

Attachment 4

(Clean Air Council Comments on
Proposed Act 2 Rulemaking, dated April 30, 2020)



**Environmental Quality Board
(Department of Environmental Conservation)**

**Proposed Rulemaking
Administration of the Land Recycling Program
25 Pa. Code Chapter 250**

50 Pa.B. 1011-1097 (February 15, 2020)

Written Comments by Clean Air Council

April 30, 2020

Via email -- RegComments@pa.gov

The Council appreciates the opportunity to provide these written comments on the proposed rulemaking of the Environmental Quality Board and the Department of Environmental Protection (“the Department”) relating to Act 2, the state law regarding cleanup standards for voluntary and involuntary cleanups.

The Council is a non-profit environmental health organization headquartered at 135 South 19th Street, Suite 300, Philadelphia, Pennsylvania, 19103. The Council also maintains an office in Pittsburgh. The Council has been working to protect everyone’s right to a clean environment for over 50 years. The Council has members throughout the Commonwealth who support its mission.

While the Environmental Quality Board is the government entity proposing the rulemaking, the Council will refer to the Department as the source of the proposed rulemaking, in the interest of clarity.

On Saturday, February 15, 2020 the Department published a notice of proposed rulemaking, setting a deadline of April 14, 2020 for the public comment period. [50 Pa.B. 1011-1097](#) (February 15, 2020). The deadline was extended to April 30, 2020 due to the ongoing COVID-19 pandemic. [50 Pa.B. 1650](#) (March 21, 2020).



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Summary of Comments

The Council's comments are directed to the Department's proposed increase in the direct contact numeric value for lead in nonresidential soil from 1000 ppm to 2500 ppm. The proposal would not be protective of public health.

The proposal is erroneously based on a target blood concentration of 10 µg/dL for a fetus, which is based on a "level of concern" value set by the Centers for Disease Control in 1991 -- nearly thirty years ago. In 2012, the Centers for Disease Control lowered the number to 5 µg/dL, and since then it has used this number as a "reference value" for case management for pregnant women and children up to 5 years old. The Pennsylvania Department of Public Health, the Allegheny County Health Department, and the City of Philadelphia have also been using 5 µg/dL for case management.

There is no adequate public health justification for the proposal. There was no credible attempt to set an appropriate target blood concentration or direct contact numeric value. Minutes of meetings of the Cleanup Standards Scientific Advisory Board (CSSAB) and related documents do not reflect any meaningful discussion of the choice between a target blood concentration of 10 µg/dL and 5 µg/dL.

The proposal would be far weaker than comparable cleanup levels in five of the six states neighboring Pennsylvania.

The direct contact numeric value for lead in nonresidential soil is important to the ongoing remedial investigation at the Philadelphia oil refinery. This site is two and a half miles from the Council's office, and it is located in the poorest large city in the nation. In December 2019, the Department informed people in the community that the proposed direct contact numeric value would affect the cleanup at this site.

In using a target blood concentration of 10 µg/dL as a basis for the proposal, the Department makes the same error that it made when it approved a site-specific standard of 2240 ppm for the Philadelphia oil refinery in 2015. The proposal would endorse this error and enable property owners at contaminated sites to benefit from even less stringent site-specific standards for lead -- in the neighborhood of 2500 ppm. This would be material to a cleanup of the Philadelphia oil refinery, as it would result in a much smaller number of lead exceedances that would have to be dealt with by way of corrective action. For example, for two Areas of Interest (AOI-5 and AOI-9), this would mean only 10 or 11 exceedances each, rather than 55 exceedances each under a value of 1000 ppm.

In a legal challenge, the proposed direct contact numeric value of 2500 ppm would be unreasonable as a matter of law and "not in accordance with law."

The Department should not finalize the proposal. It should retain the current value of 1000 ppm.

Factual Background

“Any remediation standards adopted by this Commonwealth must provide for the protection of public health and the environment.” [Act 2](#), § 102(3).

Under the regulations, the Department must review new scientific information that is used to calculate Medium-Specific Concentrations (MSCs) and propose appropriate changes at least 36 months after the most recently promulgated MSCs:

The Department will review new scientific information that relates to the basis of the MSCs as it becomes available and will propose appropriate changes for the consideration of the EQB as necessary, but in no case more than 36 months after the effective date of the most recently promulgated MSCs.

25 Pa. Code §250.11 (page 250-9) (bold italics added for emphasis). *See also* Proposed Rule, 50 Pa.B. 1011 (Section D. Background and Purpose).

In preparing this rulemaking, the Department sought the input of the Cleanup Standards Scientific Advisory Board (CSSAB):

The Department worked with the Cleanup Standards Scientific Advisory Board (CSSAB) during the development of this proposed rulemaking. The CSSAB, which was established by section 105 of Act 2 (35 P.S. § 6026.105), consists of persons representing a cross section of experience, including engineering, biology, hydrogeology, statistics, medicine, chemistry, toxicology and other related fields. The purpose of the CSSAB is to assist the Department and the Board in developing Statewide health standards, determining the appropriate statistically and scientifically valid procedures and risk factors to be used, and providing other technical advice as needed to implement Act 2.

Proposed Rule, 50 Pa.B. 1012 (Section D. Background and Purpose).

Currently, the nonresidential direct contact numeric value for lead is calculated based on a method developed by the Society for Environmental Geochemistry and Health (SEGH model). 25 Pa. Code §250.306(e), page 250-29, [Chapter 250 regulations \(pdf\)](#). Based on that model, the current regulations set the nonresidential direct contact numeric value for lead at 1000 ppm. *Id.*, 25 Pa. Code chapter 250, Appendix A, Table 4A, page 250-104.

- A. The Department proposes to substitute the Adult Lead Methodology for the SEGH Model.

In the proposed rulemaking, the Department proposes to discontinue use of the SEGH model and instead adopt EPA's Adult Lead Methodology (ALM) for calculating the nonresidential direct contact numeric value for lead in soil. *See* Proposed Rule, 50 Pa.B. 1019 (to be codified at 25 Pa. Code §250.306(e)). As defined by EPA, the "(ALM) estimate[s] the concentration of lead in the blood of children, pregnant women and their developing fetuses who might be exposed to lead-contaminated soils." U.S. Environmental Protection Agency, [Lead at Superfund Sites](#) (Attachment 1). Because the ALM involves a formula, the Department has also proposed input variables for that formula. *See id.*, 50 Pa.B. 1097 ([Draft Chapter 250 rulemaking Table 7](#), Attachment 2).

While the Department accepted the Centers for Disease Control and Prevention's baseline blood concentration of 0.6 µg/dL (which has decreased since 2012), it did not accept the reference value of 5 µg/dL (which the Centers for Disease Control and Prevention has used since 2012) as the target blood concentration. The Department's choice results in an increase in the direct contact numeric value for lead from 1000 ppm to 2517 ppm, which rounds to 2500 ppm.

- B. The Department proposes using a target blood concentration ($PbB_{fetal,0.95}$) of 10 µg/dL.

In the notice of the proposed rulemaking the Department does not identify the target blood concentration that it used. Rather, it lists "TBD" as the target blood concentration ($PbB_{fetal,0.95}$). *See* 50 Pa.B. 1097 ([Draft Chapter 250 rulemaking Table 7](#), Attachment 2).

In April 2018, minutes from a CSSAB meeting show that the Department was aware of adverse health effects associated with a lead blood concentration of 10 µg/dL, and requested guidance from the CSSAB as to which blood lead level, 5 µg/dL or 10 µg/dL, should be used to calculate the lead direct contact numeric value:

EPA and Centers for Disease Control and Prevention (CDC) have determined that childhood blood lead concentrations at or above 10 micrograms of lead per deciliter (µg/dL) present risks to children's health. However, CDC has a blood lead action level of 5 µg/dL. Additionally, the input parameters used in calculating the residential ingestion numeric value for lead in soil are based on EPA's Integrated Exposure Uptake Biokinetic (IEUBK) model from 1990. Guidance was requested regarding which level should be used and whether DEP should update the model used for the input parameters. Ms. Guiseppi-Elie stated that blood lead action levels are a top priority for EPA and it is possible that the action level could go as low as 3 µg/dL.

Cleanup Standards Scientific Advisory Board, [Meeting Minutes](#), page 4 (April 4, 2018, Attachment 3) (bold italics added for emphasis).

Although the EPA member offered to research the issue and report back, the minutes from the subsequent meetings do not indicate any further discussion. See Department of Environmental Protection, [Agendas and Handouts](#).

In August 2018, the Department made a presentation to the CSSAB at its meeting, noting the adverse health effects associated with a blood lead concentration of 10 µg/dL and that EPA was updating its strategy to address them:

EPA – Recent scientific evidence has demonstrated adverse health effects at blood lead concentrations below 10 µg/dL down to 5 µg/dL, and possibly below. OSRTI [Office of Superfund Remediation and Technology Innovation] is developing a new soil lead policy to address this new information.

Department of Environmental Protection, [PowerPoint Presentation](#) (August 1, 2018, Attachment 4), page 9 (bold italics added for emphasis). The CSSAB made a recommendation to use a target blood concentration of 10 µg/dL:

CSSAB recommended that 10 µg/dL be used in the equation to calculate medium-specific concentrations (MSCs) for residential and non-residential lead exposure.

Cleanup Standards Scientific Advisory Board, [Meeting Minutes](#), page 4 (August 1, 2018, Attachment 5) (bold italics added for emphasis). But the minutes do not provide any discussion or justification for this recommendation. See *id.* Among “potential action items,” the meeting minutes mention the formation of a workgroup to further discuss lead blood level concentrations. See *id.*, page 5. It is not clear whether such a workgroup was ever formed.

In February 2019, the CSSAB held its next meeting, apparently reviewing a lead model comparison sheet prepared by the Department. See Department of Environmental Protection, [Lead Model Comparison Sheet](#) (undated, Attachment 6).¹ This sheet compares the current direct contact numeric value (1000 ppm) with two other values calculated using the ALM. With a target blood concentration of 5 µg/dL, the direct contact numeric value would be 1050 ppm. With a target blood concentration of 10 µg/dL, the direct contact numeric value would be 2517 ppm. (Apparently, the Department rounded down the 2517 ppm figure to arrive at the proposed value of 2500 ppm).

But the minutes from the CSSAB meeting provide no discussion of the choice between the two target blood concentrations. See Cleanup Standards Scientific Advisory Board, [Meeting Minutes](#) (February 13, 2019, Attachment 7).

For the February 2019 meeting, the Department’s presentation demonstrates that the choice of a target blood concentration had been made before that meeting:

¹ Although undated, the document was posted among the materials for the February 13, 2019 meeting. See Department of Environmental Protection, [Agendas and Handouts](#).

Residential and non-residential direct contact values [were] calculated for lead using updated models and target blood lead level of 10 µg/dL.

Department of Environmental Protection, [PowerPoint Presentation](#), page 12 (February 13, 2019, Attachment 8). Accordingly, the Department prepared a draft Table 4A for cleanup levels, containing a nonresidential direct contact numeric value of 2517 ppm. *See* [Draft Chapter 250 rulemaking Table 4A](#) (February 13, 2019, Attachment 9). However, draft Table 7 did not identify the chosen blood lead concentration, instead listing it as “TBD.” *See* Department of Environmental Protection, [Draft Chapter 250 rulemaking Table 7](#) (February 13, 2019, Attachment 2).

For subsequent meetings of the CSSAB on June 12, 2019 and October 29, 2019, the Department posted updated versions of these proposed tables. For the nonresidential direct contact numeric value, the Department rounded down the 2517 ppm number to 2500 ppm. *See* [Draft Chapter 250 rulemaking Table 4A](#) (June 12, 2019, Attachment 10), [Draft Chapter 250 rulemaking Table 4A](#) (October 29, 2019, Attachment 11).

However, the Department continued to list the target concentration as “TBD,” even though it had clearly made a determination to use a target blood lead level of 10 µg/dL. *See* [Draft Chapter 250 rulemaking Table 7](#) (June 12, 2019, Attachment 12), [Draft Chapter 250 rulemaking Table 7](#) (October 29, 2019, Attachment 13). This is also how the Tables appear in the notice of the proposed rulemaking. *See* 50 Pa.B. 1072 (Table 4A), 1097 (Table 7).

Comments

1. It is the Policy of Public Health Agencies and Medical Organizations to Monitor Pregnant Women With Blood Lead Levels Over 5 ug/dL.

The Department used the Adult Lead Methodology (ALM) as a basis for proposing the direct contact numeric value for lead. This methodology is designed to be protective of the fetus of a pregnant worker at a contaminated site. U.S. Environmental Protection Agency, [Lead at Superfund Sites: Frequent Questions from Risk Assessors on the Adult Lead Methodology](#) (“We assume that cleanup goals (preliminary remediation goals, or PRGs) that are protective of a fetus will also afford protection for male or female adult workers,” Attachment 14). Accordingly, it is important to keep in mind the medical literature relating to fetal blood levels. A sample of that literature demonstrates that there is no “safe” maternal lead blood level for fetuses.

Maternal blood lead levels below 10 µg/dL have been linked to adverse birth outcomes (See, e.g., The American College of Obstetricians and Gynecologists, Committee Opinion, [Lead Screening During Pregnancy and Lactation](#) (August 2012, reaffirmed in 2016, Attachment 15)). The World Health Organization states that “[t]here is no known 'safe' blood lead concentration; even blood lead concentrations as low as 5 µg/dL, may be associated with decreased intelligence in children, behavioral difficulties and learning problems. As lead exposure increases, the range and severity of symptoms and effects also increases.” The World Health Organization, [Lead Poisoning and Health](#), (August 23, 2019, Attachment 16).

The Committee on Obstetric Practice of the American College of Obstetricians and Gynecologists identifies pregnant women with blood lead levels higher than 5 µg/dL as requiring “avoidance of further exposure,” “specific nutritional recommendations regarding calcium and iron supplementation” (to reduce risk from lead), and may be asked to discontinue breastfeeding their infants if the infant’s blood lead level is higher than 5 µg dL. The American College of Obstetricians and Gynecologists, Committee Opinion, [Lead Screening During Pregnancy and Lactation](#) (August 2012, reaffirmed in 2016, Attachment 15).

The Centers for Disease Control and Prevention notes that “If a pregnant or lactating woman has blood lead levels (BLLs) ≥ 5 µg/dL, the health care provider should attempt to determine the source(s) of lead exposure, working with the local health department and occupational medicine specialists as needed for environmental assessment and case management.” Centers for Disease Control and Prevention, [Breastfeeding](#) (Attachment 17).

The National Capital Poison Center and HealthyChildren.org (associated with the American Academy of Pediatrics) also use a value of 5 µg/dL as a threshold for additional health interventions. See The National Capital Poison Center, [Lead and Pregnancy](#) (“If the level is 5 or above, repeat testing is needed. How often a woman is re-tested depends on her blood lead level. Pregnant women with lead levels of 5 mcg/dL or above also need extra calcium and iron in their diets. These supplements help prevent higher blood lead levels.”, Attachment 18); see also HealthyChildren.org, [Blood Lead Levels in Pregnant & Breastfeeding Moms](#) (“Although most people will have some lead in their blood, levels greater than 5 micrograms per deciliter (µg/dL) indicate that there is some exposure that needs to be addressed.”, Attachment 19).

In using a target blood concentration of 10 µg/dL for lead as a basis for calculating a proposed direct contact numeric value of 2500 ppm, the Department disregards policies set by the Centers for Disease Control and Prevention, the American College of Obstetricians and Gynecologists, and other medical organizations, putting pregnant women and their fetuses at risk.

2. Public Health Agencies Use a Blood Lead Level of 5 µg/dL as a Basis for Managing Lead Exposure in Children 0-6, a Particularly Sensitive Population.

The dangers of children's exposure to lead are well-documented and have been known for centuries. U.S. Department of Health and Human Services, National Toxicology Program, [NTP Monograph on Health Effects of Low-Level Lead](#), page xv (June 2012, Attachment 20). Blood lead concentrations under 10 µg/dL are associated with reduced postnatal growth, decreased hearing, increased hypersensitivity to allergens, increased incidence of essential tremor, increased blood pressure, increased risk of hypertension, increased incidence of ALS, and increased cardiovascular-related mortality. *Id.*, Executive Summary, page xix, Table 1.1. The NTP Report "concludes that there is *sufficient* evidence for adverse health effects in children and adults at blood [lead] levels" less than 10 µg/dL and less than 5 µg/dL. *Id.*, Executive Summary, page xviii.

Federal and state public health agencies have applied a reference level of 5 ug/dL to guide their case management for children exposed to lead, starting at birth. Of course, any target blood concentration for a fetus should be as stringent or more stringent than an "elevated blood lead level" set by a public health agency for the protection of children.

- A. The Centers for Disease Control and Prevention uses a reference level of 5 µg/dL for case management for children exposed to lead.

As part of the U.S. Department of Health and Human Services, the Centers for Disease Control and Prevention implements a lead poisoning prevention program. Centers for Disease Control and Prevention, [Lead Poisoning Prevention](#) (Attachment 21). Over time, the Centers for Disease Control and Prevention have lowered the concentration of lead in blood that is considered "elevated" in children, from 30 µg/dL to 25 µg/dL (in 1985), to 10 µg/dL (in 1991), and to 5 µg/dL (in 2012). *See* National Toxicology Program, [NTP Monograph on Health Effects of Low-Level Lead](#), page xv (Attachment 20); *see also* Centers for Disease Control and Prevention, [Blood Lead Levels in Children](#) (Attachment 22).

In 2012, an advisory committee recommended that the Centers for Disease Control and Prevention eliminate the use of the phrase "level of concern" and lower the number from 10 µg/dL to 5 µg/dL:

KEY POINTS/RECOMMENDATIONS

Based on the scientific evidence, *the ACCLPP recommends that the term "level of concern" be eliminated from all future agency*

policies, guidance documents, and other CDC publications, and that current recommendations based on the “level of concern” be updated according to the recommendations contained in this report.

CDC should use a childhood BLL reference value based on the 97.5th percentile of the population BLL in children ages 1-5 (currently 5 µg/dL) to identify children and environments associated with lead-exposure hazards. The reference value should be updated by CDC every four years based on the most recent population based blood lead surveys among children.

Advisory Committee on Childhood Lead Poisoning Prevention of the Centers for Disease Control and Prevention, [Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention](#), page 3 (January 4, 2012, Attachment 23) (bold italics added for emphasis).

The Centers for Disease Control and Prevention concurred with this recommendation, discontinuing the use of the phrase “level of concern” and adopting the term “reference value.” Centers for Disease Control and Prevention, [CDC Response to Advisory Committee on Childhood Lead Poisoning Prevention Recommendations in “Low Level Lead Exposure Harms Children: A Renewed Call of Primary Prevention”](#), page 5, Recommendation I (June 7, 2012, Attachment 24). In addition, it lowered the number from 10 µg/dL to 5 µg/dL, committing to use the lower number for case management and distribution of public health information:

In FY12, CDC will:

- a. ***Use the reference value*** in recommendations that ***involve follow-up evaluation of children*** after BLL testing.
- b. ***Use the reference value*** as defined to ***identify high-risk childhood populations*** and geographic areas most in need of primary prevention.
- c. ***Provide this information***, including specific high-risk areas, ***to a wide variety of federal, state, and local government agencies*** and nongovernment organizations interested in lead-poisoning prevention.

Id., pages 6-7, Recommendation II.

To illustrate, the website of the Centers for Disease Control and Prevention sets forth a matrix tailoring case management activities to particular blood lead levels (less than 5 µg/dL, 5–9 µg/dL, 10–19 µg/dL, etc.). Centers for Disease Control and Prevention, [Recommended Actions Based on Blood Lead Level](#) (Attachment 25). At blood lead levels of 5-9 µg/dL, “case management” includes follow-up testing, an investigation of potential sources of lead exposure, and nutritional counseling. *See id.*

- B. The Department of Housing and Urban Development uses a blood lead level of 5 µg/dL for case management for children exposed to lead.

The Department of Housing and Urban Development has adopted the 5 µg/dL reference value of the Department of Health and Human Services (Centers for Disease Control and Prevention) in its regulatory approach to exposure to lead-based paint in public housing. In 2016 and 2017, it proposed and finalized a rule that defined an “[e]levated blood lead level” as “a confirmed concentration of lead in whole blood of a child under age 6 equal to or greater than the concentration in the most recent guidance published by the U.S. Department of Health and Human Services (HHS) on recommending that an environmental intervention be conducted....”). [Proposed Rule](#), 81 Fed. Reg. 60,304, 60,324 col. 1 (September 1, 2016), [Final Rule](#), 82 Fed. Reg. 4151, 4167 (January 13, 2017) (to be codified at 40 C.F.R. 35.110 (Definitions)).

At the time of the rulemaking, the Centers for Disease Control and Prevention had already adopted the reference value of 5 µg/dL. *See* Proposed Rule, 81 Fed. Reg. 60,306 col. 2 (“CDC’s current reference range level is 5 mg/dL (5 micrograms of lead per deciliter).”).

For the Department of Housing and Urban Development, an “elevated blood lead level” is the threshold for lead in blood in a child that triggers a number of regulatory requirements for investigation. *See id.*, 82 Fed. Reg. 4167-4172 (to be codified at 40 C.F.R. §§35.325(a), 35.730(a), 35.830(a), 35.1130(a), 35.1225(a)).

- C. The Pennsylvania Department of Health defines a blood lead level of 5 µg/dL as “elevated,” requiring monitoring and case management for children.

The Pennsylvania Department of Health follows the Centers for Disease Control and Prevention’s reference value of 5 µg/dL as an “elevated lead blood level” for children:

Exposure to lead, even at low levels, can cause intellectual, behavioral and academic deficits. [footnotes omitted]. For this reason, *in 2012, the Centers for Disease Control and Prevention (CDC) defined an elevated blood lead level (EBLL) as a blood lead level (BLL) ≥ 5 micrograms per deciliter (µg/dL).* [footnote omitted]. *This value is also used to identify children who require case management* because, even at low levels, lead has been known to affect IQ, the ability to pay attention and educational achievement.

See Pennsylvania Department of Public Health, Childhood Lead Poisoning Prevention Program, [2018 Childhood Lead Surveillance Annual Report](#) (January 2020, Attachment 26), page 3 (Executive Summary) (bold italics added for emphasis). The Department of Health applies this level for its own purposes by defining an elevated blood level as a level equal to or greater than 5 µg/dL. *See id.*, page 12 (Definitions) (“Elevated blood lead level (EBLL): A BLL ≥ 5 µg/dL”). The Department of Health also uses the terms “confirmed EBLL ≥ 5 µg/dL” and “confirmed EBLL ≥ 5 µg/dL,” but only to differentiate among effects of different ranges, both of which are considered “elevated.” *See id.* Those ranges become important in differentiating impacts and

responses. *See id.*, pages 17-47, Tables 1-14). To illustrate, in 2018, among children aged 0-71 months, 2.99% had elevated levels between 5 and 9.9 µg/dL, and 1.10% had elevated levels equal to or greater than 10 µg/dL. *Id.*, page 16 (Table 3).

The Department of Health then uses the 5 µg/dL level for monitoring children throughout the state in areas not subject to the jurisdiction of the county and municipal health departments:

The Department's community health nurses (CHNs) continue to monitor elevated lead levels (≥ 5 µg/dL) in children aged 6 and under living in Pennsylvania. The Department's community health nurses cover the counties and areas of the state not covered by the 10 county and municipal health departments (CMHDs). ***The CMHDs include six county (Allegheny, Bucks, Chester, Erie, Montgomery, and Philadelphia) and four municipal (Allentown, Bethlehem, Wilkes-Barre, and York city) health departments and have their own specific case management protocols.***

Id., page 5 (bold italics added for emphasis).

- D. The Allegheny County Health Department uses a blood lead level of 5 µg/dL for case management for children exposed to lead.

The Allegheny County Health Department has jurisdiction over the metropolitan area of Pittsburgh and neighboring communities in Allegheny County. Its universal lead testing regulation went into effect on January 1, 2018. *See* Article XXIII, [Universal Blood Lead Level Testing Regulations](#), Section 10 (effective July 5, 2017, Attachment 27). It requires all children to be tested for lead exposure at approximately 9-12 months old and then again at approximately 24 months old. *See* Allegheny County Health Department, [Blood Lead Level Testing](#) (Attachment 28).

If the blood level is below 5 µg/dL, a follow-up test is not needed:

If the result is below 5 µg/dL:

- Your child's blood level is not elevated at this time. It is below the CDC's reference value, which is 5 µg/dL.
- Your child does not need a follow-up test now.
- If your child is younger than 2 years old, s/he will need another test when s/he is approximately 24 months old.
- Your child may need another test if s/he moves to a different home, daycare, school, etc. that was built before 1978.
- Go to our [Prevention page](#) to see how to keep your child safe from lead exposure.

Id. (“What Do the Test Results Mean?”). If the blood level is above 5 µg/dL, the Health Department considers the blood level to be elevated, requiring a confirmatory test:

If the result is at or above 5 µg/dL:

- Your child’s blood level is elevated.
- If the test was a capillary test (in which blood is drawn from a finger stick) it needs to be confirmed with a venous test, in which blood is drawn from the arm. Capillary samples are easier to contaminate and sometimes the result is not accurate.
- Confirmatory tests need to be prescribed by your child’s doctor. If your child is under- or uninsured, please see ACHD’s [Guide for Under and Uninsured Residents](#) for a list of pediatric healthcare resources in Allegheny County that can help.
- Check the table below to see when your child should get a confirmatory test:

Recommended Schedule for Obtaining a Confirmatory Venous Sample

BLL (µg/dL)	Time to confirmation testing
<5	No confirmation required
5-9	1 week - 1 month ^a
10-44	1 week - 1 month ^a
45-59	48 hours
60-69	24 hours
≥70	Urgently as emergency test

^a The higher the BLL on the screening test, the more urgent the need for confirmatory testing.

If the venous test confirms result at or above 5ug/dl, get more information on next steps by visiting [My Child Has an Elevated Blood Lead Level](#).

Id. Like the Centers for Disease Control and Prevention and the Pennsylvania Department of Health, the Allegheny County Health Department draws an important line at 5 µg/dL.

E. The Philadelphia Department of Public Health uses a blood lead level of 5 µg/dL for case management for children exposed to lead.

Like the state health department, the Philadelphia Department of Public Health defines an elevated blood level as a level equal to or greater than 5 µg/dL. *See* Philadelphia Department of Public Health, [Childhood Lead Poisoning Surveillance Report](#) (2017, Attachment 29), page 3 (Definitions) (“Elevated BLLs (EBLLs) in this report are classified as either 5-9 µg/dL or ≥10 µg/dL”). Like the state health department, it creates different categories of elevated blood levels (5-9 µg/dL and ≥10 µg/dL) for the purpose of gathering information and tailoring case management. To illustrate, in 2017, among children aged 0-71 months, 4.6% of newly identified blood lead levels were between 5 and 9 µg/dL, and 1.1% were equal to or greater than 10 µg/dL. *Id.*, page 10 (Table 4).

In using a target blood concentration of 10 µg/dL for lead as a basis for calculating a proposed direct contact numeric value of 2500 ppm, the Department disregards policies set by the Centers for Disease Control and Prevention, the Department of Housing and Urban Development, the Pennsylvania Department of Public Health, the Allegheny County Health Department, and the City of Philadelphia for children 0-6, and by extension the fetuses that are the target population of the ALM.

3. The Proposed Direct Contact Numeric Value Would Have a Significant Negative Impact on Cleanups Throughout the Commonwealth.

The Commonwealth of Pennsylvania recognizes the risks of exposure to lead and the prevalence of lead throughout the state. Joint State Government Commission, Advisory Committee and Task Force on Lead Exposure, [Lead Exposure Risks and Responses in Pennsylvania](#) (April 2019, Attachment 30). The conclusions of this state report are consistent with the conclusions about the detrimental health effects of lead outlined above. *See id.*, page 5 (“Children are at the greatest risk of lead poisoning, which can cause neurological damage, organ damage and death, but adults and the elderly can also suffer health concerns from lead exposure.”), page 46 (“Intensive medical studies have found that young children are particularly vulnerable to the toxic effects of lead and can suffer profound and permanent adverse health effects, most notably affecting the development of a child’s brain and nervous system.”).

The state report noted that lead is a special concern in this Commonwealth due to “the age of Pennsylvania’s infrastructure and history as an industrial center.” *Id.*, page 5. The prevalence of elevated blood lead levels above 10 µg/dL in adults in Pennsylvania is among the highest in the nation:

Of the 28 states reporting blood lead levels of greater than or equal to 10 µg/dL to the CDC under its Adult Blood Lead Epidemiology and Surveillance (ABLES) programs in 2013, ***Pennsylvania had the third highest prevalence rate at 49.1 per 100,000 employed adults aged 16 or older.*** This is more than twice the average of 20.4. ***Pennsylvania had the highest prevalence rate for blood lead levels greater than or equal to 25 µg/dL at 25.7.*** The average rate at this blood lead level was 5.2.

Id., page 46 (bold italics added for emphasis). But 10 µg/dL is not the goal. In the next sentence, the report notes that “[r]ecent studies have “found decreased renal function associated with BLLs at <5 µg/dL and increased risk of hypertension and essential tremor at BLLs <10 µg/dL.” *Id.* (citing authority).

The proposed direct contact numeric value is not protective of human health because it is calculated using a target blood concentration for lead that is associated with significant negative health effects. Additionally, using this outdated target blood concentration enables remediators to develop site-specific standards that are not protective of public health. This is important because the flawed methodology would affect a broad range of sites.

A. The direct contact numeric value is not protective of human health.

In the notice of the proposed rulemaking, the Department erroneously asserts that the proposed direct contact numeric value for lead would protect public health:

These proposed changes, based on new information, would protect public health and the environment and would provide the regulated community with clear information regarding the requirements of Act 2 and Chapter 250 related to the remediation of contaminated sites.

50 Pa.B. 1011, col. 1 (February 15, 2020) (bold italics added for emphasis). This statement is erroneous because the Department includes “new scientific information” that is favorable to a higher value (the baseline blood concentration), but does not include updated scientific information that is favorable to a lower value (the target blood concentration). *See* 25 Pa. Code §250.11 (requiring the Department to review “new scientific information” and propose “appropriate changes”).

Numerically, the proposed direct contact numeric value is located in a table. 50 Pa.B. 1072 (proposing a direct contact numeric value of 2500 ppm, and deleting existing direct contact numeric value of 1000 ppm). The methodology for calculating the proposed standard is set forth in a subsection relating to ingestion numeric values. *See* 50 Pa.B. 1019-1020 (proposed regulatory text). The Department proposes to discontinue use of the existing model of the Society for Environmental Geochemistry (SEGH) and instead use the Adult Lead Methodology of EPA:

(e) The residential ingestion numeric value for lead in soil was developed using the [**Uptake Biokinetic (UBK) Model for Lead (version 0.4)**] **Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children, Windows® version (IEUBKwin v1.1 build 11) 32-bit version** developed by the EPA (U.S. Environmental Protection Agency. ([**1990**] **February 2010**) [**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**] **IEUBK** 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), using the following equations:**

$$S = \frac{1000 \left[\left(\frac{T}{G^n} \right) - B \right]}{\delta}$$

using EPA's Adult Lead Methodology (ALM) in accordance with the guidance, exposure factors, equations, and spreadsheets provided in EPA's *Recommendations of the Technical Review Workgroup for Lead for an Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil* (EPA-540-R-03-001, OSWER Dir # 9285.7-54, January 2003), *OLEM Directive 9285.6-56 "Update to the Adult Lead Methodology's Default Baseline Blood Lead Concentration and Geometric Standard Deviation Parameters"* (May 2017) and the associated June 14, 2017, version of the *Calculations of Preliminary Remediation Goals (PRGs) for Soil in Nonresidential Areas U.S. EPA Technical Review Workgroup for Lead, Adult Lead Committee spreadsheets*. Table 7 identifies each of the variables [in this equation] used to calculate the nonresidential ingestion numeric value for lead.

Id. (proposed §250.306(e)) (emphasis in original; bold underlining in original represents new material; brackets in original represents deleted material).

The proposed rule states that the direct contact numeric value was calculated using the ALM and in accordance with the guidance, and spreadsheets, contained in three documents.

The first document is an EPA guidance document regarding the use of the ALM, published in 2003. U.S. EPA, Technical Review Workgroup for Lead, [Recommendations of the Technical Review Workgroup for Lead for an Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil](#) (EPA-540-R-03-001, January 2003, Attachment 31). At that time, EPA was recommending a target blood lead concentration of 10 µg/dL. *See id.*, page 6, Table 1. EPA published this document before the Centers for Disease Control lowered its threshold from 10 µg/dL to 5 µg/dL in 2012.

The second document is an update published by EPA in 2017 that addressed newer scientific information regarding blood levels. That document set forth a table of calculations for Preliminary Remediation Goals (essentially, cleanup levels), based on a “5% probability that a fetus' blood lead level will not exceed a 5 µg/dL blood lead target level”:

Table 3. Current and previous PbB₀ and GSD_i parameter values shown in the ALM PRG calculation tab of the ALM spreadsheet. Calculations of PRGs 5% probability that a fetus' blood lead level will not exceed a 5 µg/dL blood lead target level.

Variable	Description of Variable	Units	Current	Previous
			GSD _i and PbB ₀ from Analysis of NHANES: 2009-2014	GSD _i and PbB ₀ from Analysis of NHANES 1999-2004
PbB _{fetal, 0.95}	95 th percentile PbB in fetus	µg/dL	5	5
R _{fetal/maternal}	Fetal/maternal PbB ratio	--	0.9	0.9
BKSF	Biokinetic Slope Factor	µg/dL per µg/day	0.4	0.4
GSD _i	Geometric standard deviation PbB	--	1.8	1.8
PbB ₀	Baseline PbB	µg/dL	0.6	1.0
IR _s	Soil ingestion rate (including soil-derived indoor dust)	g/day	0.050	0.050
AF _{s, D}	Absorption fraction (same for soil and dust)	--	0.12	0.12
EF _{s, D}	Exposure frequency (same for soil and dust)	days/yr	219	219
AT _{s, D}	Averaging time (same for soil and dust)	days/yr	365	365
PRG	Preliminary Remediation Goal Soil Lead Concentration where PbB_t = 5 µg/dL	ppm	1050	773

U.S. EPA, OLEM Directive 9285.6-56, [Update of the Adult Lead Methodology's Default Baseline Blood Lead Concentration and Geometric Standard Deviation Parameters and the Integrated Exposure Uptake Biokinetic Model's Default Maternal Blood Lead Concentration at Birth Variable](#), page 6, Table 3 (May 2017, Attachment 32).

Attached to the two-page transmittal memorandum was a set of Frequently Asked Questions that stated that EPA was updating its soil lead strategy to incorporate new scientific information recognizing adverse health effects at blood lead concentrations below 10 µg/dL, and that the release date was pending:

OLEM [Office of Land and Emergency Management] recognizes adverse health effects at blood lead concentrations below 10 µg/dL. ***Accordingly, OLEM is updating the soil lead strategy to incorporate this new information.*** However, the release date for the updated strategy is pending.

Id., Transmittal Memorandum, page 3 (bold italics added for emphasis). In the meantime, the TRW Lead Committee recommended the following considerations for all non-residential risk assessments where lead is a contaminant of concern:

1. ***The updated NHANES values are appropriate for lead risk assessments for residential and non-residential exposures*** both in

assessing risk and in developing preliminary remediation goals (PRGs) for your site.

2. ***Lead risk assessments should include a discussion of the most current toxicity information and Centers for Disease Control and Prevention Reference level.***

3. Consistent with risk management best practices, ***caution should be applied when implementing cleanup levels based on the updated NHANES values for non-residential scenarios (PRGs are greater than 2000 ppm using default values)***. Ineffective controls or incorrect land use assumptions could have potentially greater health consequences on children who are exposed (e.g., by visiting, trespassing, or tracking the material to the residence) to these high concentrations (especially given the new toxicity information).

Users are encouraged to contact the technical support hotline, TRW Lead Committee, or regional risk assessor with any questions.

Id. (bold italics added for emphasis).

The third document represents an Excel spreadsheet prepared in 2017 by EPA for calculating Preliminary Remediation Goals for nonresidential soils based on the new scientific information, including the updated target blood concentration. U.S. EPA Technical Review Workgroup for Lead, [Spreadsheet for Calculation of PRGs: Appendix B of ALM document\(2 pp, 18 K\)](#) (June 14, 2017, Attachment 33).² In this document there are two sheets: (1) one sheet for Calculations of Blood Lead Concentrations (PbBs) and Risk in Nonresidential Areas and (2) one sheet for Calculations of Preliminary Remediation Goals (PRGs) for Soil in Nonresidential Areas. *See id.* Rather than using 10 µg/dL, EPA used 5 µg/dL as the target blood concentration in both sheets. *See id.* Together with other inputs, this leads to a Preliminary Remediation Goal of 1050 ppm. *See id.*

The use of the 5 µg/dL target blood concentration in this spreadsheet is significant because this spreadsheet was based on a template attached to the 2003 guidance document, which had used 10 µg/dL as the target blood concentration. See [Recommendations of the Technical Review Workgroup for Lead for an Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil](#) (January 2003, Attachment 31), Appendix B (“Calculations of Preliminary Remediation Goals (PRGs),” page B-1.

The Department was aware that EPA recognized adverse health effects below 10 µg/dL, and even quoted cautionary language from EPA in its lead model comparison sheet:

² The link is on EPA’s website: [Lead at Superfund Sites: Software and Users' Manuals](#).

EPA's lead guidance website states, ***'Recent scientific evidence has demonstrated adverse health effects at blood lead concentrations below 10 µg/dL down to 5 µg/dL, and possibly below.*** OSRTI is developing a new soil lead policy to address this new information.

....

EPA's guidance for the ALM cautions that the values calculated using this new model are high and may not be protective of all receptors, i.e. a school or playground that borders a non-residential property. This is not necessarily in-line with the purpose of the statewide health standard which should be protective across the entire state.

See Department of Environmental Protection, [Lead Model Comparison Sheet](#) (undated, Attachment 6) (bold italics added for emphasis). Still, the Department used 10 µg/dL, rather than 5 µg/dL.

In fact, in the notice of the proposed rulemaking the Department suggests that new scientific information regarding lead exposure leads to the conclusion that the direct contact numeric value should be *weakened*, rather than strengthened:

The soil numeric values represent a proposed decrease for approximately 83% of the values and an increase for 17% of the values. For groundwater, the proposed changes reflect a decrease for approximately 92% of the values and an increase in approximately 8% of the values. Lowering the values may indicate a more stringent cleanup is required at a site ***and increasing the values may indicate a less stringent cleanup is required at a site. These proposed changes reflect updated information related to exposure limitations to these substances and recognize that a higher or lower standard is better representative of those substances' exposure thresholds.***

See 50 Pa.B. 1012 col. 1 (bold italics added for emphasis). But the Department is going in the *opposite* direction of the science. In the context of a lack of a safe level of exposure to lead, the public health agencies have been focusing on lower blood lead levels, not higher levels. See discussion in Comment #2, above.

In the calculation of the direct contact nonresidential soil standard of 2500 ppm, the Department used all the default parameters provided in the 2017 Adult Lead Methodology (Attachment 33), *except* for the target blood level (Department of Environmental Protection, [Draft Chapter 250 rulemaking Table 7](#), February 13, 2019, Attachment 2). In response to an inquiry regarding the development of the proposed direct contact numeric value, the Department stated that "DEP is using EPA's lead methodologies, generally with EPA's default values." See Attachment 34 -- Email from C. David Brown to Peter Winslow, dated January 3, 2020.

By asserting that it “generally” used EPA’s default values, the Department demonstrated that it was ignoring a value that it considered to be a default value in EPA’s 2017 spreadsheet.

In 2020, the Department may not cherry-pick new scientific information -- at least not reasonably. It cannot apply new scientific information that tends to make a standard less stringent (the baseline blood concentration) while ignoring other new scientific information that tends to make a standard more stringent (the target blood concentration). In proposing the direct contact numeric value, the Department adopted the 10 µg/dL target blood concentration in EPA’s 2003 guidance document, ignoring the 5 µg/dL target blood concentration in EPA’s 2017 guidance document, and ignoring the 5 µg/dL target blood concentration in EPA’s 2017 spreadsheet.

Because the target blood concentration used by the Department is not protective of public health, the proposed direct contact numeric value is not protective of public health.

- B. The proposed direct contact numeric value would make site-specific standards for lead not protective of public health.

In addition to causing a dramatic increase in the proposed direct contact numeric value, the Department’s use of the 10 µg/dL target blood concentration would enable owners of contaminated sites to develop site-specific standards that are not protective of public health.

It does this in two ways. First, it increases the threshold at which a property owner will have an incentive to request a site-specific standard, where the direct contact numeric value prevails over the soil-to-groundwater numeric value. Under the regulations, sometimes the medium-specific concentration is set by the direct contact numeric value, and other times it is set by the soil-to-groundwater numeric value. *See* 25 Pa. Code §250.305(d)(1)-(2). Second, its use of the 10 µg/dL target blood concentration validates the development of a site-specific standard near 2500 ppm, superseding both the direct contact numeric value and the soil-to-groundwater numeric value.

The Department recognizes that the proposed amendments do not change the statutory right of a remediator to develop a site-specific standard for lead:

The proposed amendments to Statewide health standard MSCs would not affect the cleanup options available to remediators under other cleanup standards. Persons conducting remediation under Act 2 may choose from three different cleanup standards: background, Statewide health ***or site-specific***.

See 50 Pa.B. 1015 col. 1 (bold italics added for emphasis).

Under the statute, a property owner has the option of developing a site-specific standard rather than applying a statewide health standard:

Section 301. Remediation standards.

(a) Standards.--***Any person*** who proposes or is required to respond to the release of a regulated substance at a site and ***who wants to be eligible for the cleanup liability protection under Chapter 5 shall select and attain compliance with one or more of the following environmental standards when conducting remediation activities:***

(1) a background standard which achieves background as further specified in section 302;

(2) ***a Statewide health standard adopted by the Environmental Quality Board*** which achieves a uniform Statewide health-based level so that any substantial present or probable future risk to human health and the environment is eliminated as specified in section 303; or

(3) ***a site-specific standard which achieves remediation levels based on a site-specific risk assessment*** so that any substantial present or probable future risk to human health and the environment is eliminated or reduced to protective levels based upon the present or currently planned future use of the property comprising the site as specified in section 304.

See [Act 2 of 1995](#), §301(a) (bold italics added for emphasis). The regulations also contemplate the use of a risk assessment for developing a site-specific standard. See 25 Pa. Code §250.402 (“The development of site-specific standards shall be based on a site-specific risk assessment, if required.”).

For lead in soil, this would mean that a site-specific standard would “almost always” be based on EPA’s Adult Lead Methodology:

I’m assuming the ALM was used to calculate the non-residential site-specific lead standard at the Philadelphia Refinery which resulted in a value of 2,240 mg/kg. ***When we calculated the non-residential direct contact value for the proposed rulemaking using the ALM default exposure factors we ended up with a very similar number of 2,500 mg/kg.*** Thus, it is probably safe to say that the differences in the default exposure factors from the SEGH model and the ALM resulted in the difference between the current non-residential direct contact lead value and the site-specific value calculated for the Philadelphia Refinery.

Keep in mind that the non-residential direct contact numeric value will never be the MSC because it is higher than the generic soil to groundwater numeric value of 450 mg/kg. So in cases where the

SHS is being used, the soil MSC for lead will always be 450 mg/kg. ***For site-specific analyses, such as the Philadelphia Refinery, the ALM is almost always used which results in a value closer to our proposed direct contact non-residential soil lead value.***

Attachment 35, Email from Michael Maddigan, Environmental Group Manager (Land Recycling Program) to C. David Brown, Professional Geologist Manager (Southeast Regional Office), dated December 20, 2019 (bold italics added for emphasis).

In fact, the consultant used the ALM when it developed a site-specific standard of 2240 ppm for its remedial investigation at the Philadelphia oil refinery in 2015, based on a target blood concentration of 10 µg/dL. See Evergreen Resources Group, LLC, [Human Health Risk Assessment](#), Section 8.0 (Risk Characterization), pages 9-11 (February 24, 2015, Attachment 36).

The Department approved the site-specific 2240 ppm standard several months later. See [Memo from C. David Brown to Stephan Sinding, Regional Manager \(Environmental Cleanup and Brownfields\)](#) (April 30, 2015, Attachment 37) (recommending approval of 2240 ppm standard), [Approval Letter from C. David Brown to Evergreen Resources Management Operations](#) (May 6, 2015, Attachment 38).

The Department not only approved the site-specific standard of 2240 ppm for the Philadelphia oil refinery, but also endorsed the use of 10 µg/dL; See [Memo from C. David Brown to Stephan Sinding, Regional Manager \(Environmental Cleanup and Brownfields\)](#), page 2 (“The target blood lead concentration is 10 µg/dL, which is considered to be a level in a pregnant worker above which fetal neurological damage could occur,” Attachment 37).

The site-specific standard of 2240 ppm for the Philadelphia oil refinery and the Department’s proposed nonresidential soil direct contact standard of 2500 ppm were both calculated using the same model (ALM) and the same target blood concentration (10 µg/dL). The minor difference in the two resulting values is due to the Department’s use of EPA’s updated values for the other model parameters. See [Spreadsheet for Calculation of PRGs: Appendix B of ALM document \(2 pp, 18 K\)](#), June 14, 2017, Attachment 33).

- C. The proposed direct contact numeric value would not be protective of public health at a broad range of nonresidential properties.

The Department’s proposed increase in the direct contact numeric value from 1000 ppm to 2500 ppm would apply to nonresidential sites undergoing cleanups throughout Pennsylvania. The term “nonresidential” is broadly defined to include all industrial and commercial uses of land, as well as related administrative activities:

Any real property on which commercial, industrial, manufacturing or any other activity is done to further either the development, manufacturing or distribution of goods and

services, intermediate and final products, including, but not limited to, *administration of business activities*, research and development, warehousing, shipping, transport, remanufacturing, stockpiling of raw materials, storage, repair and maintenance of commercial machinery and equipment, and solid waste management. This term shall not include schools, nursing homes or other residential-style facilities or recreational areas.

See [Act 2 of 1995](#), §103 (bold italics added for emphasis). Nonresidential means not only oil refineries, but also office buildings and commercial properties. It means properties in both urban and rural areas. Because the proposed direct contact numeric value is not protective of public health, people working on nonresidential properties could be exposed to harmful levels of lead.

The Department proposes a direct contact numeric value that is not protective of human health and enables remediators developing their own site-specific standards to do the same. This is especially inappropriate given the wide range of nonresidential properties to which such standards would apply.

- D. The proposed direct contact numeric value would be much greater than comparable cleanup levels in most of the states neighboring Pennsylvania.

With one exception, the states neighboring Pennsylvania have comparable cleanup levels for lead in nonresidential soil that are much lower than the proposed direct contact numeric value of 2500 ppm. The Department should follow the states that recognize harm at lower levels, and maintain the existing direct contact numeric value of 1000 ppm.

Maryland applies a cleanup level of 800 ppm for nonresidential soil in its guidance document. Maryland Department of the Environment, [Cleanup Standards for Soil and Groundwater, Interim Final Guidance \(Update No. 3\)](#) (October 2018, Attachment 39), page 24, Table 1 (setting forth non-residential clean-up standard of 800 mg/kg for soil).

Delaware applies a cleanup level of 1000 ppm in its guidance document. See Delaware Department of Natural Resources and Environmental Control, [Remediation Standards Guidance Under the Delaware Hazardous Substance Cleanup Act](#) (Revised December 1999, Attachment 40), page 12 (defining “restricted use setting” to essentially mean nonresidential use), Attachment 3, page 8 (1000 mg/kg for restricted use). See also Delaware Department of Natural Resources and Environmental Control, [Guidance for Human Health Risk Assessments \(HHRA\) under the Hazardous Substance Cleanup Act \(HSCA\)](#) (October 2017, Attachment 41), page 19 (“Remediation for lead will normally be required if the EPC [Exposure Point Concentration] is greater than 400 mg/kg (or 800 mg/kg for restricted use sites”).

New Jersey applies a cleanup level of 800 ppm in its regulations for nonresidential soil. See [N.J.A.C. 7:26D \(Remediation Standards\)](#) (last amended September 18, 2017, Attachment 42), Appendix 1, page 19, Table 1B (setting forth non-residential direct contact soil remediation standard of 800 mg/kg).

Ohio applies a cleanup level of 800 ppm in its regulations. *See* Ohio Environmental Protection Agency, [VAP Rules Effective October 17, 2019](#), [OAC 3745-300-08 Appendix A](#), page 42, Table III (Attachment 43) (setting forth direct-contact soil standard of 800 mg/kg for commercial and industrial land use).

West Virginia applies a cleanup level of 1000 ppm in its legislative rule. West Virginia Department of Environmental Protection, [Technical Guidance and Templates, Voluntary Remediation and Redevelopment Rule \(W. Va. Legislative Rule 60CSR3\)](#) (effective April 1, 2018, Attachment 44), page 3, §60-3-2.24 (defining “industrial land use” to include “land used for commercial establishments”), page 80, Table 60-3B (setting forth risk-based concentration of 1000 mg/kg for industrial soil).

Unlike other neighboring states that set a single standard for nonresidential sites (applying to both commercial and industrial use), New York has set different standards for commercial and for industrial use. For commercial use, New York has set a soil cleanup objective of 1000 ppm, which is the current direct contact numeric value in Pennsylvania ([6 CRR-NY 375-6.8\(b\): Restricted Use Soil Cleanup Objectives](#), Attachment 45).

For industrial use, New York has set a soil cleanup objective of 3900 ppm (*See* [6 CRR-NY 375-6.8\(b\): Restricted Use Soil Cleanup Objectives](#), Attachment 45). New York set this soil cleanup objective in 2006 -- six years before the Centers for Disease Control and Prevention embraced a reference value of 5 µg/dL. *See* [6 NYCRR PART 375 \(Effective December 14, 2006\)](#), Attachment 45). Moreover, the Technical Support Document in that rulemaking notes that it was following the Centers for Disease Control and Prevention’s “level of concern” from 1991:

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).

See New York State Department of Environmental Conservation and New York State Department of Health, [Technical Support Document](#) (September 2006, page 40, Attachment 46). The fact that New York has not amended its soil cleanup objective for industrial use to catch up with the science is not a justification for Pennsylvania to do the same for all nonresidential uses - including both commercial and industrial uses.

4. The Soil-to-Groundwater Numeric Value Does Not Render the Proposed Direct Contact Numeric Value Meaningless.

The Department has asserted that the proposed direct contact numeric value for lead has no legal effect because it will always be superseded by a more stringent soil-to-groundwater numeric value. This is incorrect. Moreover, if the Department truly believes this, it should not

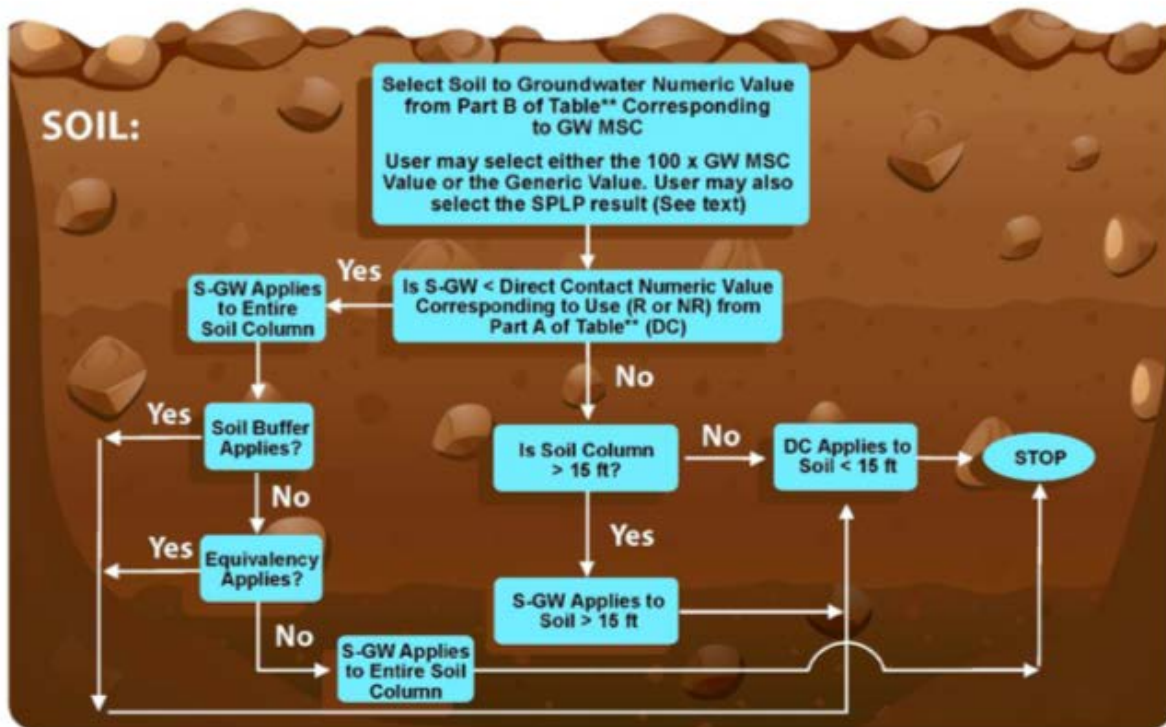
have any objection to not finalizing its proposed direct contact numeric value and retaining the current value of 1000 ppm in the regulations.

The source of the Department's position appears to be an email to the Southeast Regional Office relating to the remedial investigation at the Philadelphia oil refinery:

Keep in mind that the non-residential direct contact numeric value will never be the MSC because it is higher than the generic soil to groundwater numeric value of 450 mg/kg. ***So in cases where the SHS is being used, the soil MSC for lead will always be 450 mg/kg.***

See Attachment 35, Email from Michael Maddigan, Environmental Group Manager (Land Recycling Program) to C. David Brown, Professional Geologist Manager (Southeast Regional Office), dated December 20, 2019 (bold italics added for emphasis). This statement framed the Department's erroneous press release relating to the proposed direct contact numeric value. See Department of Environmental Protection, [Press Release](#), dated March 16, 2020 (Attachment 47), asserting that "[t]he non-residential statewide health standard of 450 ppm will remain unchanged."

The process of selecting statewide health standards is illustrated in the following decision tree [Figure II-11: Decision Tree for Selecting Statewide Health Standard MSCs for Groundwater and Soil]



See Department of Environmental Protection, [Technical Guidance Memorandum](#) (revised January 19, 2019, Attachment 48), Section II (Act 2 Remediation Process), page II-52.

The Department is incorrect in asserting that a soil-to-groundwater numeric value will always prevail over a direct contact numeric value. In support of its argument, the Department relies on a subsection of the regulations that defines a medium-specific concentration as the lowest of three numbers -- the ingestion numeric value, the inhalation numeric value, and the soil-to-groundwater numeric value. *See* 25 Pa. Code §250.305(d)(1)(i)-(iii). But that is one-half the definition. The Department ignores the other half.

The other half of the definition defines a medium-specific concentration as the lowest of the first *two* numbers -- the ingestion numeric value and the inhalation numeric value, *without regard to the soil-to-groundwater numeric value*. *See id.*, §250.305(d)(2). To satisfy that other half of the definition, a remediator must perform a demonstration of the soil-to-groundwater pathway soil buffer or a soil-to-groundwater pathway equivalency demonstration. *See id.*, §250.305(d)(2)(i)-(iii).

The first demonstration involves a showing that “[t]he concentration of the regulated substance cannot exceed the limit related to the PQL [Practical quantitation limit] or background throughout the soil buffer,” among other things. *See id.*, §250.308(b)(2). The soil buffer depth for lead is set at 10 feet. Department of Environmental Protection, [Draft Chapter 250 rulemaking Table 4B](#) (Attachment 10).

The second demonstration involves a showing that the regulated substances will not migrate to bedrock or the groundwater within 30 years at concentrations exceeding the greater of the groundwater medium-specific concentration or background in groundwater as the endpoint in soil pore water directly under the site, among other things. *See id.*, §250.308(d)(1).

Assuming either demonstration is met, the soil-to-groundwater numeric value would not determine the medium-specific concentration. *See id.*, §250.305(d)(2).

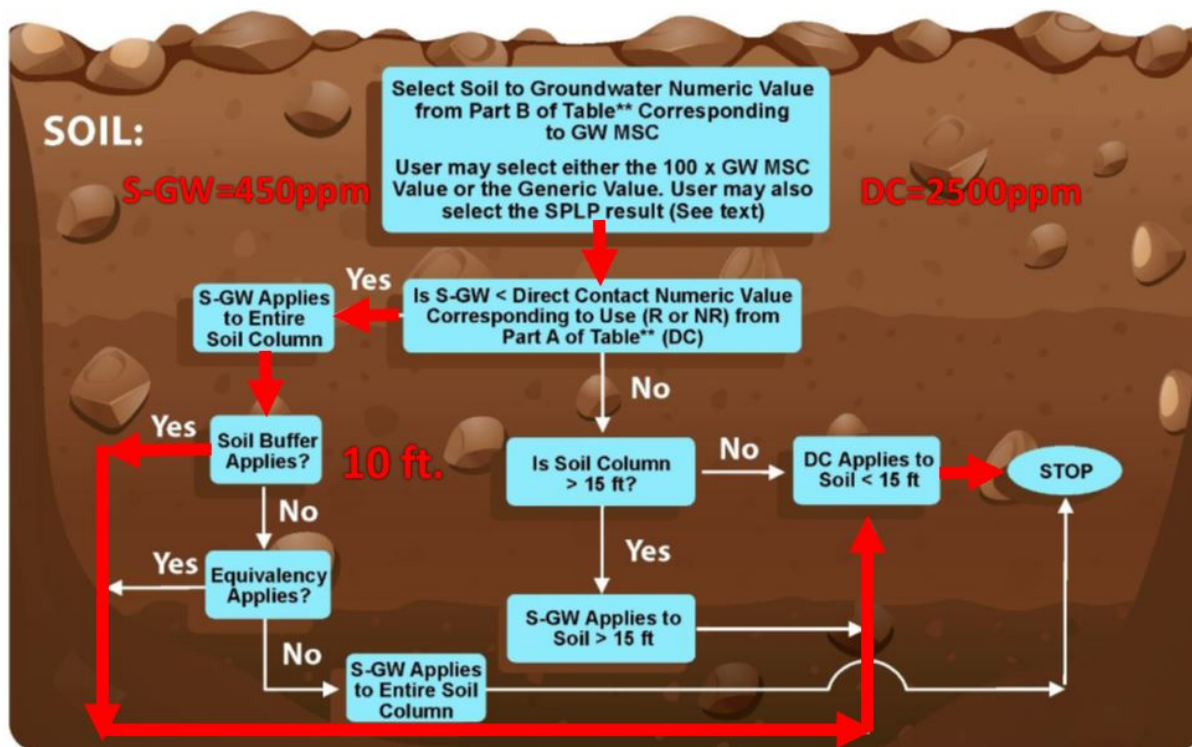
In its own Technical Guidance Manual, the Department makes it clear that when either demonstration is met, the medium-specific concentration for soil will be the direct contact numeric value:

ii) Determining Soil MSCs

In determining the applicable soil standard, the remediator must compare the appropriate soil-to-groundwater numeric value to the direct contact numeric value for the corresponding depth interval within 15 feet from the ground surface. The lower of these two values is the applicable MSC for soil. ***If either the soil buffer distance (described in 25 Pa. Code § 250.308(b) and (c)) or the equivalency demonstration (described in 25 Pa. Code § 250.308(d)) is met, the soil-to-groundwater numeric value will be deemed to be satisfied, and the soil MSC will be the direct contact numeric value.*** The soil-to-groundwater numeric value is the MSC

for soil at depths below 15 feet, unless either the soil buffer distance or the equivalency demonstration is met.

See Department of Environmental Protection, [Technical Guidance Memorandum](#) (revised January 19, 2019, Attachment 48), Section II (Act 2 Remediation Process), page II-51 (bold italics added for emphasis).³ To demonstrate how the direct contact numeric value of 2500 ppm for lead could apply, the Council has highlighted the following route in red below:



See *id.*, page II-52 (arrows, lines, and text in red added for emphasis).

Therefore, there is no merit to the Department's argument that the proposed direct contact numeric value has no legal effect.

Moreover, it is presumed that when an agency proposes to do something, it intends some effect. In the past, the Department has told the Independent Regulatory Review Commission that its statewide health standards (including its direct contact numeric values) are important for the protection of public health:

The Land Recycling Act requires the EQB to establish by regulation *a uniform Statewide health standard that can be used to eliminate any substantial present or probable future risk to human health, welfare, and the environment*. The original standards were promulgated in 1997 and codified in Chapter 250.

³ The document is on the Department's [Web Page for Technical Guidance Manual](#).

Section 104(a) of the Land Recycling Act explicitly recognizes that these standards would need to be updated over time as better science became available and as the need for clarification or enhancement of the program became apparent. *Updating the standards serves the public, as DEP is able to use the most up-to-date health and scientific information to establish the cleanup standard for exposure to substances that cause cancer or have other toxic effects on human health or welfare.* The Statewide health standard is expressed as a list of MSCs, which apply to either soil or groundwater contamination and to residential and non-residential exposure scenarios as authorized under the Land Recycling Act.

The changes in the MSCs in these amendments to Chapter 250 serve both the public and the regulated community as they provide clear information on what is required at contaminated sites. Having access to that information allows the public to know the acceptable level of contamination at a site based on the intended use of the property, and it provides remediators with a uniform endpoint to the remediation process. *Because each site and situation is unique, it is necessary to provide different MSCs for:* 1) specific constituents in groundwater at points of compliance, 2) *specific constituents in soil, where there may be direct contact through ingestion or inhalation,* and 3) specific constituents in soil that may leech [sic] into groundwater. *Each of these MSCs is based on the physical, toxicological, and esthetic properties of a specific regulated substance, which are based on scientific sources of information.*

Department of Environmental Protection, [Regulatory Analysis Form](#), filed May 13, 2016, pages 2-3, Box No. 10 (Attachment 49. Bold italics added for emphasis).

If the Department feels compelled to come up with a number simply because it had to do so (as it has suggested), the Department should maintain the current direct contact numeric value of 1000 ppm.

5. As a Matter of Law, the Proposed Direct Contact Numeric Value is Unreasonable.

The Department has cherry-picked scientific information for the Adult Lead Methodology. It has used new scientific information that tends to make a standard less stringent (the baseline blood concentration) while ignoring other new scientific information that tends to make a standard more stringent (the target blood concentration). This is legally unreasonable.

It is significant that the target blood concentration is the only value in the EPA 2017 spreadsheet that the Department did *not* use when it calculated the proposed direct contact numeric value of 2500 ppm. See 50 Pa.B. 1097 (Appendix A, Table 7 (“Input Values Used in

the Adult Lead Model”); *see also* [Spreadsheet for Calculation of PRGs: Appendix B of ALM document \(2 pp, 18 K\)](#) (June 14, 2017, Attachment 33).

As a basis for its choice of a target blood concentration of 10 µg/dL, the Department apparently relies solely on the EPA guidance document from 2003, ignoring new scientific information reflected in the 2017 EPA guidance document and the 2017 EPA spreadsheet. The Department has not identified any other documentary justification as a basis for using 10 µg/dL.

The meeting minutes of the CSSAB do not contain any discussion of arguments for or against a target blood concentration of 10 µg/dL or 5 µg/dL. The minutes only state that the Department sought input regarding the choice between these target blood concentrations, and that the CSSAB recommended the less protective one. *See* [Meeting Minutes](#) (April 4, 2018, Attachment 3), [Meeting Minutes](#) (August 1, 2018, Attachment 5), [Meeting Minutes](#) (February 13, 2019, Attachment 7).

Apart from the EPA representative, the only academic representative on the CSSAB has a field of expertise outside of environmental remediation and public health. *See* Cleanup Standards Scientific Advisory Board Members, [Membership List](#) (Updated June 2018, Attachment 50) (Tina M. Serafini, D.Sc.). The other members are representatives of business and industry.

One member of the CSSAB who was present at all three meetings is a consultant who prepared remedial investigation reports for lead contamination for the Philadelphia oil refinery. *See* Colleen Costello, [Linkedin Page](#) (employed with GHD from March 2015-March 2020, Attachment 51). Her company performed ongoing work relating to the delineation of lead contamination in the soil and anticipated remedies under the site-specific standard for lead approved in 2015. *See* Colleen Costello, GHD, [Remedial Investigation Report](#) (November 21, 2017, Attachment 52), Section 9.6 (“AOI 6 areas with identified soil exceedances of the direct-contact MSC for BaP and benzene, with the exception of BH-16-025, and SSS for lead have been delineated and remedies will be addressed in future Act 2 submissions, including a Facility-Wide Cleanup Plan.”); *see also* Colleen Costello, GHD, [Letter to David Brown](#) (April 30, 2018, Attachment 53), page 1 (“Additionally, lead in the area between BH-17-004 and the bulkhead will be assessed through Risk Assessment activities as presented in the site-wide Risk Assessment Report or the site-wide Cleanup Plan. Additional sampling is anticipated to support either the Risk Assessment or the Cleanup Plan activities.”). In addition, another representative of GHD (who was not a member of the CSSAB) attended the second and third meetings.

Neither the CSSAB’s recommendation of 10 µg/dL nor the Department’s acceptance of the recommendation was credible. Given the science and the implementation of policy by federal and state health agencies, the selection of 10 µg/dL was unreasonable as a matter of law.

6. As a Matter of Law, the Proposed Direct Contact Numeric Value is “Not in Accordance with Law.”

According to the Pennsylvania state courts, the pre-enforcement doctrine generally forecloses a party from immediately challenging a final rulemaking. However, such a party does not forfeit the right to challenge the regulation. When the regulation is implemented in such a manner as to cause harm, a party with standing may commence a legal challenge at that time. *See Rand v. Pennsylvania State Bd. of Optometry*, 762 A.2d 392 (Cmwlth., 2000) (regulation establishing a testing deadline to qualify for a license invalidly exceeded the agency's statutory authority, where the deadline was unnecessary to advance the intent of the act and therefore outside the grant of authority).

This is not an academic point. The proposed direct contact numeric value would have an effect on the remedial investigation at the Philadelphia oil refinery, either by setting a medium-specific concentration or by affecting a site-specific standard. If and when the Department makes another determination regarding the applicability of cleanup standards for that project, a party with standing will have the opportunity to challenge the proposed direct contact numeric value (if finalized) at that time.

On a number of accounts, the proposed direct contact numeric value is legally flawed. Because it violates a number of statutory and regulatory requirements, it is “not in accordance with law.”

A. The proposed direct contact numeric value violates a number of statutory requirements.

A state court may strike down a regulation that is “not in accordance with law.” *See* 2 Pa.C.S. § 704, [Pennsylvania Consolidated Statutes, Title 2](#). Because the proposed direct contact numeric value violates a number of statutory requirements, it is “not in accordance with law.”

According to the declaration of policy in the statute, “[a]ny remediation standards adopted by this Commonwealth must provide for the protection of public health and the environment.” [Act 2](#), § 102(3). As discussed above, the Department proposes a direct contact numeric value based on a target blood lead concentration that has been linked to serious and irreversible health effects. Because the proposed direct contact numeric value was calculated using this variable (as will almost all site-specific standards for lead), the resulting standards would not be protective of public health, causing them to violate this declaration of policy.

The declaration of policy also states that “[p]ublic health and environmental hazards cannot be eliminated without clear, predictable environmental remediation standards and a process for developing those standards.” [Act 2](#), § 102(3). But the Department’s presentation and discussion of the proposed direct contact numeric value has not been clear and predictable. The Department asserts that the proposed direct contact numeric value would have no legal effect, under the mistaken rationale that a much lower soil-to-groundwater value will always apply. In addition, it ignores the fact that it would have a significant legal effect by enabling property owners to develop site-specific standards near 2500 ppm, by endorsing a target blood

concentration that is two times the blood lead level used by public health agencies for dealing with children exposed to lead.

The lack of clarity is compounded by the fact that the Department did not include the target blood concentration of 10 µg/dL anywhere in the notice of the proposed rulemaking. It actually set forth “TBD” (presumably, “to be determined”) as the target blood concentration in the proposed table. *See* 50 Pa.B. 1097 (Appendix A, Table 7 (“Input Values Used in the Adult Lead Model”). This makes it difficult for the public to recognize the connection between the proposed direct contact numeric value and site-specific standards for lead -- a connection that the Department has emphatically denied.

By asserting that the proposed direct contact numeric value is essentially meaningless, and by listing a key variable used to calculate that value as “TBD,” the Department proposes a regulation that lacks “clear, predictable” standards, in violation of the declaration of policy in Act 2.

The statute also requires the Environmental Quality Board to promulgate Statewide health standards “along with the methods used to calculate” those standards.” [Act 2](#), §303(a) (“The Environmental Quality Board shall promulgate Statewide health standards for regulated substances for each environmental medium.... The Environmental Quality Board shall also promulgate along with the standards the methods used to calculate the standards.”). Again, the Department does not identify the target blood concentration for determining the proposed direct contact numeric value of 2500 ppm. Rather, it merely identifies it as “TBD.” *See* 50 Pa.B. 1097 (Appendix A, Table 7). The fact that the Council was able to deduce that the Department is using a 10 µg/dL target blood concentration does not excuse this violation of the statute.

The statute requires the direct contact numeric value to be based on “valid scientific methods.” *See* [Act 2](#), §303(b)(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)”). The Department’s use of EPA’s model with only *some* of EPA’s updated default variables makes this proposal scientifically invalid and, therefore a violation of Act 2.

The statute also requires that exposure scenarios for medium-specific concentrations for nonresidential conditions be based on “valid scientific methods.” *Id.*, §303(b)(6) (“Exposure scenarios for medium-specific concentrations for nonresidential conditions shall be established using valid scientific methods reflecting worker exposure.”). For the same reason as above, the proposal violates this requirement.

Finally, the statute requires site-specific standards to be based on “sound scientific principles.” *Id.*, §304(e) (“Concentrations of regulated substances in soil shall not exceed values calculated in accordance with subsections (b) and (c) based on human ingestion of soil where direct contact exposure to the soil may reasonably occur; Such determinations ... shall be based on sound scientific principles”). The proposal enables property owners to violate this

requirement by endorsing the use of methods and variables that are based on outdated information.

B. The proposed direct contact numeric value violates existing regulations.

The Department is required to “review new scientific information that relates to the basis of the MSCs as it becomes available” and “propose appropriate changes for the consideration of the EQB as necessary.” 25 Pa. Code §250.11. The proposal violates this requirement by *ignoring* new scientific data and by proposing a change to the nonresidential direct contact value for lead based on outdated information.

A person is required to “implement a remedy under the Statewide health standard that is protective of human health and the environment.” 25 Pa. Code §250.305(a). As discussed above, the proposed nonresidential direct contact value is not protective of human health. The proposal enables parties remediating a site to a Statewide health standard or site-specific standard to implement a remedy that violates the regulation.

For all these reasons, the proposal is unreasonable, violates statutory and regulatory requirements, and would not survive a legal challenge under 2 Pa.C.S. § 704.

Conclusion

The Department should not finalize the proposed direct contact numeric value of 2500 ppm. It should retain the current value of 1000 ppm.

Thank you for your consideration of the Council’s comments.

Sincerely,



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Table of Attachments

1. U.S. Environmental Protection Agency, [Lead at Superfund Sites](#)
2. Department of Environmental Protection, [Draft Chapter 250 rulemaking Table 7](#) (February 13, 2019)
3. Cleanup Standards Scientific Advisory Board, [Meeting Minutes](#) (April 4, 2018)
4. Department of Environmental Protection, [PowerPoint Presentation](#) (August 1, 2018)
5. Cleanup Standards Scientific Advisory Board, [Meeting Minutes](#) (August 1, 2018)
6. Department of Environmental Protection, [Lead Model Comparison Sheet](#) (undated)
7. Cleanup Standards Scientific Advisory Board, [Meeting Minutes](#) (February 13, 2019)
8. Department of Environmental Protection, [PowerPoint Presentation](#) (February 13, 2019)
9. Department of Environmental Protection, [Draft Chapter 250 rulemaking Table 4A](#) (February 13, 2019)
10. Department of Environmental Protection, [Draft Chapter 250 rulemaking Table 4A](#) (June 12, 2019)
11. Department of Environmental Protection, [Draft Chapter 250 rulemaking Table 4A](#) (October 29, 2019)
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18. The National Capital Poison Center, [Lead and Pregnancy](#)
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34. Email from C. David Brown to Peter Winslow, dated January 3, 2020
35. Email from Michael Maddigan, Environmental Group Manager (Land Recycling Program) to C. David Brown, Professional Geologist Manager (Southeast Regional Office), dated December 20, 2019
36. Evergreen Resources Group, LLC, [Human Health Risk Assessment](#) (Risk Characterization) (February 24, 2015)
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