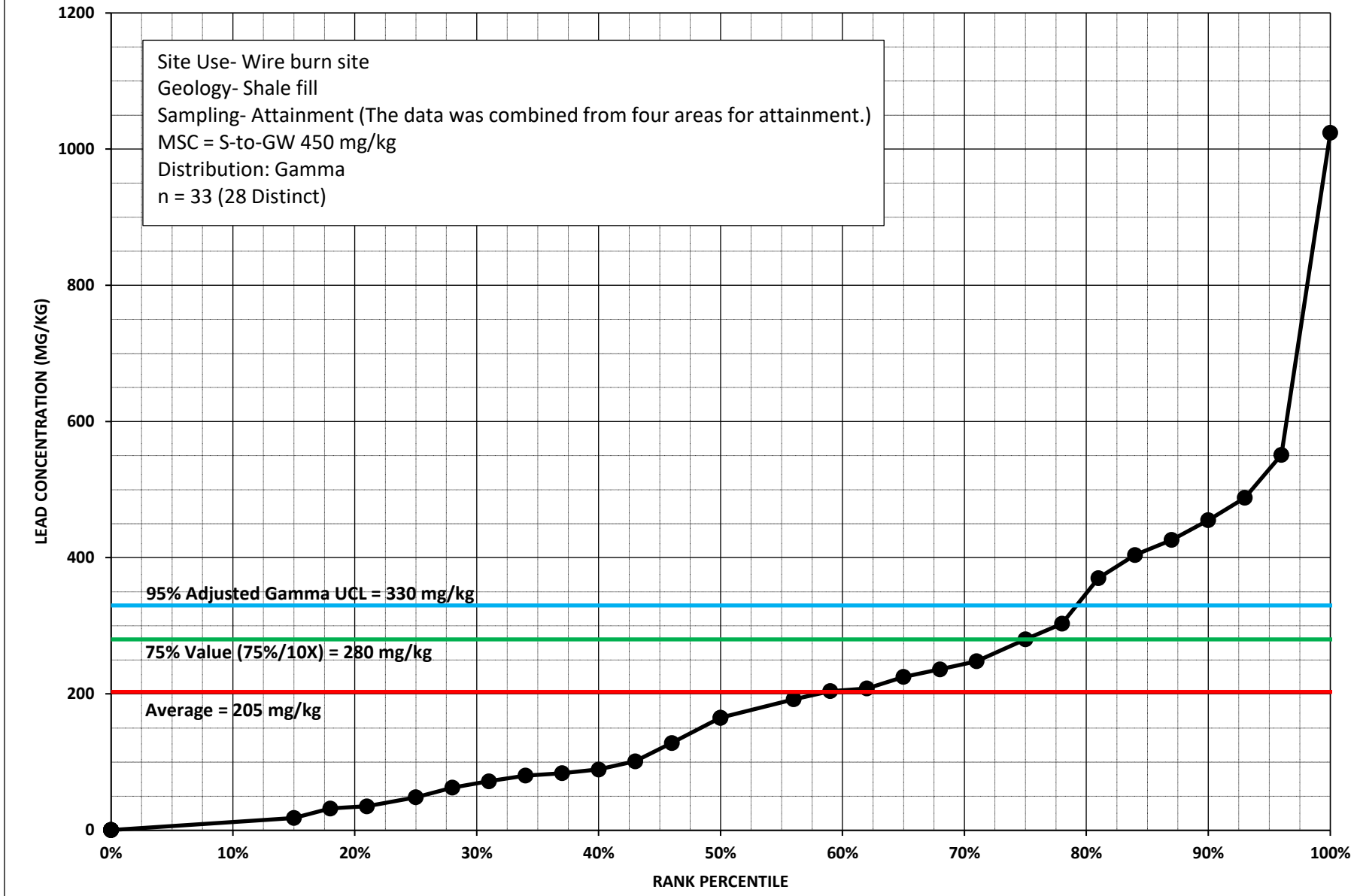
Ohio

Environmental Protection Agency 3745-300-08 Appendix A (Enacted October 7, 2019)

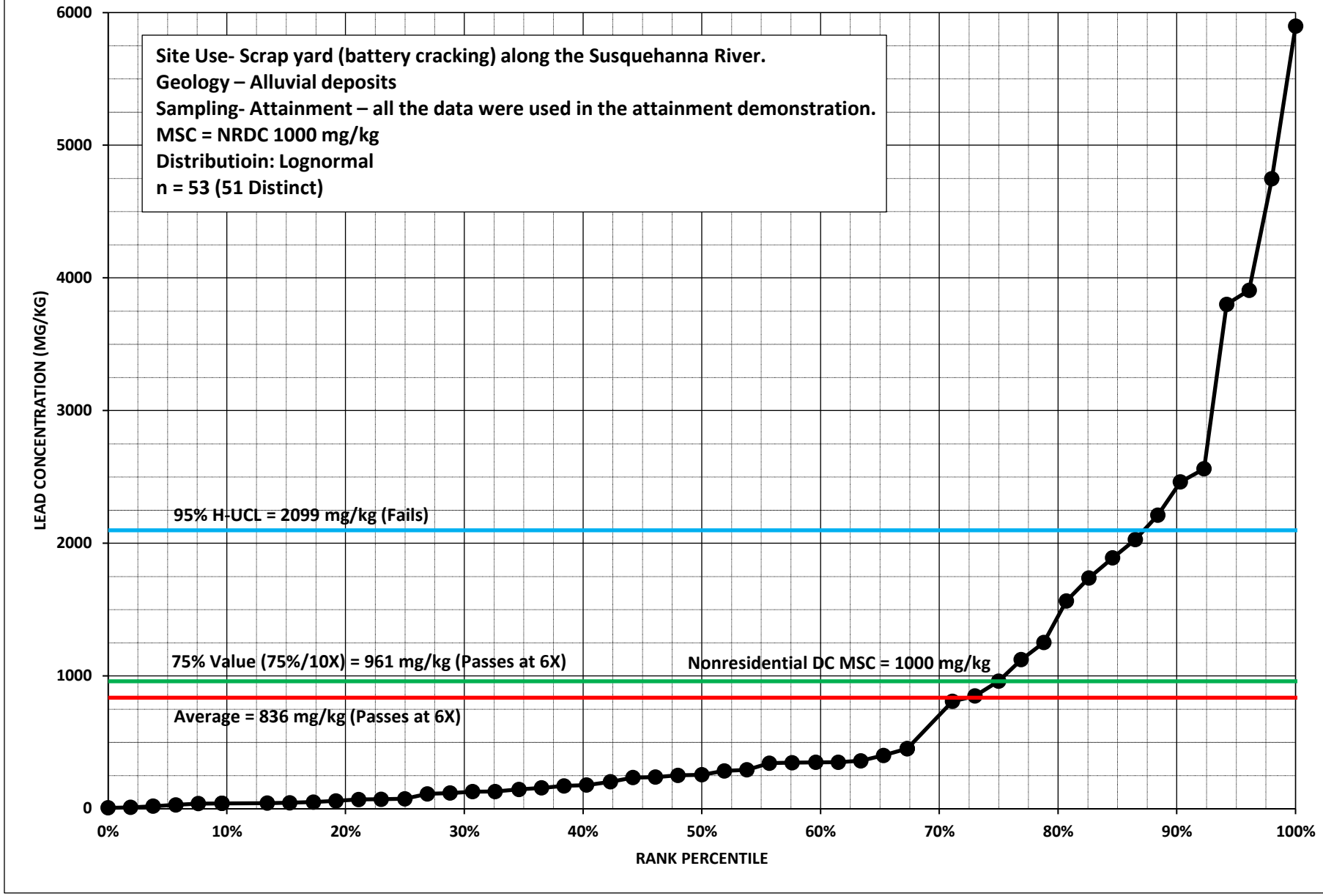
Generic Direct Contact Soil Standard for a Single Chemical			
Residential Land Use Category	Commercial Land Use with High Frequency Child Exposure	Commercial or Industrial Land Use Category	Construction Activities Category
400 *	400 *	800 *	400 *

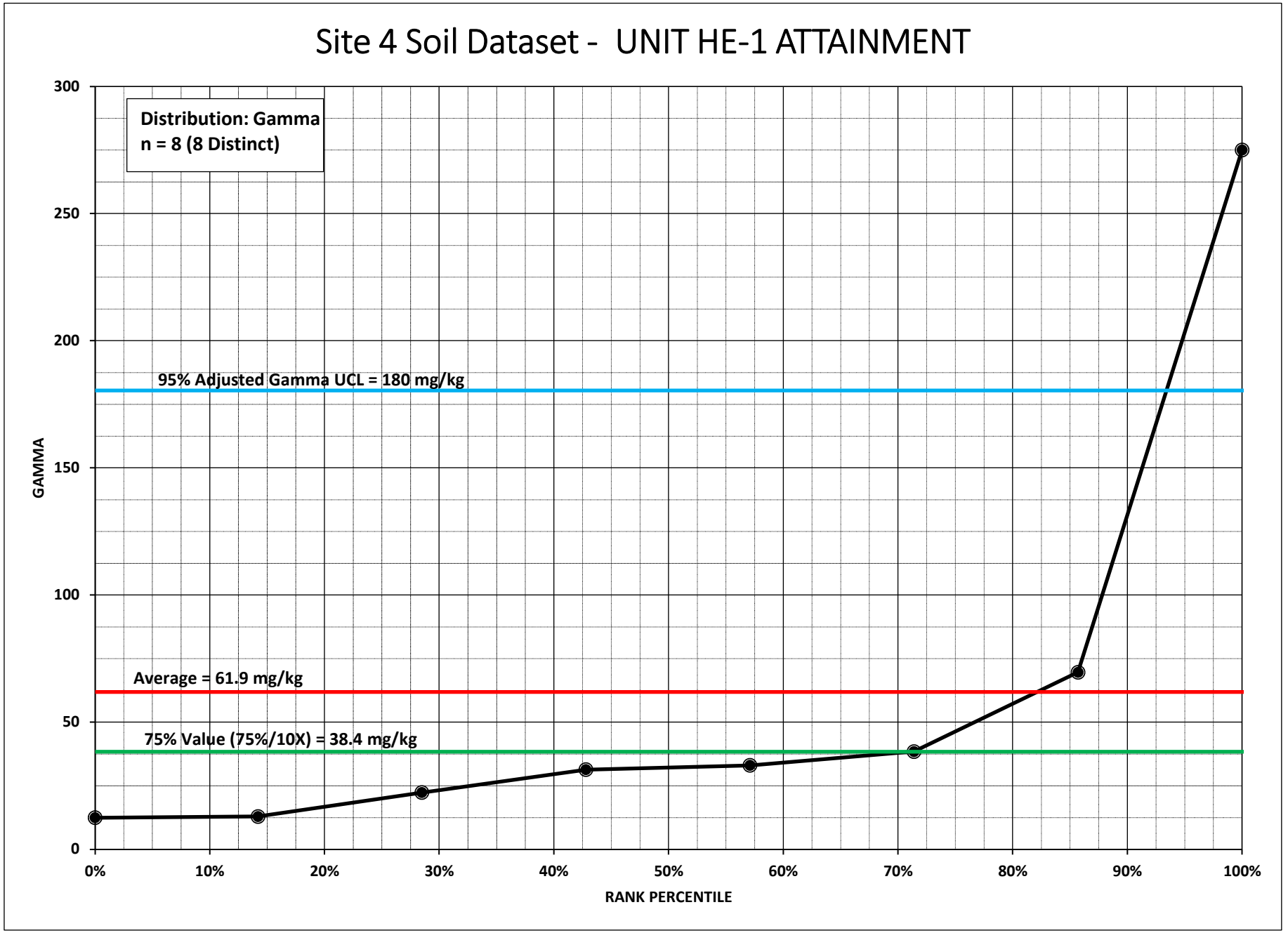
* - The lead standards in Appendix A account for other factors and assumptions in addition to the carcinogenic or non-carcinogenic risk of lead. Therefore, the cumulative risk considerations in this rule are not appropriate and need not be performed for lead.

Site 2 Soil Dataset - ATTAINMENT

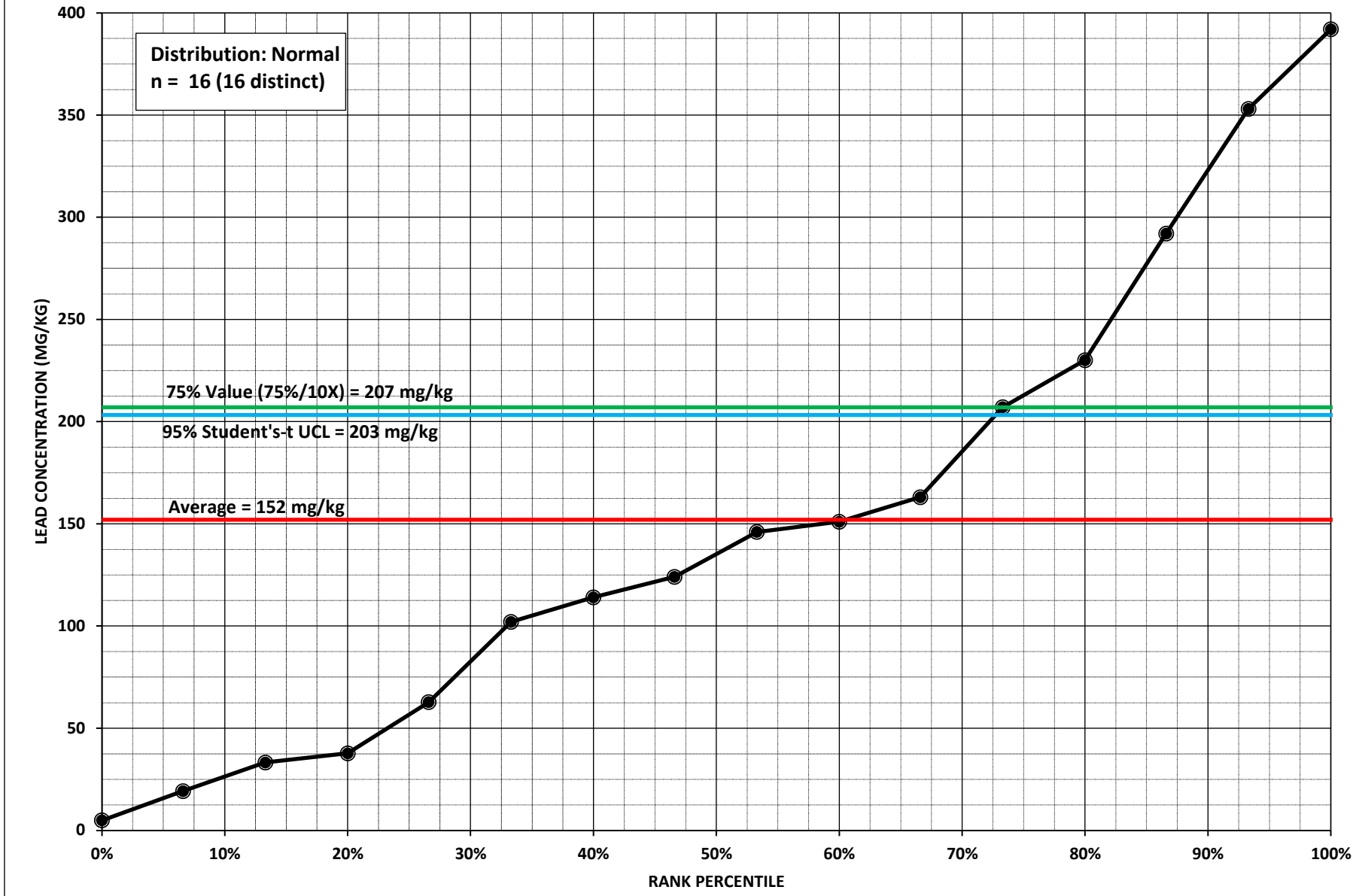


Site 3 Soil Dataset

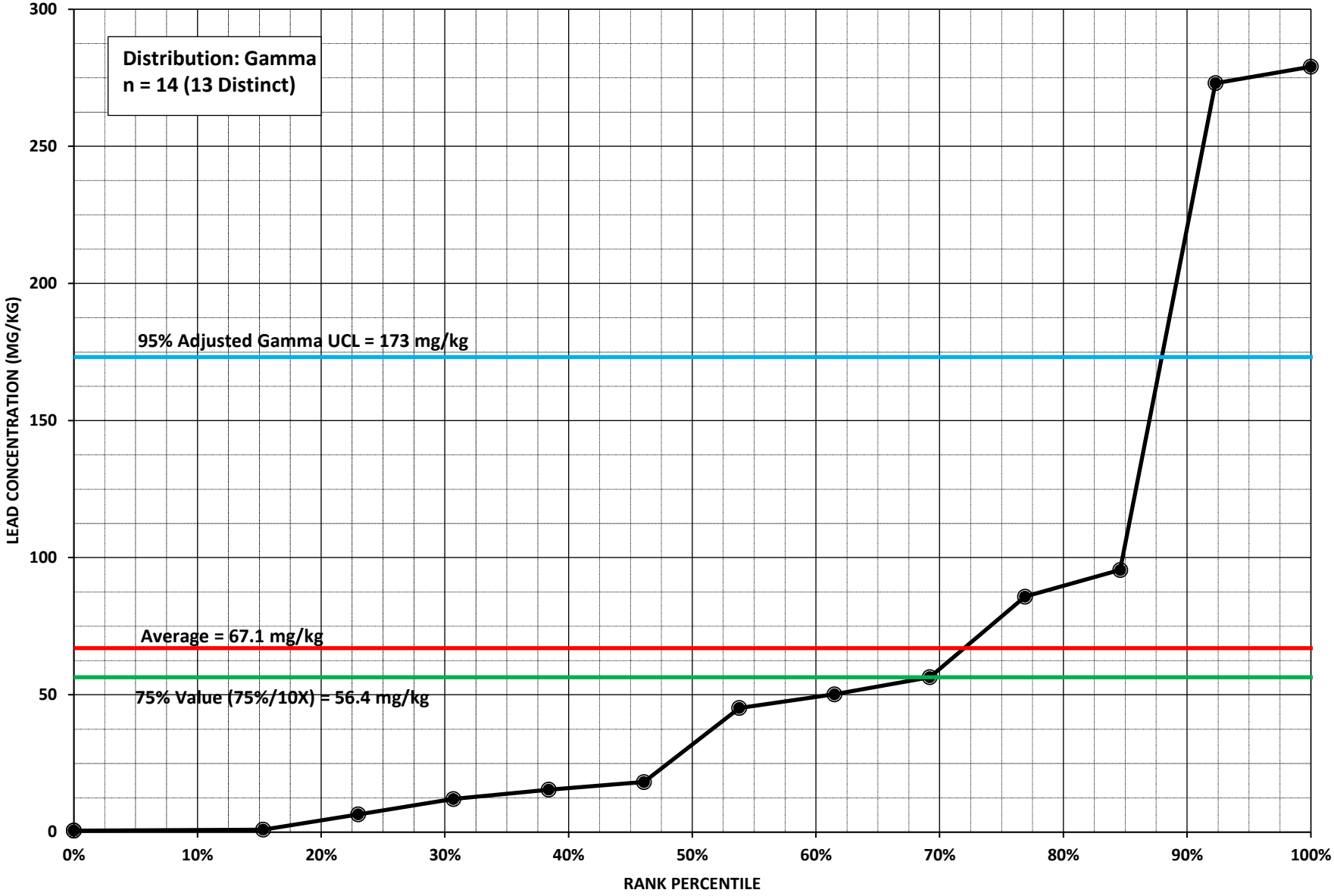



Site 4 Soil Dataset - UNIT HE-1 ATTAINMENT
Distribution: Gamma
n = 8 (8 Distinct)
95% Adjusted Gamma UCL = 180 mg/kg
Average = 61.9 mg/kg
75% Value (75%/10X) = 38.4 mg/kg
GAMMA
RANK PERCENTILE
0
50
100
150
200
250
300
0%
10%
20%
30%
40%
50%
60%
70%
80%
90%
100%

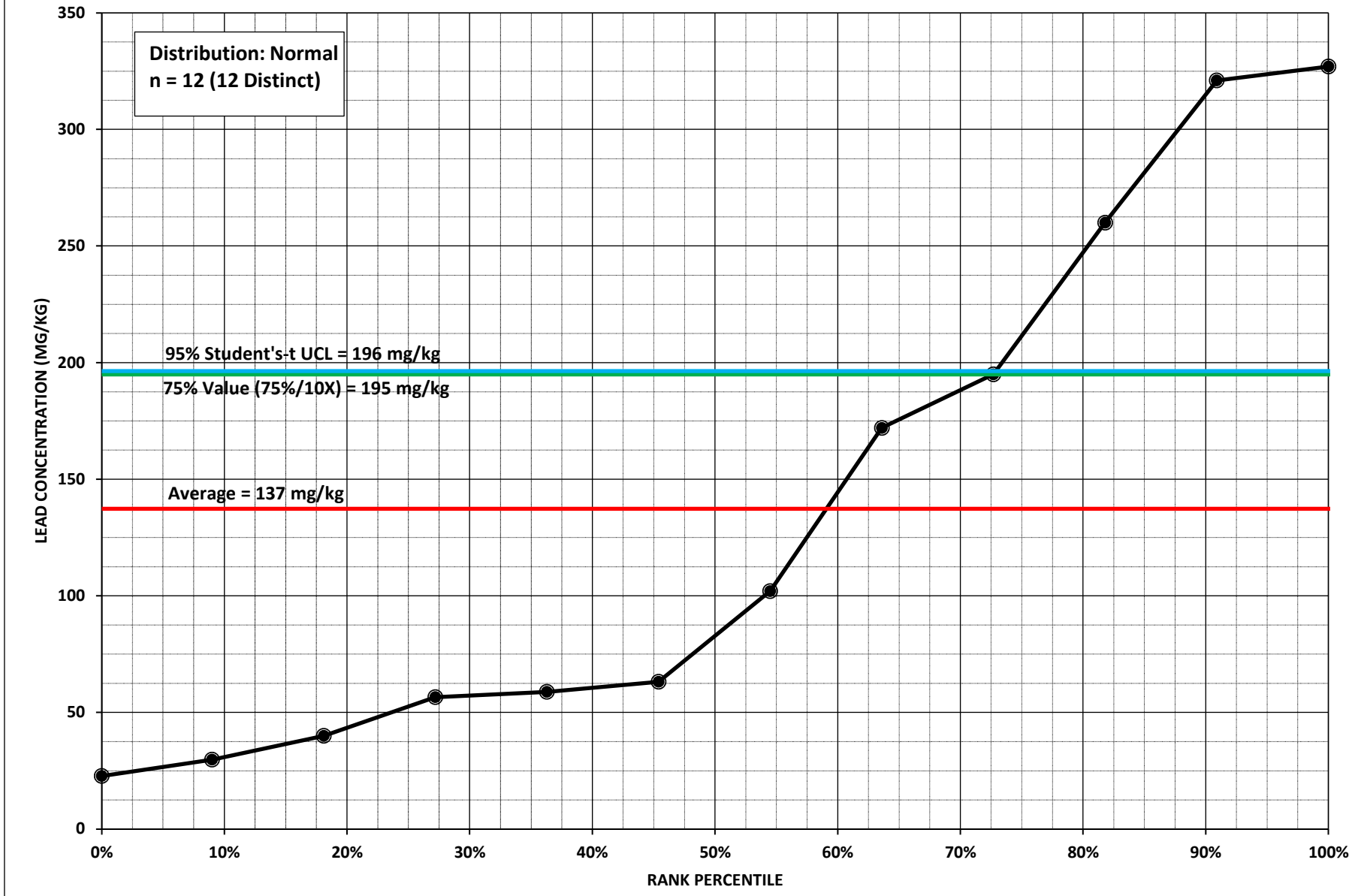
Site 4 Soil Dataset - UNIT HE-2 ATTAINMENT



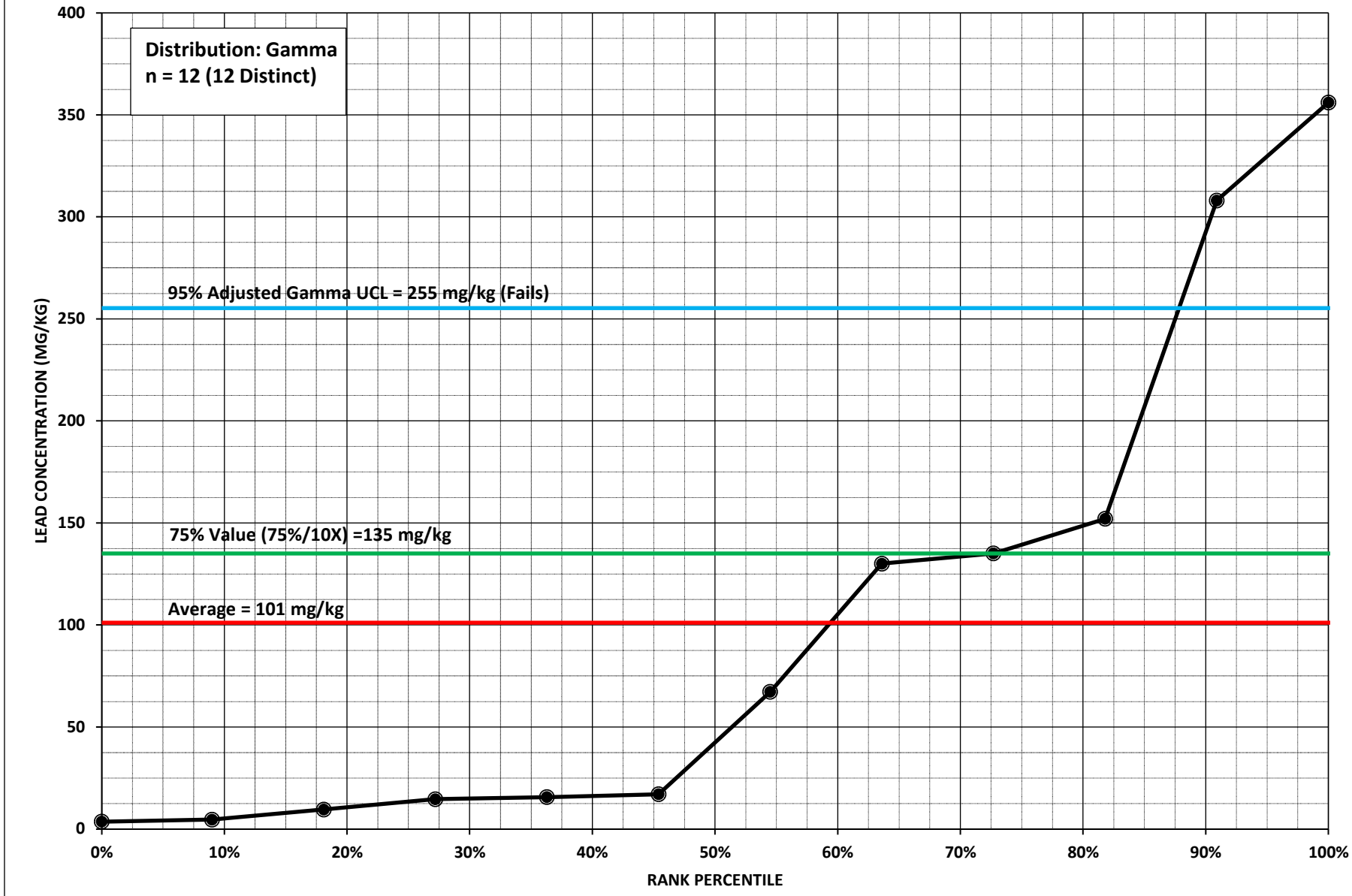
Site 4 Soil Dataset - UNIT HE-3 ATTAINMENT



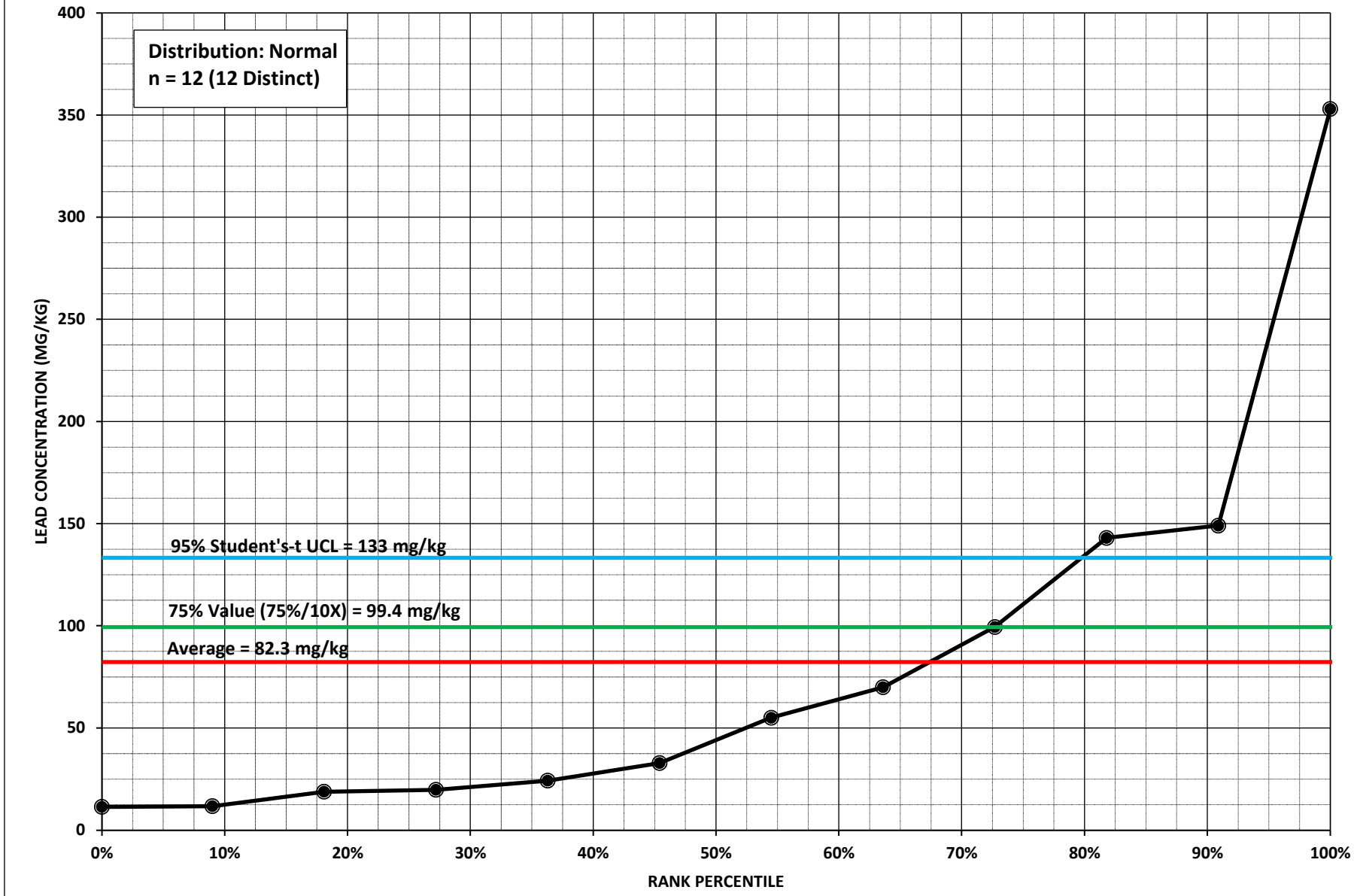
Site 4 Soil Dataset - UNIT HE-4 ATTAINMENT



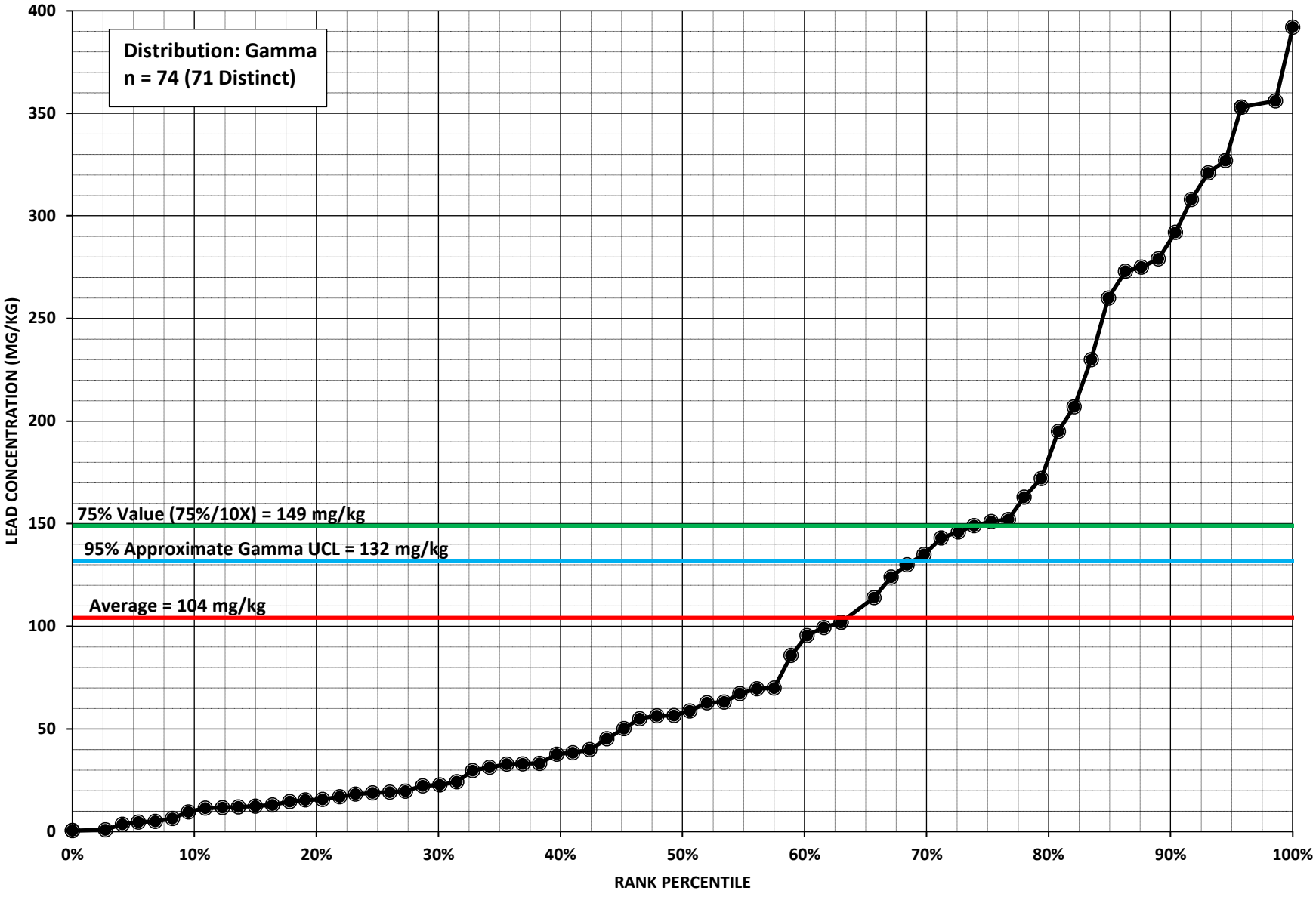
Site 4 Soil Dataset - UNIT HE-5 ATTAINMENT



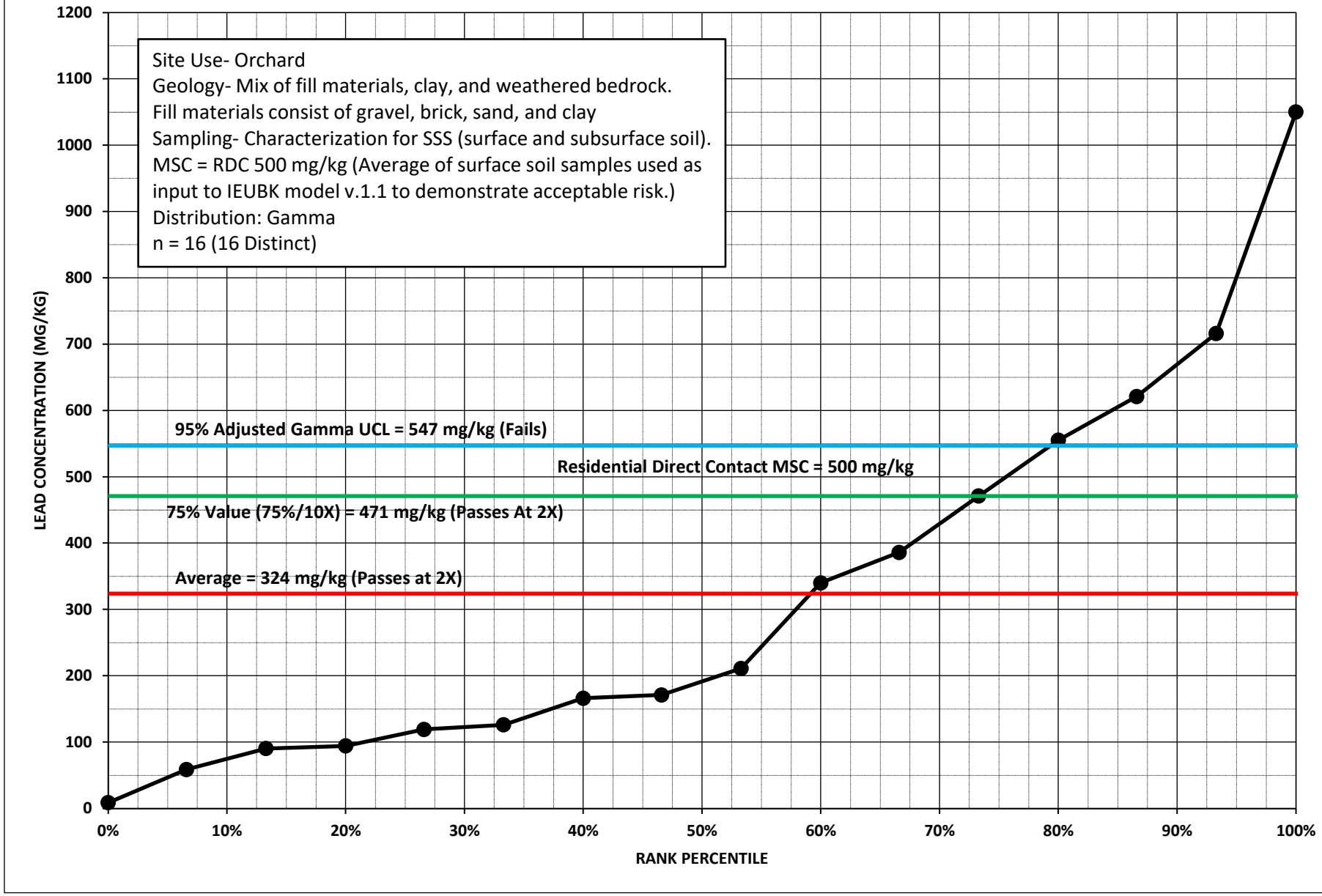
Site 4 Soil Dataset - UNIT HE-6 ATTAINMENT



Site 4 Soil Dataset - ALL ATTAINMENT DATA



Site 5 Soil Dataset - SURFACE SOIL DATA



	A	B	C	D	E	F	G	H	I	J	K	L
1	UCL Statistics for Uncensored Full Data Sets											
2												
3	User Selected Options											
4	Date/Time of Computation	ProUCL 5.12/3/2022 12:51:55 PM										
5	From File	Dataset Statistics.xls										
6	Full Precision	OFF										
7	Confidence Coefficient	95%										
8	Number of Bootstrap Operations	2000										
9												
10												
11	Site 2											
12												
13	General Statistics											
14	Total Number of Observations					33			Number of Distinct Observations			28
15									Number of Missing Observations			0
16	Minimum					0.25			Mean			202.8
17	Maximum					1024			Median			165
18	SD					216.3			Std. Error of Mean			37.65
19	Coefficient of Variation					1.066			Skewness			1.932
20												
21	Normal GOF Test											
22	Shapiro Wilk Test Statistic					0.822			Shapiro Wilk GOF Test			
23	5% Shapiro Wilk Critical Value					0.931			Data Not Normal at 5% Significance Level			
24	Lilliefors Test Statistic					0.174			Lilliefors GOF Test			
25	5% Lilliefors Critical Value					0.152			Data Not Normal at 5% Significance Level			
26	Data Not Normal at 5% Significance Level											
27												
28	Assuming Normal Distribution											
29	95% Normal UCL								95% UCLs (Adjusted for Skewness)			
30	95% Student's-t UCL					266.6			95% Adjusted-CLT UCL (Chen-1995)			278.3
31									95% Modified-t UCL (Johnson-1978)			268.7
32												
33	Gamma GOF Test											
34	A-D Test Statistic					1.291			Anderson-Darling Gamma GOF Test			
35	5% A-D Critical Value					0.809			Data Not Gamma Distributed at 5% Significance Level			
36	K-S Test Statistic					0.143			Kolmogorov-Smirnov Gamma GOF Test			
37	5% K-S Critical Value					0.162			Detected data appear Gamma Distributed at 5% Significance Level			
38	Detected data follow Appr. Gamma Distribution at 5% Significance Level											
39												
40	Gamma Statistics											
41	k hat (MLE)					0.522			k star (bias corrected MLE)			0.495
42	Theta hat (MLE)					388.8			Theta star (bias corrected MLE)			410.2
43	nu hat (MLE)					34.43			nu star (bias corrected)			32.64
44	MLE Mean (bias corrected)					202.8			MLE Sd (bias corrected)			288.4
45									Approximate Chi Square Value (0.05)			20.58
46	Adjusted Level of Significance					0.0419			Adjusted Chi Square Value			20.08
47												
48	Assuming Gamma Distribution											
49	95% Approximate Gamma UCL (use when n>=50)					321.7			95% Adjusted Gamma UCL (use when n<50)			329.6
50												
51	Lognormal GOF Test											
52	Shapiro Wilk Test Statistic					0.743			Shapiro Wilk Lognormal GOF Test			
53	5% Shapiro Wilk Critical Value					0.931			Data Not Lognormal at 5% Significance Level			

54					Lilliefors Test Statistic	0.232	Lilliefors Lognormal GOF Test					
55					5% Lilliefors Critical Value	0.152	Data Not Lognormal at 5% Significance Level					
56					Data Not Lognormal at 5% Significance Level							
57												
58					Lognormal Statistics							
59					Minimum of Logged Data	-1.386			Mean of logged Data	4.103		
60					Maximum of Logged Data	6.931			SD of logged Data	2.518		
61												
62					Assuming Lognormal Distribution							
63					95% H-UCL	11523			90% Chebyshev (MVUE) UCL	2975		
64					95% Chebyshev (MVUE) UCL	3851			97.5% Chebyshev (MVUE) UCL	5066		
65					99% Chebyshev (MVUE) UCL	7454						
66												
67					Nonparametric Distribution Free UCL Statistics							
68					Data appear to follow a Discernible Distribution at 5% Significance Level							
69												
70					Nonparametric Distribution Free UCLs							
71					95% CLT UCL	264.8			95% Jackknife UCL	266.6		
72					95% Standard Bootstrap UCL	262.4			95% Bootstrap-t UCL	289.9		
73					95% Hall's Bootstrap UCL	305.1			95% Percentile Bootstrap UCL	265.4		
74					95% BCA Bootstrap UCL	278.9						
75					90% Chebyshev(Mean, Sd) UCL	315.8			95% Chebyshev(Mean, Sd) UCL	367		
76					97.5% Chebyshev(Mean, Sd) UCL	438			99% Chebyshev(Mean, Sd) UCL	577.5		
77												
78					Suggested UCL to Use							
79					95% Adjusted Gamma UCL	329.6						
80												
81					When a data set follows an approximate (e.g., normal) distribution passing one of the GOF test							
82					When applicable, it is suggested to use a UCL based upon a distribution (e.g., gamma) passing both GOF tests in ProUCL							
83												
84					Note: Suggestions regarding the selection of a 95% UCL are provided to help the user to select the most appropriate 95% UCL.							
85					Recommendations are based upon data size, data distribution, and skewness.							
86					These recommendations are based upon the results of the simulation studies summarized in Singh, Maichle, and Lee (2006).							
87					However, simulations results will not cover all Real World data sets; for additional insight the user may want to consult a statistician.							
88												
89												
90	Site 3											
91												
92					General Statistics							
93					Total Number of Observations	53			Number of Distinct Observations	51		
94									Number of Missing Observations	0		
95					Minimum	7			Mean	836.3		
96					Maximum	5897			Median	255		
97					SD	1297			Std. Error of Mean	178.2		
98					Coefficient of Variation	1.551			Skewness	2.274		
99												
100					Normal GOF Test							
101					Shapiro Wilk Test Statistic	0.663	Shapiro Wilk GOF Test					
102					5% Shapiro Wilk P Value	6.883E-15	Data Not Normal at 5% Significance Level					
103					Lilliefors Test Statistic	0.315	Lilliefors GOF Test					
104					5% Lilliefors Critical Value	0.121	Data Not Normal at 5% Significance Level					
105					Data Not Normal at 5% Significance Level							
106												

	A	B	C	D	E	F	G	H	I	J	K	L
107	Assuming Normal Distribution											
108	95% Normal UCL						95% UCLs (Adjusted for Skewness)					
109	95% Student's-t UCL				1135		95% Adjusted-CLT UCL (Chen-1995)				1189	
110							95% Modified-t UCL (Johnson-1978)				1144	
111												
112	Gamma GOF Test											
113	A-D Test Statistic				1.401		Anderson-Darling Gamma GOF Test					
114	5% A-D Critical Value				0.81		Data Not Gamma Distributed at 5% Significance Level					
115	K-S Test Statistic				0.178		Kolmogorov-Smirnov Gamma GOF Test					
116	5% K-S Critical Value				0.129		Data Not Gamma Distributed at 5% Significance Level					
117	Data Not Gamma Distributed at 5% Significance Level											
118												
119	Gamma Statistics											
120	k hat (MLE)				0.554		k star (bias corrected MLE)				0.535	
121	Theta hat (MLE)				1509		Theta star (bias corrected MLE)				1562	
122	nu hat (MLE)				58.73		nu star (bias corrected)				56.74	
123	MLE Mean (bias corrected)				836.3		MLE Sd (bias corrected)				1143	
124							Approximate Chi Square Value (0.05)				40.43	
125	Adjusted Level of Significance				0.0455		Adjusted Chi Square Value				40.04	
126												
127	Assuming Gamma Distribution											
128	95% Approximate Gamma UCL (use when n>=50))				1174		95% Adjusted Gamma UCL (use when n<50)				1185	
129												
130	Lognormal GOF Test											
131	Shapiro Wilk Test Statistic				0.971		Shapiro Wilk Lognormal GOF Test					
132	5% Shapiro Wilk P Value				0.39		Data appear Lognormal at 5% Significance Level					
133	Lilliefors Test Statistic				0.075		Lilliefors Lognormal GOF Test					
134	5% Lilliefors Critical Value				0.121		Data appear Lognormal at 5% Significance Level					
135	Data appear Lognormal at 5% Significance Level											
136												
137	Lognormal Statistics											
138	Minimum of Logged Data				1.946		Mean of logged Data				5.6	
139	Maximum of Logged Data				8.682		SD of logged Data				1.637	
140												
141	Assuming Lognormal Distribution											
142	95% H-UCL				2099		90% Chebyshev (MVUE) UCL				1883	
143	95% Chebyshev (MVUE) UCL				2293		97.5% Chebyshev (MVUE) UCL				2862	
144	99% Chebyshev (MVUE) UCL				3981							
145												
146	Nonparametric Distribution Free UCL Statistics											
147	Data appear to follow a Discernible Distribution at 5% Significance Level											
148												
149	Nonparametric Distribution Free UCLs											
150	95% CLT UCL				1129		95% Jackknife UCL				1135	
151	95% Standard Bootstrap UCL				1130		95% Bootstrap-t UCL				1226	
152	95% Hall's Bootstrap UCL				1218		95% Percentile Bootstrap UCL				1153	
153	95% BCA Bootstrap UCL				1191							
154	90% Chebyshev(Mean, Sd) UCL				1371		95% Chebyshev(Mean, Sd) UCL				1613	
155	97.5% Chebyshev(Mean, Sd) UCL				1949		99% Chebyshev(Mean, Sd) UCL				2609	
156												
157	Suggested UCL to Use											
158	95% H-UCL				2099							
159												

Note: Suggestions regarding the selection of a 95% UCL are provided to help the user to select the most appropriate 95% UCL.
Recommendations are based upon data size, data distribution, and skewness.
These recommendations are based upon the results of the simulation studies summarized in Singh, Maichle, and Lee (2006).
However, simulations results will not cover all Real World data sets; for additional insight the user may want to consult a statistician.

ProUCL computes and outputs H-statistic based UCLs for historical reasons only.
H-statistic often results in unstable (both high and low) values of UCL95 as shown in examples in the Technical Guide.
It is therefore recommended to avoid the use of H-statistic based 95% UCLs.
Use of nonparametric methods are preferred to compute UCL95 for skewed data sets which do not follow a gamma distribution.

Site 4_Attain

General Statistics

Total Number of Observations	74	Number of Distinct Observations	71
		Number of Missing Observations	0
Minimum	0.5	Mean	104.2
Maximum	392	Median	57.65
SD	109.5	Std. Error of Mean	12.73
Coefficient of Variation	1.051	Skewness	1.156

Normal GOF Test

Shapiro Wilk Test Statistic	0.812	Shapiro Wilk GOF Test
5% Shapiro Wilk P Value	5.004E-13	Data Not Normal at 5% Significance Level
Lilliefors Test Statistic	0.204	Lilliefors GOF Test
5% Lilliefors Critical Value	0.103	Data Not Normal at 5% Significance Level

Data Not Normal at 5% Significance Level

Assuming Normal Distribution

95% Normal UCL		95% UCLs (Adjusted for Skewness)	
95% Student's-t UCL	125.5	95% Adjusted-CLT UCL (Chen-1995)	127
		95% Modified-t UCL (Johnson-1978)	125.7

Gamma GOF Test

A-D Test Statistic	0.505	Anderson-Darling Gamma GOF Test
5% A-D Critical Value	0.792	Detected data appear Gamma Distributed at 5% Significance Level
K-S Test Statistic	0.0659	Kolmogorov-Smirnov Gamma GOF Test
5% K-S Critical Value	0.108	Detected data appear Gamma Distributed at 5% Significance Level

Detected data appear Gamma Distributed at 5% Significance Level

Gamma Statistics

k hat (MLE)	0.777	k star (bias corrected MLE)	0.755
Theta hat (MLE)	134.1	Theta star (bias corrected MLE)	138.1
nu hat (MLE)	115.1	nu star (bias corrected)	111.7
MLE Mean (bias corrected)	104.2	MLE Sd (bias corrected)	120
		Approximate Chi Square Value (0.05)	88.33
Adjusted Level of Significance	0.0468	Adjusted Chi Square Value	87.92

Assuming Gamma Distribution

95% Approximate Gamma UCL (use when n>=50)	131.9	95% Adjusted Gamma UCL (use when n<50)	132.5

Lognormal GOF Test

Shapiro Wilk Test Statistic	0.921	Shapiro Wilk Lognormal GOF Test

213				5% Shapiro Wilk P Value	9.9070E-5	Data Not Lognormal at 5% Significance Level					
214				Lilliefors Test Statistic	0.0841	Lilliefors Lognormal GOF Test					
215				5% Lilliefors Critical Value	0.103	Data appear Lognormal at 5% Significance Level					
216	Data appear Approximate Lognormal at 5% Significance Level										
217											
218	Lognormal Statistics										
219				Minimum of Logged Data	-0.693	Mean of logged Data	3.88				
220				Maximum of Logged Data	5.971	SD of logged Data	1.517				
221											
222	Assuming Lognormal Distribution										
223				95% H-UCL	252.6	90% Chebyshev (MVUE) UCL	255.8				
224				95% Chebyshev (MVUE) UCL	304.5	97.5% Chebyshev (MVUE) UCL	372.1				
225				99% Chebyshev (MVUE) UCL	504.9						
226											
227	Nonparametric Distribution Free UCL Statistics										
228	Data appear to follow a Discernible Distribution at 5% Significance Level										
229											
230	Nonparametric Distribution Free UCLs										
231				95% CLT UCL	125.2	95% Jackknife UCL	125.5				
232				95% Standard Bootstrap UCL	125.5	95% Bootstrap-t UCL	126.8				
233				95% Hall's Bootstrap UCL	127.4	95% Percentile Bootstrap UCL	125.4				
234				95% BCA Bootstrap UCL	128.5						
235				90% Chebyshev(Mean, Sd) UCL	142.4	95% Chebyshev(Mean, Sd) UCL	159.7				
236				97.5% Chebyshev(Mean, Sd) UCL	183.8	99% Chebyshev(Mean, Sd) UCL	230.9				
237											
238	Suggested UCL to Use										
239				95% Approximate Gamma UCL	131.9						
240											
241	Note: Suggestions regarding the selection of a 95% UCL are provided to help the user to select the most appropriate 95% UCL.										
242	Recommendations are based upon data size, data distribution, and skewness.										
243	These recommendations are based upon the results of the simulation studies summarized in Singh, Maichle, and Lee (2006).										
244	However, simulations results will not cover all Real World data sets; for additional insight the user may want to consult a statistician.										
245											
246											
247	Site 4 HE1										
248											
249	General Statistics										
250				Total Number of Observations	8	Number of Distinct Observations	8				
251						Number of Missing Observations	0				
252				Minimum	12.4	Mean	61.86				
253				Maximum	275	Median	32.15				
254				SD	88	Std. Error of Mean	31.11				
255				Coefficient of Variation	1.423	Skewness	2.604				
256											
257	Note: Sample size is small (e.g., <10), if data are collected using ISM approach, you should use										
258	guidance provided in ITRC Tech Reg Guide on ISM (ITRC, 2012) to compute statistics of interest.										
259	For example, you may want to use Chebyshev UCL to estimate EPC (ITRC, 2012).										
260	Chebyshev UCL can be computed using the Nonparametric and All UCL Options of ProUCL 5.1										
261											
262	Normal GOF Test										
263				Shapiro Wilk Test Statistic	0.596	Shapiro Wilk GOF Test					
264				5% Shapiro Wilk Critical Value	0.818	Data Not Normal at 5% Significance Level					
265				Lilliefors Test Statistic	0.355	Lilliefors GOF Test					

266				5% Lilliefors Critical Value	0.283	Data Not Normal at 5% Significance Level					
267	Data Not Normal at 5% Significance Level										
268											
269	Assuming Normal Distribution										
270	95% Normal UCL					95% UCLs (Adjusted for Skewness)					
271				95% Student's-t UCL	120.8				95% Adjusted-CLT UCL (Chen-1995)	143.6	
272									95% Modified-t UCL (Johnson-1978)	125.6	
273											
274	Gamma GOF Test										
275				A-D Test Statistic	0.749	Anderson-Darling Gamma GOF Test					
276				5% A-D Critical Value	0.735	Data Not Gamma Distributed at 5% Significance Level					
277				K-S Test Statistic	0.295	Kolmogorov-Smirnov Gamma GOF Test					
278				5% K-S Critical Value	0.301	Detected data appear Gamma Distributed at 5% Significance Level					
279	Detected data follow Appr. Gamma Distribution at 5% Significance Level										
280											
281	Gamma Statistics										
282				k hat (MLE)	1.05				k star (bias corrected MLE)	0.74	
283				Theta hat (MLE)	58.9				Theta star (bias corrected MLE)	83.63	
284				nu hat (MLE)	16.8				nu star (bias corrected)	11.84	
285				MLE Mean (bias corrected)	61.86				MLE Sd (bias corrected)	71.93	
286									Approximate Chi Square Value (0.05)	5.119	
287				Adjusted Level of Significance	0.0195				Adjusted Chi Square Value	4.059	
288											
289	Assuming Gamma Distribution										
290	95% Approximate Gamma UCL (use when n>=50)				143				95% Adjusted Gamma UCL (use when n<50)	180.4	
291											
292	Lognormal GOF Test										
293				Shapiro Wilk Test Statistic	0.895	Shapiro Wilk Lognormal GOF Test					
294				5% Shapiro Wilk Critical Value	0.818	Data appear Lognormal at 5% Significance Level					
295				Lilliefors Test Statistic	0.222	Lilliefors Lognormal GOF Test					
296				5% Lilliefors Critical Value	0.283	Data appear Lognormal at 5% Significance Level					
297	Data appear Lognormal at 5% Significance Level										
298											
299	Lognormal Statistics										
300				Minimum of Logged Data	2.518				Mean of logged Data	3.578	
301				Maximum of Logged Data	5.617				SD of logged Data	1.001	
302											
303	Assuming Lognormal Distribution										
304				95% H-UCL	216.5				90% Chebyshev (MVUE) UCL	113.5	
305				95% Chebyshev (MVUE) UCL	140.3				97.5% Chebyshev (MVUE) UCL	177.4	
306				99% Chebyshev (MVUE) UCL	250.4						
307											
308	Nonparametric Distribution Free UCL Statistics										
309	Data appear to follow a Discernible Distribution at 5% Significance Level										
310											
311	Nonparametric Distribution Free UCLs										
312				95% CLT UCL	113				95% Jackknife UCL	120.8	
313				95% Standard Bootstrap UCL	110.3				95% Bootstrap-t UCL	391.6	
314				95% Hall's Bootstrap UCL	389.2				95% Percentile Bootstrap UCL	119.6	
315				95% BCA Bootstrap UCL	151.9						
316				90% Chebyshev(Mean, Sd) UCL	155.2				95% Chebyshev(Mean, Sd) UCL	197.5	
317				97.5% Chebyshev(Mean, Sd) UCL	256.2				99% Chebyshev(Mean, Sd) UCL	371.4	
318											

319	Suggested UCL to Use										
320				95% Adjusted Gamma UCL	180.4						
321											
322	When a data set follows an approximate (e.g., normal) distribution passing one of the GOF test										
323	When applicable, it is suggested to use a UCL based upon a distribution (e.g., gamma) passing both GOF tests in ProUCL										
324											
325	Note: Suggestions regarding the selection of a 95% UCL are provided to help the user to select the most appropriate 95% UCL.										
326	Recommendations are based upon data size, data distribution, and skewness.										
327	These recommendations are based upon the results of the simulation studies summarized in Singh, Maichle, and Lee (2006).										
328	However, simulations results will not cover all Real World data sets; for additional insight the user may want to consult a statistician.										
329											
330											
331	Site 4 HE2										
332											
333	General Statistics										
334				Total Number of Observations	16			Number of Distinct Observations	16		
335								Number of Missing Observations	0		
336				Minimum	4.9			Mean	152		
337				Maximum	392			Median	135		
338				SD	117.2			Std. Error of Mean	29.3		
339				Coefficient of Variation	0.771			Skewness	0.745		
340											
341	Normal GOF Test										
342				Shapiro Wilk Test Statistic	0.93			Shapiro Wilk GOF Test			
343				5% Shapiro Wilk Critical Value	0.887			Data appear Normal at 5% Significance Level			
344				Lilliefors Test Statistic	0.15			Lilliefors GOF Test			
345				5% Lilliefors Critical Value	0.213			Data appear Normal at 5% Significance Level			
346	Data appear Normal at 5% Significance Level										
347											
348	Assuming Normal Distribution										
349				95% Normal UCL				95% UCLs (Adjusted for Skewness)			
350				95% Student's-t UCL	203.3			95% Adjusted-CLT UCL (Chen-1995)	206		
351								95% Modified-t UCL (Johnson-1978)	204.3		
352											
353	Gamma GOF Test										
354				A-D Test Statistic	0.239			Anderson-Darling Gamma GOF Test			
355				5% A-D Critical Value	0.758			Detected data appear Gamma Distributed at 5% Significance Level			
356				K-S Test Statistic	0.141			Kolmogorov-Smirnov Gamma GOF Test			
357				5% K-S Critical Value	0.22			Detected data appear Gamma Distributed at 5% Significance Level			
358	Detected data appear Gamma Distributed at 5% Significance Level										
359											
360	Gamma Statistics										
361				k hat (MLE)	1.283			k star (bias corrected MLE)	1.084		
362				Theta hat (MLE)	118.4			Theta star (bias corrected MLE)	140.2		
363				nu hat (MLE)	41.06			nu star (bias corrected)	34.7		
364				MLE Mean (bias corrected)	152			MLE Sd (bias corrected)	146		
365								Approximate Chi Square Value (0.05)	22.22		
366				Adjusted Level of Significance	0.0335			Adjusted Chi Square Value	21.09		
367											
368	Assuming Gamma Distribution										
369				95% Approximate Gamma UCL (use when n>=50))	237.3			95% Adjusted Gamma UCL (use when n<50)	250		
370											
371	Lognormal GOF Test										

372				Shapiro Wilk Test Statistic	0.901	Shapiro Wilk Lognormal GOF Test					
373				5% Shapiro Wilk Critical Value	0.887	Data appear Lognormal at 5% Significance Level					
374				Lilliefors Test Statistic	0.201	Lilliefors Lognormal GOF Test					
375				5% Lilliefors Critical Value	0.213	Data appear Lognormal at 5% Significance Level					
376				Data appear Lognormal at 5% Significance Level							
377											
378				Lognormal Statistics							
379				Minimum of Logged Data	1.589	Mean of logged Data	4.586				
380				Maximum of Logged Data	5.971	SD of logged Data	1.173				
381											
382				Assuming Lognormal Distribution							
383				95% H-UCL	481.4	90% Chebyshev (MVUE) UCL	363.2				
384				95% Chebyshev (MVUE) UCL	444.9	97.5% Chebyshev (MVUE) UCL	558.3				
385				99% Chebyshev (MVUE) UCL	781.1						
386											
387				Nonparametric Distribution Free UCL Statistics							
388				Data appear to follow a Discernible Distribution at 5% Significance Level							
389											
390				Nonparametric Distribution Free UCLs							
391				95% CLT UCL	200.2	95% Jackknife UCL	203.3				
392				95% Standard Bootstrap UCL	197.9	95% Bootstrap-t UCL	212.6				
393				95% Hall's Bootstrap UCL	209.7	95% Percentile Bootstrap UCL	200.3				
394				95% BCA Bootstrap UCL	204						
395				90% Chebyshev(Mean, Sd) UCL	239.9	95% Chebyshev(Mean, Sd) UCL	279.7				
396				97.5% Chebyshev(Mean, Sd) UCL	335	99% Chebyshev(Mean, Sd) UCL	443.5				
397											
398				Suggested UCL to Use							
399				95% Student's-t UCL	203.3						
400											
401				Note: Suggestions regarding the selection of a 95% UCL are provided to help the user to select the most appropriate 95% UCL.							
402				Recommendations are based upon data size, data distribution, and skewness.							
403				These recommendations are based upon the results of the simulation studies summarized in Singh, Maichle, and Lee (2006).							
404				However, simulations results will not cover all Real World data sets; for additional insight the user may want to consult a statistician.							
405											
406											
407	Site 4 HE3										
408											
409				General Statistics							
410				Total Number of Observations	14	Number of Distinct Observations	13				
411						Number of Missing Observations	0				
412				Minimum	0.5	Mean	67.07				
413				Maximum	279	Median	31.7				
414				SD	93.8	Std. Error of Mean	25.07				
415				Coefficient of Variation	1.399	Skewness	1.82				
416											
417				Normal GOF Test							
418				Shapiro Wilk Test Statistic	0.7	Shapiro Wilk GOF Test					
419				5% Shapiro Wilk Critical Value	0.874	Data Not Normal at 5% Significance Level					
420				Lilliefors Test Statistic	0.26	Lilliefors GOF Test					
421				5% Lilliefors Critical Value	0.226	Data Not Normal at 5% Significance Level					
422				Data Not Normal at 5% Significance Level							
423											
424				Assuming Normal Distribution							

425	95% Normal UCL					95% UCLs (Adjusted for Skewness)					
426				95% Student's-t UCL	111.5				95% Adjusted-CLT UCL (Chen-1995)	121.3	
427									95% Modified-t UCL (Johnson-1978)	113.5	
428											
429	Gamma GOF Test										
430				A-D Test Statistic	0.284	Anderson-Darling Gamma GOF Test					
431				5% A-D Critical Value	0.796	Detected data appear Gamma Distributed at 5% Significance Level					
432				K-S Test Statistic	0.119	Kolmogorov-Smirnov Gamma GOF Test					
433				5% K-S Critical Value	0.242	Detected data appear Gamma Distributed at 5% Significance Level					
434	Detected data appear Gamma Distributed at 5% Significance Level										
435											
436	Gamma Statistics										
437				k hat (MLE)	0.485	k star (bias corrected MLE)	0.428				
438				Theta hat (MLE)	138.4	Theta star (bias corrected MLE)	156.6				
439				nu hat (MLE)	13.57	nu star (bias corrected)	11.99				
440				MLE Mean (bias corrected)	67.07	MLE Sd (bias corrected)	102.5				
441						Approximate Chi Square Value (0.05)	5.223				
442				Adjusted Level of Significance	0.0312	Adjusted Chi Square Value	4.644				
443											
444	Assuming Gamma Distribution										
445				95% Approximate Gamma UCL (use when n>=50)	154	95% Adjusted Gamma UCL (use when n<50)	173.2				
446											
447	Lognormal GOF Test										
448				Shapiro Wilk Test Statistic	0.904	Shapiro Wilk Lognormal GOF Test					
449				5% Shapiro Wilk Critical Value	0.874	Data appear Lognormal at 5% Significance Level					
450				Lilliefors Test Statistic	0.167	Lilliefors Lognormal GOF Test					
451				5% Lilliefors Critical Value	0.226	Data appear Lognormal at 5% Significance Level					
452	Data appear Lognormal at 5% Significance Level										
453											
454	Lognormal Statistics										
455				Minimum of Logged Data	-0.693	Mean of logged Data	2.889				
456				Maximum of Logged Data	5.631	SD of logged Data	2.141				
457											
458	Assuming Lognormal Distribution										
459				95% H-UCL	3382	90% Chebyshev (MVUE) UCL	350.8				
460				95% Chebyshev (MVUE) UCL	455.4	97.5% Chebyshev (MVUE) UCL	600.7				
461				99% Chebyshev (MVUE) UCL	885.9						
462											
463	Nonparametric Distribution Free UCL Statistics										
464	Data appear to follow a Discernible Distribution at 5% Significance Level										
465											
466	Nonparametric Distribution Free UCLs										
467				95% CLT UCL	108.3	95% Jackknife UCL	111.5				
468				95% Standard Bootstrap UCL	107.2	95% Bootstrap-t UCL	172.1				
469				95% Hall's Bootstrap UCL	334.5	95% Percentile Bootstrap UCL	111.1				
470				95% BCA Bootstrap UCL	127.3						
471				90% Chebyshev(Mean, Sd) UCL	142.3	95% Chebyshev(Mean, Sd) UCL	176.3				
472				97.5% Chebyshev(Mean, Sd) UCL	223.6	99% Chebyshev(Mean, Sd) UCL	316.5				
473											
474	Suggested UCL to Use										
475				95% Adjusted Gamma UCL	173.2						
476											
477	Note: Suggestions regarding the selection of a 95% UCL are provided to help the user to select the most appropriate 95% UCL.										

478	Recommendations are based upon data size, data distribution, and skewness.										
479	These recommendations are based upon the results of the simulation studies summarized in Singh, Maichle, and Lee (2006).										
480	However, simulations results will not cover all Real World data sets; for additional insight the user may want to consult a statistician.										
481											
482											
483	Site 4 HE4										
484											
485	General Statistics										
486				Total Number of Observations	12			Number of Distinct Observations	12		
487								Number of Missing Observations	0		
488				Minimum	22.7			Mean	137.3		
489				Maximum	327			Median	82.55		
490				SD	114			Std. Error of Mean	32.91		
491				Coefficient of Variation	0.83			Skewness	0.734		
492											
493	Normal GOF Test										
494				Shapiro Wilk Test Statistic	0.851			Shapiro Wilk GOF Test			
495				5% Shapiro Wilk Critical Value	0.859			Data Not Normal at 5% Significance Level			
496				Lilliefors Test Statistic	0.242			Lilliefors GOF Test			
497				5% Lilliefors Critical Value	0.243			Data appear Normal at 5% Significance Level			
498	Data appear Approximate Normal at 5% Significance Level										
499											
500	Assuming Normal Distribution										
501				95% Normal UCL				95% UCLs (Adjusted for Skewness)			
502				95% Student's-t UCL	196.4			95% Adjusted-CLT UCL (Chen-1995)	198.9		
503								95% Modified-t UCL (Johnson-1978)	197.6		
504											
505	Gamma GOF Test										
506				A-D Test Statistic	0.456			Anderson-Darling Gamma GOF Test			
507				5% A-D Critical Value	0.746			Detected data appear Gamma Distributed at 5% Significance Level			
508				K-S Test Statistic	0.21			Kolmogorov-Smirnov Gamma GOF Test			
509				5% K-S Critical Value	0.25			Detected data appear Gamma Distributed at 5% Significance Level			
510	Detected data appear Gamma Distributed at 5% Significance Level										
511											
512	Gamma Statistics										
513				k hat (MLE)	1.494			k star (bias corrected MLE)	1.176		
514				Theta hat (MLE)	91.89			Theta star (bias corrected MLE)	116.7		
515				nu hat (MLE)	35.86			nu star (bias corrected)	28.23		
516				MLE Mean (bias corrected)	137.3			MLE Sd (bias corrected)	126.6		
517								Approximate Chi Square Value (0.05)	17.11		
518				Adjusted Level of Significance	0.029			Adjusted Chi Square Value	15.8		
519											
520	Assuming Gamma Distribution										
521				95% Approximate Gamma UCL (use when n>=50))	226.6			95% Adjusted Gamma UCL (use when n<50)	245.4		
522											
523	Lognormal GOF Test										
524				Shapiro Wilk Test Statistic	0.927			Shapiro Wilk Lognormal GOF Test			
525				5% Shapiro Wilk Critical Value	0.859			Data appear Lognormal at 5% Significance Level			
526				Lilliefors Test Statistic	0.167			Lilliefors Lognormal GOF Test			
527				5% Lilliefors Critical Value	0.243			Data appear Lognormal at 5% Significance Level			
528	Data appear Lognormal at 5% Significance Level										
529											
530	Lognormal Statistics										

531				Minimum of Logged Data	3.122				Mean of logged Data		4.552
532				Maximum of Logged Data	5.79				SD of logged Data		0.94
533											
534				Assuming Lognormal Distribution							
535				95% H-UCL	326.8				90% Chebyshev (MVUE) UCL		262.2
536				95% Chebyshev (MVUE) UCL	317.3				97.5% Chebyshev (MVUE) UCL		393.8
537				99% Chebyshev (MVUE) UCL	544.1						
538											
539				Nonparametric Distribution Free UCL Statistics							
540				Data appear to follow a Discernible Distribution at 5% Significance Level							
541											
542				Nonparametric Distribution Free UCLs							
543				95% CLT UCL	191.4				95% Jackknife UCL		196.4
544				95% Standard Bootstrap UCL	188.5				95% Bootstrap-t UCL		215.3
545				95% Hall's Bootstrap UCL	191.2				95% Percentile Bootstrap UCL		192.5
546				95% BCA Bootstrap UCL	195.8						
547				90% Chebyshev(Mean, Sd) UCL	236				95% Chebyshev(Mean, Sd) UCL		280.8
548				97.5% Chebyshev(Mean, Sd) UCL	342.8				99% Chebyshev(Mean, Sd) UCL		464.8
549											
550				Suggested UCL to Use							
551				95% Student's-t UCL	196.4						
552											
553				When a data set follows an approximate (e.g., normal) distribution passing one of the GOF test							
554				When applicable, it is suggested to use a UCL based upon a distribution (e.g., gamma) passing both GOF tests in ProUCL							
555											
556				Note: Suggestions regarding the selection of a 95% UCL are provided to help the user to select the most appropriate 95% UCL.							
557				Recommendations are based upon data size, data distribution, and skewness.							
558				These recommendations are based upon the results of the simulation studies summarized in Singh, Maichle, and Lee (2006).							
559				However, simulations results will not cover all Real World data sets; for additional insight the user may want to consult a statistician.							
560											
561											
562	Site 4 HE5										
563											
564				General Statistics							
565				Total Number of Observations	12				Number of Distinct Observations		12
566									Number of Missing Observations		0
567				Minimum	3.55				Mean		101.1
568				Maximum	356				Median		42.1
569				SD	121.6				Std. Error of Mean		35.1
570				Coefficient of Variation	1.203				Skewness		1.282
571											
572				Normal GOF Test							
573				Shapiro Wilk Test Statistic	0.79				Shapiro Wilk GOF Test		
574				5% Shapiro Wilk Critical Value	0.859				Data Not Normal at 5% Significance Level		
575				Lilliefors Test Statistic	0.255				Lilliefors GOF Test		
576				5% Lilliefors Critical Value	0.243				Data Not Normal at 5% Significance Level		
577				Data Not Normal at 5% Significance Level							
578											
579				Assuming Normal Distribution							
580				95% Normal UCL					95% UCLs (Adjusted for Skewness)		
581				95% Student's-t UCL	164.1				95% Adjusted-CLT UCL (Chen-1995)		172.7
582									95% Modified-t UCL (Johnson-1978)		166.3
583											

	A	B	C	D	E	F	G	H	I	J	K	L
584	Gamma GOF Test											
585	A-D Test Statistic					0.513	Anderson-Darling Gamma GOF Test					
586	5% A-D Critical Value					0.774	Detected data appear Gamma Distributed at 5% Significance Level					
587	K-S Test Statistic					0.244	Kolmogorov-Smirnov Gamma GOF Test					
588	5% K-S Critical Value					0.257	Detected data appear Gamma Distributed at 5% Significance Level					
589	Detected data appear Gamma Distributed at 5% Significance Level											
590												
591	Gamma Statistics											
592	k hat (MLE)					0.64	k star (bias corrected MLE)					0.536
593	Theta hat (MLE)					157.9	Theta star (bias corrected MLE)					188.7
594	nu hat (MLE)					15.37	nu star (bias corrected)					12.86
595	MLE Mean (bias corrected)					101.1	MLE Sd (bias corrected)					138.1
596							Approximate Chi Square Value (0.05)					5.797
597	Adjusted Level of Significance					0.029	Adjusted Chi Square Value					5.091
598												
599	Assuming Gamma Distribution											
600	95% Approximate Gamma UCL (use when n>=50)					224.2	95% Adjusted Gamma UCL (use when n<50)					255.3
601												
602	Lognormal GOF Test											
603	Shapiro Wilk Test Statistic					0.915	Shapiro Wilk Lognormal GOF Test					
604	5% Shapiro Wilk Critical Value					0.859	Data appear Lognormal at 5% Significance Level					
605	Lilliefors Test Statistic					0.194	Lilliefors Lognormal GOF Test					
606	5% Lilliefors Critical Value					0.243	Data appear Lognormal at 5% Significance Level					
607	Data appear Lognormal at 5% Significance Level											
608												
609	Lognormal Statistics											
610	Minimum of Logged Data					1.267	Mean of logged Data					3.66
611	Maximum of Logged Data					5.875	SD of logged Data					1.626
612												
613	Assuming Lognormal Distribution											
614	95% H-UCL					1120	90% Chebyshev (MVUE) UCL					302.4
615	95% Chebyshev (MVUE) UCL					385.5	97.5% Chebyshev (MVUE) UCL					500.8
616	99% Chebyshev (MVUE) UCL					727.4						
617												
618	Nonparametric Distribution Free UCL Statistics											
619	Data appear to follow a Discernible Distribution at 5% Significance Level											
620												
621	Nonparametric Distribution Free UCLs											
622	95% CLT UCL					158.8	95% Jackknife UCL					164.1
623	95% Standard Bootstrap UCL					155.9	95% Bootstrap-t UCL					203.1
624	95% Hall's Bootstrap UCL					209.7	95% Percentile Bootstrap UCL					158.3
625	95% BCA Bootstrap UCL					169.9						
626	90% Chebyshev(Mean, Sd) UCL					206.4	95% Chebyshev(Mean, Sd) UCL					254.1
627	97.5% Chebyshev(Mean, Sd) UCL					320.3	99% Chebyshev(Mean, Sd) UCL					450.3
628												
629	Suggested UCL to Use											
630	95% Adjusted Gamma UCL					255.3						
631												
632	Note: Suggestions regarding the selection of a 95% UCL are provided to help the user to select the most appropriate 95% UCL.											
633	Recommendations are based upon data size, data distribution, and skewness.											
634	These recommendations are based upon the results of the simulation studies summarized in Singh, Maichle, and Lee (2006).											
635	However, simulations results will not cover all Real World data sets; for additional insight the user may want to consult a statistician.											
636												

	A	B	C	D	E	F	G	H	I	J	K	L
637												
638	Site 4 HE6											
639												
640						General Statistics						
641					Total Number of Observations	12			Number of Distinct Observations			12
642									Number of Missing Observations			0
643					Minimum	11.4			Mean			82.33
644					Maximum	353			Median			43.9
645					SD	98.35			Std. Error of Mean			28.39
646					Coefficient of Variation	1.195			Skewness			2.157
647												
648						Normal GOF Test						
649					Shapiro Wilk Test Statistic	0.734			Shapiro Wilk GOF Test			
650					5% Shapiro Wilk Critical Value	0.859			Data Not Normal at 5% Significance Level			
651					Lilliefors Test Statistic	0.235			Lilliefors GOF Test			
652					5% Lilliefors Critical Value	0.243			Data appear Normal at 5% Significance Level			
653						Data appear Approximate Normal at 5% Significance Level						
654												
655						Assuming Normal Distribution						
656					95% Normal UCL				95% UCLs (Adjusted for Skewness)			
657					95% Student's-t UCL	133.3			95% Adjusted-CLT UCL (Chen-1995)			147.9
658									95% Modified-t UCL (Johnson-1978)			136.3
659												
660						Gamma GOF Test						
661					A-D Test Statistic	0.428			Anderson-Darling Gamma GOF Test			
662					5% A-D Critical Value	0.756			Detected data appear Gamma Distributed at 5% Significance Level			
663					K-S Test Statistic	0.176			Kolmogorov-Smirnov Gamma GOF Test			
664					5% K-S Critical Value	0.252			Detected data appear Gamma Distributed at 5% Significance Level			
665						Detected data appear Gamma Distributed at 5% Significance Level						
666												
667						Gamma Statistics						
668					k hat (MLE)	1.022			k star (bias corrected MLE)			0.822
669					Theta hat (MLE)	80.52			Theta star (bias corrected MLE)			100.1
670					nu hat (MLE)	24.54			nu star (bias corrected)			19.74
671					MLE Mean (bias corrected)	82.33			MLE Sd (bias corrected)			90.78
672									Approximate Chi Square Value (0.05)			10.66
673					Adjusted Level of Significance	0.029			Adjusted Chi Square Value			9.654
674												
675						Assuming Gamma Distribution						
676					95% Approximate Gamma UCL (use when n>=50))	152.5			95% Adjusted Gamma UCL (use when n<50)			168.3
677												
678						Lognormal GOF Test						
679					Shapiro Wilk Test Statistic	0.946			Shapiro Wilk Lognormal GOF Test			
680					5% Shapiro Wilk Critical Value	0.859			Data appear Lognormal at 5% Significance Level			
681					Lilliefors Test Statistic	0.141			Lilliefors Lognormal GOF Test			
682					5% Lilliefors Critical Value	0.243			Data appear Lognormal at 5% Significance Level			
683						Data appear Lognormal at 5% Significance Level						
684												
685						Lognormal Statistics						
686					Minimum of Logged Data	2.434			Mean of logged Data			3.848
687					Maximum of Logged Data	5.866			SD of logged Data			1.107
688												
689						Assuming Lognormal Distribution						

690				95% H-UCL	244.6			90% Chebyshev (MVUE) UCL		163.5	
691				95% Chebyshev (MVUE) UCL	201.2			97.5% Chebyshev (MVUE) UCL		253.4	
692				99% Chebyshev (MVUE) UCL	356						
693											
694				Nonparametric Distribution Free UCL Statistics							
695				Data appear to follow a Discernible Distribution at 5% Significance Level							
696											
697				Nonparametric Distribution Free UCLs							
698				95% CLT UCL	129			95% Jackknife UCL		133.3	
699				95% Standard Bootstrap UCL	125.6			95% Bootstrap-t UCL		177.2	
700				95% Hall's Bootstrap UCL	297.3			95% Percentile Bootstrap UCL		132.8	
701				95% BCA Bootstrap UCL	147.7						
702				90% Chebyshev(Mean, Sd) UCL	167.5			95% Chebyshev(Mean, Sd) UCL		206.1	
703				97.5% Chebyshev(Mean, Sd) UCL	259.6			99% Chebyshev(Mean, Sd) UCL		364.8	
704											
705				Suggested UCL to Use							
706				95% Student's-t UCL	133.3						
707											
708				When a data set follows an approximate (e.g., normal) distribution passing one of the GOF test							
709				When applicable, it is suggested to use a UCL based upon a distribution (e.g., gamma) passing both GOF tests in ProUCL							
710											
711				Note: Suggestions regarding the selection of a 95% UCL are provided to help the user to select the most appropriate 95% UCL.							
712				Recommendations are based upon data size, data distribution, and skewness.							
713				These recommendations are based upon the results of the simulation studies summarized in Singh, Maichle, and Lee (2006).							
714				However, simulations results will not cover all Real World data sets; for additional insight the user may want to consult a statistician.							
715											
716											
717	Site 5 SUR										
718											
719				General Statistics							
720				Total Number of Observations	16			Number of Distinct Observations		16	
721								Number of Missing Observations		0	
722				Minimum	8.7			Mean		324	
723				Maximum	1050			Median		191	
724				SD	290.7			Std. Error of Mean		72.68	
725				Coefficient of Variation	0.897			Skewness		1.193	
726											
727				Normal GOF Test							
728				Shapiro Wilk Test Statistic	0.876			Shapiro Wilk GOF Test			
729				5% Shapiro Wilk Critical Value	0.887			Data Not Normal at 5% Significance Level			
730				Lilliefors Test Statistic	0.214			Lilliefors GOF Test			
731				5% Lilliefors Critical Value	0.213			Data Not Normal at 5% Significance Level			
732				Data Not Normal at 5% Significance Level							
733											
734				Assuming Normal Distribution							
735				95% Normal UCL				95% UCLs (Adjusted for Skewness)			
736				95% Student's-t UCL	451.4			95% Adjusted-CLT UCL (Chen-1995)		466.7	
737								95% Modified-t UCL (Johnson-1978)		455	
738											
739				Gamma GOF Test							
740				A-D Test Statistic	0.217			Anderson-Darling Gamma GOF Test			
741				5% A-D Critical Value	0.76			Detected data appear Gamma Distributed at 5% Significance Level			
742				K-S Test Statistic	0.118			Kolmogorov-Smirnov Gamma GOF Test			

743				5% K-S Critical Value	0.22	Detected data appear Gamma Distributed at 5% Significance Level					
744	Detected data appear Gamma Distributed at 5% Significance Level										
745											
746	Gamma Statistics										
747				k hat (MLE)	1.168	k star (bias corrected MLE)				0.991	
748				Theta hat (MLE)	277.3	Theta star (bias corrected MLE)				326.9	
749				nu hat (MLE)	37.39	nu star (bias corrected)				31.71	
750				MLE Mean (bias corrected)	324	MLE Sd (bias corrected)				325.5	
751						Approximate Chi Square Value (0.05)				19.84	
752				Adjusted Level of Significance	0.0335	Adjusted Chi Square Value				18.78	
753											
754	Assuming Gamma Distribution										
755			95% Approximate Gamma UCL (use when n>=50)		517.8	95% Adjusted Gamma UCL (use when n<50)				547.1	
756											
757	Lognormal GOF Test										
758				Shapiro Wilk Test Statistic	0.927	Shapiro Wilk Lognormal GOF Test					
759				5% Shapiro Wilk Critical Value	0.887	Data appear Lognormal at 5% Significance Level					
760				Lilliefors Test Statistic	0.127	Lilliefors Lognormal GOF Test					
761				5% Lilliefors Critical Value	0.213	Data appear Lognormal at 5% Significance Level					
762	Data appear Lognormal at 5% Significance Level										
763											
764	Lognormal Statistics										
765				Minimum of Logged Data	2.163	Mean of logged Data				5.295	
766				Maximum of Logged Data	6.957	SD of logged Data				1.19	
767											
768	Assuming Lognormal Distribution										
769				95% H-UCL	1019	90% Chebyshev (MVUE) UCL				756.8	
770				95% Chebyshev (MVUE) UCL	928.4	97.5% Chebyshev (MVUE) UCL				1167	
771				99% Chebyshev (MVUE) UCL	1634						
772											
773	Nonparametric Distribution Free UCL Statistics										
774	Data appear to follow a Discernible Distribution at 5% Significance Level										
775											
776	Nonparametric Distribution Free UCLs										
777				95% CLT UCL	443.5	95% Jackknife UCL				451.4	
778				95% Standard Bootstrap UCL	442.4	95% Bootstrap-t UCL				493.8	
779				95% Hall's Bootstrap UCL	480.2	95% Percentile Bootstrap UCL				446.7	
780				95% BCA Bootstrap UCL	470						
781				90% Chebyshev(Mean, Sd) UCL	542	95% Chebyshev(Mean, Sd) UCL				640.8	
782				97.5% Chebyshev(Mean, Sd) UCL	777.9	99% Chebyshev(Mean, Sd) UCL				1047	
783											
784	Suggested UCL to Use										
785				95% Adjusted Gamma UCL	547.1						
786											
787	Note: Suggestions regarding the selection of a 95% UCL are provided to help the user to select the most appropriate 95% UCL.										
788	Recommendations are based upon data size, data distribution, and skewness.										
789	These recommendations are based upon the results of the simulation studies summarized in Singh, Maichle, and Lee (2006).										
790	However, simulations results will not cover all Real World data sets; for additional insight the user may want to consult a statistician.										
791											

(d) Except for the statistical methods identified in subsections (a)(1)(i) and (b)(1)(i) and (2)(i), a demonstration of attainment of one or a combination of remediation standards shall comply with the following:

(1) When statistical methods are to be used for demonstration of attainment of Statewide health or site-specific standards, the null hypotheses (Ho) shall be that the true site arithmetic average concentration is at or above the cleanup standard, and the alternative hypothesis (Ha) shall be that the true site arithmetic average concentration is below the cleanup standard. When statistical methods are to be used to determine that the background standard is exceeded, the null hypothesis (Ho) shall be that the background standard is achieved and the alternative hypothesis (Ha) shall be that the background standard is not achieved.

(2) A statistical method chosen shall comply with the following performance standards:

(i) The underlying assumptions of the statistical method shall be met, such as data distribution.

(ii) The statistical method shall be recommended for this use in Department-approved guidance or regulation and shall be generally recognized as appropriate for the particular remediation implemented at the site.

(iii) Compositing cannot be used with nonparametric methods or for volatile organic compounds.

(iv) For parametric methods, the censoring level for each nondetect shall be the assigned value randomly generated that is between zero and the limit related to the PQL.

(v) Tests shall account for seasonal and spatial variability as well as temporal correlation of data, unless otherwise approved by the Department.

(vi) Tests used to determine that the background standard is exceeded shall maintain adequate power to detect contamination in accordance with current EPA guidances, regulations or protocols.

(vii) For the limits relating to the PQLs, Statewide health and site-specific standards, the false-positive rate for a statistical test may not be greater than 0.20 for nonresidential and 0.05 for residential.

(viii) Statistical testing shall be done individually for each regulated substance present at the site.

(3) The following information shall be documented in a final report when a statistical method is applied:

(i) A description of the statistical method.

(ii) A clear statement of the applicable decision rule in the form of statistical hypotheses for each spatial unit and temporal boundary including the applicable statistical parameter of interest and the specific cleanup standard.

(iii) A description of the underlying assumptions of the method.

(iv) Documentation showing that the sample data set meets the underlying assumptions of the method and demonstrating that the method is appropriate to apply to the data.

(v) Specification of false positive rates and, in addition for the background standard, specification of false negative rates.

(vi) Documentation of input and output data for the statistical test, presented in tables or figures, or both, as appropriate.

(vii) An interpretation and conclusion of the statistical test.

(e) The references identified in subsection (b)(1)(ii) and (2)(ii) are as follows:

(1) EPA, Office of Policy, Planning and Evaluation, *Methods for Evaluating the Attainment of Cleanup Standards*, Volume 1: Soils and Solid Media, EPA 230/02-89-042, Washington, D. C. 1989.

(2) EPA, Office of Solid Waste Management Division, *Test Methods for Evaluating Solid Waste*, SW-846 Volume II: Field Methods, EPA, November 1985, Third Edition.

(3) EPA, Office of Solid Waste Management Division, *Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities*, Interim Final Guidance, EPA, Washington, D.C., April, 1989.

(4) EPA, Office of Solid Waste Management Division, *Statistical Analysis of Groundwater Monitoring Data at RCRA Facilities*, Addendum to Interim Final Guidance, EPA, Washington, D.C., June, 1992.

(5) 40 CFR 264 and 265 (relating to standards for owners and operators of hazardous waste treatment, storage, and disposal facilities; and interim status standards for owners and operators of hazardous waste treatment, storage, and disposal facilities).

Authority

The provisions of this § 250.707 issued under sections 104(a) and 303(a) of the Land Recycling and Environmental Remediation Standards Act (35 P. S. §§ 6026.104(a) and 6026.303(a)).

Source

The provisions of this § 250.707 amended November 23, 2001, effective November 24, 2001, 31 Pa.B. 6395; amended January 7, 2011, effective January 8, 2011, 41 Pa.B. 230. Immediately preceding text appears at serial pages (285794) to (285801).

Cross References

This section cited in 25 Pa. Code § 250.702 (relating to attainment requirements); 25 Pa. Code § 250.703 (relating to general attainment requirements for soil); 25 Pa. Code § 250.703 (relating to general attainment requirements for soil); and 25 Pa. Code § 250.704 (relating to general attainment requirements for groundwater).

§ 250.708. Postremediation care attainment.

(a) After engineering controls are in place and the groundwater concentration levels have stabilized following any effects from the remediation, a statistical test shall be used to demonstrate that regulated substances in groundwater do not