

Progress Report of the 2021 Lead Workgroup

Presented to:

Cleanup Standards Scientific Advisory Board

June 30, 2022

Triggering Change in Residential MSCs from Soil-to GW to Direct Contact

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

- Current use of the UBK Model results in the soil-to-GW numeric value (NV) of 450 mg/kg being lower than the residential direct contact NV (500 mg/kg), therefore, in most circumstances the MSC is 450 mg/kg, and the two current attainment tests apply as they have since 1997.
- Proposed adoption of the IEUBK Model will result in the new direct contact NV (200 mg/kg) being lower than the soil-to-GW NV (450 mg/kg), therefore, the new MSC will be 200 mg/kg.
- PADEP has already adopted use of the IEUBK Model under the Site-specific standard (SSS) using the average of sampling results as input to the model to determine attainment of an acceptable risk level, consistent with the IEUBK v. 2.0 User's Guide.
- The PADEP's use of this same model to calculate the 200 mg/kg MSC has raised the question of adding the average of lead sampling results as an attainment test under the Statewide health standard (SHS). This issue was first referred to a Lead Workgroup in 2020.

2021 Workgroup History & Charge

- ▶ Successor to the 2020 Lead Workgroup
 - ▶ 2020 Lead Workgroup Recommendations to CSSAB:
 - ▶ Replace existing residential and nonresidential models with the IEUBK Model & Adult Lead Model (ALM)
 - ▶ Add the average of sampling results as an attainment test
 - ▶ Retain the existing 95% UCL and 75%/10X tests
 - ▶ All three recommendations were then recommended to the PADEP by the CSSAB, with one dissenting vote regarding the use of the average as an attainment test.

Workgroup History & Charge (cont'd.)

August 11, 2021 CSSAB Meeting: DEP Presentation Excerpts

- ▶ **Soil Lead Averaging:** DEP considering use of average lead concentrations as an additional statistical test option for Statewide health standard attainment demonstration for lead in soil.
- ▶ **Concerns with Averaging:**
 - ▶ Averaging described in IEUBK's supporting documentation is for calculating risk or a cleanup goal at specific sites, not for attainment of statewide health standard.
 - ▶ If IEUBK is designed only for the use of averages, shouldn't that exclude the use of 75%/10X or 95% UCL statistical tests to demonstrate attainment?
 - ▶ Averages do not account for high variability in smaller datasets.
 - ▶ Averages could allow for hot spots of very high lead concentrations to remain in soil at some sites.

Workgroup History & Charge (cont'd.)

- ▶ August 11, 2021 CSSAB Meeting Assignment: Form new Lead Workgroup to address PADEP concerns regarding the use of the average as an attainment test under the statewide health standard (SHS).
- ▶ New Lead Workgroup formed in September 2021 with the following members:

CSSAB Members	PADEP Members	Non-CSSAB Members
Colleen Costello, Chair	Michael Maddigan	Neil Ketchum
Charles Campbell	Frank Nemec	William Hitchcock
Craig Robertson	Jessica Ritenour	
Annette Guiseppi-Elie	Pam Trowbridge	
Mark Urbassik	David Brown	
Donald Wagner		
Michael Meloy		
Tina Serafini		

Full Lead Workgroup

- ▶ Initial organizational meeting- September 22, 2021
- ▶ First Technical Meeting- October 4, 2021:
 - ▶ Established two subgroups:
 - ▶ Lead Attainment Subgroup (LAS)
 - ▶ Lead Characterization Subgroup (LCS)
 - ▶ Focus of the evaluation shifted to the LAS with consideration of characterization awaiting the attainment test analysis.
- ▶ Full Lead Workgroup held three more meetings in Oct., Nov. and Dec.
 - ▶ Received and reviewed work product from the LAS
 - ▶ Provided feedback and broad direction to LAS
- ▶ Final Meeting to review and approve draft final workgroup report to CSSAB
 - ▶ Anticipated for mid-February 2022 - postponed pending PADEP review
 - ▶ PADEP comments on conclusions received in May and discussed on June 16th.
 - ▶ Follow-up Workgroup meeting to be held in the weeks following the CSSAB meeting on June 30, 2022, to finalize the report supporting recommendations made by the CSSAB to the PADEP at that meeting.

Lead Attainment Subgroup (LAS)

- ▶ Held eight meetings from October 12, 2021 to January 21, 2022
- ▶ Published two principal work products
 - ▶ December 21, 2021: Draft White Paper of the Lead Attainment Subgroup
 - ▶ February 5, 2022: Draft Report of the Lead Attainment Subgroup
(February 11, 2022: Draft Report of the Lead Workgroup to the CSSAB)
- ▶ Members drawn from members of the 2020 Lead Workgroup

CSSAB Members	PADEP Members	Non-CSSAB Members
Charles Campbell, Chair	Frank Nemec	Neil Ketchum
Craig Robertson		William Hitchcock
Annette Guiseppi-Elie		
Mark Urbassik		
Donald Wagner		
Michael Meloy		

Draft White Paper of the Lead Attainment Subgroup - December 21, 2021

▶ **Contents:**

- ▶ Facts and figures relating to the science and regulation of lead in soil
- ▶ No opinions, conclusions or recommendations

▶ **Topics include:**

- ▶ Unique treatment of lead under Act 2 of 1995 and Chapter 250
- ▶ PADEP proposed numeric values and medium-specific concentrations
- ▶ History of CDC Guidance on blood lead levels in children and EPA's adoption thereof
- ▶ Discussion of the IEUBK Model v. 2.0
- ▶ Examination of naturally-occurring lead in PA surficial soils
- ▶ Analysis of four examples using target blood lead levels from 3.5 to 10 ug/dL
- ▶ Documentation of screening values and cleanup goals from other states and EPA

Draft Report of the Lead Workgroup to the CSSAB - February 11, 2021

▶ **Topics Carried Over from the White Paper:**

- ▶ Unique treatment of lead under Act 2 of 1995 and Chapter 250
- ▶ Existing and PADEP proposed numeric values and medium-specific concentrations
- ▶ Discussion of the IEUBK Model v. 2.0

▶ **Topics Added:**

- ▶ Use of the IEUBK Model at LRP Sites
- ▶ Comparative evaluation of the three attainment tests
- ▶ Conclusions and recommendations

How does the IEUBK Model Work?

There are three components to the model:

Exposure Component

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.

Uptake Component

The uptake component models the processes by which Pb intake... is transferred to the blood plasma.

Biokinetics Component

The biokinetic module addresses the transfer of absorbed Pb between blood and other body tissues; the elimination of Pb from the body... and the storage and/or disposition of Pb....in the body.

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

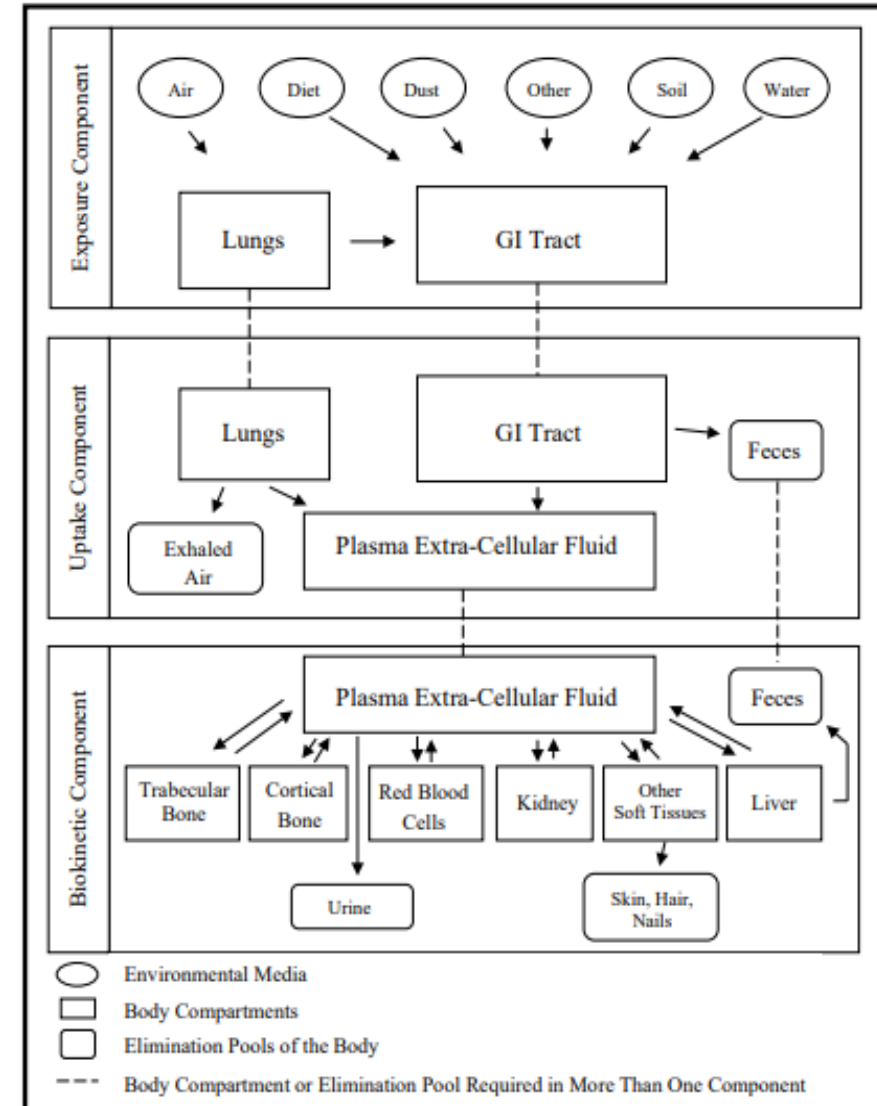


FIGURE I-1. Biological Structure of the IEUBK Model.

Uses of the IEUBK Model in the LRP

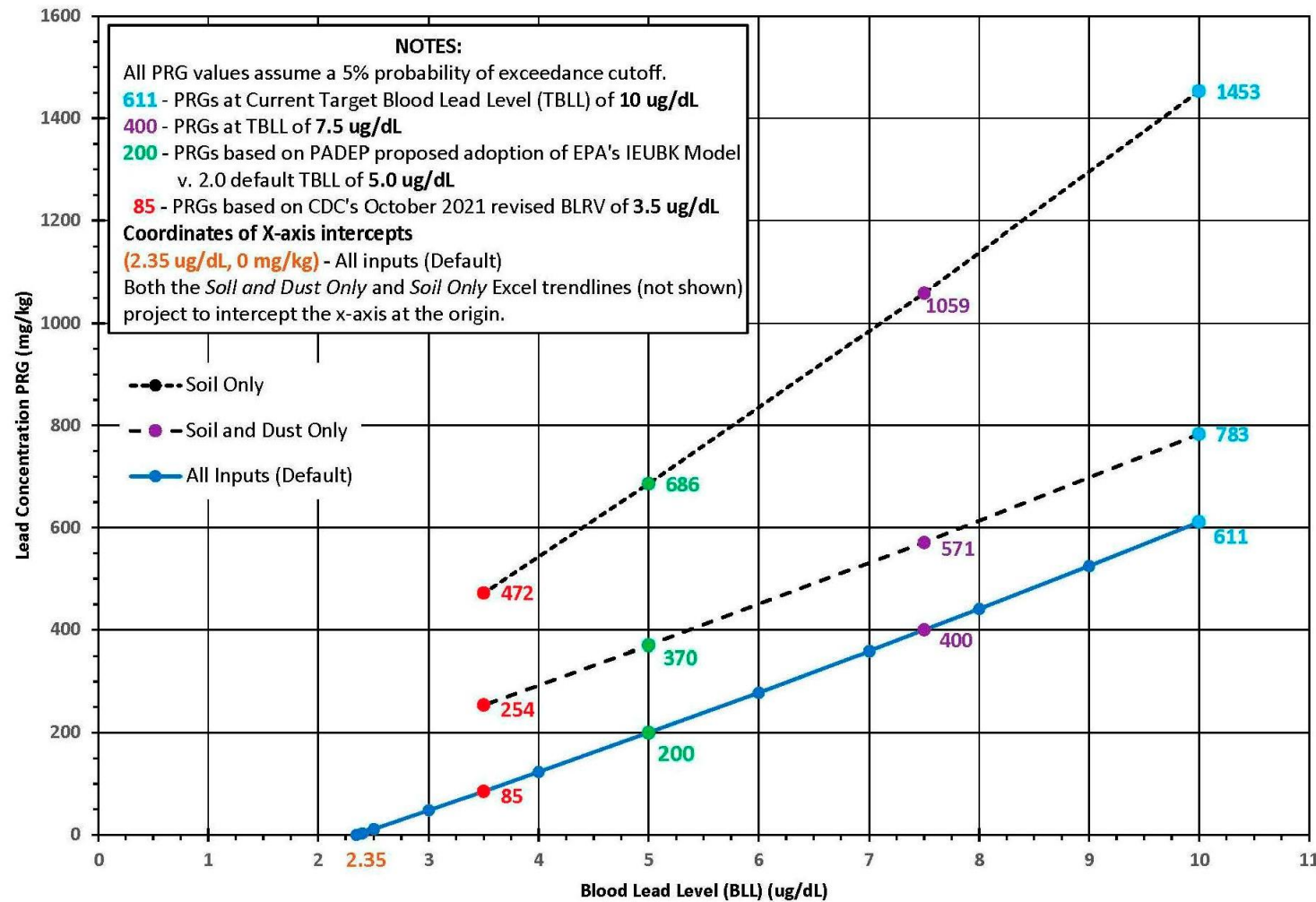
- ▶ The IEUBK Model was used by PADEP in Preliminary Remediation Goal (“PRG”) Mode to calculate a PRG of 200 mg/kg which was adopted as the proposed MSC. EPA defines the PRG as *“the average concentration of a chemical in an exposure area that will yield the specified target risk in an individual who is exposed at random within the exposure area.”* ([Calculating Preliminary Remediation Goals \(PRGs\) | US EPA](#)) Therefore, the 200 mg/kg proposed MSC is an average generated by the model.
- ▶ The PADEP also permits RPs to run the model in Risk Assessment Mode to calculate the probability of exceedance of a user-specified TBLL under the SSS. In this mode, the Department permits RPs to enter the average of lead concentrations in soil to which children may be exposed. If no changes have been made to model inputs and defaults, any average above 200 mg/kg will indicate an unacceptable probability of exceedance.
- ▶ The question at hand is, Would it also be appropriate to permit the average of attainment sampling lead concentrations in soil to be used as an attainment test under the SHS?

How does EPA address the use of an Upper confidence limit (UCL) on the mean as it would be relevant to the PADEP's use of the model for determination of attainment under the SSS?

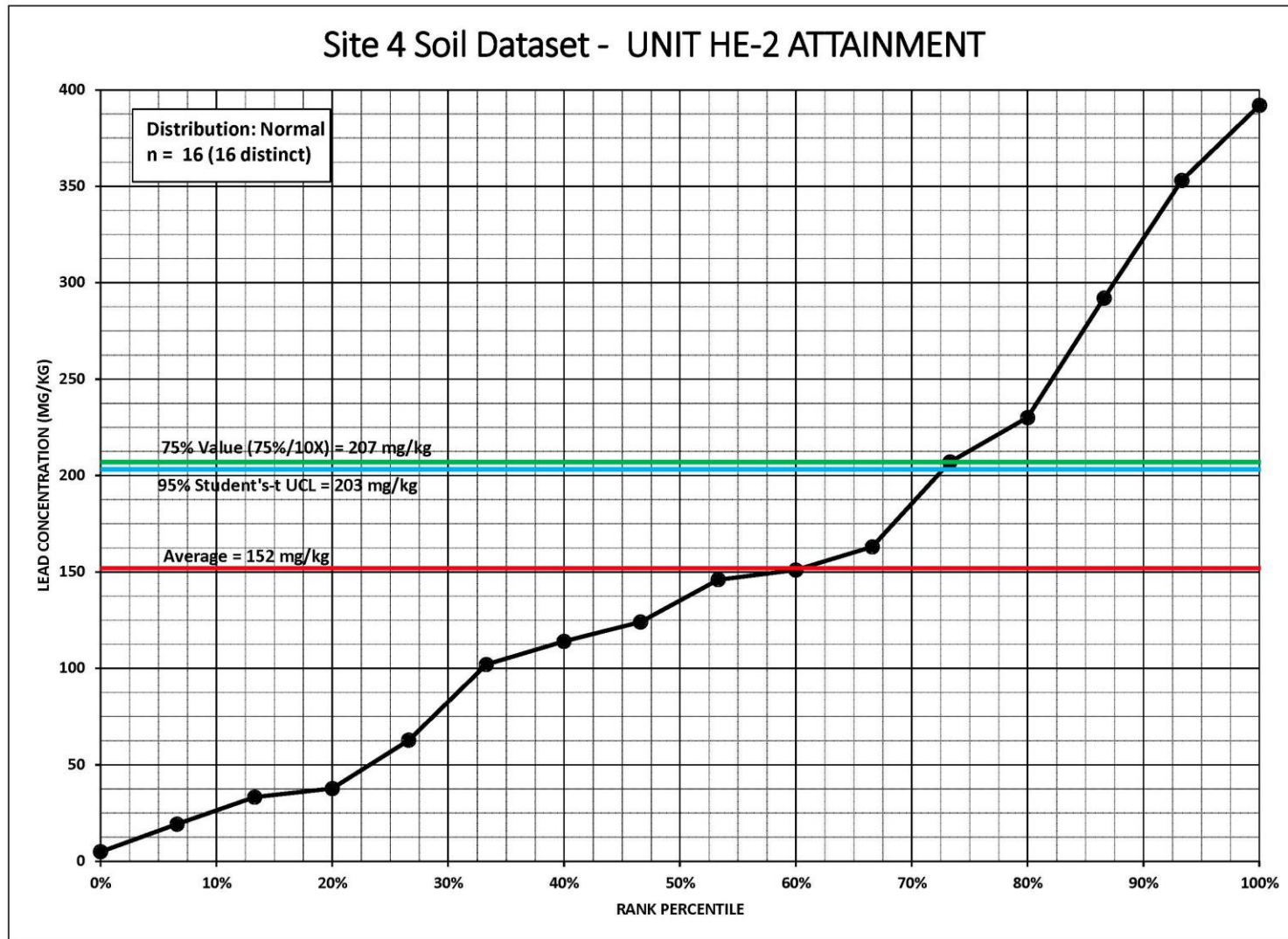
- ▶ EPA indicates that the use of an UCL as the soil lead concentration (PbS) (i.e., the input value for determination of attainment under the SSS) to account for uncertainty in the variability of lead concentrations in the soil is not commonly done in site risk assessments as stated in the current User's Guide as follows:
 - ▶ *There will be some uncertainty in the estimate of the PbS due to the variability of Pb concentration in the DU [Decision Unit] soil. Theoretically, the distribution of PbB [blood lead] concentration that is predicted by the IEUBK model accounts for the uncertainty in the PbS... 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).*

Effect of Multimedia Inputs on PRGs

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



Example of Dataset Graph



Actual Act 2 Site Datasets Evaluated for Attainment Test Comparisons

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	ST 203
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	^{AG} 132

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

An 11th dataset was used by combining all the characterization and attainment data (167 samples) from Site #4.

This dataset resulted in:

- Results ranging from <0.5 mg/kg to 24, 900 mg/kg
- The average of 998 mg/kg would attain the current nonresidential MSC of 1000 mg/kg.
- A few results exceeded 10 times the MSC, suggesting the need for a hotspot protocol.

Draft Lead Workgroup Report Conclusions

- ▶ **Conclusion #1:** Lead is unique among regulated substances that are systemic toxicants, i.e., there are no systemic toxicity values available for lead to calculate numeric values (NVs).
 - ▶ Lead NVs are calculated using multimedia models based on a public health policy tool (the Target Blood Lead Level (TBLL)), that include lead inputs not only from soil, but also from air, drinking water, house dust, food, and maternal blood. Multimedia inputs have been used since the UBK Model was adopted in 1997.
 - ▶ By way of observation, 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's no suggestion being made to make this change.)
 - ▶ 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.

Draft Lead Workgroup Report Conclusions (Cont'd)

▶ **Conclusion #2:** While allowing for the use of an Upper Confidence Limit (UCL), EPA provides clear instructions to use the average concentration of lead in soil with the IEUBK Model and ALM to set the PbS otherwise allowed by PADEP as the model input under the SSS to demonstrate attainment of an acceptable risk level for direct contact to lead in soil, as documented in the following excerpts from the IEUBK Model v. 2.0 User's Guide:

▶ *2.3.4.2 Lead in Soil*

The TRW [EPA's Technical Review Workgroup Lead Committee] 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)

Draft Lead Workgroup Report Conclusions (Cont'd)

- **Conclusion #3:** Use of the average attainment test if permitted under the SHS is no less conservative or protective than its use under the SSS as currently permitted by the Department due primarily to a preference for permanent remediation remedies under the SHS.
 - Based on 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 equivalent to the SSS for lead in that respect.

Draft Lead Workgroup Report Conclusions (Cont'd)

- ▶ **Conclusion #4:** 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 on 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 a “hotspot” protocol 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.
 - ▶ 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.

Draft Lead Workgroup Report Recommendations

- ▶ Based on the conclusions enumerated above, the Lead 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), and subject to the existing sampling requirements of § 250.703(d), and the existing “hotspot” provisions 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.*

Relationship of PRGs to Background Lead in PA Surficial Soil

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

