APPENDIX E
Blood Lead Concentrations

BLOOD LEAD MONITORING

The IEUBK model was designed to predict typical blood lead concentrations representative of a population of young children exposed to environmental concentrations of lead. Representative site-specific data that are predictive of the entire exposed population are essential to accurately reflect 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) and soil or dust lead bioavailability of lead in soil.

EPA recommends collection of representative environmental data to support remedial decisions (U.S. EPA, 2003a, 1998a, 1994a), but EPA does not require blood lead information to list a site on the NPL or to take action at a lead site under the Superfund program. Blood lead information at Superfund sites may supplement the environmental data and can be useful in prioritizing response actions.

The IEUBK model predicts likely blood lead levels from current or potential exposure and helps to prevent elevated blood lead now or in the future. Because opportunistic monitoring typically associated with childhood lead poisoning prevention screening is not typically designed as a statistical sample of blood lead in a community, blood lead data from opportunistic monitoring are not typically included quantitatively in the Superfund site characterization. Information regarding blood lead 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 site assessment or risk assessment. Blood lead level information may be acquired from state or local health departments. Such data are often collected for public health monitoring. Blood lead information complements EPA's risk assessment process (see Yeoh et al., 2012) when paired with representative, site-specific environmental data, and can be effectively used at Superfund sites by:

- **Identifying individual children with elevated blood lead concentrations for public health intervention.** Blood lead data that can be paired with environmental sampling information from site-specific investigations may be useful in identifying individual children at risk (U.S. EPA, 1998a). This is most effective when blood lead data are collected at the time when blood lead levels peak for the population of interest, which may be in the late summer months, when blood lead concentrations in children are highest in many communities with lead-contaminated soil (Zahran et al., 2013a; Laidlaw et al., 2012; U.S. EPA, 1995a,b). It may be possible to acquire this information from state or local health departments.

- **Prioritizing cleanup actions at lead contaminated sites.** Blood lead data can be helpful in prioritizing Time-Critical Removal Actions (TCRA) at those residences with children or

women of child-bearing age (U.S. EPA, 1998a) and in identifying specific residential areas that do not warrant immediate action.

- **Identifying site-specific demographic and exposure variables, sources of lead exposure and pathways of exposure, and informing decisions for additional sampling of environmental media.** Blood lead information can potentially identify other sources of lead exposure. These other sources of lead exposure may include occupational "take home" exposures such as crafts or lead-based paint.

- **Identifying trends in exposure from longitudinal studies, and support community education needs to mitigate exposures.** Longitudinal blood lead studies that are implemented over time may help identify exposure trends within a community and can assess the effectiveness of the cleanup and other intervention strategies (U.S. EPA, 2003a, 1998a). If there is interest in assessing the effectiveness of the remedy, a study designed to meet this objective is necessary and consultation with CDC and ATSDR, and Pediatric Environmental Health Specialty Units (PEHSUs), as well as the state or local health districts with respect to planning and funding such a program, is strongly recommended.[1] When designing such studies, it is important to ensure that EPA will have access to the blood lead sampling results so that the results can be paired with environmental sampling results.

Blood lead monitoring is temporal and can be expected to vary with the season and current exposure conditions. In general, on-going blood lead testing would generally be done under other authorities and no part of the CERCLA response.

SAMPLE COLLECTION AND ANALYTICAL CONSIDERATIONS

Blood lead monitoring/screening programs are generally not implemented by EPA, but specific EPA Regions have provided funding in the past through a grant to the state or local health department. Blood lead surveillance programs are more typically operated and overseen by the CDC, state or local health departments.[2] CDC has issued screening and case management guidelines for increasing intensity of health intervention activities based on blood lead results (see http://www.cdc.gov/nceh/lead/publications/#screening). EPA (2003a) recommends close collaboration among the involved agencies and with ATSDR to properly implement monitoring at Superfund sites. Additionally, CDC's National Center for Environmental Health (NCEH) and

[1] The project team should consult with their regional human subjects research point of contact or the EPA'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.

[2] U.S. Department of Health and Human Services, 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 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 blood lead concentrations in children (see http://www.cdc.gov/nceh/information/about.htm for more information.

many state and local health departments have ongoing blood lead screening, as well as health education programs. Information from site-specific or targeted blood lead 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 under other authorities from CERCLA.

Where local or state screening programs are not anticipated, working with state health and social service agencies and local health care providers may support additional targeted blood lead screening. In identified high risk areas, targeted blood lead screening of children may also be recommended and funded as part of Early and Periodic Screening Diagnostic and Testing Service under Medicaid (Wengrovitz and Brown, 2009). Further information is available at https://www.medicaid.gov/medicaid/benefits/epsdt/index.html.

The World Health Organization (WHO) has developed collection and analysis protocols for blood lead surveys (WHO, 2011). In 2012, CDC adopted ACCLPP's recommendations to eliminate the term "level of concern" and use a blood lead reference value (BLRV) that is based on the 97.5th percentile of the NHANES blood lead distributions in children from one to five years of age (CDC, 2012).[3] In 2012, the BLRV was established using the 2007–2010 NHANES data and the 97.5th percentile was equal to 5 µg/dL. In 2021, the evaluation of 2015-2016 and 2017-2018 NHANES data established an updated BLRV of 3.5 µg/dL.

UNCERTAINTIES AND LIMITATIONS

Blood lead data from public health surveys or opportunistic monitoring are generally inappropriate for risk assessment, and such data generally should not be used to predict blood lead concentrations in future populations,[4] for estimating IEUBK model parameters (including GSD), for evaluating IEUBK model predictions,[5] or for empirical comparison with the IEUBK model predictions because of the following characteristics of blood lead surveys:

[3] 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 blood lead concentrations in the U.S. population. Data from the NHANES are used to track trends in blood lead concentrations, identify high-risk populations, and support regulatory and policy decisions. In the context of childhood blood lead concentrations in the United States, NHANES data provides an appropriate source for characterizing a reference value for in children 1–5 years old (CDC, 2012).

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

[5] It is generally not recommended that the results of a community blood lead surveys be used to evaluate or adjust specific IEUBK model parameters. Statistical models relating community blood lead 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 blood lead concentrations to specific IEUBK model parameters will be accompanied with large uncertainties.

(5) Blood lead 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.[6] Results do not represent temporal variability (*e.g.*, seasonality) in individual or population blood lead concentration (Zahran et al., 2013a; Laidlaw et al., 2012; U.S. EPA, 1995a,b; David et al., 1982; Rabinowitz et al., 1974). In this regard, it is recommended that blood lead data not be used to establish long-term remedial or non-time-critical removal cleanup goals (U.S. EPA, 1998a). Blood lead studies are more representative if they are repeated for several years.

(6) Blood lead 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 blood lead survey). In most cases, health agencies do not include EPA in their consent forms so that blood lead information can be paired with environmental sampling information that is needed to evaluate the association between environmental and blood lead. Moreover, because of the interpersonal variability in exposure frequency for various media, it is expected that blood lead will differ among and between individuals, even under the same environmental conditions.

(7) Blood lead surveys are voluntary rather than based on a statistically random selection study design and may not represent the entire population of children at the site.[7] Typically, voluntary blood lead surveys do not achieve sufficient participation for detecting the occurrence of occasional sub-locations where risk may be elevated, even if average risks are not above a target blood lead level.

Well-designed blood lead studies that attempt to pair environmental and blood lead data and use statistically proven techniques may be initiated and funded by EPA if the project team believes that the data will inform site decisions. However, due to the difficulties in designing and interpreting blood lead studies, consultation and collaboration with CDC, ATSDR and PEHSUs is recommended.

In the event that EPA contributes to funding blood lead studies, 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 U.S. EPA Conducted or Supported Research (U.S. EPA Order 1000.17 A) are met. In addition, Institutional

[6] By contrast, IEUBK modeling can be used to predict future blood lead concentrations (White et al., 1998).

[7] Blood lead surveys do not accurately reflect the impact of education and awareness of lead exposure on blood lead concentrations in a community. However, there are exceptions, such as states where blood lead sampling is required by state law for young children.

Review Board approval and survey approval by the Office of Management and Budget (OMB, 2006) may be necessary.