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MEMORANDUM **OLEM Directive 9285.6-52**

SUBJECT: Recommendations for Using Blood Lead Data at Superfund and RCRA Corrective Action Sites

FROM: Dana Stalcup, Director
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TO: Superfund National Policy Managers, Regions 1 - 10

The purpose of this memorandum is to transmit the Technical Review Workgroup for Metals and Asbestos Technical document entitled "Recommendations for Using Blood Lead Data at Superfund Sites". This document clarifies the role of blood lead (PbB) data in Superfund lead risk assessments. This document provides the technical basis for appropriate uses of PbB data from various monitoring programs and from specifically designed studies at Superfund sites.

This report and other efforts related to addressing lead in soil can be found on the internet at https://www.epa.gov/superfund/lead-superfund-sites-guidance. Please contact Michele Burgess at Burgess.Michele@epa.gov or (703) 603-9003 if you have questions or concerns.

Attachment

1. "Recommendations for Using Blood Lead Data at Superfund Sites"

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Recommendations for Using Blood Lead Data at Superfund Sites and RCRA Corrective Action Facilities

OVERVIEW

The purpose of this document is to clarify the role of blood lead (PbB) data in Superfund lead risk assessments. This document provides the technical basis for appropriate uses of PbB data from various opportunistic monitoring programs and from specifically designed surveys at Superfund sites or Resource Conservation and Recovery Act (RCRA) corrective action facilities. The intended audience for this document is human health risk assessors, Superfund remedial project managers and on-scene coordinators, RCRA facility managers and others who are familiar with EPA Superfund lead risk assessment. For further background information on the use of PbB data in Superfund lead risk assessment, refer to U.S. EPA (1994a, 2003) or the Technical Review Workgroup for Metals and Asbestos (TRW) Lead Committee website (http://www2.epa.gov/superfund/lead-superfund-sites-technical-assistance). This document provides supplemental information to the policy established by Environmental Protection Agency (EPA) (1994c, 1998) directives concerning use of PbB data.

The Office of Land and Emergency Management (OLEM) recommends using the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) model as the primary risk assessment tool to support environmental cleanup decisions for residential scenarios at Superfund and RCRA Corrective Action Sites (U.S. EPA, 1994a, b, c, 1998). EPA does not require PbB information to add a site to the National Priorities List (NPL) or to take action at a lead site under the Superfund program. The IEUBK model is based on empirical data from numerous scientific studies of lead uptake and biokinetics, contact rates of children with contaminated media (*e.g.*, soil, air, water, food), and data on the presence and movement of environmental lead to predict a plausible distribution or geometric mean (GM) of PbB for a hypothetical child or population of children.[1] The predicted variability of PbB concentrations around the GM PbB is defined as the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, and measurement variability.[2] From this distribution, the IEUBK model estimates

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[1] See U.S. EPA (1994a) and Hogan et al. (1998) for further information.

[2] The IEUBK model uses a log-normal probability distribution to characterize this variability (U.S. EPA, 1994a). The biokinetic component of the IEUBK model output provides a central estimate (geometric mean) of PbB concentration, which is used to provide the geometric standard deviation (GSD). The GSD encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability. In the IEUBK model, the GSD is intended to reflect only individual PbB variability, not variability in PbB concentrations where different individuals are exposed to substantially different media

the risk (*i.e.*, probability) that a child's (or a population of children's) PbB concentration will exceed a certain level of concern (U.S. EPA, 1994a; White et al., 1998).

Blood lead data may be available from state or local health departments. Such data are often collected for public health monitoring to identify children at risk and intervene. However, these data are neither random nor directed to characterize exposure and are often referred to as opportunistic monitoring. PbB data from opportunistic monitoring are not typically collected as part of the Superfund site characterization because the data are not random or directed to characterize exposure, where the objective is to monitor PbB in a general population (opportunistic PbB monitoring is distinctly different from national surveys such as NHANES[3]). When paired with representative, site-specific environmental data (e.g., soil, house dust, etc.) that represent the typical, integrated exposure in a child's residence, however, these investigations can:

- Identify individual children with elevated PbB concentrations for public health evaluation;
- Aid preliminary prioritization of remediation at lead contaminated sites;
- Identify for further consideration site-specific factors and sources of lead and pathways of exposure to be evaluated in the risk assessment and IEUBK modeling at residential sites; and
- Support community education needs to mitigate exposures.

The TRW Lead Committee continues to recommend using the IEUBK model as the primary risk assessment tool to support environmental cleanup decisions for residential scenarios at Superfund sites. Furthermore, the TRW Lead Committee recommends that any community PbB surveys conducted as part of a Superfund remedial investigation be reviewed independently of the baseline human health risk assessment. In cases where measured PbB data vary significantly from IEUBK model predictions, the TRW Lead Committee should be contacted to further identify the sources of those differences (U.S. EPA, 1998).

INTRODUCTION

EPA recommends collection of representative environmental data to support remedial decisions at lead-contaminated sites (U.S. EPA, 1994c, 1998, 2003).From an assessment perspective, representative site-specific data that are predictive of the entire exposed population are essential for

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concentrations of lead. The recommended default value for GSD was derived from empirical studies with young children where both blood and environmental lead concentrations were measured (White et al., 1998).

[3] National Health and Nutrition Examination Survey (see http://www.cdc.gov/nchs/nhanes.htm) NHANES is part of CDC's National Biomonitoring Program which offers an assessment of nutritional status and the exposure of the US population to environmental chemicals and toxic substances. Biomonitoring studies for PbB provide physicians and public health officials with a reference value, so that they can determine if people have been exposed to higher levels of a lead than are found in the general population.

developing a risk assessment (as well as cleanup goals) that reflects the current or potential future conditions. The most common site-specific data collected during site characterization are media-specific lead concentration (*e.g.*, air, water, soil, dust). OLEM acknowledges that while environmental data required for site-specific risk assessment can support site decisions, supplemental community-specific information can be useful in supporting other non-Superfund or RCRA Corrective Action public health intervention at sites.

Since 1994, the IEUBK model has been recommended to be used as the primary tool to generate risk-based soil cleanup goals (preliminary remediation goals) at lead sites for current and future residential use (U.S. EPA, 1994c, 1998). The IEUBK model was designed to predict PbB concentrations in young children exposed to environmental concentrations of lead (e.g., soils, dust, air, water, etc.). Comparisons involving well-conducted blood and environmental soil lead studies have demonstrated reasonably close agreement between mean observed and predicted PbB concentrations for children with adequate exposure characterizations (Hogan et al., 1998; von Lindern et al., 2003).

Response actions can be taken using IEUBK model predictions alone, and PbB information from site-based investigations are not required. While providing useful information for some purposes described below,[4] such data generally should not be used alone for establishing long-term remedial or non-time-critical removal cleanup levels at lead sites (U.S. EPA, 1998). The IEUBK model can be used proactively to predict PbB from exposure and thus prevent elevated PbB in areas where exposures may occur in the future, whereas PbB data can only indicate that an exposure has already occurred. PbB information is more appropriately used for public health monitoring, identifying children at risk, and public health interventions (e.g., medical follow up, education and outreach efforts), than for human health risk assessment. PbB information complements EPA's risk assessment process (see Yeoh et al., 2012) (Yeoh, Woolfenden et al. 2012), and therefore the TRW recommends it be limited to the following uses at Superfund sites:

- *Identifying individual children with elevated PbB concentrations*

  PbB concentration data from site-specific investigations may be useful in identifying individual children at risk (U.S. EPA, 1998). This identification is most effective when PbB data are

[4] PbB monitoring studies which include representative data on lead levels in various environmental media (e.g., soil, dust, paint, water, food) and which obtain reliable demographics data (e.g., age, sex, race, mouthing frequency, dietary status, etc.) can provide valuable insights into the media and exposure pathways that are the primary sources of concern in a population. Such data allow comparison of site statistics (mean PbB, percent of the population above the CDC reference level, etc.) with corresponding national average statistics, in order to obtain a general sense of how much impact site contamination and other lead exposures may have caused in the population. Site statistics can be compared with health based objectives and guidelines in order to determine if population-based health goals are being exceeded.

collected in the late summer months, when PbB concentrations in children are highest in most communities with lead-contaminated soil (U.S. EPA, 1995a,b; Laidlaw et al., 2012; Zahran et al., 2013).

- *Aid preliminary prioritization of remediation at lead contaminated sites*

  PbB monitoring data can prioritize Time Critical Removal Actions (TCRA) to those residences with children or women of child-bearing age (U.S. EPA, 1998).

- *Identifying for further consideration site-specific factors, sources, and pathways to consider for additional sampling of environmental media to be evaluated in the risk assessment (i.e., IEUBK modeling) at residential sites*

  Information from PbB monitoring may identify potential data gaps in the environmental data collection. These gaps may include occupational "take home" exposures, crafts, or lead-based paint. The IEUBK model estimates risk of elevated PbB under the assumption of lognormality of PbB levels. The model supplies the starting point estimate of PbB taken as the geometric mean (GM) PbB, and generates a Pb distribution. Note that the appropriate comparison is between the measured PbB value (from the late summer months, when PbB concentrations in children are expected to be highest in most communities [U.S. EPA, 1995a,b; Laidlaw et al., 2012; Zahran et al., 2013]) and the prediction interval around the geometric mean PbB concentration predicted by the IEUBK model (see Hogan et al., 1998 for more information).

- *Identifying trends in exposure from longitudinal studies*

  Longitudinal PbB studies that are implemented over time may help identify exposure trends within a community and can help to assess the effectiveness of the cleanup along with other intervention strategies (U.S. EPA, 1998, 2003, (Von Lindern et al., 2003). If there is interest in assessing the effectiveness of the remedy, a study designed to meet this objective is necessary and consultation with the Centers for Disease Control and Prevention (CDC) and Agency for Toxic Substances and Disease Registry (ATSDR), Pediatric Environmental Health Specialty Units (PEHSUs),[5] as well as the state or local health district with respect to planning and funding such a program is strongly recommended.[6]

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[5] The U.S. Environmental Protection Agency supports the PEHSU by providing funds to ATSDR under Inter-Agency Agreement number DW-75-92301301-0. For more information see: http://aoec.org/pehsu/findhelp.html.

[6] The project team should consult with their regional human subjects research point of contact or the Agency's Human Subjects Research Review Official (HSRRO) prior to designing a blood lead study at a Superfund site. The regional human subjects research point of contact and the HSRRO can ensure EPA's responsibilities pertaining to

PbB SAMPLE COLLECTION AND ANALYTICAL CONSIDERATIONS

Blood lead monitoring programs are typically overseen by the CDC or by state or local health departments.[7] CDC has issued screening and case management guidelines for increasing intensity of health intervention activities based on PbB results. EPA (2003) recommends close collaboration among the involved agencies and with ATSDR to properly implement PbB monitoring at Superfund sites. Additionally, CDC's National Center for Environmental Health (NCEH) and many state and local health departments have ongoing lead screening as well as health education programs. Information from site-specific or targeted PbB monitoring at contaminated sites is valuable for targeting follow-up health education to individual families with children identified as having elevated blood lead levels and determining the area and demographic extent of elevated blood lead levels. The Attachment provides some examples of techniques that may be used to address the limitations of PbB studies.

The World Health Organization (WHO) has developed protocols for the collection and analysis of PbB surveys (WHO, 2011). In 2012, CDC adopted the Advisory Committee on Childhood Lead Poisoning Prevention (ACCLPP)'s recommendations to eliminate the term "level of concern" and use a blood lead reference value that is based on the 97.5th percentile of the National Health and Nutrition Examination Survey (NHANES) PbB distributions in children from 1 to 5 years of age.[8] Using the 2007–2010 NHANES, the PbB reference value associated with the 97.5th percentile is currently 5 μg/dL (ACCLPP, 2012). As blood lead levels have continued to decline in the U.S. population, more sensitive analytical methods have been required to reduce the rates of non-detect values. Therefore, for PbB monitoring at contaminated sites, the TRW Lead Committee currently recommends that labs primarily

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Human Subjects Research as specified in the Common Rule (40 CFR 26) and the Policy and Procedures on Protection of Human Subjects in EPA Conducted or Supported Research (EPA Order 1000.17 Change A1) are met.

[7] U.S. Department of Health and Human Services (DHHS), through CDC, provides grants to support childhood lead poisoning prevention programs. These grants, mainly to support secondary prevention efforts, are provided to State and local health departments. The National Center for Environmental Health (NCEH) also oversees CDC's Healthy Homes and Lead Poisoning Program by providing grants and technical assistance for States to develop laboratory-based monitoring systems to determine PbB concentrations in children (see http://www.cdc.gov/nceh/information/about.htmhttp://www.cdc.gov/nceh/information/about.htm for more information).http://www.cdc.gov/nceh/default.htm for more information).

[8] NHANES is a continuous program that is designed to assess the health and nutritional status of children and adults in the United States (http://www.cdc.gov/nchs/nhanes.htm). NHANES is the only source of periodic nationally-representative data on PbB concentrations in the U.S. population. Data from the NHANES are used to track trends in PbB concentrations, identify high-risk populations, and support regulatory and policy decisions. In the context of childhood PbB concentrations in the U.S., NHANES data provides an appropriate source for characterizing a reference value for in children 1-5 years old (CDC, 2012).

assess whole blood measurements (preferably using venous blood sampling)[9] including sample specificity and sensitivity adequate for the endpoint of interest, such as anodic stripping voltammetry (ASV), atomic absorption spectroscopy (AAS), and inductively coupled plasma mass spectrometry (ICP-MS) (U.S. EPA, 2006; Caldwell and Jones, 2010; WHO, 2011). The latest information on the recommended analytical method for blood lead monitoring is available from CDC (www.cdc.gov/nceh/lead).

UNCERTAINTY

PbB information derived from public health surveys or opportunistic monitoring are generally inappropriate for risk assessment, and such data generally should not be used to predict PbB in future populations,[10] for estimating IEUBK model parameters (including GSD), for evaluating IEUBK model predictions,[11] or for empirical comparison with the IEUBK model predictions because of the following characteristics of PbB surveys:

(1) PbB surveys are typically cross-sectional and single events, and provide a snapshot of current exposures that may not necessarily represent past or future site conditions or risks.[12] Results do not represent temporal variability (e.g., seasonality) in individual or population PbB (David et al., 1982; Rabinowitz et al. 1984; U.S. EPA, 1995a,b; Laidlaw et al. 2012; Zahran et al., 2013). In this regard, it is recommended that PbB data not be used to establish long-term remedial or non-time-critical removal cleanup goals (U.S. EPA, 1998). PbB studies are more representative if they are repeated for several years.

(2) PbB surveys typically lack paired environmental exposure data (i.e., dust and soil lead concentrations collected at the same time and from the residences of those individuals in the PbB survey). Because of the interpersonal variability in exposure frequency for various media, it is expected that PbB values will differ (either lower or higher) among and between individuals, even under the same environmental conditions. Thus, a PbB result below a level of concern in

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[9] According to Caldwell and Jones (2010): *"[t]ypically, labs collect venous blood samples for lead assessment; however, finger-stick capillary samples may prove to be equally useful. For the latter, the sample collection process must be performed carefully to avoid external contamination."*

[10] PbB survey data represent a snapshot in time and may not necessarily represent future risks (which are a component of remedial decision making for Superfund).Generally, it is not recommended that PbB concentration data to be used to establish long-term remedial or non-time-critical removal cleanup goals (U.S. EPA, 1998).

[11] It is generally not recommended that the results of a community PbB survey be used to evaluate or adjust specific IEUBK model parameters. Statistical models relating community PbB concentrations data to community media exposures are highly complex (e.g., Lanphear et al., 1998; Succop et al., 1998) and, as a result, attributing differences between predicted and observed PbB concentrations to specific IEUBK model parameters will be accompanied with large uncertainties.

[12] By contrast, IEUBK modeling can be used to predict future PbB (White et al., 1998).

one child living at a specific residence does not necessarily mean that child or some other child who might be exposed at the same location might not have a higher PbB level. PbB surveys are more powerful if they include contemporaneous, representative measures of environmental exposure media (soil, dust, drinking water, food, etc.).

(3) PbB survey data are most often collected as part of a voluntary program rather than from a statistically-based random selection study design and, therefore, may not represent the entire population of children at the site.[13] Typically voluntary PbB surveys do not achieve sufficient participation to be considered representative, and population-based studies are not well-suited for detecting the occurrence of occasional sub-locations where risk may be elevated, even if average risks are not above a level of concern (LOC). The Attachment provides some examples of techniques that may be used to address the limitations of PbB studies.

Because studies are difficult to design and interpret, consultation and collaboration with ATSDR and PEHSUs are recommended. Also, because such studies involve human subjects, the project team should consult with their regional human subject's research point of contact or the Agency's Human Subjects Research Review Official (HSRRO) prior to designing a blood lead study at a Superfund site. The regional human subjects research point of contact and the HSRRO can ensure EPA's responsibilities pertaining to Human Subjects Research as specified in the Common Rule (40 CFR 26) and the Policy and Procedures on Protection of Human Subjects in EPA Conducted or Supported Research (EPA Order 1000.17 Change A1) are met. In addition, IRB approval by CDC and survey approval by OMB (2006) may be necessary (http://www.whitehouse.gov/sites/default/files/omb/inforeg/pmc_survey_guidance_2006.pdf).

RECOMMENDATIONS

EPA does not require that PbB data be collected to take action and should not be used for establishing long-term remedial cleanup goals, non-time critical removal levels or for site-specific lead risk assessment. The IEUBK model is the primary risk tool. PbB data from opportunistic monitoring can be used to help identify site-specific exposure pathways and to direct public health intervention to individuals needing immediate assistance in reducing lead exposure. However, EPA (1998) recommends

[13] PbB surveys typically cannot be used to assess the impact of education and awareness of lead exposure on PbB in a community. However, there are exceptions, such as states where PbB sampling is required by state law for young children.

that, "... *blood lead data not be used alone to assess risk from lead exposure or to develop soil lead cleanup levels.*"

The utility of PbB data for more than public health monitoring at Superfund sites depends on how representative the information is of the site population, the design of the data collection, and the quality of the laboratory analysis. Similarly, the utility of IEUBK model predictions depends on the representativeness of the exposure data input into the model. To this end, the TRW Lead Committee recommends that EPA Regions consult with ATSDR or CDC to assess, design, and analyze PbB monitoring programs for their intended use. Furthermore, the TRW Lead Committee recommends the Data Quality Objectives (U.S. EPA, 2006) process to provide a structured data (including both environmental and biomonitoring) collection approach to yield defensible and reproducible results to support site decisions.

The TRW Lead Committee continues to recommend using the IEUBK model as the primary tool for site-specific risk assessment to support environmental cleanup decisions for residential scenarios at Superfund and RCRA Corrective Action Sites (U.S. EPA, 1994a,c, 1998). The TRW recommends that PbB information be reviewed independent of the site risk assessment. With adequate design and representative sampling, measured PbB data and IEUBK model predictions (specifically the prediction interval around the geometric mean)[14] are expected to show a general concordance for most sites. However, some deviations between measured and predicted levels are expected. This can be caused by errors or uncertainty in the IEUBK model input parameters, the representativeness of the exposure data (including non-environmental lead sources), or the representativeness of the PbB concentrations (Mushak, 1998).

When there is a discrepancy between PbB data and IEUBK model results, the TRW Lead Committee notes that it may not be possible to reconcile the difference between PbB data and IEUBK model results because of limitations of the PbB study and the environmental samples that were taken.[15]

[14] See Hogan et al., 1998.

[15] Cross-sectional PbB studies need to avoid designs that may inadvertently incorporate interventional features and thus, influence PbB levels they seek to measure. A principal concern regards investigations in which significant contacts with study participants occur at times in advance of the collection of PbB samples. For example, if residential lead sampling, briefings on study purposes, interviews, or consent forms are completed prior to PbB sampling, these activities may lead parents to alter practices regarding household cleaning or supervision of children. These actions could subsequently lead to changes in their children's PbB concentrations. Changes in parental behavior may result from direct information (e.g., being told that a lead risk is present in their community), implicit information (e.g., being asked to answer a series of questions about their child's behavior or their household cleaning practices), or by inference (from the knowledge that their home and child will soon be screened by expert personnel). There is evidence that individual contacts with parents can contribute to the success of intervention efforts seeking to reduce children's lead exposures. Accordingly, a PbB investigation that includes significant

Data for households where high PbB values were observed, but not predicted, may reveal some additional sources of exposure (such as parental occupation, hobbies, or lead-based paint exposures to children). Additionally, children may live on relatively clean lots, but be in proximity to or frequently visit more contaminated areas. Factors that reduce the exposure of children to the contaminated areas (hand washing, soil cover, etc.) may result in a measured community PbB that is lower than predicted by the IEUBK model. A small degree of over prediction by the IEUBK model may be due to the general protectiveness that is built into the IEUBK model exposure assumptions. If observed PbB levels are below the risk management goal for the site, then modeling would be working as intended. The TRW Lead Committee may be consulted to further identify the source of those differences (U.S. EPA, 1998).

The TRW Lead Committee encourages risk assessors to collaborate with local and state health officials, as well as ATSDR and PEHSUs, to interpret existing PbB data from opportunistic monitoring in communities impacted by lead at Superfund sites and to work with ATSDR and PEHSUs to determine whether a PbB study is appropriate and feasible for the impacted community.

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contact with parents in advance of PbB collections may result in unintended interventional effects on PbB concentrations. If a parent's awareness of potential risk decreases and the behavioral modifications cease, then higher levels of lead exposure may occur in the future, resulting in elevated PbB concentrations.

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ATTACHMENT: Information on Techniques to Address Limitations of Blood Lead Data

1. Maximize participation
   a. Finite population error is inversely proportional to participation rate; 100% participation is zero error
   b. High participation reduces self-selection biases
2. Reduce temporal variability
   a. Limit blood lead measures to capture summer peak
3. Attempt to match blood lead with contemporaneous environmental data (von Lindern et al., 2003a,b)
   a. Soil – immediate, adjacent, and community samples
   b. Indoor dust
   c. Water
   d. Local food
4. Develop multi-year repeated samples for large sites
   a. Properties without associated blood lead measure in one year may have PbB data for other years
5. Conduct exposure questionnaire to survey families of all children
   a. Age, lead in representative environmental samples, income, occupational exposure, hobbies, housing type and condition, recreation
   b. Assess differences between participants and refusals

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