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**REFERENCE MANUAL:
DOCUMENTATION OF UPDATES FOR THE
INTEGRATED EXPOSURE UPTAKE BIOKINETIC
MODEL FOR
LEAD IN CHILDREN (IEUBK)
WINDOWS® VERSION – 32-BIT VERSION**

Office of Solid Waste and Emergency Response
U.S. Environmental Protection Agency
Washington, DC 20460

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TECHNICAL REVIEW WORKGROUP FOR LEAD**

The Technical Review Workgroup for Lead (TRW) is an interoffice workgroup convened by the U.S. EPA Office of Solid Waste and Emergency Response/Office of Emergency and Remedial Response (OSWER/OERR).

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Reference Manual: Documentation of Updates for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) Windows[®] version

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1.0 Introduction to IEUBKwin Model

This Reference Manual describes the Integrated Exposure Uptake Biokinetic Model for Lead in Children, Windows version (IEUBKwin) and the changes made to the model since the release of the DOS version (0.99d) in 1994. This manual provides a general overview of the changes to the IEUBKwin model so that users who are familiar with the DOS version (0.99d) can quickly get up to speed. This manual includes a synopsis of the types of guidance documentation available for the IEUBK model, including directives, software documentation, short sheets, and fact sheets; and points of contact for additional information.

Lead contamination poses significant health risks because it can affect the neurological development of children. Young children (0–7 years) are particularly sensitive to adverse health effects from lead exposure. The most frequently used biomarker for lead exposure is the concentration of lead in a child's blood. Blood lead concentrations provide useful information about recent and historical exposures to lead, and are the most widely used index of internal lead body burdens. Health effects associated with childhood lead exposure have been determined to occur at or below the 10 micrograms per deciliter ($\mu\text{g}/\text{dL}$) blood lead level of concern (U.S. Environmental Protection Agency [EPA], 1986, 1990; Center for Disease Control and Prevention [CDC], 1991). The probability that children will have blood lead levels exceeding the level of concern is an important consideration for risk assessors and may be a useful component of remediation strategies for lead in the environment.

The IEUBKwin model is a stand-alone, PC-compatible software package developed to assess the risks posed to children from exposure to environmental lead. The IEUBKwin model alone does not determine the level of cleanup required for a specific site.

The IEUBKwin model is a product of the EPA's Technical Review Workgroup for Lead (TRW), an interoffice workgroup convened by the Office of Solid Waste and Emergency Response/Office of Emergency and Remedial Response (OSWER/OERR). The TRW is composed of senior scientists with diverse technical expertise and perspectives in lead toxicology and risk assessment. The goal of the TRW is to support and promote consistent application of the best science in the field of lead risk assessment. Development of the IEUBKwin model furthers this goal by providing users with an easier way to relate environmental concentrations of lead with potential blood lead levels in children. The release of the IEUBKwin model represents an ongoing effort of the EPA to provide the most current information on lead risk assessment science and policy. The EPA will update this model periodically and issue accompanying technical guidance.

1.1 OVERVIEW OF THE IEUBKWIN MODEL

The IEUBKwin model combines estimates of lead intake from air, water, soil, dust, diet, and paint with an absorption module for the uptake of lead from the lung and gastrointestinal tract, and a biokinetic model of lead distribution and elimination from a child's body. This allows the IEUBKwin model to predict plausible distributions of blood lead levels in children 6 months to 7 years of age.

The IEUBKwin model uses the following four components to calculate blood lead levels:

- **Exposure Component.** Uses lead concentrations in environmental media to calculate the amount of lead entering a child's body. The exposure component uses media-specific consumption rates and lead concentrations to estimate media-specific lead intake rates.
- **Uptake Component.** Uses lead intake into the lungs and digestive tract and considers absorption of lead to calculate the amount of lead that enters a child's bloodstream.
- **Biokinetic Component.** Considers the transfer of lead between blood and other body tissues, or elimination of lead from the body in determining a blood lead concentration.
- **Probability Distribution Component.** Shows the probability of a certain outcome (*e.g.*, a blood lead concentration greater than 10 $\mu\text{g/dL}$ in an exposed child based on the parameters used in the model).

The biological structure of the first three components is illustrated in Figure 1–1.

Like the DOS model (0.99d), the IEUBKwin model allows a user to estimate, for a hypothetical child or population of children, a plausible distribution of blood lead levels centered on a geometric mean blood lead concentration. This distribution is predicted from user-specified information about children's exposure to lead, and is used to calculate the probability (*i.e.*, the risk) that children's blood lead levels will exceed the health-based level of concern (*i.e.*, 10 $\mu\text{g/dL}$). In simple terms, the IEUBKwin model relates environmental lead concentrations to estimated blood lead levels in children 0 to 7 years of age. After obtaining a range of blood lead levels for a child or group of children exposed to lead at a specific site, the user can then explore an array of possible changes in exposure parameters and contaminated media to examine the effects such changes have on the probability estimates predicted by the model (sensitivity analysis).

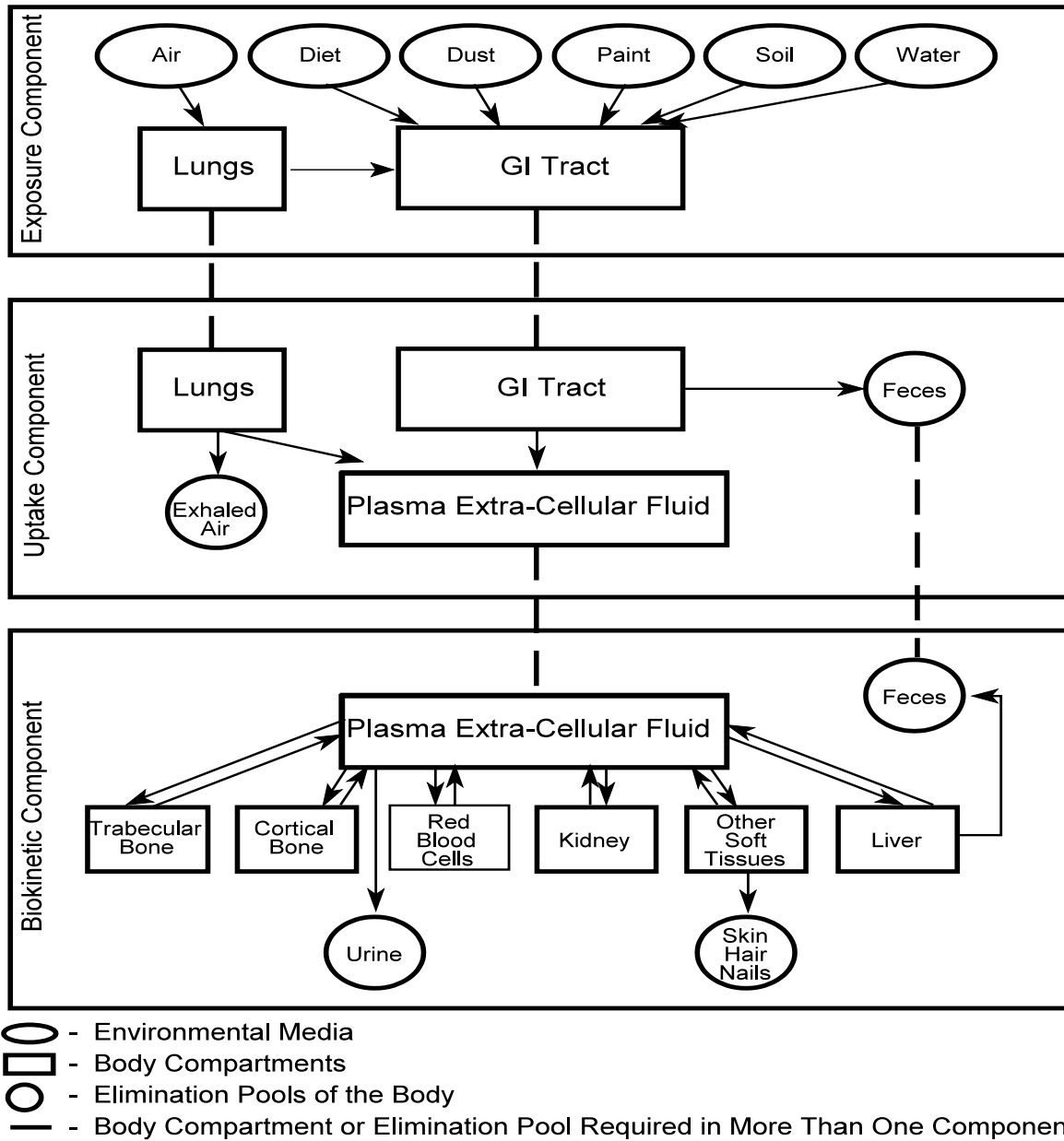


Figure 1-1. Biological Structure of the IEUBKwin Model.

1.2 CONVERSION OF IEUBK MODEL (0.99d) TO IEUBKWIN MODEL

The conversion of the DOS-based IEUBK model (0.99d) to Windows began after the completion of the Independent Validation and Verification (IV&V) of the IEUBK model. Thorough review during the IV&V identified no programming problems that would provide inappropriate results. However, a number of changes were recommended to conform with coding practices which would allow an independent reviewer to replicate the functionality of the model. The results of this process have been reported in a series of articles in a supplement to *Environmental Health Perspectives* (Vol. 106, Suppl 6, December 1998). All issues identified during the IV&V were addressed during the conversion to Windows. Aside from a number of corrections and minor enhancements, the functionality and calculations of the IEUBKwin model are identical to those of the IEUBK model (0.99d) except for the calculation of Pc (see Section 3.0). The conversion to a Windows platform has also resulted in a more user-friendly model.

To ensure compatibility with the Windows platform, several file names and data input windows required modification. All the modifications suggested by the IV&V review were also incorporated in the Windows version of the model. For example, the naming conventions used in the model were changed. The modifications made have no effect on the functionality of IEUBKwin model. A detailed list of all the modifications is presented in Chapter 2. The parameters and equations for the IEUBKwin model are described in the System Requirements and Design Document for IEUBKwin.

1.3 ORGANIZATION OF THE REFERENCE MANUAL

This Reference Manual is intended to provide detailed information on all changes incorporated into the IEUBKwin model since version 0.99d (1994). The remainder of this manual is organized as follows:

- Chapter 2 discusses the modifications made since version 0.99d was released, as well as the characteristics specific to the IEUBKwin model.
- Chapter 3 describes the new functional enhancements of the IEUBKwin model.
- Chapter 4 provides a list and brief descriptions of guidance documents available for the IEUBKwin model, as well as additional sources of technical assistance for lead risk assessment.
- Chapter 5 summarizes the scope of this manual and contains a listing of the references cited in the text.

2.0 Changes to IEUBK in Development of IEUBKwin

While the general functionality and mathematical basis for the model have not been altered, several enhancements have been incorporated into the IEUBKwin model. The first apparent change is in menu option names. For example, the *Air Lead* window under the *Parameter Input* menu in the DOS (0.99d) version of the model has been changed to the *Air Data* window in the IEUBKwin model. In addition, the user is no longer prompted with questions requiring “Yes/No” responses to proceed to associated screens. The IEUBKwin model has simplified the process of entering site-specific data by combining screens, thereby, reducing the number of data input screens. Contact-sensitive help information for each parameter has been included in the *Parameter Input* and the *Computation* pull-down menus. *General Help* and *Menu Information* options provide general information about the IEUBKwin model and the process for saving and loading files. Reminder and disclaimer windows have been included to prompt the user when changes in one parameter require changes in another (e.g., changing *Alternate Source* intakes requires changing *GI Tract Absorption Percent* in the *GI/Bioavailability Information* window). Similar message windows have been included to alert the user when input parameters are outside the valid range or in cases where default values should not be changed without first contacting the TRW. The new parameter input menus and features are described in the following sections.

2.1 PARAMETER INPUT

The *Parameter Input* pull-down menu has several new options, including *Reset All Parameters* (reverts to model defaults), *Load Input From File*, and *Save Input To File*. A separate *GI Values/Bioavailability* option has been added to allow the user to adjust the gastrointestinal absorption coefficients to account for site-specific information on bioavailability.

2.2 COMPUTATION

The menu options for the *Computation* pull-down menu have been simplified and combined into fewer input windows. The menu options are similar to those in version 0.99d; however, selections such as *Run model with current parameters*, *Change biokinetic default parameters*, and *General information about the model* have been deleted from the *Single Simulation* option. *General information about the model* has been moved to the *Help* pull-down menu in the IEUBKwin model. For the *Run the Model (Single Run)* option, the user needs only to select the iteration time step and run the model.

2.3 OUTPUT

The IEUBKwin model’s *Output* pull-down menu allows the user to view and rename results files. Some file extensions have also been changed in the IEUBKwin model (Table 2-1). Since the PBSTAT module was not part of the conversion effort, no file extension equivalent exists in the IEUBKwin model for the DOS batch mode output file with the *.asc file extension. However, the Windows *.txt output file can be used with the PBSTAT module (in DOS version of IEUBK 0.99d) by changing the file extension from *.txt to *.asc (see IEUBKwin *User’s Guide* for details).

Table 2-1. File Extensions for DOS and Windows Versions of the IEUBK Model

Description	DOS File Name (0.99d)	Windows File Name
Single Run Model Text Results File	*.txt	*.txt
Single Run Model Plot File Distribution Probability Percent Plot File Probability Density Histogram Plot File	none none	*.grf *.grf
Multiple Runs Text Results File	*.txt	*.txt
Multiple Runs Plot File Distribution Probability for Multiple Runs Plot File Probability Density for Multiple Runs Plot File	*.lay *.lay	*.lay *.lay
Blood Pb Conc vs. Media Pb Conc Text Results File	*.txt	*.txt
Blood Pb Conc vs. Media Pb Conc Plot File	*.pbm	*.lin
Load Parameters from File	*.sv3	*.svd
Save Parameters to File	*.sv3	*.svd
Batch Mode Input File	*.dat	*.dat
Batch Mode Output Files	*.txt *.asc (used in PBSTAT)	*.txt none
Media-specific Parameter Inputs Storage Files	none	*.tmp

2.4 GRAPHING RESULTS

Separate pull-down menus have been added for graphing results. In the DOS version (0.99d), the graphing menu was an option on the *Output* menu. In the IEUBKwin model, the *Graph* pull-down menu provides a comprehensive list of options for graphing results, including *Blood Pb Concentrations vs. Media Pb Concentrations*, *Distribution Probability Percent*, *Probability Density Histogram*, *Distribution Probability for Multiple Runs*, and *Probability Density for Multiple Runs*.

3.0 New Functionality of IEUBKwin

Several new functional enhancements were added to the IEUBKwin model in conversion from DOS to Windows. These enhancements were identified during an informal requirements analysis session with the TRW and recognized members of the scientific community. The addition of enhancements is based on acceptance testing of the development stage described in the *OSWER System Life Cycle Management Guidance* (U.S. EPA, 1988). None of these enhancements has any effect on the mathematical basis or the biokinetics of the IEUBKwin model. The new enhancements include the following:

- Self-installing program – the model can be downloaded from the Internet. To install the model and other files on the hard drive from a diskette, the user must select the appropriate setup executable to run. The setup executable used depends on the existing operating system (*i.e.*, Windows98/ME, Windows2000, Windows NT).
- The constant soil concentration within the *Soil/Dust Data* input window automatically populates the soil concentration for each age group.
- IEUBKwin defaults to Multiple Source analysis, whereas DOS (v.99d) defaulted to Constant Value.
- Parameter inputs can be reset to their default values without closing and restoring the model.
- The *GI Values/Bioavailability* input window is separated from the specific media data entry screens.
- Model results can be viewed as a text file without first saving the results to a text file.
- The *Blood Pb vs. Media Concentration* is a separate option in the *Computation* Pull-down menu in the IEUBKwin model.
- Text result and plot files can be renamed.
- The IEUBKwin model directory structure contains both an *Input* and an *Output* subdirectory for the user to save, store, and load input or output files.
- The IEUBKwin model has two run mode options: (1) research mode where the user is not prompted to provided explanations for changing model defaults; and (2) site risk assessment mode where all default and site-specific data are captured.
- The IEUBKwin model captures input data for the risk assessment mode in a tabular format.
- The IEUBKwin model provides a warning on the model output (text or graph file) whenever the predicted blood lead concentration exceeds 30 µg/dL. The purpose of the warning is to inform the user than any blood lead concentrations greater than 30 µg/dL are outside the calibrated and validated range of the IEUBK model.

Since it was not part of the Windows conversion effort, the probability distribution component (PBSTAT) cannot be accessed from the IEUBKwin model. However, the *Batch Mode* text results file (*.txt) generated from the IEUBKwin model can be used in the DOS version of PBSTAT by renaming the file extension from *.txt to *.asc in File Manager or Windows Explorer. Note that the *.asc file generated by IEUBKwin will have to be modified for

PBSTAT: all the headers must be removed except for the ID FAM BLK line; the P (PbB>C) data column must be removed; and the data should begin at row four. Batch mode now calculates percent exceedance for the user, using the following equation:

$$Z = \frac{\ln(10) - \ln(\text{geometric mean PbB})}{\ln(GSD)}$$

The Z score corresponds to a percentile and the probability of a child's blood lead level exceeding $10 \mu\text{g/dL} = 1 - Z$ score percentile. After calculating the probability, the IEUBKwin model uses a standard normal distribution to simulate the distribution and uses a difference approximation method to calculate the probability values. This method has simplified the calculation from the IEUBK DOS version and the result is very precise. Additional statistical analyses can be performed using a third party software package by exporting the results file.

The TRW has developed several guidance documents on lead risk assessment, and on the proper use of the IEUBK model and interpretation of the model results. This chapter introduces and explains the types of lead risk assessment guidance currently available and provides a list of additional sources of assistance.

The user should note that results obtained from this version of IEUBKwin may differ slightly from results obtained from the 0.99d version and earlier versions of IEUBKwin (versions 244 and earlier). A primary reason for converting the IEUBK model from DOS to Windows was to take advantage of better mathematical features that are available with Windows. The IEUBKwin model results are more accurate than those obtained with the DOS version of the model. IEUBKwin v244 used distinct numerical integration algorithms to calculate Pc in the batch and single run mode. The single run mode used an approach known as the midpoint rule with a fixed integration interval (set as a multiple of the standard deviation of the Z-score), and batch mode used Simpson's Rule. For risk assessment purposes, in which low error is needed at the decision point of P10 = 5%, both approaches are sufficiently accurate. However, they yield slightly different results. The earlier versions of the model, when run in single run mode, produced step changes in P10 values as the geometric mean changed and yielded P10 values that were slightly lower than the values calculated in batch mode. In this version of IEUBK Win, the Pc algorithms have been revised so that the same algorithm is used in the batch and single modes. The current version of the model uses the polynomial function, shown below, to calculate Pc. This approach is more accurate (error $< 10^{-8}$), more stable (*i.e.*, it is not affected by the integration interval), and is more computationally efficient (*i.e.*, iterative calculations are not needed to achieve a low error rate).

4.0 Guidance for IEUBKwin Model

The most current information pertaining to the IEUBKwin model and lead risk assessment is accessible online via the help buttons and available through the EPA TRW web page at the following uniform resource locator (URL):

<http://www.epa.gov/superfund/programs/lead>

This link allows access to the following types of guidance documents on the TRW homepage:

- EPA guidance: general information on lead risk assessment (e.g., *OSWER Directive: Revised Interim Soil Lead (Pb) Guidance for CERCLA Sites and RCRA Corrective Action Facilities [August 1994]*).
- Software and model documentation: information on the use and interpretation of the results of the IEUBK model as well as specific information on how data are used by the model (e.g., *Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children [February 1994]*).
- Short sheets: guidance on key parameters of the IEUBKwin model, specifically modification of defaults and evaluation of site-specific data (e.g., *IEUBK Model Mass Fraction of Soil in Indoor Dust (M_{SD}) Variable [June 1998]*, *Bioavailability [October 1999]*, *Soil Ingestion Rates [December 1999]*, and *Sieving [April 2000]*).
- Fact sheets: general information on various lead-related issues (e.g., *Technical Review Workgroup for Lead of U.S. Environmental Protection Agency [June 1997]* and *Overview of the IEUBK Model for Lead in Children. [August 1997]* [NTIS #PB99-9635-8, OSWER #9285.7-31]

All TRW products including the IEUBK model (1994) and guidance can now be downloaded directly from the TRW web site. Printed copies of the IEUBK guidance manual and Technical Support Document are also available through the National Technical Information Services (NTIS) by calling 1-800-553-NTIS and providing the NTIS publication number.

4.1 GUIDANCE DOCUMENTS

Several general EPA guidance documents pertaining to lead risk assessment are available on the TRW web site.

- *OSWER Directive: Revised Interim Soil Lead (Pb) Guidance for CERCLA Sites and RCRA Corrective Action Facilities (August 1994)*; OSWER #9355.4-12. As part of the Superfund Administrative Improvements Initiative, this interim directive establishes a streamlined approach for determining protective levels for lead in soil at CERCLA sites and RCRA facilities.
- *OSWER Directive: Clarification to the 1994 Revised Interim Soil Lead (Pb) Guidance for CERCLA Sites and RCRA Corrective Action Facilities (August 1998)*; OSWER #9200.4-27P. This directive clarifies OSWER's policy on (1)

using the IEUBK and blood lead studies; (2) determining the geographic area to use in evaluating human exposure to lead contamination; (3) addressing multimedia lead contamination; and (4) determining appropriate response actions at lead sites.

- *Validation Strategy for The Integrated Exposure Uptake Biokinetic Model for Lead in Children (December 1994)*; OSWER #9285.7-21. The Validation Strategy describes the considerations and methods for characterizing the confidence that can be placed in the output of the IEUBK (0.99d) model. The validation strategy primarily addresses the empirical comparison of the IEUBK model predictions of blood lead levels with those observed in epidemiologic studies in which environmental lead levels were also characterized.

4.2 MODEL SOFTWARE AND DOCUMENTATION

Because the IEUBKwin model is functionally similar to the IEUBK (0.99d) model, the guidance documents for the IEUBK (0.99d) model are to be used for the IEUBKwin model.

- *Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (February 1994)*; NTIS #PB93-963510; EPA Publication #9285.7-15-1. The Guidance Manual assists user by providing detailed information on environmental exposure parameters and recommendations for tailoring the model for conducting site-specific risk assessments. It emphasizes the correct use and interpretation of model outputs, as well as integration of the results into a remediation strategy.
- *Technical Support Document for the Integrated Exposure Uptake Biokinetic Model for Lead in Children (TSD) (December 1994)*; NTIS #PB94-963505; OSWER #9285.7-22. The TSD describes in detail the basis for the parameters and equations used in the IEUBK model. The TSD is not a line-by-line documentation of the model source code; instead, for clarity, it presents an interpreted version of the model source code.

4.3 SHORT SHEETS

The TRW releases updates and clarifications on the use and interpretation of the IEUBK model and other lead related issues. These guidance documents are released as short sheets and are published on the TRW web site as they become available.

- *Lead at Outdoor Firing Ranges [May 2000]*. This short sheet was developed in an effort to address concerns regarding lead toxicity at outdoor firing ranges. The short sheet focuses on the lead toxicology and the fate of lead at outdoor firing ranges.
- *TRW Recommendations for Sampling and Analysis of Soil at Lead (Pb) Sites [April 2000]*. This short sheet provides a standard set of recommendations and protocols for the collection, preparations, and analysis of lead in soil and dust for use in lead modeling.

- IEUBK Model Soil/Dust Ingestion Rates [December 1999]. This short sheet provides recommendations on the substitution of default soil/dust ingestion rates in the IEUBK model.
- IEUBK Model Bioavailability Variable [October 1999]. This short sheet discusses issues to consider and applicable methods for determining a site-specific bioavailability value for soil-borne lead.
- IEUBK Model Mass Fraction of Soil in Indoor Dust (M_{SD}) Variable [June 1998]. This short sheet provides guidance on the parameter referred to as the K_{SD} in the IEUBK (0.99d) model. The M_{SD} short sheet explains the definition and correct derivation of M_{SD} , as well as considerations when modifying the default. The short sheet also outlines the applications of the M_{SD} parameter to lead risk assessment and preliminary remediation goals for soil lead.

4.4 OTHER GUIDANCE DOCUMENTS

Additional documents supplementing this Reference Manual have been prepared during the conversion from DOS to Windows and are currently available:

- *User's Guide for the Integrated Exposure Uptake Biokinetic Model for Lead in Children, Windows Version.* The User's Guide is intended to serve as a quick reference for the IEUBKwin model. It provides users with the basic information necessary for appropriate application and interpretation of the model, including information on model installation, inputs, analysis, output, interpretation of results, application of results to risk assessment, and example scenarios.
- *System Requirements and Design for the Integrated Exposure Uptake Biokinetic Model for Lead in Children, Windows Version.* This is an all inclusive synopsis of the requirements and design specifications for the development of the IEUBKwin model. It is intended to serve as a reference for programmers to facilitate future enhancements to the IEUBKwin model.

4.5 SOURCES OF ASSISTANCE

Questions concerning the use and interpretation of IEUBKwin model may be submitted to the IEUBK technical support center via the Technical Review Workgroup for Lead (TRW) web site:
<http://www.epa.gov/superfund/programs/lead>

5.0 Summary and References

5.1 SUMMARY

This Reference Manual has been developed to assist in the use of the IEUBKwin model. The manual is intended to be used in conjunction with the *Guidance Manual for the Integrated Exposure Uptake Biokinetic Model for Lead in Children* and the *Technical Support Document for the Integrated Exposure Uptake Biokinetic Model for Lead in Children*. The Reference Manual emphasizes only those aspects of the IEUBK model that were changed during the recoding from IEUBK DOS (version 0.99d) to Windows (IEUBKwin). In addition, guidance pertaining to appropriate input procedures and model application is available via the TRW web site or Technical Support Center as described in Chapter 4.

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