FINAL

User's Guide for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) Version 2.0¹

Prepared for

The Technical Review Workgroup (TRW) Lead Committee

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¹ This Guidance Manual is designed to assist with the most current version of the IEUBK (version 2.0), updates to the IEUBK model software may result in differences in the results shown in screenshots and example calculations. It is the responsibility of the user to verify that the latest version of the software is being used. The most current version can be downloaded on the Technical Review Workgroup (TRW) website at: https://www.epa.gov/superfund/lead-superfund-sites-software-and-users-manuals.

DISCLAIMER

This document provides technical and policy guidance to EPA staff for contaminated sites. It also provides information to the public and to the regulated community on how EPA intends to exercise its discretion in implementing its regulations at contaminated sites. The guidance is designed to implement national policy on these issues. The document does not, however, substitute for EPA's statutes or regulations, nor is it a regulation itself. Thus, it cannot impose legally-binding requirements on EPA, States, or the regulated community, and may not apply to a particular situation based upon the circumstances. Rather, the document suggests approaches that may be used at particular sites, as appropriate, given site-specific circumstances. EPA may change this guidance in the future, as appropriate.

U.S. Environmental Protection Agency Technical Review Workgroup Lead Committee

MEMBERS

The members and participants of the Technical Review Workgroup Lead Committee (TRW) are technical staff from EPA Regions, EPA Program Offices and Agency for Toxic Substances and Disease Registry. TRW Lead Committee members and participants generally have an active interest and recognized scientific expertise in metals risk assessment. For more information see: https://www.epa.gov/superfund/lead-superfund-sites-technical-assistance.

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GLOSSARY

- Absolute Bioavailability (ABA) The ratio of the amount of lead absorbed compared to the amount ingested: ABA = (Absorbed Dose) / (Ingested Dose). (See also Relative Bioavailability)
- Absorbed dose The amount of a substance penetrating an absorption barrier (the exchange boundaries) of an organism, via either physical or biological processes.
- Absorption barrier Any of the exchange barriers of the body that allow differential transport of various substances across a boundary. Examples of absorption barriers are the skin and the epithelium of the respiratory and gastrointestinal tracts.
- Absorption Fraction (AF) The fraction of bioaccessible lead entering the body through the respiratory or gastrointestinal (GI) tracts that is absorbed into the systemic circulation.
- Accuracy The measure of the correctness of data, as given by the difference between the measured value and the true or standard value.
- Adult Lead Methodology (ALM) A mathematical equation used by EPA to predict the lead concentration in soil that would be appropriate for non-residential areas (for example, industrial or commercial areas) where children are not likely to live or play.
- Ambient Surrounding conditions.
- Ambient measurement The measurement (usually of the concentration of a chemical or pollutant) taken in an ambient medium, normally with the intent of relating the measured value to the exposure of an organism that contacts that medium.
- Ambient medium One of the basic categories of material surrounding or contacting an organism (e.g., air, water, soil, or dust) through which chemicals or pollutants can move and reach the organism. (Synonymous with environmental medium.)
- Arithmetic mean The sum of all the measurements in a data set divided by the number of measurements in the data set.
- Bioaccessibility The physiological solubility of the metal at a portal of entry into the body (lung, gut, skin).
- Bioavailability The fraction of intake at a portal of entry into the body (lung, gut, skin) that enters the blood. Bioavailability is typically a function of chemical properties, physical state of the material that an organism ingests or inhales, and ability of the individual organism to physiologically absorb the chemical. The absorption rate varies widely by type of substance and can greatly influence the toxicity of lead over that acute timeframe.

- Biokinetics Processes affecting the movement of molecules from one internal body compartment to another, including elimination from the body.
- Biokinetic Module Component of the IEUBK model that includes mathematical expressions of the movement of absorbed lead throughout the body over time by physiologic or biochemical processes.
- Comparability The ability to describe likenesses and differences in the quality and relevance of two or more data sets.
- Compartment A distinct organ, tissue, fluid pool, or group of tissues within the body that are "kinetically homogeneous."
- Dose The amount of a substance available for interaction with metabolic processes or biologically significant receptors after crossing the outer boundary of an organism. The potential dose is the amount ingested, inhaled, or applied to the skin. The applied dose is the amount of a substance presented to an absorption barrier and available for absorption (although not necessarily having yet crossed the outer boundary of the organism). The absorbed dose is the amount crossing a specific absorption barrier (e.g., the exchange boundaries of skin, lung, and digestive tract) through uptake processes; internal dose is a more general term denoting the amount absorbed, without respect to specific absorption barriers or exchange boundaries. The amount of the chemical available for interaction by any particular organ or cell is termed the delivered dose for that organ or cell.
- Environmental medium See Ambient medium.
- Exposure Contact of a chemical, physical, or biological agent with the outer boundary of an organism. Exposure is quantified as the concentration of the agent in an ambient or environmental medium in contact integrated over the time duration of that contact.
- Exposure Module Component of the IEUBK model that converts exposure to intake rates of lead in units of $\mu g/day$.
- Exposure scenario A set of facts, assumptions, and inferences about how exposure takes place that aids the exposure assessor in evaluating, estimating, or quantifying exposures.
- Gastrointestinal (GI) Of or relating to the GI tract, or affecting stomach and/or intestine.
- Geometric Mean (GM) The GM equals the exponential function of the arithmetic average of the log-transformed sample data.
- Geometric Standard Deviation (GSD) -The GSD is a dimensionless variable that equals the exponential function of the standard deviation of the log-transformed sample data.

- Geometric Standard Deviation (interindividual) (GSDi) -The GSD used in the IEUBK model that reflects the expected variability in blood lead concentration among children exposed to similar concentrations of environmental lead.
- IEUBK Model Integrated Exposure Uptake Biokinetic Model for Lead in Children.
- Intake The process by which a substance crosses the outer boundary of an organism without passing an absorption barrier (e.g., through ingestion or inhalation). (See Potential dose)
- In Vitro Bioaccessibility (IVBA) The IVBA provides a rapid and relatively inexpensive alternative to *in vivo* assays for predicting RBA of lead in soils and soil-like materials. The method is based on the concept that lead solubilization in gastrointestinal fluid is likely to be an important determinant of lead bioavailability *in vivo*. The method measures the extent of lead solubilization in an extraction solvent that resembles gastric fluid. The fraction of lead which solubilizes in an *in vitro* system is referred to as IVBA, which may then be used as an indicator of *in vivo* relative bioavailability.
- Lead concentration The mass of lead per mass or volume of a medium, typically reported as micrograms per gram ($\mu g/g$ or ppm) for soil and dust, micrograms per liter ($\mu g/L$ or ppb) for water, micrograms per cubic meter ($\mu g/m^3$) for air, and micrograms per deciliter ($\mu g/dL$) for blood.
- Mass Fraction of Soil to Dust (M_{SD}) The mass fraction of house dust that is derived from outdoor soil (g soil/g dust). It is used in Multiple Source Analysis to compute the contribution of outdoor soil Pb to the indoor dust Pb concentration. The default value for M_{SD} recommended by EPA is 0.70 g soil/g dust (<u>Section 2.3.4.3, Lead in Dust</u>).
- Pathway The physical course a chemical or pollutant takes from the source to the organism exposed.
- Potential dose The amount of a chemical contained in material ingested, air breathed, or bulk material applied to the skin. (See also Intake)
- Precision A measure of the reproducibility of a measured value under a given set of conditions.
- Probability Distribution Module Component of the IEUBK model that produces a distribution of blood lead concentration to describe the variability in blood lead concentration for children with similar exposure to lead. The distribution of blood lead concentration is modeled with a lognormal distribution that is specified by the IEUBK-predicted geometric mean (GM) blood lead concentration and the geometric standard deviation (GSD).
- Range The difference between the largest and smallest values in a measurement data set.

- Relative Bioavailability (RBA) The ratio of the Absolute Bioavailability (ABA) of lead present in some test material compared to the ABA of lead in an appropriate reference material such as soluble lead acetate: RBA = ABA(test) / ABA(reference).
- Representativeness The degree to which a sample is, or samples are, characteristic of the medium, exposure, or dose of the target population for which the samples are being used to make inferences.
- Risk The probability of deleterious health or environmental effects.
- Route The way a chemical or pollutant enters an organism after contact (e.g., by ingestion, inhalation, or dermal absorption).
- Sample A small part of something designed to show the nature or quality of the whole.

 Exposure-related measurements are usually samples of environmental or ambient media, exposures of a small subset of a population for a short time, or biological samples, all for the purpose of inferring the nature and quality of parameters important to evaluating exposure.
- Uptake The process by which a substance crosses an absorption barrier and is absorbed into the body; (μg/day) is the quantity of lead absorbed per unit time from portals of entry (gut, lung) into the systemic circulation of blood.
- Uptake Module Component of the IEUBK model that models the process by which lead intake (lead that has entered the child's body through ingestion or inhalation) is transferred to the blood plasma.

ACRYNOMNS AND ABBREVIATIONS

ABA <u>Absolute Bioavailability</u>

AF <u>Absorption Fraction</u>

ALM <u>Adult Lead Methodology</u>
BAC Bioavailability Committee

CDC <u>Centers for Disease Control and Prevention</u>

CERCLA Comprehensive Environmental Response Compensation Liability Act

dL deciliter

DU Decision Unit ECF Extracellular Fluid

EPA U.S. Environmental Protection Agency

FDA Food and Drug Administration

g gram

GI <u>Gastrointestinal</u>
GM Geometric Mean

GSD Geometric Standard Deviation

GSD_i Geometric Standard Deviation, Interindividual

ID Dust Intake

IEUBK Integrated Exposure Uptake Biokinetic Model for Lead in Children, Windows

version

IVBA In Vitro Bioaccessibility

L liter

m³ cubic meters

MSA Multiple Source Analysis
MSD Mass Fraction of Soil to Dust

NCP National Oil and Hazardous Substances Pollution Contingency Plan

NHANES National Health and Nutrition Examination Survey

ORD Office of Research and Development

OSRTI Office of Superfund Remediation and Technology Innovation

OSWER Office of Solid Waste and Emergency Response

Pb Lead

PbB Blood Lead PbD Dust Lead PbS Soil Lead

PC Personal Computer ppm Parts per Million

PRG Preliminary Remediation Goal

RBA Relative Bioavailability

RCRA Resource Conservation and Recovery Act

TRW <u>Technical Review Workgroup Lead Committee (for Metals and Asbestos)</u>

UCL Upper Confidence Limit

μg microgram

1.0 Introduction

The Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) was developed in the late 1980s and early 1990s in response to a need to evaluate lead (Pb) exposure in children at potential Superfund sites. The IEUBK model was designed as an alternative to multiple regression models, which in practice, have been difficult to apply to situations beyond those where the data were specifically collected.

The <u>IEUBK model</u>² is a stand-alone, Microsoft Windows-compatible, software package that utilizes four interrelated modules (exposure, uptake, biokinetic, and probability distribution) to estimate blood lead (PbB) levels in children (under 7 years old) who are exposed to Pb-contaminated media. The IEUBK model uses data from a variety of scientific studies of Pb biokinetics, contact rates of children with contaminated media, and data on the presence and behavior of environmental Pb.

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

The July 14, 1994, Office of Land and Emergency Management [formerly the Office of Solid Waste and Emergency Response (OSWER)] Revised Interim Soil Lead Guidance for Comprehensive Environmental Response Compensation Liability Act (CERCLA) Sites and Resource Conservation and Recovery Act (RCRA) Corrective Action Facilities (EPA, 1994a), and the subsequent August 1998 OSWER Clarification to the 1994 Revised Interim Soil Lead (Pb) Guidance for CERCLA Sites and RCRA Corrective Action Facilities (EPA, 1998a) recommended the use of IEUBK v1 as a risk assessment tool. The development of the IEUBK v1 model included Independent Validation and Verification and a limited peer review of the

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² This Guidance Manual is designed to assist with the most recent version of the IEUBK (version 2.0). It is the responsibility of the user to verify that the latest version of the software is being used. The most recent version can be downloaded on the TRW website at https://www.epa.gov/superfund/lead-superfund-sites.

software and documentation. The model was updated in 2021 to incorporate up-to-date data for six national default exposure parameters, as well as to modernize the software and user interface. Due to changes to key parameters, most notably the soil and dust ingestion rate, the model was evaluated to ensure that it accurately predicts blood lead levels in children for the purpose of assessing risk for residential hazardous waste sites.

Additional guidance that addresses the application of the IEUBK model is available on the Technical Review Workgroup (TRW) Lead Committee's <u>website</u>.

1.1 Purpose of the Guidance Manual

This manual is a <u>User's Guide</u> intended to serve as a comprehensive reference and an instructional guide for use of IEUBK. It provides the basics needed for appropriate application and interpretation of the model, including how to install and run the model, and interpret model results. This Guide provides the minimum requirements for risk assessment applications with example scenarios. Users of the model can refer to the IEUBK Structure Paper (White et al., 1998) for supplemental information concerning the parameters and correct application of IEUBK. Additional help is available from <u>Pbhelp@epa.gov</u>.

1.2 Overview of the IEUBK Model

The purpose of the IEUBK model is to predict PbB concentrations in a population of children exposed to Pb from several sources and by multiple exposure routes. The Model addresses four components of environmental risk assessments:

- (1) Multimedia nature of exposures to Pb
- (2) Pb uptake
- (3) Biokinetics
- (4) Variability in exposure and risk, through estimation of probability distributions of PbB levels for children exposed to similar environmental concentrations.

The Model first estimates a longitudinal exposure pattern (up to 84 months), from birth to the age of interest, by using default or user entered measured inputs to calculate exposure in appropriate settings. The Model accepts exposure data for environmental media to characterize a cumulative exposure. The TRW Lead Committee recommends the 12-72 month age range

be used to assess lead risk at Superfund sites (<u>U.S. EPA, 2017</u>). The Model then predicts Pb uptake and a distribution of PbB for a hypothetical child or population of similarly exposed children. The PbB distribution incorporates variability associated with repeat sampling, and inter-individual and biological variability, as determined from community PbB studies of children's residential settings.³

It is beyond the scope of this document to describe the scientific basis of the Model in detail. See EPA (1994c) and EPA (2020a) for documentation of the equations and parameter values used and the sources of data considered. In order to estimate parameters directly, the Model is based on human data, where possible. The absorption algorithm was based on data from Pb balance and feeding studies in human infants and children. The exact value of parameters within the measured ranges was selected using comparisons with human data from cross-sectional studies. The compartmental structure of the IEUBK v1 was based on earlier models for Pb in adults (Harley and Kneip, 1985).

The Model does not aim to reproduce the observed PbB level for any specific child or community blood lead levels because of the practical limitations of default exposure characterizations, uncertainty in site-specific exposure, variability in behavior and variability in uptake and biokinetics (White et al., 1998). Most importantly, the Model is not a substitute for medical evaluation of an individual child.

The Model is a four-step process that mathematically and statistically links environmental Pb exposure to PbB concentrations for a population of children (0-84 months of age) Figure 1-1 provides a schematic showing the sources of exposure to environmental Pb and the absorption and processing of Pb by the human body. The four model components (i.e., exposure, uptake, biokinetics, and variability) each reflect a different aspect of the overall biologic process.

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³ Consistent with measurements of other metals in tissues of human populations, the distribution of PbB levels for any relatively homogeneous population closely follows a lognormal distribution with as GSD of 1.6 (USEPA, 1986a). A lognormal distribution is completely specified by its GM and GSD.

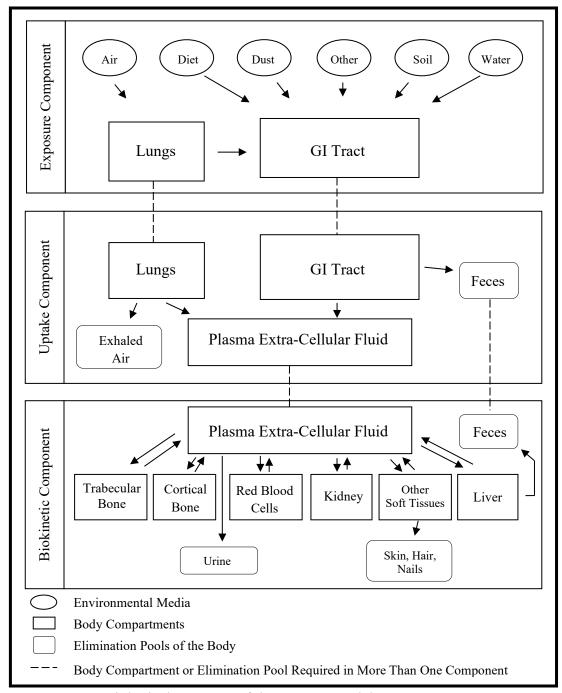


FIGURE 1-1. Biological Structure of the IEUBK Model.

1.2.1 Exposure Component

Exposure can be thought of as the contact with a chemical or other agent, which may result in the absorption or exchange across boundaries of an organism, such as the gut, lungs, and

skin. The results from the exposure component of the IEUBK model are estimated intake rates for the quantities of Pb inhaled or ingested from environmental media. The media addressed by the IEUBK model include soil, house dust, drinking water, air, and food. Paint is usually addressed in terms of its contribution to the measured concentration of Pb in soil or house dust.

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

Pb Intake Rate = Media Pb Concentration * Media Intake Rate

The values used for media Pb concentrations and media intake rates are either derived from site-specific data or standard default values established by the U.S. Environmental Protection Agency (EPA) (see Table 1-1). The media intake rates are age-specific (see Table 1-2). The Exposure Module calculates the intake of Pb from each medium for use in the Uptake Module.

TABLE 1-1. Media Concentration for Input

Parameter	Recommendation	Additional Information
<u>Soil</u>	Generally, soil should be sampled, and site-specific soil Pb concentration data are recommended to derive site-specific output.	
<u>Dust</u>	Site-specific data recommended or input value can be derived from soil concentration using multiple source analysis.	Refer to Section 2.3.4 for additional information on this input parameter.
Air	$0.1 \mu g/m^3$ (default)	Default ratio of indoor to outdoor air Pb concentration is 30%. Sitespecific data may be substituted.
<u>Drinking Water</u>	Site-specific data recommended. Default value of 0.9 µg/L may be used	Site-specific data should be used for greater accuracy.

TABLE 1-2. Media Intake or Ingestion Rates (Pb Intake Rate = Media Pb Concentration*Media Intake Rate)

Parameter	Units	Age Range (Years)	Value	Suggested Action
		0<1	0.086	Default intake values are
		1<2	0.094	recommended. The default intake
		2<3	0.067	value for total soil and dust ingestion
Soil/Dust	g/day	3<4	0.063	is a ratio of soil ingestion (45%) to
		4<5	0.067	dust ingestion (55%).
		5<6	0.052	
		6<7	0.055	
		0<1	0.40	Default values recommended.
		1<2	0.43	
Duintrin a	L/day	2<3	0.51	
<u>Drinking</u>		3<4	0.54	
<u>Water</u>		4<5	0.57	
		5<6	0.60	
		6<7	0.63	
		0<1	2.66	Site-specific data may be used to
		1<2	5.03	augment the default intake rates.
		2<3	5.21	
<u>Diet</u>	μg Pb/day	3<4	5.38	
		4<5	5.64	
		5<6	6.04	
		6<7	5.95	
Alternate		Site-specific data may		Refer to Section 2.3.6 for further
Sources	μg/day	account for intakes o		discussion.
Boarces		other sources	S.	

1.2.2 Uptake Component

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

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

Pb Uptake Rate = Pb Intake Rate * Absorption Factor

The Pb intake rates are calculated by the Exposure Module, and the absorption factors are typically standard default values established by EPA. The Pb intake rates and absorption factors are both age- and media-specific. Absorption factors reflect the percentage of Pb that enters the bloodstream after intake from a specific environmental medium. The overall Pb uptake value can be obtained by summing the media-specific Pb uptake values. At high doses, the absorption factors are modified to account for saturation effects in the gut (O'Flaherty et al., 1996). Additional information on bioavailability is available on the TRW <u>BAC</u> website. The total rate of Pb uptake is calculated for use in the Biokinetic Module.

1.2.3 Biokinetic Component

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

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

1.2.4 Variability

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

The Probability Distribution Module estimates a plausible distribution of PbB concentrations that is centered on the GM PbB concentration calculated by the Biokinetic Module. From this distribution, the model calculates the probability or risk that a child's PbB concentration will exceed a user-selected PbB level of concern (e.g. $5~\mu g/dL$). In running this portion of the model, the user specifies a PbB level of concern and a GSD. For most sites, EPA recommends use of the default values for both the GSD and PbB level of concern.

Additional <u>guidance</u> and <u>contact information</u> is available from of the <u>TRW website</u> (<u>https://www.epa.gov/superfund/lead-superfund-sites</u>).

1.2.5 Model Evaluation

As with all model applications, it is important that users of the IEUBK model understand its fundamental strengths and limitations, the process by which the numerical accuracy of model predictions has been evaluated, and the extent to which model predictions are supported by comparisons with real-world data. The process of model evaluation addresses this range of considerations, all of which bear on the level of confidence that users can have in model predictions. In broad terms, an evaluation of a model should included the following considerations (EPA, 2009):

(1) The scientific foundations of the model structure: Does the model adequately represent the biological and physical mechanisms of the modeled system? Are these mechanisms understood sufficiently to support modeling?

- (2) Adequacy of parameter estimates: How extensive and robust are the data used to estimate model parameters? Does the parameter estimation process require additional assumptions and approximations?
- (3) Verification: Are the mathematical relationships posited by the model correctly translated into computer code? Are model inputs free from numerical errors?
- (4) Empirical comparisons: What are the opportunities for comparison between model predictions and data, particularly under conditions under which the model will be applied in assessments? Are model predictions in reasonable agreement with relevant experimental and observational data?

2.0 Loading and Starting the Model

The updated model (v2) software can be downloaded from the TRW Lead Committee website (https://www.epa.gov/superfund/lead-superfund-sites-software-and-users-manuals). The following files are installed when the Model is installed. The files are loaded as described in the IEUBK model SRD and Data Flow Document (EPA 2020a,b).

CustomInstaller. exe	CustomInstaller.InstallState	IEUBK.exe	IEUBK.ICO
IEUBKHelp.pdf	splash.bmp	Version.txt	AIR.INP
BatchRunV2.0.DAT	DIET.INP	GIBIO.INP	MATERNAL.INP
MULTI.INP	OTHER.INP	SOIL.INP	WATER.INP
MultiRun.con	MultiRun.lay	MultiRun.txt	RunModel.cmt
RunModel.grf	RunModel.txt		

The "IEUBK.EXE" file is the main program file; the "*.INP" files contain the default values for the *Parameter Input* pull-down options; and the "BatchRunV2.0.dat" file is the example input file for batch mode runs. The IEUBK.exe, *.bmp and *.ICO image files, CustomInstaller.exe and CustomInstaller.InstallState, IEUBKwinHelp.pdf and the Version.txt (documents version and build of the IEUBK executable file) can be found in the folder where the Model was installed while the *.INP and *.DAT files are added to the 'Input' folder that is created in the folder where the model is installed. The exact location of the files depends on the destination folder chosen by the end user; the relative locations of the files are shown in the IEUBK model Data Flow Document (EPA, 2020b). The output folder contains Model results in text format (*.txt) as well as files that are used to create graphical output (*.grf and *.lay). Files that begin with 'MultiRun' and 'RunModel' are used by Multiple Runs and Single Run modes of the Computation menu item, respectively. The MultiRun.con file includes the parameters used by the Multirun option of the Computation menu item.

After downloading the software installation file (IEUBKwin 2 Build1.64.msi), double-click the installation file to begin the installation of the IEUBK model. Next, specify a location for installation and choose whether the software will be installed for all users of the PC/laptop or just the person installing the software. Users must have read/write privileges at the location where the program is installed. IEUBK is intended to be run as a PC (i.e., desktop or laptop) application rather than from a network installation. It is recommended that a local copy of the application be saved onto the PC from which it will be run. As part of the model installation, a

desktop icon labeled *IEUBK* will be installed. To launch the model, double-click the desktop *IEUBK* icon or locate it from the Windows *Start* menu, which is launched by pressing the Windows logo key located on the left end of the taskbar. A *Disclaimer* will appear on the screen. Read the *Disclaimer*, then close the *Disclaimer* window by clicking on the <<Close>> button. *Choose User Mode* appears; select beginner or advanced mode and click <<OK>>. If *Beginner Mode* is selected, the user is walked through a *Beginner Wizard*, which highlights the input parameters. To avoid the *Beginner Mode* at startup, the user can either select the *Always Start in Advanced User Mode* box or unselect the *Prompt me for Advanced/Beginner Mode at Startup* from the IEUBK *Start* menu option in the pull-down menu. If *Advanced Mode* is selected, the user is brought directly to the *Site Specific Soil Dust Data* window.

The most current information pertaining to IEUBK model and Pb risk assessment is available on the <u>TRW website</u>. Questions concerning the use and interpretation of IEUBK model may be submitted to the TRW hotline: <u>pbhelp@epa.gov</u>.

The Model is menu driven with context-sensitive help available in almost every menu or window. In addition to the buttons that provide quick access to commonly-used model features, the main pull-down menus and the associated options remain. The contents of each these menus are listed below:

(1) File Menu

Open

Save

Print

Print Setup

Close

Exit

(2) Start Menu Options

Start Beginner Wizard
Prompt Me for Beginner/Advanced Mode at Startup
Select Run Mode

Under Select Run Mode, the user may choose to run the model in Research or Site Risk Assessment mode, depending upon individual needs. If the user chooses to run the model in the Site Risk Assessment mode, the model will prompt the user for a username, date, site name, and operable unit. In addition, the model will require the user to input a comment into a comment screen whenever the user modifies the default value of an input parameter:

(3) View Menu Options

Status Bar Toolbar

(4) Parameter Input Menu Options

Air Data

Dietary Data

Drinking Water Data

Soil/Dust Data

Maternal Data

Alternate Source Data

GI Values/Bioavailability

Reset All Parameters

Load Input From File (*.svd)

Save Input To File (*.svd)

(5) Computation Menu Options

Run the Model (Single Run)

Multiple Runs

Blood Pb vs. Media Pb

Find Blood Pb Concentration

Batch Mode Model Runs:

Execute Batch Runs

View Batch Output File

Rename Batch Output File

(6) Output Menu Options

View Text Result File

Rename Text Result File

Rename Blood Media Graph File

Rename Single Run Graph File

Rename Multiple Run Graph File

(7) Graph Menu Options

Blood Pb Concentration vs. Media Pb Concentration

Distribution Probability Percent

Distribution Probability Density

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Probability Density for Multiple Runs

(8) Help Options

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2.1 Inputs

IEUBK contains more than 100 input parameters that are initially set to default values. Of these, many may be changed by the user; the remaining internal model parameters are set to fixed default values. The default values represent national averages or plausible central values that were developed based on peer reviewed literature and research. To most effectively use the model for site risk assessment, it is necessary to use valid site-specific information for the exposure scenario that reflects important data quality indicators such as completeness, comparability, representativeness, precision, and accuracy. This section provides a brief description of how a user can change IEUBK parameters to better match the conditions at a specific site.

Table 2-1 presents the array of valid applications for which IEUBK can be used.

TABLE 2-1. Matching Site-Specific Applications to the IEUBK

Type	Locations	Exposure Groups	Assessment	Application
A	child. ⁴ A2: On	A1: One living unit, one child. ⁴		
		A2: One living unit, more than one child.	Requires calculating only a single PbB distribution to characterize	Single run
	location	A3: More than one living unit, more than one child, homogenous media concentrations.	risk.	Single run
В	Multiple locations	One neighborhood, homogenous media concentrations.	Requires calculating a PbB distribution for each child, but since each child of the same age has the same exposure scenario, a single run of the model is sufficient to characterize risk for this subgroup.	Single run

⁴ The IEUBK model is not intended to be used as a substitute for PbB measurement and medical evaluation of a specific child at risk. Medical evaluation can take into account specific information on behavior and risk factors, such as nutritional status, that are beyond the scope of a broadly applicable environmental risk model.

С	N/1111T11010	One neighborhood, heterogeneous media concentrations.	individual. Risk estimates must be	Batch Mode or a group of single runs.
D	Willitinie	heterogeneous	1 1	

2.2 Input Windows

The user has the option to load a complete set of input data from a previously saved file (see Section 2.3). To do this, the user can either select *Open* option in the *File* pull-down menu or the *Load Input From File* option from the *Parameter Input* pull-down menus. The loaded site-specific data provide the model with the necessary information to predict PbB levels in children who live on or near the site in question. Additionally, IEUBK input values can be entered by clicking on the desired parameter at the top of the screen, or by selecting the desired parameter from the *Parameter Input* pull-down menu. The seven parameter input windows that can be modified to reflect the site-specific conditions, IEUBK are as follows:

Air Data

<u>Dietary Data</u>

<u>Drinking Water Data</u>

<u>Soil/Dust Data</u>

<u>Maternal Data</u>

<u>Alternate Source Data</u>

GI Values/Bioavailability

The parameter values shown in the input windows are set to EPA-specified default values. Where site-specific data are available, the user is encouraged to replace the default values with site-specific information (e.g., environmental media Pb concentration data). Typical site-specific data for IEUBK include soil, water and air Pb concentration, and bioavailability based on Site-specific IVBA data for Pb in soil.

The input windows were designed to allow users to tab between fields to facilitate the data entry process. Note that a value is not saved for use in a model run until the user clicks the <<OK>> button on the input screen. If <<Cancel>> is selected (or if the window is closed using

the "X" in the upper right corner of the window), the model retains the initial default values. When any input values are missing or set to zero, the model does not substitute default values for soil, water, or air prior to performing calculations.

When changing some of the input parameters, the user may enter values with as many as six significant figures; however, no more than 3 digits to the right of the decimal point are written to the parameter (*.svd) file. The IEUBK uses up to seven digits in all calculations. All output is generally written with three digits to the right of the decimal point. However, it should be noted that the true precision of any calculated output can be strongly influenced by the least precise input value. See Appendix C for further details about IEUBK precision.

Each *Parameter Input* menu option also includes context-sensitive help windows to aid the user. These windows are available for most input parameters and are accessed by clicking on the <<Help?>> button. This feature opens a new window, which shows guidance related to the subject. In addition, the user has access to the complete documentation for the model under the Help pull-down menu.

The user can restore any modified parameters to their default values by using the *Reset* button or the *Reset All Parameters* command (at the top of the screen or on the *Parameter Input* pull-down menu, respectively). Default values are also reset each time the IEUBK program is exited and relaunched.

Finally, IEUBK has been developed to warn the user when an unacceptable input value has been entered. Currently, IEUBK contains three classes of error messages that will alert the user of inappropriate input values. These classes of error messages address:

- Input values that result in greater than 100 percent: In cases where the user enters an input value in the form of a percent, the value may not exceed 100 percent. Similarly, when percent values are summed, the total may not exceed 100 percent.
- Negative values: Negative input values are not allowed in IEUBK.
- Valid model inputs: Although the user is permitted to enter any values into IEUBK
 model (given the limits above), in certain instances, the input is limited based on
 scientific evidence (for example, the plausible range of GSD values) or excessively
 high media concentrations.

2.3 Detailed Descriptions of Input Options

The following is a discussion of the *Parameter Input* menu options for IEUBK. Help menus provide further assistance and discussion on data entry. A detailed list of default values for IEUBK model parameters are presented in <u>Table 2-2</u>, and the user should refer to the Systems Requirement Document (EPA, 2020a), the IEUBK Guidance Manual (EPA, 1994b) or <u>IEUBK Training PowerPoint</u> for additional information.

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

Parameter	Default Value	Units
Indoor air Pb concentration (% of outdoor)	30	%
	(by year)	70
Air concentration:		
Age =		
0-1 year (0-11 months)	0.10	$\mu g/m^3$
1-2 years (12-23 months)	0.10	$\mu g/m^3$
2-3 years (24-35 months)	0.10	$\mu g/m^3$
3-4 years (36-47 months)	0.10	$\mu g/m^3$
4-5 years (48-59 months)	0.10	$\mu g/m^3$
5-6 years (60-71 months)	0.10	$\mu g/m^3$
6-7 years (72-84 months)	0.10	$\mu g/m^3$
Time outdoors:		
Age =		
0-1 year (0-11 months)	1	hours/day
1-2 years (12-23 months)	2	hours/day
2-3 years (24-35 months)	3	hours/day
3-7 years (36-84 months)	4	hours/day
Lung absorption	32	%
DATA ENTRY	FOR DIET (by year)	
Dietary Pb intake:		
Age =		
0-1 year (0-11 months)	2.66	μg Pb/day
1-2 years (12-23 months)	5.03	μg Pb/day
2-3 years (24-35 months)	5.21	μg Pb/day
3-4 years (36-47 months)	5.38	μg Pb/day
4-5 years (48-59 months)	5.64	μg Pb/day
5-6 years (60-71 months)	6.04	μg Pb/day
6-7 years (72-84 months)	5.95	μg Pb/day
DATA ENTRY FOR ALTERN	ATE DIET SOURCES (by	food class)
Concentration:		
home-grown fruits	0	μg Pb/g
home-grown vegetables	0	μg Pb/g
fish from fishing	0	μg Pb/g
game animals from hunting	0	μg Pb/g

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

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

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

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

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

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

Aside from the mathematical limits described in Section 2.2, there is no limit to the range of values permitted in IEUBK model *per se*. However, empirical validation of the model did not address situations where the predicted PbB concentration exceeds 30 µg/dL; therefore, such results must be interpreted with caution (Zaragoza and Hogan, 1998). In addition, values for some input parameters are limited by physiology or scientific data as discussed earlier. Additional information on plausible limits for certain parameters is also available from the Input Parameters section of the FAQs of the TRW website.

2.3.1 Air Data

The *Air Data* Model default values (Table 2-2) can be replaced with site-specific data for the following parameters:

- Indoor air Pb concentration as a percentage of outdoor air Pb concentration (μg/m³)
- Outdoor air Pb concentration (μg/m³)
- Time spent outdoors (hours/day)
- Lung absorption (%)

The default outdoor air Pb concentration is $0.1 \,\mu\text{g/m}^3$. As a default, the model calculates indoor air Pb concentration as 30 percent of the outdoor air Pb concentration. Because the indoor air Pb concentration is treated as a fraction of outdoor concentration, the model does not allow a value greater than 100 percent to be entered in this field. If the user is working on a site where indoor air Pb concentration is in fact greater than the outdoor air Pb concentration, contact the TRW. When site-specific information is available, the IEUBK model allows the user to vary the value of each parameter by age.

2.3.2 Dietary Data

The *Dietary Data* input window includes information on that portion of total Pb intake that enters the body through the consumption of food. The default daily dietary Pb intake values for each age apply to a typical child in the United States. These estimates are derived based upon Food and Drug Administration (FDA) food monitoring data (FDA, 2010) and food consumption

data from the What We Eat in America dietary component of the National Health and Nutrition Examination Survey (NHANES) (CDC, 2010a, 2010b). Alternative dietary lead values have also been derived (Zartarian, et al., 2017).

Furthermore, rather than calculating intakes from ingestion rates (volume or mass/day) and concentrations, Pb exposure from each food item including formula is collectively estimated by the total dietary Pb intake estimates for each one-year age group (EPA, 2018). Dietary items include:

- Dairy
- Meat
- Canned fruit
- Canned vegetables
- Juices
- Fresh fruits
- Fresh vegetables

- Nuts
- Candy

Sauce

- BreadPasta
- Formula

Beverage

• Infant items (non-formula items)

The model also allows the user to directly alter the dietary Pb intake amounts by age. If site-specific data suggest that default dietary intake rates differ due to the consumption of local produce, fish, or game animals, that information may be entered in the *Dietary Data* input window by answering <<YES>> to Use Alternate Dietary Values?. The value in the first column of the Dietary Data input window is the observed concentration of Pb in the local food item. The second column is the amount of food of a given type obtained from local sources, as a percent of total consumption of that food type. Local fish and game animal meat are part of the same "meat" category, and the percentage values for this food category may not be greater than 100. Homegrown fruit is part of the canned fruits and fresh fruits category and homegrown vegetable is part of the canned vegetables and fresh vegetables category. The percentage of the homegrown fruit is assumed to be evenly divided between the fresh fruit and canned fruit categories; likewise, the homegrown vegetable percentage is evenly divided between the fresh and canned vegetable categories. For example, 50% homegrown vegetable percentage means 50% of the mass of canned vegetables sourced from the market and 50% of the mass of the fresh vegetables sourced from the market is replaced by the consumption of homegrown vegetables. The homegrown fruit percentage may range between 0 and 100%, inclusive and the homegrown vegetable percentage may range between 0 and 100%, inclusive. Other limitations on inputs for

the "meat" and "fruit and vegetable" categories are explained in the popup shown when the *Use alternate dietary values?* radio button is enabled <<YES>>> .

Alternate dietary data should not be used in combination with changes to default age-specific dietary Pb intake data. Additional <u>guidance</u> is available from the <u>FAQs</u> of the <u>TRW</u> <u>website</u>. Section 2.3.1.2 of the System Requirements and Design document for the IEUBK model provides detailed explanation of the calculation of dietary intake in the IEUBK model (EPA, 2020a). The IEUBK model dietary module does not assess exposure through breastmilk. Breastmilk exposure may be assessed as an alternate intake (see Section 2.3.6 Alternate Source Data). The TRW Lead Committee may be contacted for assistance in assessing exposure to lead in breast milk.

2.3.3 Drinking Water Data

The *Drinking Water Data* input window is divided into two sections: water consumption rates and water concentrations. The default consumption rates are age-dependent and based on national averages (Kahn and Stralka, 2009). These consumption rates should be changed only when valid site-specific monitoring data are available. When entering a water Pb concentration, the user has two options:

(1) Use one concentration for all water sources

By answering <<NO>> to *Use Alternate Water Values?* the user can either select the default value $(0.9 \mu g/L)$ or change the water Pb default concentration to reflect conditions at the site.

(2) Use source-dependent values

By answering <<YES>> to the *Use Alternate Water Values?*, the user can enter site-specific values for the following parameters:

- Percentage of total consumed as first draw (%) [default=50%]
- Concentration of Pb in first draw (μg/L) [default=0.9 μg/L]
- Concentration of Pb in flushed (μg/L) [default=0.9 μg/L]
- Percentage of total consumed from fountains (%) [default=15%]
- Concentration of Pb in fountain water (μg/L) [default=0.9 μg/L]

Note that total water consumed is the sum of first draw, flushed, and fountain water. In addition, the percentages and concentrations are default values that should be updated to reflect site-specific conditions.

The IEUBK model accounts for Pb intake from direct tap water consumption⁵ via the *Drinking Water* menu, and Pb intake from indirect tap water consumption⁶ via the *Diet menu*.

2.3.4 Soil/Dust Data

The *Soil/Dust Data* input window allows the user to adjust the child's exposure to Pb in outdoor soil and indoor dust to represent site-specific conditions. Since soil and dust are often the primary sources of Pb exposure at a given site (Manton et al., 2000; Mielke & Reagan, 1998; Succop et al., 1998; von Lindern et al., 2003, 2016; Yankel et al., 1977), the *Soil/Dust Data* menu option is the most detailed and complex of the input windows. While site-specific data for soil Pb concentration are used for most applications of the IEUBK model for site risk assessment, input values for other soil/dust exposure inputs (e.g., ingestion rates and [Mass Fraction of Soil to Dust (M_{SD})] are rarely changed. It is strongly recommended that users consult with the TRW Lead Committee if changes to ingestion rates or M_{SD} are being considered for a site risk assessment. This promotes better science and facilitates sharing of information so that all EPA Regions can benefit from updated information on these model parameters. The process for consulting with the TRW Lead Committee is to submit all information pertaining to the ingestion study review to an EPA regional risk assessor or via pbhelp@epa.gov.

2.3.4.1 Soil/Dust Ingestion Rates

One of the parameters that the IEUBK model uses to estimate child PbB concentrations is the mass of soil and household dust ingested per day. Young children are primarily exposed to Pb through fine particles of surface soil and household dust that adhere to their fingers and are incidentally ingested during normal hand-to-mouth activity. The rate at which soil/dust is ingested depends on a number of factors including a child's age, activity patterns, and total dust and soil accessible in the environment. Soil and dust ingestion rates discussed in this section include both indoor and outdoor exposures. The contribution of Pb in outdoor soil to Pb in interior dust is discussed in the M_{SD} section (Section 2.3.4.3).

⁵ Drinking water is defined as the portion of total water intake that is consumed as direct tap water (EPA, 2011).

⁶ Tap water typically ingested directly as a beverage and as an additive to prepared foods.

2.3.4.1.1 Default Soil/Dust Ingestion Rates Used in the IEUBK Model

The age-specific default soil/dust ingestion rates recommended for use in the IEUBK model are central tendency values (<u>Table 2-3</u>). The TRW Lead Committee strongly recommends using default soil/dust ingestion rates. These values are representative of average daily intake rates for the population; they do not incorporate variability in consumption patterns. Because they represent average rates, some children will have soil and dust ingestion rates higher or lower than the values reported in Table 2-3; however, as discussed in Section 2.1, the IEUBK model is intended to predict a distribution of PbB concentrations for a given set of exposure conditions. While there is uncertainty associated with the soil/dust ingestion rate values, a review conducted by the <u>TRW</u> (von Lindern et al., 2016) and other sources of information cited in the <u>Exposure Factors Handbook</u> (EPA, 2017a) determined that the values in Table 2-3 are appropriate and representative estimates of soil ingestion for U.S. children living near a hazardous waste site. The GSD accounts for the variability in the ingestion rates and other parameters to predict the PbB distribution (White et al., 1998).

TABLE 2-3. IEUBK Soil/Dust Ingestion Defaults by Age

Age Group (years)	IEUBK Model Defaults (g/day)
0-1	0.086
1-2	0.094
2-3	0.067
3-4	0.063
4-5	0.067
5-6	0.052
6-7	0.055

Basis for Default Values

The recommended age-specific, default values for the rate of soil/dust ingestion are based on an analysis of data from the Bunker Hill Superfund Site (von Lindern et al., 2016). The updated values were derived using structural equation modeling with site-specific data for Pb concentration in soil and indoor dust, site-specific soil and indoor dust bioavailability data, and PbB concentration data for children who resided in areas near the Bunker Hill Superfund Site (von Lindern et al., 2016). The recommended soil/dust ingestion rates in Table 2-3 have been

shown to predict PbB concentrations that agree well with PbB data collected from children living near the site between 1989 and 2002 (von Lindern et al., 2016).

The soil/dust ingestion rate values recommended for use in the IEUBK model are central values within the range of values observed in previous soil and dust ingestion studies. These studies were conducted in both the United States (Binder et al., 1986; Calabrese et al., 1989, 1991; Clausing et al., 1987; Davis et al., 1990) and the Netherlands (van Wijnen et al., 1990) utilizing trace elements to quantify soil ingestion rates. For comparison, Exposure Factors Handbook (EPA, 2017a) recommends the use of a central tendency estimate of 0.08 g/day for soil and dust ingestion for children 1 to <6 years that was based on an unweighted average of ingestion rates estimated by several authors (including von Lindern et al., 2016) (EPA, 2017a).

The IEUBK model default values for the rate of soil/dust ingestion may not reflect differences associated with variables that may affect ingestion rates at different sites. Examples of such variables include ground cover, climate, activity patterns, and behavior (Filippelli and Laidlaw, 2009; Laidlaw and Filippelli, 2008). While inclusion of such information in a risk assessment is desirable, because such data are not available to support quantitative adjustment of ingestion rates in the IEUBK model these variables are best addressed in the uncertainty discussion of a risk assessment.

2.3.4.2 Lead in Soil

The \underline{TRW} recommends replacing the default constant soil value (200 $\mu g/g$) (or variable values) with site-specific data representative of the average soil Pb concentration for the exposure scenario. Site-specific soil concentration data are needed to obtain modeling results that are predictive of site-specific risks. When specifying a concentration of Pb in soil, the user has the following two options:

- (1) Use an alternate site-specific constant value in place of the default value (200 μ g/g). When the user inputs a constant value for soil (or dust), the value is applied to all age ranges. The initial value is not intended to be a substitute for site data.
- (2) Use the *Variable Values* option to change the concentration of soil to which children are exposed by age. If the user chooses to enter a value instead of using the model default or a site-specific constant value across all age ranges, the user must select the *Variable Values* option and enter a value into each age field. This option may be used

if, for example, children of different ages experience different soil Pb concentrations for an exposure scenario.

2.3.4.2.1 Developing a Soil Lead Concentration (PbS)

The soil lead concentration term (PbS) is the only input parameter of the Model for which a site-specific value is necessary. The PbS should be developed from environmental data collected using the Data Quality Objective (DQO) process (EPA, 2006). The DQO process uses systematic planning to establish performance and acceptance criteria that ensure data of sufficient quality and quantity are used to develop the PbS. Guidance for estimating the PbS is available from the EPA. It is recommended that site-specific soil lead bioavailability be assessed for input into the Model; technical assistance is available from the EPA BAC at bahelp@epa.gov. A site PbS may reflect the current exposure scenario (i.e., to predict current risk) or (potential) future exposure scenarios; for example, a PbS for future exposure scenarios may reflect a preliminary remediation goal.

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

When site-specific information indicates that a child spends more time in certain areas of a property, stratified sampling methods may be used to select sample locations from each area the child spends time in and treat all the areas as a single DU, or each of the areas may be defined (and sampled) as separate DUs. Weighted estimates of the PbS may be needed when a stratified sampling method is used; the weights are determined by the sampling plan. Other weighted estimates of the PbS include both spatially- and time-weighted estimates (EPA, 2007).

The Residential Lead Sites Handbook (EPA, 2003a) as well as other guidance is available to help select appropriate sampling and estimation methods for the PbS (EPA, 2011; ITRC, 2012).

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

Children may also be exposed to Pb at locations outside of the residence (e.g., daycare center or park). Exposure to such secondary sources of Pb may be evaluated using the time-weighted approach recommended by EPA (2007).

2.3.4.3 Lead in Dust

By default, the IEUBK model uses the Multiple Source Analysis (MSA) option to estimate the residential (household) dust Pb concentration. For site risk assessment, it is strongly recommended to use the MSA option, which calculates the indoor residential dust Pb concentration as a function of the soil concentration for the residence and the outdoor air Pb concentration. It should be noted that MSA does not consider other potentially significant indoor sources of Pb dust (e.g., deteriorating Pb-based paint).

If available, site-specific indoor dust lead (PbD) concentrations may be used as inputs to the IEUBK model when conducting residential Pb risk assessments. When specifying a concentration of Pb in dust, the user has the following three options available via the Soil|Dust menu option:

- (1) Use an alternate site-specific constant value in place of the default PbD value $(150 \mu g/g)$.
- (2) Use the *Variable Values* option to change the concentration of dust that children are exposed to by age. If the user chooses to enter variable values instead of using the model default or a site-specific constant value, the user must select the *Variable Values* option and enter the new value into each age field.

(3) Use *Multiple Source Analysis* for dust concentrations. *Multiple Source Analysis* allows the use of information about the contribution of soil lead (PbS), air Pb, and other sources to derive a value for indoor dust lead (PbD).

Mass Fraction of Soil in Indoor Dust (MSD) Variable

Soil is a primary source of indoor dust in many residences (Laidlaw and Filipelli, 2008; Layton and Beamer, 2009; Succop et al., 1998; von Lindern et al., 2003, 2016). Because of the potential for Pb in soil to be transported indoors and contribute to the concentration of Pb in dust, the IEUBK model incorporates a soil-to-dust variable (M_{SD}), which is used in the MSA option. The M_{SD} is defined as the mass fraction of soil-derived particles in indoor dust (g soil/g dust). Values of the M_{SD} are fractions bounded by the values 0 and 1. A relatively low value (i.e., closer to zero) reflects a scenario in which soil contributes little to indoor dust mass (i.e., other non-soil sources of dust predominate), whereas a relatively high value (i.e., closer to 1) suggests that soil is the predominant source of dust. Many factors are believed to influence the movement of fine particles from the outdoor environment to indoors, including, but not limited to, ground cover, presence of pets or children, and wearing outdoor shoes indoors.

The default value for M_{SD} recommended for use in the IEUBK model is 0.70 g soil/g dust. The default value is based on linear regression models that were estimated for residential communities where soil was a major contribution to household dust (EPA, 1994b).

The M_{SD} is approximately equivalent to the PbD/PbS concentration ratio under the assumption that soil is the predominant source of Pb in house dust and the mean concentration of Pb in the soil transported indoors equals the mean Pb concentration of the soil that was used to estimate the M_{SD} (e.g., the transported soil is derived from the sampling area). When non-soil sources are also important contributors to indoor PbD (e.g., Pb-based paint), the M_{SD} represents the contribution of soil to dust; and total PbD levels will exceed those resulting from the soil pathway alone. In these instances, the preliminary remediation goal (PRG) for outdoor soil that was derived using MSA may not be protective of children in those residences with another source of Pb in dust (e.g., deteriorating Pb-based paint), because those sources were not assessed by the IEUBK model and will continue to be an ongoing source of additional exposure.

The M_{SD} may be used to approximate the concentration of Pb in indoor dust based on the concentration of Pb in nearby soil if the following assumptions are valid at the site:

- (1) Soil Pb is the major source of indoor dust Pb.
- (2) The soil data are representative of that portion of the soil fraction and matrix that contributes to indoor dust. There is no enrichment or reduction of Pb in the soil fraction that is most likely transported to indoor dust.
- (3) The areas where soil samples are collected coincide with the major source areas for soil derived indoor dust.

EPA risk assessors and managers are encouraged to consult the \underline{TRW} Lead Committee when they are considering the use of M_{SD} values other than the IEUBK model default of 0.70 (for use in either baseline risk assessment or for estimating soil cleanup levels) (EPA, 1998b). An alternate, site-specific M_{SD} value would be entered in the box that says *Contribution of soil lead to indoor household dust lead (conversion factor)*.

Soil/Dust Ingestion Weighting Factor

The *Soil/Dust Ingestion Weighting Factor* represents the percentage of total soil/dust ingestion that is derived from soil and the percentage that is derived from dust. The default value in the parameter input window of the model is 45 percent from soil. The combined soil/dust ingestion weighting factor must equal 100 percent. It is rare that site-specific information is available to support changes to this variable.

2.3.5 Maternal Data

The *Maternal Data* input window allows the user to consider the impact of Pb transferred from the mother to the fetus *in utero*. The Pb that is stored in the tissues of the newborn child is calculated by entering the maternal PbB value at the time of delivery (default=0.6 µg/dL; EPA, 2017b). The empirical validation effort for the IEUBK model did not include data specific to the disposition of maternally supplied Pb in a young child, and model predictions in this regard should be interpreted with caution.

2.3.6 Alternate Source Data

The *Alternate Source Data* input window allows the user to input Pb concentrations from sources that are not covered under other menus in the model. An example includes the exposure to Pb in another medium (such as cosmetics or home remedies). In addition, the dietary module

of the IEUBK model does not assess exposure through breastmilk however, breastmilk exposure may be assessed as an alternate intake. (Contact the TRW Lead Committee for assistance in assessing this exposure.) In cases where alternate sources exist, the intake of Pb (µg/day) into the GI tract must be calculated from the site-specific data available (note that information on intake rate, concentration, and bioavailability information are required to use the alternate intake pathway). If the alternate source is from exposure to media that are already included in the IEUBK model (soil, dust, air, water, or diet), then the alternate exposure is *in addition to* exposure that is already considered in the IEUBK model. This can result in double counting, which should be discussed in the Uncertainty section of the risk assessment. If values are entered in the Alternate Source Data input window, then the bioavailability value for the alternate source pathway must be changed from 0% to an appropriate value for that media. The default bioavailability for the alternate source is 0% and if it is not changed, then uptake from the alternate source will be zero. The GI Values/Bioavailability input window may be accessed from the Parameter Input pull-down menu or it may be reached directly from the Alternate Source Data input window by pressing the <<GI/Bio>> button. The user is then notified about changing default values only with adequate and defensible site-specific data. By either selecting the << Escape>> key (Esc) or clicking the << OK>> button, the user is granted access to the next screen, where changes to the bioavailability of the alternate source variable can be made. Select << Escape>> again to return to the initial screen. A << Help?>> screen is available to further assist the user. The user is advised to read Section 2.3.7, which provides information about the GI Values/Bioavailability variable in the IEUBK model.

Building an exposure scenario using the *Alternate Source Data* should be done with care. The model assumes that all entries represent chronic exposure intake into the GI tract. Remember that the model's output represents only those children included in the exposure scenario.

2.3.7 GI Values/Bioavailability

The *GI Values/Bioavailability* (GI/Bio) option allows the user to adjust the GI absorption coefficient to account for site-specific information on bioavailability. If this option is selected, a disclaimer window opens to indicate that the user should only change default values if alternative

bioavailability information is available. After selecting <<OK>>, the *GI Values/Bioavailability Information* input window appears.

Relative bioavailability (RBA) may be assessed by measuring the bioavailability of a particular substance relative to the bioavailability of a standardized reference material, such as soluble Pb acetate, and a standard method is available to characterize bioavailability of Pb in soil. For the IEUBK model, soluble Pb in water and food is estimated to have 50 percent absolute bioavailability (ABA) based on the bioavailability of soluble lead acetate. Additional guidance on bioavailability is available from the <u>TRW Bioavailability website</u>.

2.3.8 Geometric Standard Deviation (GSDi)

GSDi is a measure of the relative variability in PbB of a hypothetical child of a specified age for a user-specified exposure, or children from a hypothetical population whose Pb exposures are similar. The GSDi in IEUBK encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability. The default value of 1.6 is recommended. This GSDi value is based on specific analyses of data from several neighborhoods with paired data for environmental Pb concentration and measured PbB levels (White et al., 1998).

In general, the <u>Technical Review Workgroup for Lead (TRW)</u> does not recommend that site-specific estimates of the GSDi be attempted. This parameter is particularly difficult to evaluate at a site, as it is demanding with regard to the amount and quality of the data and the potential complications in the analysis. Unless there are substantial differences and scientifically defensible studies documenting child behavior and Pb biokinetics at a site, the default GSDi should be used (since it is based on national averages). Thus, site-specific GSDi values should not be needed for most site assessments. Should the user decide to modify the GSDi, IEUBK currently accepts values within the range of 1.3-1.8 for the GSDi based on results of site-specific data. If the user enters values outside of this range, a warning screen will appear telling the user to select a different value. The GSDi is not intended to match the GSD of a population (see definition in the Acronyms and Abbreviations section.) In these instances where a site-specific GSDi is being considered, the reader is encouraged to review Appendix A of the 1994 IEUBK Guidance Manual (EPA, 1994b) and consultation with the TRW Lead Committee is strongly recommended.

3.0 Model Analysis

This section describes the types of analyses that can be run with IEUBK.

3.1 Options for model analyses

Effective use of the IEUBK model is achieved by entering data that are appropriate to the site(s), exposure(s), and subject(s). To accomplish this, users will construct a multi-media, site-specific exposure scenario based on the conceptual site model and collect site-specific information that inform inputs to the IEUBK model that represent the exposures of young children. A site-specific risk assessment requires site-specific soil concentrations that may be augmented (as needed) by site-specific data for air, water, and other adjustable variables.

The use of site-specific data is recommended to tailor the exposure to the conditions at the site. Site-specific data are most commonly used in place of the model default values for Pb concentrations in soil, dust, air, and water, as well as site-specific soil lead bioavailability based on IVBA data. Site-specific data for locally caught fish or home-grown vegetables are sometimes used to augment dietary default values. However, such data should be evaluated for validity prior to use. Model default values should only be replaced when site-specific data specific to the parameters are more representative.

Prior to using IEUBK to calculate PbB levels, the user should decide what type of analysis should be run: single simulation run, multiple simulation run, or batch mode. Each of these is appropriate for certain scenarios. A single simulation allows the user to run scenarios for a single location, or multiple locations with homogenous media concentrations (Categories A and B of Table 2-1). By contrast, multiple runs allow the user to specify a range of Pb concentrations for a specific environmental media (e.g., soil) and obtain results of model runs at multiple points within that range. Batch mode allows the user to run input data for many locations having different media concentrations in a single run of the model (e.g., to assess risk at different residences with residence-specific media concentrations). Additionally, batch mode allows the use of different ages or different values for Pb concentration in soil, dust, water, air, and alternate Pb sources for each exposure scenario. The media intake and absorption parameters are the same for every exposure scenario in a batch mode run and must be specified before using the *Batch Mode Model Run* option, unless default values are used. Output options for results from Single, Multiple, and Batch Mode runs are presented below.

3.2 Overview of Model Output

The IEUBK model can calculate four different outputs:

- GM PbB levels, by age
- Probability of similarly exposed children having a PbB in excess of a user-specified target PbB (see Appendix B)
- Average media-specific daily Pb uptake rates
- Media-specific remediation goals

The output data can be saved and presented in tables, graphs, or text files. By default, the model will generate a text file of the output unless otherwise specified by the user prior to running the model. Screen captures of graphs (for use in technical reports) can be performed by using the Windows Accessories *Snipping Tool* or by applying the *Print Screen* feature available on most PC keyboards, re-sizing the image to the appropriate dimensions, and exporting the image to the desired application. While printed tables and graphs allow convenient documentation of IEUBK results in risk assessments, text files can also be exported to most statistical software packages for additional analysis. The appropriate procedures to follow when exporting output data to Microsoft Excel are described in Appendix A.

3.3 Selecting Output Alternatives

Results of IEUBK simulations may be saved in several forms. The user should select the most useful forms in advance, because the results of some interactive simulations cannot be recovered without repeating the analysis once the user has bypassed the opportunity to save the results.

3.3.1 Graphical Options are Included in IEUBK

IEUBK incorporates some output options that facilitate presentation of risk assessment results. The graphical output choices in the IEUBK *Graph* pull-down menu include the following:

- PbB concentration vs. media Pb concentration
- Distribution probability percent
- Distribution probability density

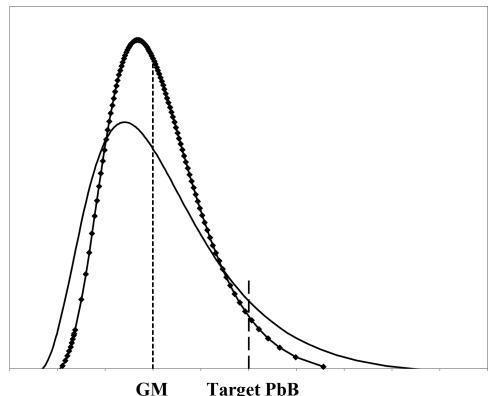
- Distribution probability for multiple runs
- Probability density for multiple runs

Some plots may be used for single runs, while others are applicable for multiple runs. These plots present estimates of a plausible distribution of PbB levels that are centered on the calculated GM PbB. To derive the distribution around the GM, IEUBK uses a GSD, a value describing the spread around the GM PbB. From this distribution, IEUBK calculates a Z-score for the exceedance probability from a child's PbB and the user-selected target PbB according to the following equation:

$$z = [ln(GM) - ln(target)]/ln(GSD)$$

The probability of exceeding the target PbB is the cumulative probability for a standard normal distribution.

As discussed above, the GSD is a measure of relative variability in PbB levels of children of a specific age or a hypothetical population of children whose Pb exposure is known. The GSD in IEUBK encompasses biological and behavioral differences, measurement variability from repeat sampling, variability as a result of sample locations, and analytical variability. The default value of 1.6 is recommended. Figure 3-1 illustrates the relationship between the GM PbB, the GSD, the target PbB and the probability of a PbB exceeding the target PbB.



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FIGURE 3-1. The relationship between the geometric mean (GM) blood lead concentration (PbB), the target PbB, the PbB geometric standard deviation (GSD) and the probability of a PbB exceeding the target PbB.

The line without markers represents the probability density function (PDF) for a lognormal distribution of PbB with GSD=1.6 while the line with markers represents the PDF with GSD=1.4. Both PDFs of PbB have the same GM PbB. The area under the curve to the right of the target PbB equals the probability of exceeding the target PbB. As the GSD increases, the probability of exceeding the target PbB increases.

3.4 Computation Options

3.4.1 Single Runs

This option uses only the currently loaded parameter set (the default values and sitespecific data specified by the user).

If you want to save the results for reference or further analysis, the user can assign a unique file name; otherwise, the default file name will be assigned. If you want to analyze the data using a spreadsheet, checking the box *Export data into a Spreadsheet Format* will save the data in a tab-delimited format for import into a statistical software package or spreadsheet program (see details in <u>Appendix A</u>).

3.4.1.1 Single-Run Options

Single-run plotting options in IEUBK include the following:

- The average of the GM PbB concentrations for children in sequential 1-year age intervals, the input concentrations for several media, and the media-specific daily Pb uptake for each year are saved internally. The output file that is automatically generated is RunModel.txt.
- Plotting the cumulative probability distribution for exceeding any user-specified
 PbB level of concern for a single exposure scenario (Option 2—Distribution

- *Probability Percent*). This is sometimes called the exceedance probability distribution.
- Plotting the log-normal probability density function of PbB levels for a single exposure scenario predicting GM PbB (Option 3—Distribution Probability Density).

The probability density function gives users a better idea of the spread of PbB levels for children exposed to the specified set of environmental Pb concentrations. The plot of the exceedance probability distribution also shows the probability that a child will exceed a user-specified target PbB level (e.g., 5 µg/dL) for the this is known as the Px, where x is the target PbB level (e.g., P5) and is expressed as a percentage(%). The user may print the probability plots after viewing. The single-run media plots are saved as "[name].GRF". If saved, these graphs may be viewed at a later date using the *Graph* pull-down menu.

3.4.2 Multiple Runs

This option uses the currently loaded parameter set (default values and site-specific data specified by the user), but the model repeats the run for a range of concentrations for a user-specified medium (soil, dust, water or air). To conduct this run, select the medium, the range of values for that medium, and the number of runs. With multiple runs, the user can determine PbB concentration by age group based on a range of media Pb concentrations and can search for the medium Pb concentration associated with an age-specified PbB concentration.

3.4.2.1 Multiple-Run Options

IEUBK has additional features that allow the user to combine output from several runs onto single plots. These multiple-run options include both PbB concentration vs. media Pb concentration plots and a sequence of graphics-overlay simulation runs (multiple runs) as described below. For both of these options, the media range option saves input data for GM PbB vs. media Pb plots for a range of evenly spaced media Pb concentrations. For example, the user may generate plots of PbB vs. PbS concentrations smoothly interpolated from calculated values at 50, 250, 500, and 1,000 μ g/g for children aged 12-24 months. Results are saved as filename MultiRun.LIN. The data in theMultiRun.LAY overlay file include the GM PbB for children in

the age range, and the Pb concentration in soil and other media. The actual plots of probability density or cumulative distribution functions depend on the GSD value selected for use in risk estimates, and these plots can be printed. While this option is useful in recognizing the pattern between increasing media concentrations and increasing PbB levels, the results are not intended to directly support risk-based decisions. These graphs show the predicted GM PbB levels, and not the probability of exceeding the target PbB.

- GM PbB concentration vs. media Pb concentration graph, where each run increases the Pb concentration in a specified medium by a user-defined amount across a range (Option 1—Distribution Probability for Multiple Runs).
- Overlaid plots of the cumulative exceedance probability distributions of PbB levels
 for multiple media concentrations, where each run increases the Pb concentration in a
 specified medium by a user-defined amount (Option 4—Distribution Probability for
 Multiple Runs).
- Overlaid plots of the log-normal probability density functions of PbB levels for multiple exposure scenarios, where each run increases the Pb concentration in a specified medium by a user-defined amount (Option 5—Probability Density for Multiple Runs).

Overlaid plots cannot be used unless the user has previously created an output file from the *Computation* menu, with the file extension *.LAY. The overlaid probability density functions give most users a better idea of how the probability of exceeding a PbB level of concern increases with each incremental increase in environmental Pb. The exceedance probability distributions may be used to estimate the increases in the probability of PbB levels above the level of concern.

3.4.3 Blood Lead vs. Media Concentration

The user may select *Blood Pb vs Media Pb* from the *Computation* pull-down menu, and select a medium (soil, dust, water or air) and a range of Pb concentration for the selected medium to determine the predicted concentration of Pb in blood associated with the inputs. This module generates text of graphical output that presents the relationship between PbB concentration and the exposure to Pb in the user-selected, environmental medium. The module can be used to

explore the sensitivity of the predicted PbB concentration to assumptions about exposures to Pb in specific media. The module can also be used to explore the sensitivity to other exposure assumptions. For example, the effect of alternative assumptions regarding the soil Pb AF can be explored by comparing plots of PbB concentration vs. soil Pb concentration, when different values for the Pb AF are assumed.

3.4.4 Find Soil Pb Concentration

The *Find Soil Pb Concentration* option on the *Computation* pull-down menu (or the "Find" icon in the Menu bar) may be used to calculate a soil and/or dust concentration associated with user-selected inputs for an age group (e.g., 12-72 months), PbB target value (e.g., 5 µg/dL), the probability for exceeding the PbB cutoff value (e.g., P=5%), and Pb exposure from all other media that have been left as default values or set by the user. The result is displayed in a text box on the form. This option may be used to calculate PRGs for a site.

3.4.5 Run Batch Mode Simulation

The input data file for a batch run must be created outside of IEUBK using software that can create a space-delimited text file (e.g., Excel). The following conventions must be observed in creating the batch file:

- The input data file must be an ASCII file with no special characters. The model does not read tab- or comma-delimited batch mode files.
- The data set must have a DAT extension (i.e., [name].dat).
- The first three lines of the input data file can be any identifiers that the user may require; the first line is usually the run name, the second line is the modeling options used in the run, and the third line consists of the headers for variables in the data set.
- The data fields are entered left justified, although the use of regular spacing and alignment of decimal points are recommended to improve readability.
- The maximum width is 8 spaces per column.
- The variable values should be separated by spaces.
- For quicker runs, the recommended limit is 500 rows of data.
- Each line of the input data must include the following 12 variables:

- (1) ID: Child identifier code
- (3) BLOCK: Area or neighborhood identifier code
- (5) SOIL: PbS concentration in $\mu g/g$
- (7) WATER: Drinking water Pb concentration in µg/L
- (9) OTHER: Daily intake of Pb from "alternate"
- soil

- (2) FAM: Family or residence unit identifier
- (4) AGE: Child's age in months
- (6) DUST: PbD concentration in μg/g
- AIR: Air Pb concentration in $\mu g/m^3$ (8)
- (10) PBB: Observed child PbB level in μg/dL
- (11) ABSSOIL: bioavailability of Pb in (12) ABSDUST: bioavailability of Pb in dust
- Missing values must be shown by an asterisk (*). Missing values are not allowed for the first four variables (ID, FAM, BLOCK, AGE). There are the business rules when using asterisk:

Field	Business Rule
ID	string is displayed
FAM	string is displayed
BLK	string is displayed
AGE	Invalid value; row skipped
SOIL	 If DUST is not * character, copy value from DUST If DUST is * character, display and skip row
DUST	 If SOIL is not * character, copy value from SOIL If SOIL is * character, display and skip row
WATER	Copy value from alternative water value lead concentration, in Drinking Water Data dialog window
AIR	Copy value from Outdoor Air Pb Concentration Constant Value, in Air Data dialog window
OTHER	Copy value from i-th Alternate Lead Intake field of Alternate Source Data dialog window, where i=min (AGE/12, 6)
PBB	string is displayed
ABSSOIL	Copy value from Soil absorption Fraction Percent, in GI Values/Bioavailability dialog window

ABSDUST	Copy value from Dust absorption Fraction Percent, in GI	
	Values/Bioavailability dialog window	

Values for the first variable (ID) may be text or numeric. The values for variables 2-4
must be numeric. Values for all other variables must be numeric or represented by an
asterisk to indicate a missing value.

Missing values will be replaced by the value of the variable that appears in the corresponding input box. This value is either the default value or a value the user has entered. For example, missing values for soil will be replaced with the default values for soil (200 μ g/g) and dust (150 μ g/g) unless the user has replaced the default concentrations with concentrations that were entered in the *Constant Value* box for Outdoor Soil Lead Concentration and/or the *Constant Value* box for Indoor Dust Lead Concentration on the *Site Specific Soil Dust Data* form⁷. The batch mode option can be used to develop estimates for statistical analyses of simulated community PbB distributions with or without observed PbB levels.

For many users, the easiest way to create a batch mode input file is to use a spreadsheet (see Appendix A). As noted above, the child's age (in months) must be entered. The default media concentrations for water and air from the parameter input windows will be entered if values for these media are missing. Both PbS and PbD concentration values are needed for the simulation. If the user does not have PbD concentration information, the user may calculate a value for PbD using the MSA approach, which uses the outdoor soil Pb and air Pb concentration, as described in Section 2.3.4.3. Alternatively the user may represent the missing value in the batch mode input file using a decimal point; in this case the missing value will be replaced by the

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⁷ Note the *Variable Values* option on the *Site Specific Soil Dust Data* form for soil and dust are not consistent with the batch run mode and are therefore not considered when replacing missing values in the batch run input file. The variable values option allows the user to enter concentrations for each year of a child's life while the batch run mode is used to estimate the GM PbB and Px for a single month of a child's life. Furthermore, the MSA option is not considered when replacing missing values for indoor dust concentration in the batch mode input file. If the user would like to replace missing values for soil or dust in the batch input file, values must be entered in the *Constant Value* boxes for each variable.

value that appears in Constant Value box on the Site Specific Soil Dust Data form (see preceding paragraph).

Note that the IEUBK model considers only two significant digits (to the right of the decimal point) from the data input file for running batch mode; however, the model uses seven digits in all its calculations.

Batch mode output consists of text files ([filename].TXT) that contain predicted PbB concentrations for each case or record (child) in the input data file. The output files also document the missing value imputations when some of the input data on residential media Pb concentrations are missing. The output files may be created as a tab delimited file for statistical analysis in other software programs (see Appendix A).

Multiple batch mode input files may be processed sequentially. The Batch Run Dialog window includes a list box, which shows the batch input data files that are available for processing. The user may add or remove files from the queue. The results are written to a single file BATCHRUN.TXT (unless another file name is specified). Each input file is processed sequentially, and the results are appended to the results file below the previous run. Results are identified by repeating the header, which identifies the input file name.

4.0 Interpretation of Results

4.1 Understanding the Output

Each of the output options described above allows the user to examine a different aspect of IEUBK simulation. The output from a single simulation run may be displayed in several forms. Most users wish to see the variability associated with a predicted PbB concentration. This range can be demonstrated graphically by selecting cumulative probability distribution. The range of plausible PbB values may be determined graphically as defined by upper and lower percentiles of the distribution. For example, there is an approximate 90% probability that a child with the given site- or household-specific exposure scenario or group of similarly exposed children, will have a PbB concentration that lies within the 5th and 95th percentiles of the distribution. Note that the plausible range reflects predicted variability among individuals with the same exposure scenario and should not be confused with a statistical confidence limit (which is a measure of statistical uncertainty in a predicted value such as a GM).

The other output characteristic that many users wish to see is the estimated probability of exceeding the specified PbB level of concern, corresponding to the given exposure scenario or scenarios (for multiple runs in a given medium). There are two valid interpretations for this output:

- 1. The output of the model may be the best estimate of a plausible range of PbB concentrations for a hypothetical child under a specific Pb exposure scenario. The range of values is centered on the GM PbB concentration expected for a typical child with this exposure scenario. The portion of the upper tail of the probability distribution exceeding some chosen PbB level of concern provides an estimate of the risk of exceeding that level for a typical child of that age residing in the same household and with the same exposure history.
- 2. The output of the model may also be considered the predicted GM PbB of a *population* of children under the same Pb exposure scenario. That portion of the upper tail that exceeds some chosen PbB level of concern indicates the fraction of the population exceeding that level when all of these children have the same exposure history.

A common misinterpretation of IEUBK is that it predicts *community* GM PbB and the fraction of the population of children at risk when the input is the mean or GM of household-specific environmental Pb concentrations. That misinterpretation arises, particularly when the environmental variables have a wide distribution among the neighborhoods of the community. A correct approach requires applying the model to each individual home (or area with homogeneous Pb concentrations) and combining these results as an aggregate to form an estimate of neighborhood or community risk (for more information see Hogan et al., 1998)

The Preliminary Remediation Goals (PRGs) resulting from IEUBK model runs are an integral part in designing an effective risk reduction strategy. The PRGs can be used to inform cleanup numbers for soil at sites; however, the IEUBK-derived PRGs are not the only factor in this decision. The National Oil and Hazardous Substances Pollution Contingency Plan (NCP) states that the Superfund process for establishing cleanup numbers for contaminated sites consider nine criteria concerning risks associated with remedial alternatives analysis that apply to. The nine criteria are as follows:

Primary Criteria

- 1. Overall protection of human health and the environment
- Compliance with applicable or relevant and appropriate standards, limitations, criteria, and requirements

Balancing Criteria

- 3. Long-term effectiveness and permanence
- 4. Reduction of toxicity, mobility, and volume
- 5. Short-term effectiveness
- 6. Implementability
- 7. Cost

Modifying Criteria

- 8. State acceptance
- 9. Community acceptance

5.0 Model Application and Documentation

The output of the IEUBK model helps users develop an understanding of the potential risk for elevated PbB levels in children. Through different model run scenarios, these potential risks can be calculated for a number of different hypothetical situations, including risks for a single child, a group of neighborhood children, or an entire community. With adequate site-specific information for the exposure scenario(s), proper application, and documentation, the IEUBK model can effectively and accurately estimate the risks at Pb-contaminated sites to support human health risk assessment.

5.1 Model Application

The IEUBK model is designed to facilitate two processes: rapid delineation of the relationship between environmental Pb and PbB in children and calculation of their risk of elevated PbB (i.e., the probability that a given child or group of children will have PbB concentrations exceeding a specified level of concern). As such, the Model provides a tool for site-specific risk assessment for young children exposed to Pb from different media and through different pathways in their environment. The intended applications of IEUBK are to:

- Provide a summary of children's long-term, primary residential exposure to Pb.
- Provide a best estimate of the GM PbB concentration for a typical child, aged 6-84 months, assumed to reside at a given residence. (The TRW Lead Committee recommends the 12-72 month age range be used to assess lead risk at Superfund sites (U.S. EPA, 2017.)
- Provide a basis for estimating the risk of elevated PbB (i.e., for exceeding a designated PbB concentration of concern) for a hypothetical child of specified age with a given sitespecific residential Pb exposure.
- Provide a basis for estimating the risk of elevated PbB concentrations among populations
 of children under age 7 years in a given neighborhood by aggregating the individual
 residential risk estimates.
- Predict likely changes in risk of elevated PbB concentrations from exposure to soil, dust, water, or air Pb following abatement actions designed to reduce exposure levels from one or more environmental media.

- Provide assistance in determining appropriate soil or dust Pb target cleanup levels at specific residential sites.
- Provide assistance in estimating PbB concentrations associated with soil or dust Pb concentrations at undeveloped residential sites that may be developed in the future.

EPA has established default values for all of the user-specified parameters in IEUBK, with the exception of the soil concentration.

- Use of the default parameters is recommended unless valid site-specific monitoring data exist to define values that are higher or lower.
- Site-specific data are commonly used in place of the model default values for Pb concentrations in environmental media such as soil, dust, air, and water as well as soil Pb bioavailability. However, for intake rates and PbB distribution parameters, the <u>TRW</u> recommends that the default values be used, unless accompanied by strong evidence supporting the use of site-specific values.
- Model default values should never be adjusted simply to attain a better match between modeled and empirical PbB.

5.2 Model Documentation (minimum requirements)

By reviewing every adjustable parameter in the model and noting which ones have been modified in a particular run, the user has a permanent record of the input.

- The data used in the model runs should be saved so the results can be reproduced. This may be accomplished by saving the parameter (*svd) file. Different levels of documentation are required for specific applications of the model.
- The text of risk assessments should contain a full discussion describing the inputs, use, and outputs of the model.
- Any model output referenced should be included in appendices of the risk assessment, including distribution and density curves, text outputs, and batch mode files.
- A listing of model inputs should be included in the text or as an appendix to the risk assessment. The Model captures data and comments in the risk assessment mode in a tabular format. This information can be exported to a spreadsheet application (e.g., Lotus 1-2-3, Microsoft Excel) for submission to EPA (see Appendix A).

• User should include IEUBK model parameter files (*.svd) and all graphs in their documentation (e.g., cumulative probability distribution).

5.3 User Responsibilities

In addition to documentation required by RAGS D (EPA, 2001), the following are IEUBK model specific requirements:

- The user must download the <u>current version of the IEUBK model</u> before beginning.
- Users are responsible for ensuring that the IEUBK model input variable values are appropriate for the site. Input variables (media intake rates and concentrations) should be appropriate for site-specific exposures.
- Users should always have site-specific soil Pb concentrations, and when appropriate, the user may collect other site-specific information (e.g., soil Pb bioavailability information and water and air Pb concentration data).
- Information on other Pb exposures, including outside a child's home and yard, may be assessed using intermittent exposure guidance (EPA, 2003b).
- Information on family demographics, child behavior patterns in the community that may affect exposure to Pb sources, or other non-environmental factors may be considered in the Uncertainty section of the risk assessment.

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Appendix A: Using Spreadsheets With IEUBK

Data from the Integrated Exposure Uptake Biokinetic (IEUBK) Model for Lead in Children, including batch mode output, can be readily exported to spreadsheets. The following information is provided to facilitate this process.

A.1 Importing IEUBK Single Run Output File in Spreadsheet Software

The IEUBK model output data (*.txt) for the risk assessment mode can be opened and saved as a spreadsheet file (e.g., Excel, LibreOffice) for submission to EPA. The IEUBK model output data are written in a tabular format to the text file (e.g., RunModel.txt). To import the IEUBK model output file with spreadsheet software, the user should employ the following procedure:

- 1. Start the spreadsheet software.
- 2. Click on *File/Open* and select the option '*All Files*', if necessary, to list all file types (i.e., files with all types of file extensions).
- 3. Locate your *.txt output file and click *Open*.
- 4. In Excel, on the *Text Import Wizard* screen, choose *Delimited* and then click *Finish* (see Figure A-1). In LibreOffice, accept default settings and click on *Open*.
- 5. Save the file in the spreadsheet format (e.g., in Excel, save as *.xlsx and in LibreOffice, save as *.ODS).

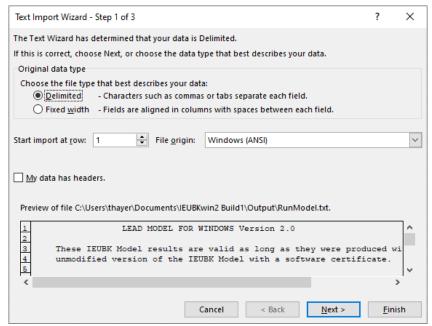


FIGURE A-1. Import IEUBK Data Output with Microsoft Excel.

A.2 Importing IEUBK Batch Run Output Files in Spreadsheet Software

The IEUBK model BatchRun output data can be opened and saved as a spreadsheet file (e.g., Excel, LibreOffice) for submission to EPA. To import the IEUBK model output file with the spreadsheet software, the user should employ the following procedure:

- 1. Start the spreadsheet software.
- 2. Click on *File/Open* and select the option '*All Files*', if necessary, to list all file types (i.e., files with all types of file extensions)
- 3. Locate your *.tab output file and click *Open*.
- 4. On the *Text Import Wizard* screen, choose *Tab Delimited* and *Finish* (in Microsoft Excel) (see Figure A-2) or *OK* (in LibreOffice Calc).
- 5. Save the file in the spreadsheet format (e.g., in Excel, save as *.xlsx and in LibreOffice save as *.ODS).

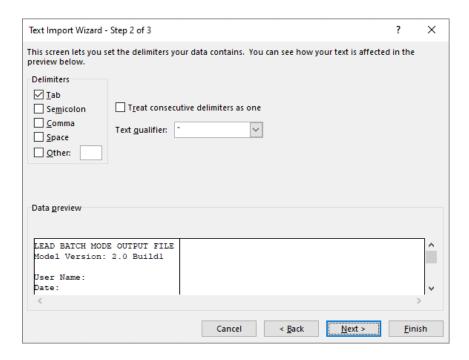


FIGURE A-2. Import IEUBK Batchrun Data Output with Microsoft Excel.

Note that Excel will break the header text of the file into columns as well. Also, an IEUBK batch mode output file requires little to no editing before it is imported to other statistical programs. If the data file contains a null row, this may cause import problems with other spreadsheet packages. Once the results are loaded into a spreadsheet or statistical program, the user can apply a variety of graphical and statistical techniques in evaluating the output of IEUBK batch mode runs. Batch mode calculates the probability of exceedance as described in Appendix B.

A.3 Creating a Batch Mode Data Input File Using Spreadsheet Software

As described in Section 3, batch mode input files require rigorous formatting. These files can be quickly and easily created with spreadsheet software. As an example, the following procedure describes creation of a batch mode data file in Microsoft Excel (see Figure A-3):

- 1. Select the first 12 columns in your spreadsheet.
- 2. Format the columns to have a width of 8.0.
- 3. Right align all data (including the text descriptions at the top of the worksheet).
- 4. Save the file with a Formatted Text (Space delimited) (*.prn) extension.
- 5. Manually change the file from *.prn to *.dat in your file directory.
- 6. Run batch mode using the newly created file.

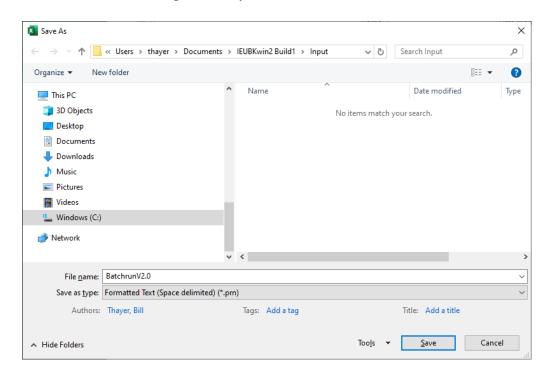


FIGURE A-3. Creating a Batch Data file with Microsoft Excel.

Appendix B: Probability Distribution Function

A Z-score is the distance between the target PbB (e.g., 5 μg/dL) and the GM PbB, *in standard normal units*. (A Z-score is also known as a *standard normal deviate*.) Furthermore, a Z-score is the inverse of the standard normal cumulative distribution function (i.e., normal distribution with mean of 0 and standard deviation of 1). The probability of a child's PbB level exceeding a target PbB is calculated as 1– the area under the standard normal cumulative distribution function to the left of the Z score. For example:

Given:

Target PbB = $5 \mu g/dL$ GM PbB = $3 \mu g/dL$ (e.g., from IEUBK model) GSD = 1.6

Calculate the Z-score given the target PbB and GM PbB predicted by the IEUBK model:

$$z = [ln(GM) - ln(target)]/ln(GSD)$$

After calculating the Z-score, the IEUBK model simulates a standard normal distribution using the predicted GM and selected GSD. The probability of exceeding the target PbB is the cumulative probability for a standard normal distribution.

This method has simplified the calculation from the IEUBK DOS version (IEUBK 0.99d).

The z-score can also be used to estimate a percentile value for a lognormal distribution given a GM and GSD:

$$X_P = GM \times GSD^{Z_P}$$

where,

 X_p = blood lead concentration at the p^{th} percentile of the lognormal distribution

GM = geometric mean of the distribution

GSD = geometric standard deviation of the distribution

 Z_p = z-score corresponding to the p^{th} percentile of the standard normal cumulative distribution

Note that taking the logarithm of both sides of the preceding equation and solving for Zp yields the equation for Z given above. The following is an example of using the preceding

equation for calculating the PbB concentration corresponding to a selected probability of exceedance (1–p):

Calculate the 95^{th} percentile blood lead concentration (X_p):

Given:

GM PbB = $3 \mu g/dL$ (e.g., from IEUBK)

GSD = 1.6

 $Z_p = 1.645$ (the 95th percentile Z score)

$$X_P = 3 \times (1.6)^{1.645} = 6.50 \ \mu g/dL$$

The results indicate that there is a 5% probability of a child's PbB concentration exceeding 6.5 μ g/dL, given a GM PbB concentration of 3 μ g/dL and a GSD of 1.6.

Appendix C: IEUBK Field Precision

While IEUBK model output is generally written with three digits to the right of the decimal point, the true precision of the output is strongly influenced by the least precise input value.

These are the Batch Run Mode field precisions:

Field	Precision Format
ID	%7s
FAM	%3.3d
BLK	%3.3d
AGE	%3d
SOIL	%8.1f
DUST	%9.1f
WATER	%6.2f
AIR	%5.2f
OTHER	%6.3f
ABSSoil	%6.3f
ABSDust	%6.3f
PBB	%5.1f
PRED	%7.2f
P(PbB>C)	%8.3f

These are the Distribution and Density curve field precisions:

Field	Precision Format
Cutoff	%.3f
Geo Mean	%.3f
GSD	%.3f
% Above	%.3f
% Below	%.3f

The precision format is interpreted as:

- %s is a string
- %d is signed integer
- %f is float value
- A number after % specifies minimum number of characters to be printed. If the value to be printed is shorter than this number, the result is padded with blank spaces. The value is not truncated even if the result is larger. For floating point specifiers (f), the number of characters includes the decimal point.
- A period (.) is used to separate field width and precision.
 - o For integer specifiers (d): precision specifies the minimum number of digits to be written. If the value to be written is shorter than this number, the result is padded with leading zeros. The value is not truncated even if the result is longer.
 - For floating point specifiers (f): this is the number of digits to be printed after the decimal point (by default, this is 6).