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UNIVERSITY OF COLORADO

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LEAD RISK ASSESSMENT MODEL EVALAUATION

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EXECUTIVE SUMMARY

This document presents a review of the scientific veracity of lead risk assessment models currently used to predict blood lead levels (PbB levels) in exposed individuals. The major goals of this report are to:

- Provide background information on lead toxicity associated with childhood and adult exposures and determine whether any new information has been developed;
- Conduct a critical evaluation of all technical aspects of the USEPA *Integrated Exposure Uptake Biokinetic* (*IEUBK*) model, the California *Lead Spread* (Ca*LS*) model, the USEPA *Adult Lead* (*AL*) model, and the *Integrated Stochastic Exposure* (*ISE*) model;
- Provide detailed information on critical input parameters for each risk assessment model to accurately predict lead risks;
- Evaluate existing default assumptions to determine whether they are realistic and reflect current scientific, toxicological, and public health data;
- Provide detailed guidance on sampling and analysis of lead impacted environmental media; and
- Develop acceptable default cleanup levels for different reuse/exposure scenarios incorporating newly developed information.

This document is organized into the following chapters:

- Chapter 1: Introduction;
- Chapter 2: Background Lead Levels;
- Chapter 3: Overview Of Lead Risk Assessment Models;
- Chapter 4: USEPA *Integrated Exposure Uptake Biokinetic* Model;

- Chapter 5: USEPA *Adult Lead* Model;
- Chapter 6: California DTSC *Lead Spread* Model;
- Chapter 7: *Integrated Stochastic Exposure* Model; and
- Chapter 8: Conclusions And Recommendations.

Chapter 1 provides background information on the health effects of excess lead exposure to children and adults. This information is presented to support risk management decisions based on the results of risk assessment PbB level predictions. This chapter also presents recent information on the dramatic recent decrease in PbB levels in the U.S. population. Later sections discuss how this information is used to make more precise estimates of risk. USEPA risk assessment & management frameworks are presented together with other regulatory standards for numerous environmental media.

Chapter 2 presents naturally occurring and anthropogenic background levels for lead in different environmental media. This information is necessary to distinguish between site-specific sources of lead (for which the Navy is responsible) and ubiquitous background levels of lead, which can confound remediation efforts.

Chapter 3 provides an overview of the four lead risk assessment models evaluated in this report. A summary is prepared which compares different the different models. Detailed cost-effective sampling strategies are presented for different lead containing media. Additionally, a section on bioavailability provides guidance on how to conduct an investigation to evaluate bioavailability associated with different mineral and chemical forms of lead.

Chapter 4 describes the USEPA *Integrated Exposure Uptake Biokinetic* (*IEUBK*) Model that has been developed solely for predicting PbB levels in children. This model is described in considerable detail because a fundamental understanding of its complex formulation is critical to correct implementation and for making well-informed and appropriate risk management decisions. Default input parameters are presented and compared to revised default parameters based on new scientific information and recently published population statistics.

Chapter 5 presents background information and the technical aspects of the USEPA *Adult Lead* (*AL*) model that has been developed to evaluate exposures at non-residential sites. Although the title suggests the model has been developed for an adult, the actual receptor is a fetus carried to term by a woman of childbearing age who is chronically exposed to lead in the workplace. Default exposure parameters are presented and discussed together with suggested alternate default parameters based on new data and information.

Chapter 6 describes the California DTSC Lead Spread (Ca*LS*) model. It has recently been revised from Version 6 to Version 7. The revised input parameters are discussed and additional changes are recommended. This simple but all-purpose model has been developed to predict risks in diverse residential and non-residential populations exposed to lead from numerous environmental media in the state of California. Its use and limitations are discussed.

Chapter 7 presents an overview of the recently developed *Integrated Stochastic Exposure* (*ISE*) model that is a probabilistic model used to predict PbB levels in children. This model developed by Drs. Susan Griffin (EPA Region 8) and Philip Goodrum (SRC) uses the same scientific paradigm and equations as the *IEUBK* model. In contrast to the deterministic *IEUBK* model where single input values are used to predict PbB levels, the *ISE* model uses the entire distribution with a probabilistic simulation approach. While not yet in widespread use, the *ISE* model appears to be a better predictor of PbB levels than the *IEUBK* model. A case study is presented where the *IEUBK* and *ISE* model results are compared to actual measured PbB levels.

Chapter 8 presents the conclusions and recommendations for conducting scientifically defensible risk assessments that will yield accurate PbB level estimates and cost-effective, health-protective risk management decisions based on information in preceding chapters. A summary of revised acceptable PRGs to screen Navy lead sites is presented.

1 INTRODUCTION

This chapter presents toxicological background information on the effects of high and low exposures to many lead sources. Of particular interest was whether any new toxicological information has been recently published that should be considered in making risk management decisions.

The human health effects of excess lead exposure were first recognized in 1768 and have been extensively studied since (Rabinowitz 1998). Advances in clinical diagnosis of lead exposure, biomonitoring, toxicology, and epidemiological studies have resulted in very sensitive tests to identify subtle cognitive and physiological changes resulting from low-level lead exposure. The public health threats to infants, children, and fetuses have been the primary focus of the United States Environmental Protection Agency (USEPA) in mitigating lead exposure in order to reduce risks. As part of this effort, USEPA (as well as some state regulatory agencies) has developed mathematical models and a set of default input parameters to predict risks associated with exposure to sources of lead in all environmental media, but primarily to soil and dust lead. These models have been developed to investigate health threats posed by lead at residential properties, as well as non-residential occupational sites. To date, no predictive model has yet been developed to evaluate the health risks associated with direct ingestion of leaded paint chips or other discreet forms of lead in targeted residences [It should be noted that the term "lead-based paint" incorrectly characterizes paint with lead added as a pigment. Paint with lead added to it should be referred to as "leaded paint" or "lead-pigment paint" which will be conventionally used throughout this document). However, existing models do evaluate health risks associated with lead paint loading of soil and house dust as a result of deteriorating or weathered paint.

Lead occupies a unique position within USEPA risk assessment guidance and policy. While all other chemicals are evaluated on the basis of a hazard quotient (noncarcinogenic effects) or carcinogenic effects, lead is evaluated based on the predicted or measured concentration in the circulatory system (blood). That is, the concentration of lead in whole blood is used as a biomarker to assess potential risk to an individual. In contrast, risks are estimated for all other environmental contaminants as the probability of increased cancer risk or the potential for noncarcinogenic systemic effects based simply on chemical intake. Furthermore, unlike other contaminants, no toxicity value (reference dose or carcinogenic slope factor) has been developed for lead for use in risk assessment by USEPA. This document presents a detailed description and

evaluation of several regulatory mathematical risk assessment models used to predict health risks associated with lead. As with other types of mathematical models, the predicted results are only as precise and accurate as the assumptions and input data used to run the model.

1.1 Health Effects Associated with Lead Exposure

Lead is a heavy metal that can, under some exposure conditions, cause harmful effects when humans are exposed to high lead concentrations in different environmental media. It should be emphasized that lead is ubiquitous in the environment and that all humans are exposed to lead from diverse sources on a daily basis. However, lead is, by definition, not a "poison" because it is neither toxic nor lethal at low doses (corresponding to the normal average daily intake for the U.S. population). According to the Centers for Disease Control and Prevention (CDC), the term "lead poisoning" is defined as a case in which a measured whole blood level of lead is found to be in excess of 50 micrograms per deciliter (μg/dL). As will be discussed below, a blood level of 10 μg/dL in children is considered elevated, but not dangerously high. This PbB level has become the "health-protective bright line" for most health and regulatory agencies (discussed below).

Toxic effects associated with lead exposure are manifest only after exposure to relatively high lead doses under specific exposure conditions. A high soil lead concentration by itself does not necessarily cause elevation of PbB levels. Indeed, recent studies have shown residents chronically exposed to soil lead levels far in excess of 1,000 milligrams per kilogram (mg/kg) (and higher) to have measured PbB levels within the normal range. Although not all factors have been isolated, it appears that, under some exposure conditions, soil and lead concentrations may not always be good predictors of actual site-specific PbB levels.

Lead produces similar toxic effects in similar target organs in both children and adults; however, there are differences in the dose-response relationship and sensitivity. All exposure conditions being equal, children are more susceptible to the toxic effects of lead when compared with adults. Additionally, it appears that some toxic effects may be irreversible in children. The reasons for the increased toxicity and particular focus on childhood exposure in lead risk assessment are as follows:

- Children have higher intake rates per unit body weight of environmental media (soil, dust, food, water, air, and paint), compared with adults;

- Children absorb a higher fraction of ingested lead from the gastrointestinal tract than do adults; and

- Children's developing nervous systems are uniquely sensitive and susceptible to toxic effects, compared with adults.

1.1.1 Lead Toxicity Associated with Childhood Exposures

Lead toxicity in children was first recognized in the 18th and 19th centuries as congenital lead poisoning in offspring of lead workers exposed to very high lead concentrations in the workplace (Lin-Fu 1982). Sterility, abortion, stillbirth, and premature delivery were common for workers in lead industries. A high frequency of reproductive failure was also observed among wives of lead workers. With improved industrial hygiene practices and the removal of women from lead industries, congenital lead poisoning became rare and remains so today. Only in rare cases of pica (perverted appetite for non-food items, particularly soil) involving direct ingestion of lead-contaminated substances is frank toxicity seen today.

Over the last few decades, numerous toxicological and epidemiological studies have revealed subtle lead-induced health effects in infants and small children. New, highly sensitive diagnostic techniques, coupled with advances in analytical methods, have revealed that subtle toxic effects occur in children at much lower PbB levels than previously thought. Accordingly, regulatory agencies have responded by lowering the maximum allowable PbB level to protect against even the subtlest toxic effects.

In the early 1970s, the acceptable PbB level was 60 μg/dL. In early 1990, the acceptable concentration was sequentially lowered by various governmental agencies and scientific organizations until, finally, the USEPA Science Advisory Board (SAB) set maximum PbB level considered safe for young children at 10 μg/dL.

Similarly, in October 1991, CDC revised its policy on preventing lead exposure among young children (CDC 1991). In this new policy, CDC adapted the following policies:

- Lowered the PbB level of concern from 25 μg/dL to 10 μg/dL;

- Recommended phasing in virtually universal screening (i.e., screening of all young children except in communities where large numbers or percentages of children were screened and did not have elevated PbB levels);

- Emphasized the importance of primary prevention (i.e., identifying and remediating lead hazards *before* a child's PbB level is elevated); and

- Selected biomonitoring of PbB levels as the screening test of choice for lead exposure.

CDC policy also included an approach for investigating sources of lead, remediating lead hazards, and conducting medical follow-up, based on an affected child's PbB level (CDC 1991).

State programs are also based on biomonitoring. In 1986, California established a Childhood Lead Poisoning Prevention Program (CLPPP) and reporting requirements for a laboratory-based surveillance system for all people with PbB levels greater than 25 μg/dL. The surveillance system documented an increasing number of children with elevated PbB levels in 1989 and 1990. In response to this increase, the legislature passed additional laws supporting childhood lead poisoning prevention efforts in 1991. One law mandated that all children in California be screened according to standards set by regulations that are at least as stringent as the CDC guidelines and authorized the CLPPP to change the reporting requirements for PbB levels as necessary. In addition, under the Child Health and Disability Prevention program, physicians providing health care to low-income children are required to provide PbB screening to all children who attend publicly funded well-child daycare facilities. Surprisingly, data from the surveillance system showed that children living outside metropolitan areas also have elevated PbB levels. The California CLPPP has used this information to educate health-care providers on the need to screen children not usually thought to be at risk for lead exposure. In addition to paint sources of lead, the system has shown the importance of non-paint sources, such as traditional medicines and ceramic ware that are not site-specific sources of lead. Because the California CLPPP currently collects only reports of elevated PbB levels—rather than reports of all PbB levels measured—rates of elevated PbB levels among children cannot be calculated. The California CLPPP is currently adapting its reporting requirement and surveillance system to collect all PbB levels tested.

The National Research Council (NRC) of the National Academy of Sciences comprehensively reviewed all the available scientific studies and information and concurred that PbB levels greater than 10 μg/dL should be regarded a level of concern in children (NRC 1993). The justification for their opinion is presented in *"Measuring Lead Exposure in Infants, Children, and Other Sensitive Populations"* (NRC 1993). This report was also sponsored by the Agency for Toxic

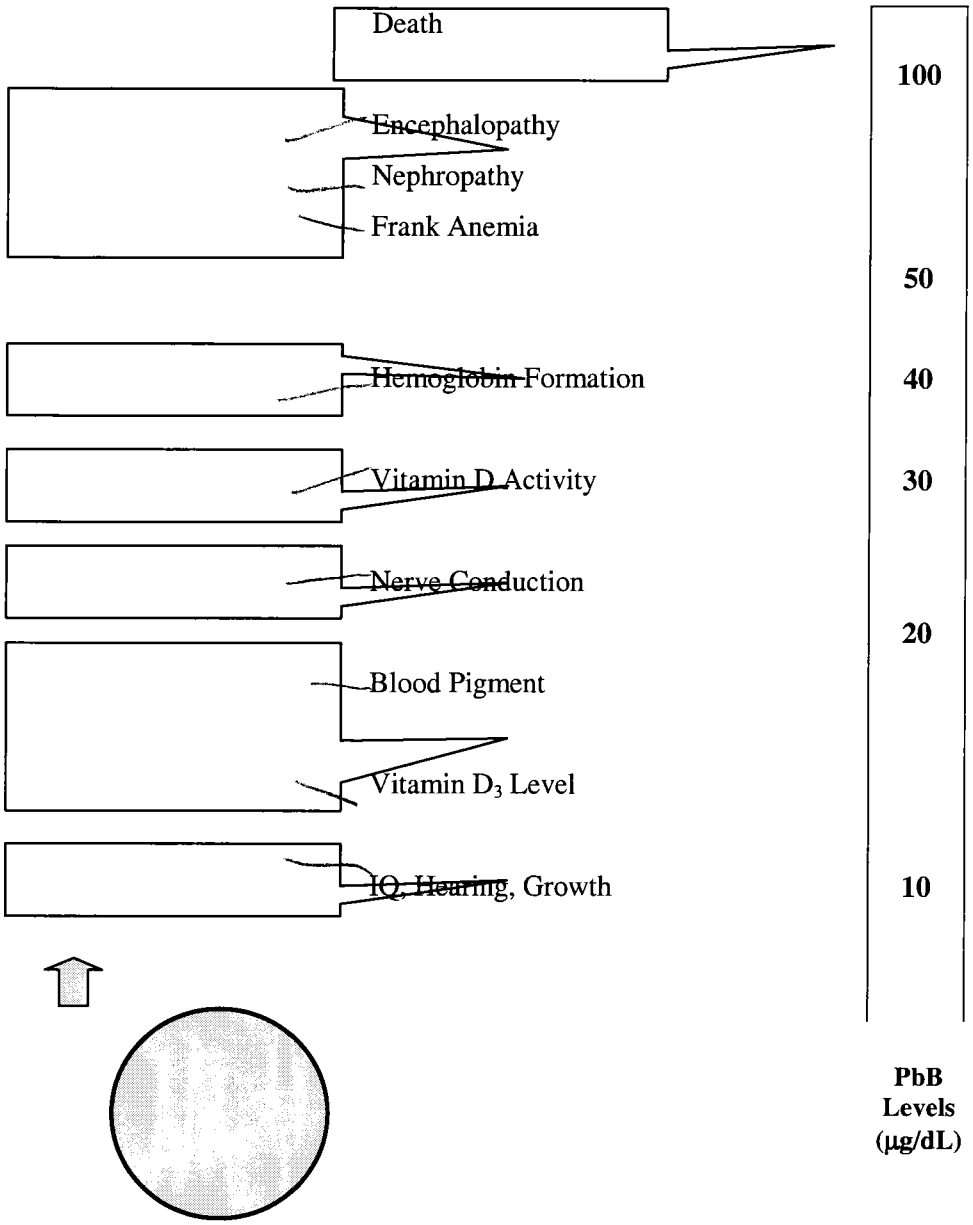
Substances and Disease Registry (ATSDR). The NRC report concludes that the following are the most salient toxicological aspects associated with PbB levels of approximately 10 μg/dL:

- Impaired central nervous system (CNS) and other organ development in fetuses;
- Impaired cognitive function and various behavioral disorders in young children;
- Increased systolic and diastolic blood pressure in adults, including pregnant women; and
- Impaired calcium function and homeostasis found in relevant target organ systems among sensitive populations.

Figure 1.1 (adapted from ATSDR 1990) shows the dose-response of corresponding toxic effects associated with increasing PbB levels in children.

FIGURE 1.1

DOSE-RESPONSE RELATIONSHIP OF LEAD TOXICITY IN CHILDREN



Source: Adapted from ATSDR Toxicological Profile for Lead.

As shown, the toxic effects in infants, children, and fetuses occur in the central nervous system (brain), bone marrow (blood forming elements), and kidney. At PbB levels as low as 10 μg/dL, impaired cognitive function, behavior difficulties, and fetal organ development may be manifest. Reduced intelligence, impaired hearing, and stunted growth may result. Of these deleterious effects, subtle changes in intelligence are generally regarded as the most quantifiable.

Shwartz (1994) conducted a meta-analysis of seven different and independent studies in which he quantified the correlation between PbB levels and Intelligence Quotient (IQ) scores. In this analysis, he used the results from the seven studies to identify an inverse relationship between IQ scores and PbB levels among young, school-aged children. One of the primary questions that this study addressed was the possibility that there is a threshold for lead-induced cognitive impairment or a PbB level below which cognitive ability is unaffected. Although the results are equivocal, the argument has been made that no human health threshold for cognitive effects exists. However, since the average PbB level among U.S. children is approximately 2 to 3 μg/dL, it is difficult to believe that cognitive impairment occurs even at baseline PbB levels.

Table 1.1 presents a summary of the results from the Shwartz study that evaluated the inverse correlation between PbB levels and IQ in children.

TABLE 1.1

SUMMARY INFORMATION FOR STUDIES INCLUDED IN THE SCHWARTZ (1994) META-ANALYSIS OF PbB LEVELS AND IQ

		BLOOD-LEAD CONCENTRATION (µg/dL)			
STUDY	**NUMBER OF CHILDREN**	**RANGE**	**MEAN (SD)**	**ESTIMATED EFFECT ON IQ SCORE (1)**	**STUDY INFORMATION**
Hawk, et al. (1986)	75	6.2 – 47.4	20.9 (9.7)	2.55 (1.5)	Cross-sectional study of children age 3-7 in Lenoir and New Hanover counties, NC; Linear regression model
Hatzakis, et al. (1987)	509	7.4 – 63.9	23.7 (9.2)	2.66 (0.7)	Cross-sectional study of primary school age children in a lead smelter community (Lavrion, Greece); Linear regression model
Fulton, et al. (1987)	501	3.3 – 34.0	11.5	2.56 (0.9)	Cross-sectional study of primary school age children in Edinburgh, Scotland; Log-linear regression model
Yule, et al. (1981)	166	7.0 – 33.0	13.5 (4.1)	5.6 (3.2)	Cross-sectional study of primary school age children in London, England; Log-linear regression model
Bellinger, et al. (1992)	147	0 – 25	6.5 (4.9)	5.6 (2.1)	Longitudinal study in Boston, MA; PbB levels at age 2; IQ measured at school age; Linear regression model
Dietrich, et al. (1993)	231	NA	15.2 (11.3)	1.3 (0.9)	Longitudinal study in Cincinnati, OH; Integrated PbB levels up to age 3; IQ measured at school age; Linear regression model
Baghurst, et al. (1992)	494	<12.2 - >28.2	20 (NA)	3.33 (1.5)	Longitudinal study in Port Pirie, Australia; Integrated PbB levels up to age 3; IQ measured at school age; Log-linear regression model

(1) Effect represents average declines in IQ points associated with an increase in blood-lead concentration from 10 µg/dL to 20 µg/dL.

NA Not available

Combining these studies and using linear regression analysis, Schwartz concluded that there was a decrease in the average IQ of approximately 2.6 IQ points when PbB levels doubled from 10 μg/dL to 20 μg/dL. This represents a loss of about 0.26 IQ points per 1 μg/dL increase in PbB concentration in this range of PbB levels.

As a matter of risk assessment policy, governmental agencies now recognize 10 μg/dL as a human health standard bright line and recognize impaired cognitive function (as measured by IQ tests) as the most sensitive lead-induced health effect in children. This policy appears to be well supported by recent studies and serves as the basis for current regulatory strategies aimed at preventing or mitigating childhood lead exposure. Risk management strategies that will lead to reduced PbB levels are not always effective and should be carefully evaluated before implementation. For example, because PbB levels are not always correlated with soil and dust lead, it is axiomatic that targeting soil and dust lead for remediation will not necessarily reduce PbB levels among children.

Some remedial efforts aimed at lead sources have become highly focused. For example, the President signed into law the Residential Leaded paint Hazard Reduction Act of 1992 (42U.S.C. 4851), which included an amendment to the Toxic Substances Control Act (Title IV: Lead Exposure Reduction), requiring the USEPA Administrator to initiate activities that would identify sources of lead hazards to reduce exposures (USEPA 1998). Specifically, §403 of TSCA (15 U.S.C. 2683) states:

> *"... the Administrator shall promulgate regulations which shall identify, for purposes of this title and the Residential Leaded paint Hazard Reduction Act of 1992, leaded paint hazards, lead-contaminated dust, and lead-contaminated soil."*

USEPA is required to define a leaded paint hazard and what constitutes lead contamination of dust and soil. A cost-benefit analysis of risk management options must be conducted, as part of the analysis. The Agency must show how risks will be reduced following promulgation of the §403 rule with the benefits of each option quantified based on reducing health risks. This information is then used to consider various standards for rulemaking and as input to the Regulatory Impacts Analysis (RIA) for the proposed rule (which is required by law). It is noteworthy that the 10 μg/dL bright-line benchmark was the standard to which all options were compared.

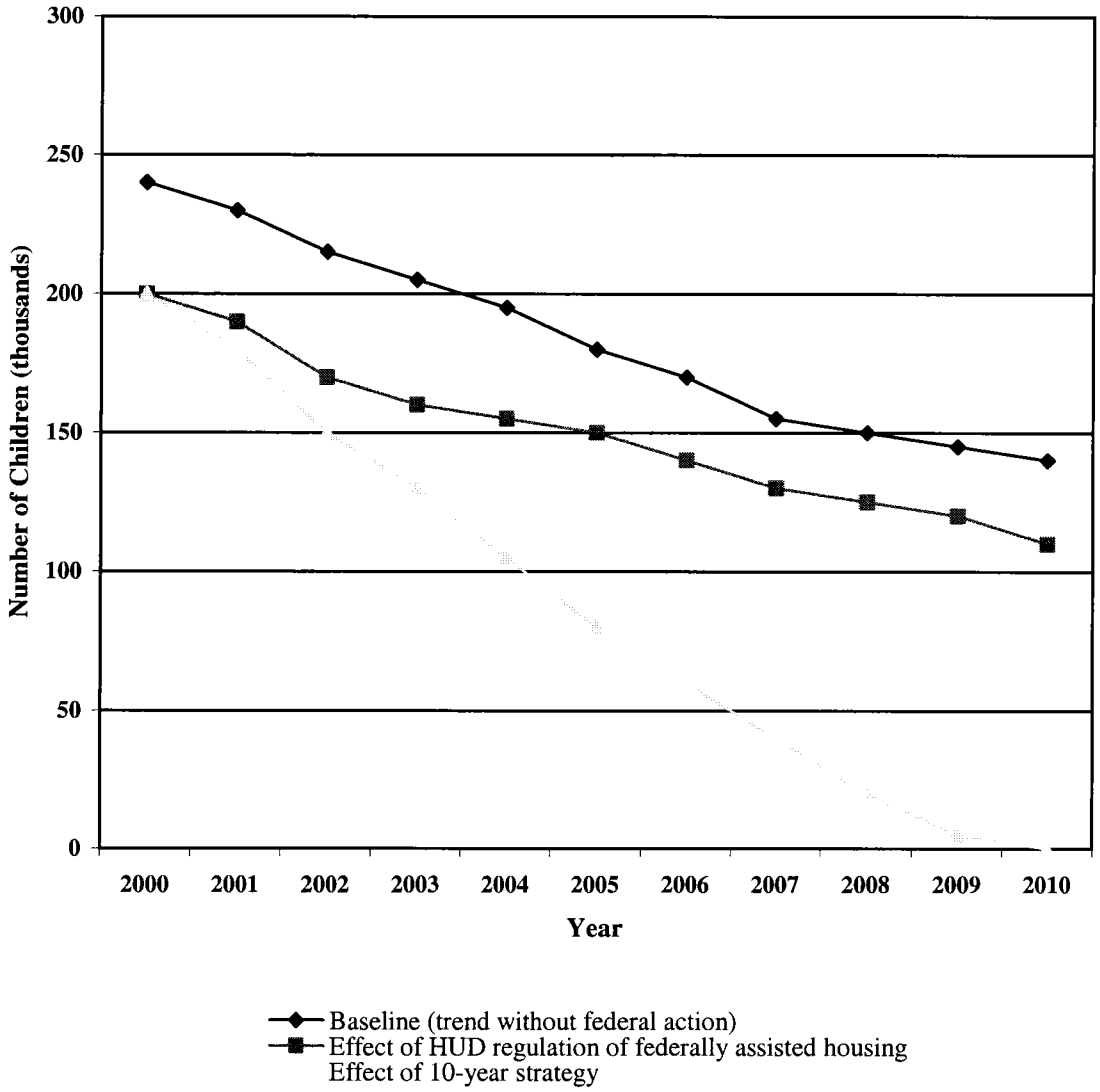
Another major effort was recently initiated as a response to the President's executive order (1305) of April 21, 1997, directing each federal agency to make it a high priority to identify, assess, and address lead risks. In issuing this order, the President created the Task Force on Environmental Health Risks and Safety Risks to Children, which was charged with recommending strategies for protecting the environmental health and safety of children. It recently issued the government's strategy detailed in:

> *"Eliminating Childhood Lead Poisoning: A Federal Strategy Targeting Lead Paint Hazards,"* President's Task Force on Environmental Health Risks and Safety Risks to Children (February 2000).

The goal of the workgroup was to develop a set of recommendations intended to eliminate childhood lead poisoning in the United States as a major public health problem by the year 2010. This report focuses primarily on expanding efforts to correct leaded paint hazards (especially in low-income housing). Figure 1.2 shows the predicted effect on the targeted population both with and without implementing the strategy. Note that the y-axis is defined as the "number of poisoned children." This is a definition created by the taskforce, since children with PbB levels slightly exceeding 10 μg/dL are not conventionally deemed "poisoned."

FIGURE 1.2

CHILDREN UNDER 6 LIVING IN PRE-1960 HOUSING WITH POVERTY-INCOME RATIO BELOW 1.3 AND PBB LEVELS GREATER THAN 10 μg/dL



1.1.2 Lead Toxicity Associated with Adult Exposures

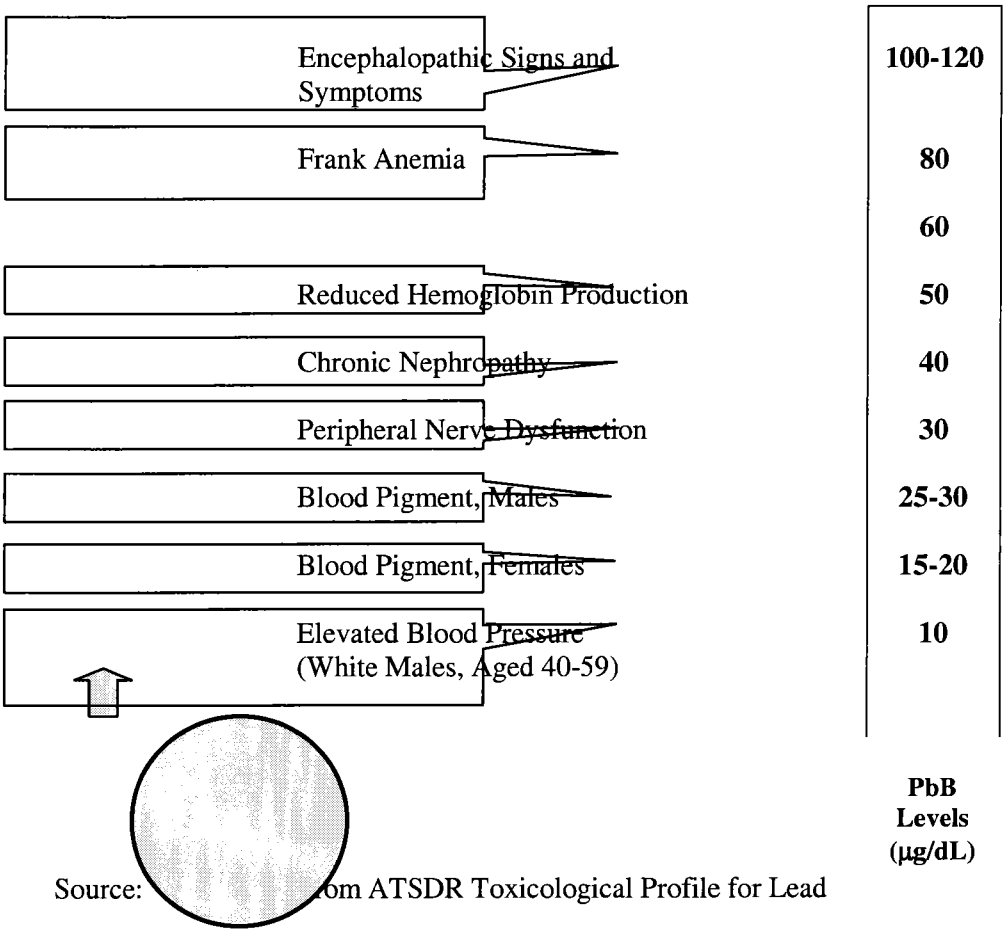
Adults exposed to high concentrations of lead may suffer the following toxic effects:

- Nervous system effects;
- Blood system effects;
- Kidney effects;
- Reproductive and developmental effects;
- Cardiovascular effects; and
- Carcinogenic effects.

The appearance and severity of the toxic effect are dose-dependent. Unlike lead exposure in children, however, it is thought that most toxic affects in adults are reversible. That is, the toxic effect (at least at lower doses) is ameliorated once lead exposure is terminated. Figure 1.3 presents the dose-response chart for lead exposure in adults.

FIGURE 1.3

DOSE-RESPONSE RELATIONSHIP OF LEAD TOXICITY IN ADULTS



Source: [illegible]om ATSDR Toxicological Profile for Lead

The following section presents an overview of the primary toxicity effects observed in adults exposed to relatively high concentrations of lead.

Nervous System Effects

One of the major targets of lead toxicity in adults is the nervous system. However, while lead-induced effects target the *central nervous system* (brain) in children, the *peripheral nervous system* (PNS) is targeted in adults. Additionally, the PNS is not as sensitive to lead toxicity, since damage is only observed at PbB levels greater than 80 μg/dL, which is rarely (if ever) observed today, even under occupational conditions. Historically, the peripheral nervous system effects are associated with high, chronic, and direct workplace exposures to lead [two or more times higher than the current Occupational Safety and Health Administration (OSHA) airborne lead Permissible Exposure Limit (PEL) of 50 $\mu g/m^3$, (National Institute of Occupational Safety and Health—NIOSH—1978)], which can cause a local paralysis to develop in nerves and can lead to "wrist drop" or "foot drop" (Feldman *et al.* 1977).

Blood System Effects

Anemia is one of the most characteristic symptoms of high and prolonged exposures to lead that are observed at PbB levels greater than 80 μg/dL. Anemia results from direct damage to red blood cells. Lead inhibits the synthesis of hemoglobin and damages the function of red blood cells, which can lead to fatigue and headache. Measurement of protoporphyrin (a red blood cell protein) in red blood cells is a biomarker of lead exposure (Piomelli 1981).

Kidney Effects

Chronic high exposure to lead, above the OSHA PEL, may cause chronic kidney damage and, in extreme cases, kidney failure. There is substantially less evidence of kidney disease at lower exposures to lead (Goyer 1989).

Reproductive and Developmental Effects

Studies indicate that exposures to high lead concentrations can result in stillbirths and miscarriages (Rom 1976). Several studies indicate that exposures to lower concentrations of lead, with PbB levels in the adult mother at or below 15 μg/dL, may result in adverse pregnancy outcomes, such as shortened time of gestation, and decreased fetal mental development and growth. The developing nervous system of the fetus is particularly vulnerable to lead toxicity.

Toxicity in the nervous system has been observed in children of exposed female workers as a result of *in utero* fetal exposure. It is thought that some of the lead stored in the mother's bone is released into the blood during pregnancy.

In males, PbB levels greater than 60 μg/dL may cause infertility. Studies also suggest that PbB levels as low as 40 μg/dL may cause decreased sperm count and abnormal sperm (Alexander *et al.* 1996; Lancranjan 1975; Braunstein 1978).

Cardiovascular Effects

Chronic exposures to high lead doses that existed earlier in this century in the workplace were associated with an increased incidence of hypertension and cardiovascular disease (Dingwall-Fordyce 1963). Today, these effects are rarely observed in the United States. However, in some cases, modest hypertension is observed at a PbB level of 10 μg/dL (Schwartz 1991).

Carcinogenic Effects

At maximum tolerated doses (levels just below the lethal dose), lead has been shown to produce tumors in animals (Azar et al. 1973). The International Agency for Research on Cancer (IARC) has designated lead and inorganic lead compounds as *possibly carcinogenic to humans* (Group 2B), based on evidence of carcinogenicity in animals (IARC 1987). However, conclusive evidence is absent.

OSHA and USEPA have both set health-protective standards based on PbB levels in workers, with some significant differences. USEPA policy is based on the assumptions that, in all occupational exposures, a pregnant worker *will* be exposed to lead. Under this least-common denominator scenario, there is no allowance for a determination of the *probability* that a pregnant woman will be exposed. Furthermore, while a PbB level of 10 μg/dL in adults is deemed health protective, USEPA believes that this level would result in an unacceptable PbB level in the fetus if the exposed adult is a pregnant woman. Consequently, the safe PbB level for a female worker of childbearing age is significantly less than the safe level for a male worker.

In 1978, OSHA promulgated an occupational PbB standard of 50 μg/dL for workers, although it recognized that the fetuses of pregnant women could be at risk. At that time, OSHA determined it was not practical or feasible to establish a universal lead exposure standard (similar to USEPA) that would protect workers from all physiologic changes, symptoms, and reproductive effects in

men and women. As a result, OSHA advised that men or women planning to have children should limit their PbB levels to below 30 μg/dL. Subsequently, several large corporations developed "fetal protection" policies that excluded all fertile women from lead-exposed jobs, which were often the highest paying. In March 1991, the U.S. Supreme Court banned employers from barring women from hazardous jobs, finding that fetal protection policies constitute illegal sex discrimination in violation of the Civil Rights Act.

The current OSHA standard for lead exposure (29 CFR 1910.1025) is set at a PEL of 50 $\mu g/m^3$. This standard is intended to protect workers from excessive lead exposure, which OSHA defines as a PbB level greater than 40 μg/dL (compared with the much more restrictive USEPA levels).

In addition to OSHA, other scientific groups have made recommendations for acceptable lead exposure for workers. The American Conference of Governmental Industrial Hygienists (ACGIH) has recommended that airborne lead levels be kept below 50 $\mu g/m^3$ (as an 8-hour 3 time weighted average), with worker PbB levels less than 30 μg/dL (ACGIH 1995). To protect lead-exposed workers, a World Health Organization (WHO) study group recommended a PbB level of 40 μg/dL in 1980 and further recommended that PbB levels in women of reproductive ages should not exceed 30 μg/dL (WHO 1980).

1.2 Decreasing PbB Levels in the U.S. Population

CDC's National Health and Nutrition Examination Surveys (NHANES), an ongoing series of national examinations of the health and nutritional status of the civilian non-institutionalized population, have been the primary source for monitoring PbB levels in the U.S. population (CDC 1994). PbB levels in all sectors of the U.S. population have declined dramatically over the last decade.

Figure 1.4 shows that during the 1991-1994 period (the most recent period for which data is available), the measured PbB level was 2.3 μg/dL (for all age groups older than 1 year of age). From NHANES II (1976 to 1980) to Phase 1 of NHANES III (October 1988 to September 1991), PbB levels for the general U.S. population (persons aged 1 to 74 years) declined from 15 μg/dL to 3.2 μg/dL. Additionally, as shown in Figure 1.5, the percentage of individuals with PbB levels greater than 10 μg/dL decreased dramatically, from 88 to 4.4% (Pirkle *et al.* 1994).

FIGURE 1.4

REDUCTION IN PbB LEVELS IN THE U.S. POPULATION

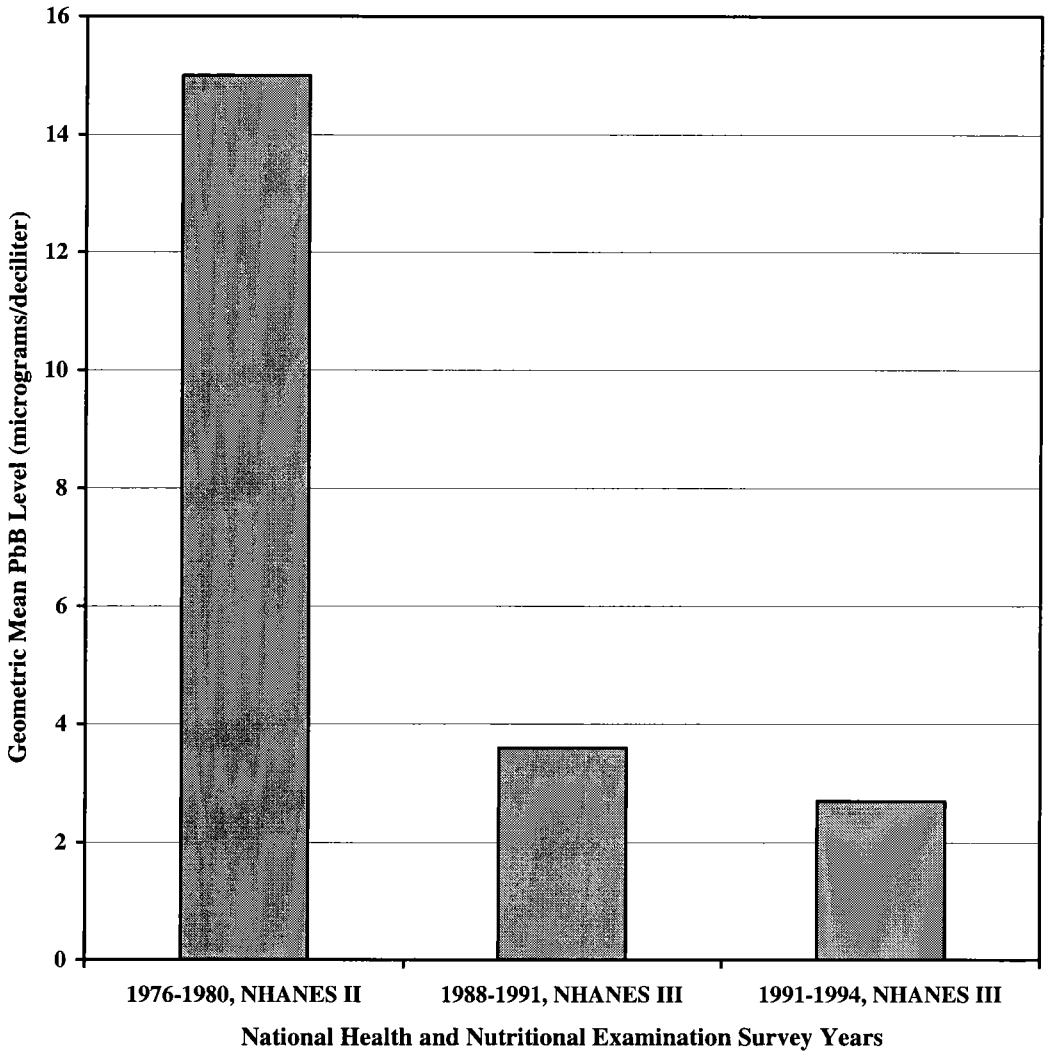
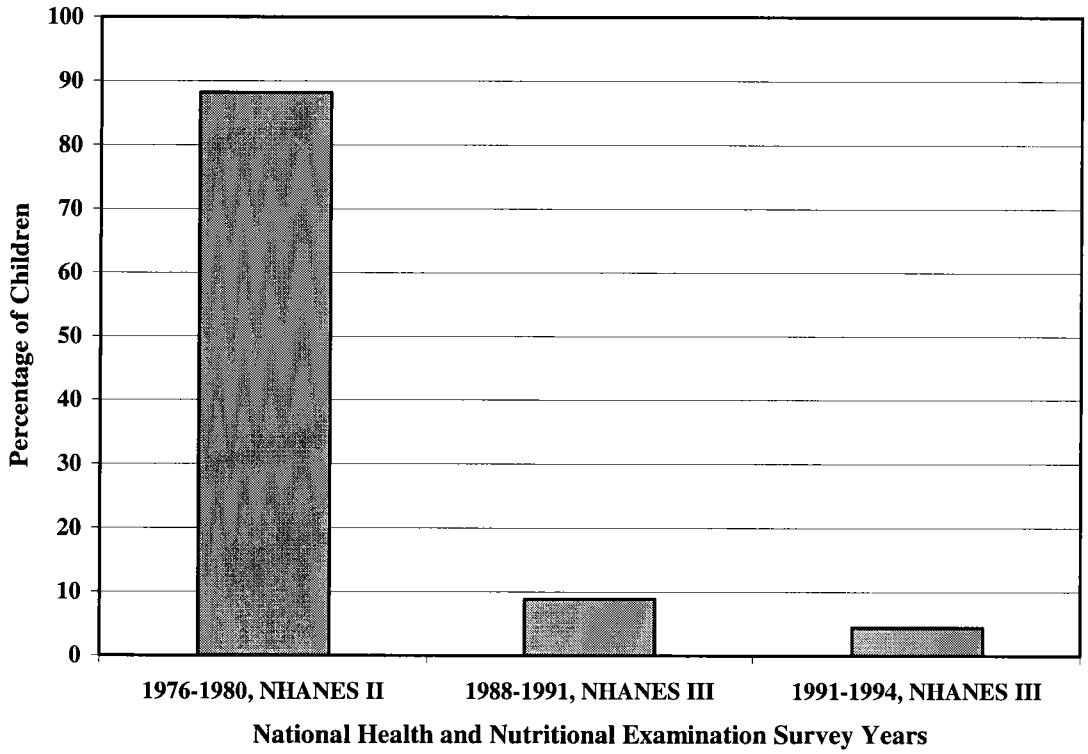


FIGURE 1.5

PERCENTAGE OF U.S. CHILDREN 1-5 YEARS OF AGE WITH PbB LEVELS ≥10 μg/dL, NHANES II AND III



PbB levels varied by age and were highest among children aged 1 to 2 years and persons aged 50 years and older. As shown in Table 1.2, approximately 2.2% of the population (older than 1 year of age) had PbB levels higher than 10 μg/dL. Among those aged 1 to 5 years, approximately 4.4% had PbB levels higher than 10 μg/dL, representing an estimated 930,000 U.S. children.

TABLE 1.2

PbB LEVELS AND PERCENTAGE OF POPULATION WITH PbB LEVELS ≥10 μg/dL, BY AGE GROUP

Age Group (Years)		PbB Levels (μg/dL)		Percent With PbB Levels ≥10 μg/dL	
	Sample Size	PbB Level [1]	95% CI[2]	Percent	95% CI
1-5	2,392	2.7	(2.5-3.0)	4.4%	(2.9%-6.6%)
1-2	987	3.1	(2.8-3.5)	5.9%	(3.7%-9.2%)
3-5	1,405	2.5	(2.3-2.7)	3.5%	(2.2%-5.4%)
6-11	1,345	1.9	(1.8-2.1)	2.0%	(1.2%-3.3%)
12-19	1,615	1.5	(1.4-1.7)	0.8%	(0.3%-1.9%)
20-49	4,716	2.1	(2.0-2.2)	1.5%	(1.0%-2.2%)
50-69	2,026	3.1	(2.9-3.2)	2.9%	(2.1%-3.8%)
≥70	1,548	3.4	(3.3-3.6)	4.6%	(3.4%-6.0%)
Total	**13,642**	**2.3**	**(2.1-2.4)**	**2.2%**	**(1.6%-2.8%)**

Source: United States, Third National Health And Nutrition Examination Survey-Phase 2, 1991-1994

(1) Weighted geometric mean PbB levels

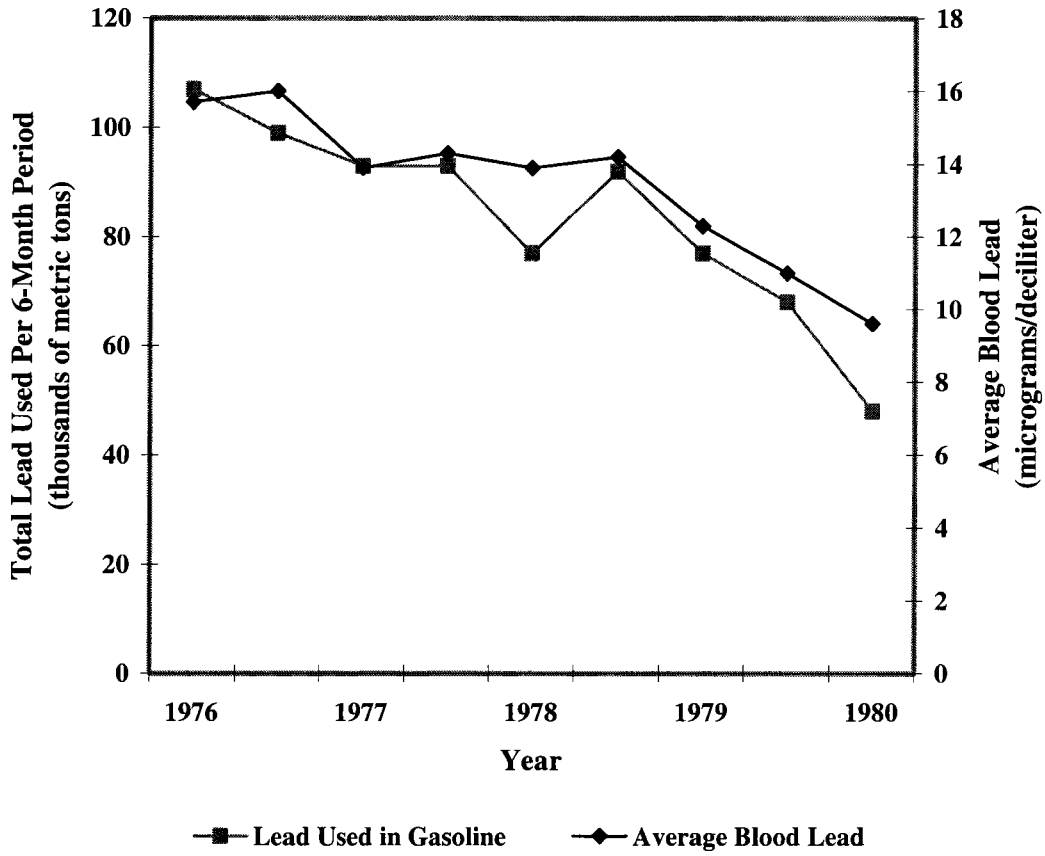
(2) (2) Confidence interval.

The findings in NHANES III indicate that the PbB levels for the U.S. population decreased by 22% (between 1970-1980 and 1991-94), and the prevalence of PbB levels above 10 μg/dL decreased by 51% over the same period. The decreases in PbB levels follow even larger decreases from NHANES II (1976 to 1980) to Phase 1 of NHANES III among individuals aged 1

to 74 years, the PbB levels declined 77% from NHANES II to Phase 1 of NHANES III, and the incidence of PbB levels above 10 μg/dL decreased by 94. CDC has concluded that the dramatic decline in PbB levels in the U.S. population, particularly among children, since the late 1970s is primarily the result of the regulatory ban on leaded gasoline. Figure 1.6 shows the parallel trend in the reduction of leaded gasoline use and PbB levels.

FIGURE 1.6

LEAD USED IN GASOLINE PRODUCTION AND AVERAGE NHANES II PbB LEVELS, FEBRUARY 1976-FEBRUARY 1980



Source: Annest, 1983.

Other contributors may include bans on leaded household paint, food and drink cans, and plumbing systems.

The NHANES study also showed a dramatic decline within the adult population. The adult PbB level (ages 20 to 74 years) declined significantly between 1976 and 1991, from 13.1 μg/dL to 3.0 μg/dL. This decline was largely the result of stricter federal regulations and changes in regulated industries that reduced workplace exposures. To protect workers from lead poisoning, OSHA promulgated a lead standard for general industry in 1978 and an interim lead standard for the construction industry in 1993. More than 90% of adults now have a PbB level less than 10 μg/dL, and more than 98% have PbB levels less than15 μg/dL.

Noting a decrease in PbB levels is important when conducting risk assessments because background (or baseline) PbB levels are *added* to the site-specific levels predicted with the model. Before occupationally exposed workers even begin working where they may be exposed to site-related lead, it is assumed they already have a PbB level corresponding to background levels. For example, PbB levels predicted with the USEPA Adult Lead (*AL*) model comprise the following two components:

- Baseline or background PbB levels resulting from lead ubiquitously distributed in the environment (air, soil, dust, food, and water); and

- Site-specific sources with which a worker of childbearing age comes into contact at the workplace.

1.3 USEPA Risk Management Policy for Soil Lead

Residential Sites

Risk assessment and management policy for soil lead is presented in "*Revised Interim Soil Lead Guidance for CERCLA Sites and RCRA Corrective Action Facilities.*" (USEPA 1994). This policy recommends a streamlined approach for evaluating soil lead concentrations and setting protective levels at both Comprehensive Environmental Response and Compensation and Liability Act (CERCLA) and Resource Conservation and Recovery Act (RCRA) facilities. Remedial decisions are based on the results of the *IEUBK* model, which is applied within a tiered risk assessment approach. The *IEUBK* model serves as both a screening tool (using default input parameters) and a site-specific risk assessment tool in which PbB levels are more accurately predicted. There are three steps within the tiered approach (USEPA 1994), which are as follows:

- **Step 1:** Screen sites by comparing site lead soil concentrations with the default acceptable concentration of 400 ppm for unrestricted residential use.
- **Step 2:** For sites where soil lead concentrations exceed 400 parts per million (ppm), use the *IEUBK* model to predict site-specific PbB levels.
- **Step 3:** Develop site-specific preliminary remediation goals (PRGs) for those sites needing remediation.

It should be noted that the *IEUBK* model predicts PbB levels based on lead exposure from all environmental sources in all environmental media, including site *and* background sources of lead. The 400-ppm screening level represents the acceptable soil concentration, assuming all other environmental media are at background levels. That is, instead of starting with a background PbB level directly used in the risk assessment, background lead *concentrations* in environmental media (including food, air, and water) are incorporated as lead intake. Background values used for all non-soil and dust environmental media should be based on current levels. Some current default values are based on levels that existed in the 1980s. As discussed, there has been a marked decrease in environmental lead concentrations, primarily due to the ban on leaded gasoline, and the most current conditions should be used in the risk assessment (USEPA has not yet revised the default parameters). Incorporating the decreasing levels of lead in the ambient environment will have the effect of raising the default acceptable soil lead concentration, which is currently set at 400 ppm. USEPA further issues a cautionary note in using default parameters:

> *"For the purpose of deriving a residential screening level, the background lead exposure inputs to the IEUBK model were determined using national averages, where suitable, or typical values. Thus, the estimated screening level of 400 ppm is associated with an expected "typical" response to these exposures, and should not be taken to indicate that a certain level of risk (e.g., exactly 5% of children exceeding 10 μg/dl blood) will be observed in a specific community, e.g., in a blood lead survey. Because a child's exposure to lead involves a complex array of variables, because there is population sampling variability, and because there is variability in environmental lead measurements and background levels of lead in food and drinking water, results from the model may differ from results of blood lead screening of children in a community".*

Furthermore, USEPA emphasizes that the 400-ppm soil lead concentration is only applicable for screening sites:

> *"Screening levels are not cleanup goals. Rather, these screening levels may be used as a tool to determine which sites or portions of sites do not require further study and to encourage voluntary cleanup. Screening levels are defined as a level of contamination above which there may be enough concern to warrant site-specific study of risks. Levels of contamination above the screening level would NOT automatically require a removal action, nor designate a site as "contaminated."*

In some situations, this explicitly stated intent has been subverted because a soil lead concentration of 400 ppm has become the *de facto* remediation goal, rather than a bright line intended to trigger subsequent investigation.

In addition to the soil lead guidance, USEPA (1994) clarifies distinctions and similarities between the Office of Solid Waste and Emergency Response (OSWER) Soil Lead Directive (which is applicable to CERCLA sites and RCRA sites) and Toxic Substance Control Act (TSCA) 403 Guidance, applicable to residential properties with leaded paint:

> *"Above the 400 ppm level, the Section 403 guidance identifies ranges over which various types of responses are appropriate, commensurate with the level of potential risk reduction, and cost incurred to achieve such risk reduction. For example, in the range of 400 to 5000 ppm, limited interim controls are recommended depending, as noted above, on conditions at the site, while above 5000 ppm, soil abatement is recommended. This OSWER guidance does not include comparable numbers above 400 ppm; instead, as*

> *discussed above, it recommends the site-specific use of the IEUBK model to set PRGs and MCSs, when necessary. The remedy selection process specified in the National Contingency Plan (NCP) should then be used to decide what type of action is appropriate to achieve those goals".*

More recent USEPA (1998) Soil Lead guidance for CERCLA sites recommends:

> *"Flexibility in determining appropriate response actions that provide protection at the individual residence should be considered in context of the NCP remedy selection criteria."*

In setting 400 ppm as the screening concentration for soil lead, USEPA assumes that it represents a soil lead level resulting in a hypothetical child or group of similarly exposed children with an estimated risk of no more than 5% exceeding the PbB level of 10 μg/dL. USEPA further assumes that a screening level that is protective for young children will protect the older population as well. However, the levels that are protective for young children are overly protective for adults.

FIGURE 1.7

RISK MANAGEMENT DECISION LOGIC FOR RESIDENTIAL SCENARIOS AT CERCLA AND RCRA SITES

STEP	ACTION
Step 1	Determine soil lead concentration at the site. If *average* soil lead concentration is less than 400 ppm, ***STOP***, no further action is required, unless special circumstances (such as the presence of wetlands, other areas of ecological risk, agricultural areas, shallow aquifers, or other areas of potentially high exposure) warrant further study. If soil lead is greater than 400 ppm, ***PROCEED*** to Step 2, unless 400 ppm is selected as a cleanup goal based on consideration of all relevant risk management factors.
Step 2	Evaluate probable land use and develop exposure scenarios.
Step 3	Collect appropriate ***site-specific data*** based on selected scenarios. For example, sampling data may include soil and dust (at a minimum), paint, water, and air; for unique site situations, data on speciation and particle size, and behavioral activities may be required.
Step 4	Run *IEUBK* model with site-specific data to estimate risk and evaluate key exposure pathways at the site. If PbB levels data are available, compare the data to the model results.
Step 5	Where risks are significant, evaluate remedial options. If leaded exterior paint is the only major contributor to exposure, no Superfund action or RCRA corrective action is warranted. If soil is the only major contributor to elevated PbB levels, a response to soil contamination is warranted, but paint abatement is not. If both exterior leaded paint and soil are major contributors to exposure, consider remediating both sources, using alternative options. If the indoor dust levels are greater than soil levels, consider evaluating the contribution of interior lead based paint to the dust levels. If interior leaded paint is a major contributor, consider remediating indoor paint to achieve a greater overall risk reduction at a lower cost. NOTE: Available authority to remediate leaded paint under CERCLA and RCRA is extremely limited.)
Step 6	If the *IEUBK* model predicts elevated PbB levels, rerun the model using the site-specific parameters selected to reflect remedial options in Step 5 to determine site-specific PRGs or MCSs for soil.

Source: USEPA 1994

FIGURE 1.8

RISK MANAGEMENT DECISION LOGIC FOR LEADED PAINT CERCLA AND RCRA SITES

STEP	ACTION
Step 1	Examine condition of exterior paint and determine its lead content, if any. If the paint is deteriorated, assess contribution or potential contribution of paint to elevated soil lead levels through speciation studies, structural equation modeling, or other statistical methods.
Step 2	Evaluate potential for recontamination of soil by exterior paint.
Step 3	Remediate exterior paint only in conjunction with soil.
Step 4	Examine condition of indoor paint and determine its lead content, if any. If indoor dust lead concentration is greater than outdoor soil lead concentration (because of contamination from both interior paint and outdoor soil), remediate indoor dust (e.g., through a removal action, or making HEPA-VACS available to community).
Step 5	Once the risk from indoor paint has been assessed, examine options to abate indoor paint (e.g., PRP, State, local, HUD) and consult TSCA Section 403 program for additional information and/or guidance.
Step 6	While RCRA and CERCLA have very limited authority regarding the cleanup of interior paint, the remedy may take into account the reduction of total risk that may occur if interior paint is addressed by other means. Thus, for example, a Record of Decision (ROD) or Statement of Basis (SB) may recognize that interior leaded paint is being addressed by other means, and narrow the response accordingly (possibly making this contingent on completion of the interior leaded paint abatement effort).

Source: USEPA 1994

Non-residential Sites

At non-residential sites where children are not currently exposed or will not likely be (chronically) exposed in the future, the 400-ppm soil concentration bright line is an overly conservative screening level. Furthermore, the Adult Lead Model must be used for non-residential sites because the *IEUBK* model can only be used to evaluate lead exposures in *children.* It cannot be used to establish a safe exposure lead concentration for *adults.*

USEPA (1996) has developed an interim risk assessment guidance approach for non-residential lead exposures that is presented in *"Recommendations of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil."* The title of this document, however, is somewhat misleading since the actual target receptor is not an adult (as suggested by the title), but a hypothetical fetus that an adult woman, it is assumed, will carry to term while employed at the site. In accordance with USEPA's policy of protecting the most sensitive receptor, it has been concluded that the fetus is more sensitive to the adverse affects of lead than an adult. In other words, the Agency believes that, even for non-residential sites where children will not be directly exposed to lead in environmental media, it is plausible that a *fetus* may be exposed *in utero* via a hypothetical female worker of childbearing age. Under this scenario, the risk assessment methodology relates soil lead intake to PbB levels in women of childbearing age, which is then extrapolated to fetuses.

Similar to the tiered approach developed for residential sites, USEPA (1998) recommends screening non-residential sites against a health-protective lead concentration for the fetus. The Agency has concluded that a reasonable screening level for soil lead at commercial/industrial (i.e., non-residential) sites is 750 ppm, but stresses:

> *"A screening goal is different from a cleanup goal. A screening goal is intended to incorporate an appropriate level of conservatism to provide for health protection in the absence of data on the specific conditions of exposure at a site. A cleanup goal can be derived using exposure assumptions based on site-specific data rather than conservative default values."*

If the site concentration is higher than the screening level, a site-specific risk assessment is warranted.

1.4 USEPA Risk Management Policy for Multimedia Lead

According to USEPA's (1998) policy of addressing multimedia exposure to lead at residential sites, the Agency's statutory authority is limited. Multimedia exposure is defined by USEPA as exposures occurring via contact with soil, ground water, airborne particulates, lead plumbing, interior dust, and interior and exterior leaded paint. While these sources of lead may contribute to total exposure and need to be evaluated to predict PbB levels, USEPA recognizes that the Agencies may not have the authority to initiate remediation:

> *"However, there are limitations on the Agency's statutory authority under CERCLA to abate some of these sources, such as indoor leaded paint and lead plumbing, because CERCLA responses may be taken only to releases or threatened releases into the environment (CERCLA §104 (a)(3) and (4)."*

The Agency (USEPA 1998) provides the following recommendations for lead-contaminated media for which USEPA has limited authority or no authority to remediate:

> ***Interior Paint:*** *EPA has limited legal authority to use Superfund to address exposure from interior leaded paint. As a policy matter, OSWER recommends that such exposures not be addressed through actual abatement activities. However, EPA Regions should promote addressing interior paint risks through actions by others, such as HUD, local governments, or individual homeowners, as a component of an overall site management strategy. Any activities to clean up interior leaded paint by PRPs or other parties should not result in an increase of the risk-based cleanup levels.*
>
> ***Exterior Paint:*** *Because of other competing demands on the Superfund Trust Fund, OSWER recommends that EPA Regions avoid using the Superfund Trust Fund for removing exterior leaded paint and soil contaminated from leaded paint. Superfund dollars may be used to respond to exterior leaded paint for protecting the overall site remedy (i.e., to prevent re-contamination of soils that have been remediated) but only after determining that other funding CERCLA monies to remediate exterior leaded paint on homes/buildings, around which soil contaminated by other sources has been cleaned up to prevent recontamination of the soil. The Superfund should not be used to remediate exterior leaded paint where no soil cleanup has occurred. As with interior leaded paint abatement, EPA Regions should promote remediation of exterior leaded paint by others, such as PRPs, local governments, or individual homeowners. Cleanup activities of*

exterior paint conducted by PRPs or other parties should not result in an increase of the risk-based soil cleanup levels.

Interior Dust: *Lead contaminated interior dust can be derived from several sources, including interior paint, homeowner hobbies, exterior soil, and other exterior sources. In many cases, it may be difficult to differentiate the source(s) for the lead contamination in the dust. In general, EPA Regions should refrain from using the Superfund Trust Fund to remediate interior dust. Because of the multi-sources aspects of interior dust contamination, potential for recontamination, and the need for a continuing effort to manage interior dust exposure, OSWER recommends the use of an aggressive health education program to address interior dust exposure. Such programs, administered through the local health department (or other local agency), should be implemented in conjunction with actions to control the dust source. At a minimum, the program should include blood-lead monitoring, and personal hygiene and good housekeeping education for the residents. OSWER believes that EPA Regions can also support the program by providing HEPA vacuums to the health agency for use in thoroughly cleaning home interiors.*

Lead Plumbing: *Generally CERCLA does not provide for legal authority to respond to risks posed by lead plumbing within residential dwellings. It should be noted that the water purveyor is responsible for providing clean water to the residences. As with interior dust, OSWER recommends that EPA Regions coordinate with local agencies to establish a health education program to inform residents of the hazards associated with lead plumbing and how to protect themselves by regularly flushing, or preferably, replacing lead pipes. Soil cleanup levels should not be adjusted to account for possible remediation of lead plumbing.*

1.5 Housing and Urban Development (HUD) Identification Criteria for Lead Sources

In 1992, Congress passed the Housing and Community Development Act (Public Law 102-550), which included as Title X the "Residential Leaded paint Hazard Reduction Act of 1992." Title X is a comprehensive law designed to direct the response to the public health problem of leaded paint hazards in residential housing. This law directed OSHA to increase the protection for workers exposed to lead hazards throughout the construction industry. Title X, by amending the Toxic Substances Control Act, also directed NIOSH to:

> *"...conduct a comprehensive study of means to reduce hazardous occupational lead abatement exposures. This study shall include, at a minimum, each of the following— (A) Surveillance and intervention capability in the States to identify and prevent hazardous exposures to lead abatement workers. (B) Demonstration of lead abatement control methods and devices and work practices to identify and prevent hazardous lead exposures in the workplace. (C) Evaluation, in consultation with the National Institute of Environmental Health Sciences, of health effects of low and high levels of occupational lead exposures on reproductive, neurological, renal, and cardiovascular health. (D) Identification of high-risk occupational settings to which prevention activities and resources should be targeted. (E) A study assessing the potential exposures and risks from lead to janitorial and custodial workers."*

NIOSH (1998) prepared a report titled "*Protecting Workers Exposed to Leaded paint Hazards*" that presents the results and recommendations pertaining to occupational exposures to lead. It focuses not only on lead abatement exposures, but also on other important exposures to leaded paint in residential and industrial construction work.

1.6 Summary of Federal Lead Standards

The following is a summary of lead sources and conditions for identifying "lead hazards," according to federal standards:

Leaded Paint: CDC defines *"leaded paint"* as paint containing lead in excess of 1.0 mg/cm^2 or 5,000 mg/g (0.5%). Hazardous conditions for leaded paint include the following:

- Paint that is peeling, flaking, chipping, or chalking;
- Paint areas subject to friction or abrasion;
- Paint with the possibility of being chewed; and
- Paint areas undergoing renovation.

Highest priority is housing built before 1950. Next-highest priority is housing built between 1950 and 1978. (Residential paint containing up to 50% lead was in widespread

use through the 1940s; lead use in residential paint declined thereafter and was banned in 1978).

Dust Lead: Guidelines from the Department of Housing and Urban Development (HUD) recommend that the following interior house dust lead levels (determined by wipe sampling) be used for risk assessment:

- 100 micrograms per square foot ($\mu g/ft^2$) for carpeted or uncarpeted floors;
- 500 $\mu g/ft^2$ for window sills; and
- 800 $\mu g/ft^2$ for window wells (or window troughs).

Lead dust is most likely to be hazardous to children because of the potential for ingestion when it is on surfaces with which children or their toys have frequent direct contact.

Soil Lead: Interim EPA guidelines call for exposure-reduction activities (e.g., using ground cover to create a barrier over contaminated soil) when lead levels in bare residential soil are between 400 and 5,000 ppm. Permanent abatement (e.g., removal and replacement) of bare residential soil is recommended when lead concentrations exceed 5,000 ppm. The HUD guidelines set exterior dust lead levels in excess of 800 $\mu g/ft^2$ as a lead hazard. Soil lead is highest around foundations of older homes that have been painted with exterior leaded paint and around homes adjacent to heavily trafficked roadways.

Airborne Lead: OSHA has determined that occupational exposures to lead concentrations greater than 50 $\mu g/m^3$ for an 8-hour time-weighted day pose a hazard to workers. This concentration is the permissible exposure limit.

Elevated PbB levels: CDC requires environmental intervention for children who have PbB levels greater than 20 $\mu g/dL$ or PbB levels of 15 to 19 g $\mu g/dL$ in two consecutive blood samples taken several months apart.

Hazardous Waste: Waste-containing lead in concentrations greater than 5 parts per billion (ppb), as determined by the Toxicity Characteristic Leaching Procedure (TCLP) test), is considered hazardous.

2 BACKGROUND LEAD LEVELS

2.1 Background Soil Lead

2.1.1 Naturally Occurring Background Lead Levels

USEPA (1994) emphasizes the need to conduct background analyses and strongly cautions against automatically interpreting high concentrations of lead as site-related:

> *"Almost anyone involved with hazardous waste site evaluations will at some time be involved in determining background concentrations of inorganics at a site. There are two issues to be considered when addressing background. The first is whether the site and local area have a high natural variability in concentrations of inorganics. The second is to differentiate between natural and anthropogenic sources at a site with high background concentrations (e.g., lead in soil due to automobile emissions). The broad range in concentrations of naturally occurring inorganics may lead to the erroneous conclusion that an area has been contaminated with inorganics."*

Table 1.2 (adapted from USEPA 1995) presents the naturally occurring lead concentration in U.S. soils. It presents information on background chemical concentrations for different soil types. As indicated, the concentration range can vary significantly, and detecting relatively high concentrations at a particular site should not be a cause for alarm. High chemical concentrations are part of natural variability and are expected. A chemical release of lead is indicated only when a high *number* of samples exceeds some expected number *and* the sample locations are clustered within a small area (i.e., they are co-localized).

TABLE 2.1

NATURALLY OCCURRING LEAD BACKGROUND CONCENTRATIONS IN U.S. SOILS

SOIL TYPE	LEAD CONCENTRATION (mg/kg)	
	Range	Mean
Sandy Soils And Lithosols On Sandstones	<10-70	17
Light Loamy Soils	<10-50	20
Loess And Soils On Silt Deposits	10-30	19
Clay And Clay Loamy Soils	10-70	22
Alluvial Soils	10-30	18
Soils Over Granites And Gneisses	10-50	21
Soil Over Volcanic Rocks	10-70	20
Soils Over Limestones And Calcareous Rocks	10-50	22
Soils On Glacial Till And Drift	1 0-30	17
Light Desert Soils	10-70	23
Silty Prairie Soils	10-30	21
Cherrnozems And Dark Prairie Soils	10-70	19
Organic Light Soils	10-50	24
Forest Soils	10-50	20
Various Soils	<10-70	26

Source: Table adapted from EPA 1995. *Determination Of Background Concentrations Of Inorganics In Soils And Sediments At Hazardous Waste Sites.* EPA/540/S-96/500. December 1995.

2.1.2 Anthropogenic Background Lead Levels

According to USEPA (1995), anthropogenic background lead conditions are defined as those resulting from human activities, but which are unrelated to site operations. Anthropogenic background conditions can result from (1) historical operations that occurred prior to site development, or (2) chemical releases from off-site or regional sources. Anthropogenic background lead levels are usually the result of deposition of airborne lead in the air from stationary (stack emissions) and non-stationary sources (vehicular exhaust). Sampling and analysis plans should be developed to identify anthropogenic non-site related sources of lead at all sites, regardless of the region in which the site is located, because anthropogenic background conditions exist in both urban and rural areas.

Urban Areas

Although lead-containing paint may initially be identified as the primary source of lead at urban sites, this conclusion should only be based on the results of careful sampling and chemical analysis. At many sites, soil lead may simply be due to deposited vehicular exhaust from local traffic. Samples collected near garages, parking areas, or driveways are frequently high in lead resulting from deposition of automobile exhaust. The proximity of stop signs, traffic lights, or high-density traffic in the area can result in significant soil and dust lead loading of nearby residential and non-residential soil and dust. Failure to evaluate all potential sources can lead to costly and misdirected remediation. Table 2.2 presents soil lead concentrations developed by USEPA showing the elevated anthropogenic lead levels that have been detected in a variety of urban soils.

TABLE 2.2

ANTHROPOGENIC BACKGROUND CONCENTRATIONS OF SOIL LEAD

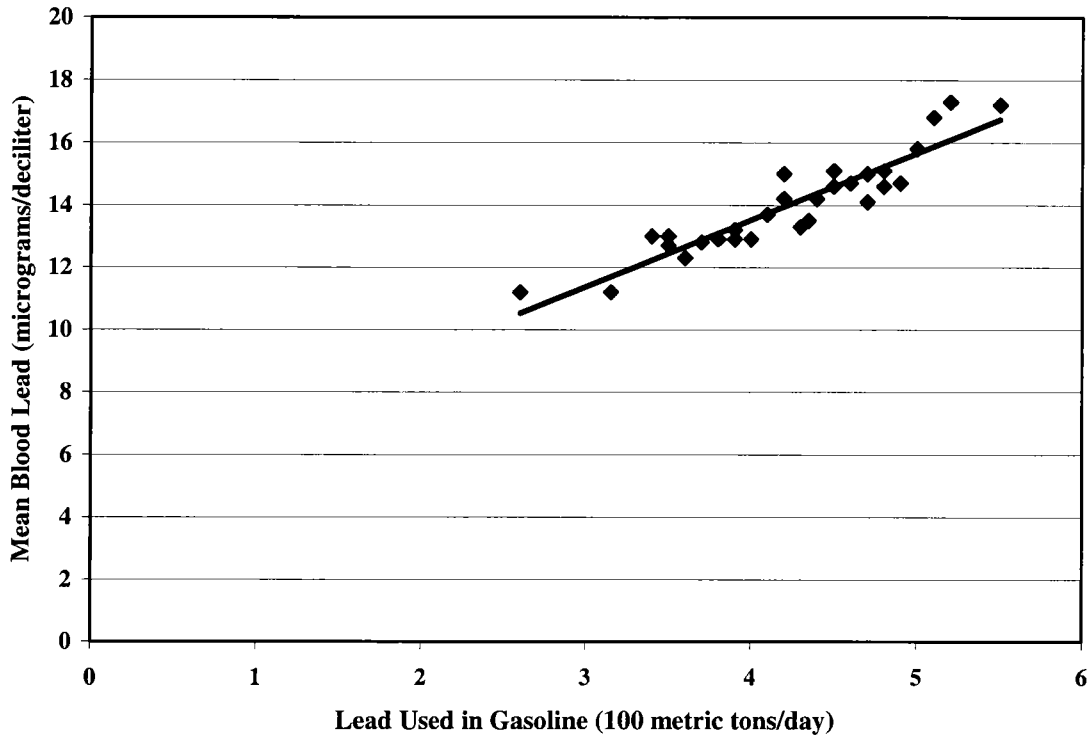
Site And Anthropogenic Source	Concentration Range (mg/kg)
Urban Garden And Urban Vicinity	**218-10,900**
Roadside Soil	**960-7,000**
Lead Metal Processing Industry	**500–6,500**
Non-Ferric Metal Mining	**15–13,000**

Source: *Determination Of Background Concentrations Of Inorganics In Soils And Sediments At Hazardous Waste Sites* (USEPA 1995).

It is well documented that soils next to high-density or high-traffic roadways have very high concentrations of lead as a result of decades of lead particle deposition from vehicular exhaust (NRC 1980; USEPA 1986). At individual residences, lead-impacted areas from leaded gasoline include zones around driveways, garages, and carports. Dzubay *et al.* (1970) showed that lead in gasoline was typically emitted at concentrations of approximately 24,000 ug/m^3. Deposition of airborne lead in soils from leaded gasoline exhaust depends on the distance from vehicular traffic and the lead content of the gasoline. USEPA (1986) estimates that 4 million to 5 million metric tons have been deposited in all environmental media in the United States since the introduction of alkyl lead additives to gasoline in the mid 1920s. Gasoline (non-leaded) is now regulated to contain lead at a concentration no higher than 0.5 grams per gallon (USEPA 1995). The discontinued use of leaded gasoline has "been accompanied by a remarkable parallel decline in the mean PbB levels of the U.S. population" (NRC 1993). The highly correlated relationship between leaded gasoline and PbB levels in the U.S. is shown in Figure 2.1.

FIGURE 2.1

U.S. MEAN PbB LEVELS VERSUS LEAD USED IN GASOLINE



Source: Schwartz and Pitcher, 1989.

Analysis of the correlation between lead-gasoline and PbB levels shows that leaded gasoline has contributed significantly to PbB levels in the United States. Data from an isotopic-lead study (Facchetti and Geiss 1982) show that lead from leaded gasoline, via both direct inhalation and exposure to lead deposited in soil and dust, can account for 50% or more of total PbB levels.

External and internal leaded paint can also affect lead soil and indoor dust concentrations; however, the influence is much more difficult to quantify. Particle size, molecular form of the lead pigment, type of soil and dust matrices, and the condition of the painted surfaces will all influence dust loading and subsequent intake and absorption (Roy 1977; Baltrop and Meek 1979; Heyworth *et al.* 1981; Healey *et al.* 1982; Dornan 1986; Koh and Babidge 1986; Steele *et al.* 1990). For example, particles of different leaded paints are likely to have different solubilities,

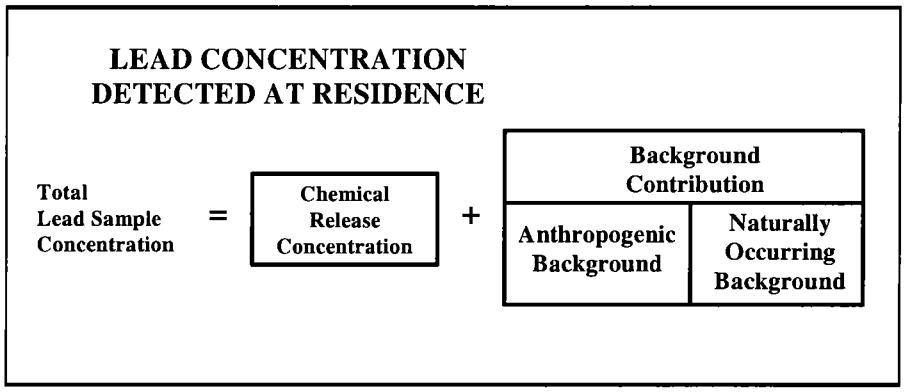
and the solubility is directly proportional to bioavailability and PbB levels. Solubility is higher for the older lead carbonate paints and lower for the newer lead chromate paints. Also, larger particles of leaded paint are not absorbed as efficiently as small or fine particles.

Other major anthropogenic sources of lead include leaded solder used in indoor plumbing and on exterior gutters, flashing, and downspouts.

As shown in Figure 2.2, the total lead concentration detected in a soil or dust sample collected at a residence comprises two parts. That is, there is a site-related component and a non-site related component (e.g., from nearby vehicular traffic). It is prudent to winnow these sources in order to make cost-effective and health-protective risk management decisions. That is, targeting the wrong environmental media for remediation may not have the intended effect of reducing PbB levels. For example, nearby automobile exhaust resulting in high lead concentrations detected in soil and dust samples at a residence may unknowingly be interpreted as being derived from leaded paint. This conclusion may direct remediation efforts to lead-paint abatement when, in fact, lead-loading from automobile exhaust (unrelated to site activities) may be the major source of lead in soil and dust.

FIGURE 2.2

THE SAMPLE LEAD CONCENTRATION IS MADE UP OF TWO PARTS



Exhaust lead is discharged in forms of halides and oxides that are eventually converted to the sulfate. These forms should be distinguished from other site-specific sources of lead. Geochemical background methods and analyses have been developed for this purpose.

Rural Areas

Table 2.3 (EPA 1995) presents information on anthropogenic background lead levels in agricultural areas. Although anthropogenic background conditions are most often associated with organic contaminants resulting from industrialized activities in urban areas, many rural areas in the United States have high concentrations of soil lead. Large rural areas were contaminated during widespread agricultural pesticide application (i.e., cropping dust). Thus, background analyses in rural areas (far removed from urban industrial activities), can be confounded by the presence of anthropogenic background lead. Sites located in areas previously used for agriculture or close to existing agricultural operations must be carefully evaluated. Elevated lead concentrations in these areas may represent normal and routine historical agricultural practices.

For example, Table 2.3 shows that land farming sludges can increase the naturally occurring lead concentrations thousands of parts per million.

TABLE 2.3

AGRICULTURAL SOURCES OF ANTHROPOGENIC CHEMICALS

Anthropogenic Source	Concentration Range (mg/kg)
Sewage Sludges	50-3,000
Phosphate Fertilizers	7-225
Limestones	20-1,250
Nitrogen Fertilizers	2-27
Manure	6.6-15
Pesticides (Percent)	60

Source: USEPA, 1995

2.2 Background Airborne Lead

Although lead is not volatile, it can be bound to small particles in air. Some of these particles may be small enough to reach the lung, where, depending on the chemical form, lead may be absorbed into the body. Airborne sources of lead are used in multi-pathway lead risk assessment models, including the *IEUBK* and Ca*LS* models. It should be noted, however, that under most circumstances lead exposure via the inhalation route is very small, compared with other routes of exposure. Despite the relative insignificance of airborne lead in directly contributing to elevated PbB levels, it is important to determine whether historical anthropogenic airborne sources significantly contributed to soil and dust loading. For example, airborne lead has historically affected urban soil and dust levels.

There are several up-to-date sources of information on current and historical ambient airborne lead levels. One of the most complete and detailed is the USEPA Aerometric Information and Retrieval System (AIRS), which can be accessed through the AIRS*Data* Internet site (www.epa.gov/airsdata/monreps.htm). This site provides air pollution data for the entire United States. AIRS*Data* can be used to create regional reports and maps, and it provides contact names for additional information. The database is updated on a monthly basis so that current site-specific information can be used in the lead risk assessment. Information is displayed to determine the estimated annual emissions of air pollutants from individual sources (plants, factories, etc.) and indicate whether the sources are near the site under investigation and are (or have been) in compliance. Monitoring data provide annual summaries of air pollution measurements at individual monitoring stations and tell where the monitoring stations are located.

Maps show the locations of major air pollution sources, monitoring sites, and areas of the country where air pollution levels exceed health-based USEPA standards. This information is vital to making cost-effective risk management decisions intended to address site-specific lead releases.

3 OVERVIEW OF LEAD RISK ASSESSMENT MODELS

3.1 Background Information

Although, in theory, it is possible to evaluate risk associated with lead exposure at any site by simply collecting blood samples in order to directly measure PbB levels in target receptors, for most sites, this is impractical or impossible. At some sites, it may be too time consuming or costly to conduct biomonitoring while at others there may be no one currently exposed to the property. Those who are present may not be willing to provide a blood sample. Nevertheless, empirical measurements of actual site-specific PbB levels are always preferable for determining whether a current health problem exists. In cases where it is impractical or impossible to measure PbB levels, the only alternative may be to use a mathematical model to *predict* PbB levels. Obviously, as is the case with most mathematical computer models, the predictions are only as accurate as the site-specific information incorporated into the risk assessment. As will be discussed in Chapter 7.0, mathematical models oftentimes significantly overestimates site-specific measured PbB levels and the corresponding "true" risk.

Several mathematical models using different scientific approaches have been developed to predict risks associated with lead exposure. Depending on the type of site and the target exposed population; models are available to accomplish the following:

- Predict PbB levels for the following:
  - Fetal and neonatal exposures;
  - Childhood exposures (0 to 64 months of age);
  - Adult resident; and
  - Occupational worker.
- Calculate health-protective risk-based remediation goals (RBRGs) or preliminary remediation goals (PRGs).

Both USEPA and California Department of Toxic Substances Control (DTSC) have lead models that can be used for risk assessment and risk management purposes, and include the following:

- The USEPA *Integrated Exposure Uptake Biokinetic* (*IEUBK*) Model;
- The USEPA *Adult Lead* (*AL*) Model;
- California DTSC California LeadSpread (Ca*LS)* Model; and
- EPA Region 8, *Integrated Stochastic Exposure* (*ISE*) Model.

The common element among these models is that they all attempt to estimate PbB levels in exposed individuals. PbB levels, in turn, are then compared with acceptable PbB levels to evaluate the potential for the site to pose unacceptable lead exposures and determine whether remediation or intervention is warranted.

A summary of the lead risk assessment models evaluated as part of this study is presented in Table 3.1. A summary of default acceptable soil lead concentrations based on the results of these models is presented in Table 3.2.

TABLE 3.1

SUMMARY OF VARIOUS LEAD RISK ASSESSMENT MODELS

	PRIMARY RECEPTOR (1)				
RISK ASSESSMENT MODEL	**FETUS**	**CHILD**	**ADULT RESIDENT**	**OCCUPATIONAL**	**VALIDATION STUDIES?** (2)
***IEUBK* (USEPA)**	**NO**	**YES**	**NO**	**NO**	**YES**
***ISE* (EPA REGION 8)**	**NO**	**YES**	**NO**	**NO**	**YES**
***AL* (USEPA)**	**YES**	**NO**	**NO** (3)	**NO** (3)	**NO**
Ca*LS* (DTSC)	**YES**	**YES**	**YES**	**YES**	**NO**

(1) Primary Receptor: Target human receptor at the site, as defined by either current or future land use.

(2) Validation Studies: Refers to whether an attempt has been made to determine whether the model predicts PbB levels that are close to measured PbB levels. However, the *IEUBK* model has been shown to overpredict PbB levels.

(3) Primary Receptor: Based on target human receptors at the site as defined by either current or future land use. Risk is based on most sensitive receptor at the site.

TABLE 3.2

SUMMARY OF DEFAULT ACCEPTABLE SOIL LEAD CONCENTRATIONS

	PRIMARY RECEPTOR			
RISK ASSESSMENT MODEL	**FETUS**	**CHILD**	**ADULT RESIDENT**	**OCCUPATIONAL**
(USEPA) IEUBK	**NA**	**400-550 ppm**	**NA**	**NA**
(EPA REGION 8) ISE	**NA**	**1300-1500 ppm**	**NA**	**NA**
(USEPA) AL	**750-1750 ppm**	**NA**	**5750 ppm** (1)	**NA**
(DTSC) CaLS	**NA**	**94-146 ppm** (2)	**676 ppm**	**3468 ppm**

(1) The acceptable lead concentration for the *AL* model corresponds to the lowest concentration, the fetus.
(2) The range of acceptable concentrations corresponds to a child exhibiting pica and a normal child.

Lead risk assessments differ from conventional human health risk assessments for hazardous chemicals (conducted according to USEPA guidance), in two respects. First, unlike conventional risk assessments, in which human health risks are estimated for an individual based on assumptions for reasonable maximum exposures (RME) using upper-bound values, lead risks are based on central tendency or average values. A geometric standard deviation (GSD) is applied to the average PbB level to generate the entire range of plausible PbB levels around the average. This departure from conventional risk assessment practice must be recognized while developing the work plan for a lead risk assessment because using conventional RME parameters will lead to ultraconservative estimates of PbB levels. These results will likely be unrealistic and not plausible.

One common example of using an RME parameter that can significantly overestimate lead risk involves collecting data in a biased manner (hot spots) and using the 95% upper confidence limit (95UCL) of the mean soil or dust concentration. Although this approach is required for conventional risk assessments, only average or central tendency parameters must be used in lead risk assessments for all environmental media.

There are some aspects common to all lead risk assessment models. Prior to discussing the individual risk assessment models, the following brief sections present guidance for conducting sampling and analysis, which is applicable for all lead risk assessments. This is a pivotal step for all risks assessments because, once samples are collected, they will be used to establish exposure point concentrations that will directly influence predicted PbB levels. Incorrect or biased sampling can result in overestimating risk. Therefore, samples collected to define the nature and extent of contamination may not be appropriate for risk assessment purposes.

3.2 Sampling and Analysis

Soil Lead

Collecting the appropriate number of samples in the correct locations to represent plausible long-term exposure for all potentially lead-affected media is critical for accurately predicting PbB levels and lead risks. Furthermore, it is important to implement a sampling and analysis strategy that can be used to differentiate background and site-specific sources of lead (as discussed in the previous sections). For remediation purposes, site-specific sources of lead should be the primary focus of the risk assessment and not ubiquitous or ambient background lead. Not all lead resulting from off-site anthropogenic activities should be classified as site-specific hazardous waste releases. Lead will always be present and detected in all environmental samples collected at any location in the United States.

With unlimited resources and time with which to evaluate a possible lead-contaminated site, multiple samples could be collected and analyzed for lead in every environmental medium at every plausible location to predict PbB levels. However, this approach is impractical for most sites. Issues such as cost and schedule will be the predominant factors in developing a sampling strategy. How many samples, and whether or not any "special" site-specific analyses or investigations are required to estimate PbB levels, will be based on professional judgment.

Environmental media that should be sampled depend on the risk assessment model used (*IEUBK*, *AL*, *CaLS*, or *ISE* models), the required accuracy and precision of the risk estimate, and potentially impacted environmental media. The *IEUBK* model, which is a multimedia model, requires lead concentrations as input parameters for multiple sources of lead (i.e., food, water, soil, dust, and air). In contrast, the *AL* model requires that samples only be collected for soil and dust lead. As shown in Table 3.3, data for soil lead is required in all lead risk assessment models.

TABLE 3.3

DATA REQUIREMENTS FOR LEAD RISK ASSESSMENT MODELS

	DATA REQUIREMENTS				
RISK ASSESSMENT MODEL	**AIR**	**DRINKING WATER**	**SOIL**	**DUST**	**FOOD**
IEUBK	**SS/DFT**	**SS/DFT**	**SS**	**SS/DFT**	**SS/DFT**
ISE	**SS/DFT**	**SS/DFT**	**SS**	**SS/DFT**	**SS/DFT**
Adult Lead Model (AL)	**NA**	**NA**	**SS**	**SS/DFT**	**NA**
CaLS Model	**SS/DFT**	**SS/DFT**	**SS**	**SS/DFT**	**SS/DFT**

Source:

SS/DFT Site-specific data is preferred, but default values are available in the absence of site data.

SS: Site-specific data is necessary.

NA: Not applicable because model does not directly evaluate environmental media. Instead, national background PbB levels are already accounted for.

As indicated, soil is the single-most important environmental medium for two reasons. First, there are no default values that can be used as proxy values for soil lead and it is the most likely medium to be clearly related to site-specific lead releases. Second, input parameters for other environmental media are dependent on soil lead concentrations. For example, lacking indoor lead dust data, it is assumed that dust concentrations will be present in proportion to the outside soil lead concentration.

Sample locations depend on where human receptors are known to be currently exposed or are expected to be exposed in the future. The sampling strategy must focus on areas where exposure is or will occur. This area is referred to as the "exposure unit." For example, to estimate PbB levels for young children, who are likely to spend most of their time at home, the exposure unit is the entire yard. Because the purpose of lead risk assessment is to estimate the *average* PbB level (to which the GSD will subsequently applied to estimate the 95 percent upper confidence limit, which is the health protective bright line PbB level), it important that the mean soil lead concentration be determined by taking samples over the entire yard to represent exposure. If it is known or assumed that exposure is random across the yard, then sampling locations should be collected from multiple locations in the yard to reflect current or plausible random exposure (EPA Region 8 1996). In other words, the sampling strategy should parallel activity patterns. The data from biased sampling (to identify "hot spots") should not be used in the risk assessment. That is, it is not appropriate to select the boundaries of exposure based on the nature and extent of environmental patterns of soil contamination. Only when it is known or suspected that children are more likely to play in some areas of their yard than others should biased samples be collected. Biased samples might also only be pertinent in evaluating children currently exposed and may not be useful at sites where no children currently reside and might be misleading in the assessment of risks to future children who might play in other locations in the yard. When biased sampling is deemed appropriate, sampling should focus on high-activity areas, rather than biased areas defined as hot spots.

For the above reasons, random sampling most closely parallels random exposure. EPA Region 8 guidance (1998) explicitly states:

> *"Based on this, in the general case, the sample locations should not be biased toward over-representation of areas that are expected to contain higher-than-average lead levels (e.g., drip lines), areas where exposure is suspected to occur more frequently than other areas (e.g., a play area) or areas where contact with soil is thought to be more likely than*

> *for other locations (e.g., a bare area). The reason that biased sampling is not appropriate is that there is no method by which such biased data can be used to derive an unbiased estimate of the true mean over the exposure area (EPA 1994). Rather, the exposure unit should be sampled using a systematic sampling pattern to ensure balanced representation of all areas of the unit."*

When the assumption of random exposure over the exposure unit is not considered to be realistic, then the exposure unit may be divided into sub-areas. Random samples should be collected within each of the sub-areas and the sub-areas subsequently combined to develop an exposure point concentration. The objective of this approach is to develop a soil lead data set that will accurately predict PbB levels in current residents.

The number of samples necessary to make accurate PbB level predictions depends on site-specific conditions. When soil lead concentrations represent a small fraction or a very large portion of the overall lead risk, then high accuracy is not needed to make risk management decisions. That is, high accuracy is not needed for sites where the predicted PbB level is well above or below 10 μg/dl. Only sites where predicted PbB levels are close to 10 μg/dl will require sufficient samples to accurately and confidently make the correct risk management decision.

Site-specific conditions and risk management criteria should guide sampling. In general, fewer samples will need to be collected from sites where lead concentrations are fairly homogeneous, as opposed to heterogeneous sites where more samples will be required to estimate the exposure concentration. Thus, the three factors most important in determining how many samples should be collected (EPA 1998) are as follows:

- Desired accuracy;
- Sample variability; and
- Estimated average concentration.

In general, more samples will be required for sites that require high accuracy and have high intrinsic variability. Figure 3.1 presents the 95% confidence limits about the mean as a function of sample number and variability, as represented by the GSD (USEPA 1998). As shown, UCL/mean and LCL (lower confidence limit)/mean ratios asymptotically approach 1.0, which represents a point at which no uncertainty in the data set exists. It is important to note that

FIGURE 3.1

UNCERTAINTY IN EXPOSURE POINT CONCENTRATION DECREASES AS THE NUMBER OF SAMPLES INCREASES

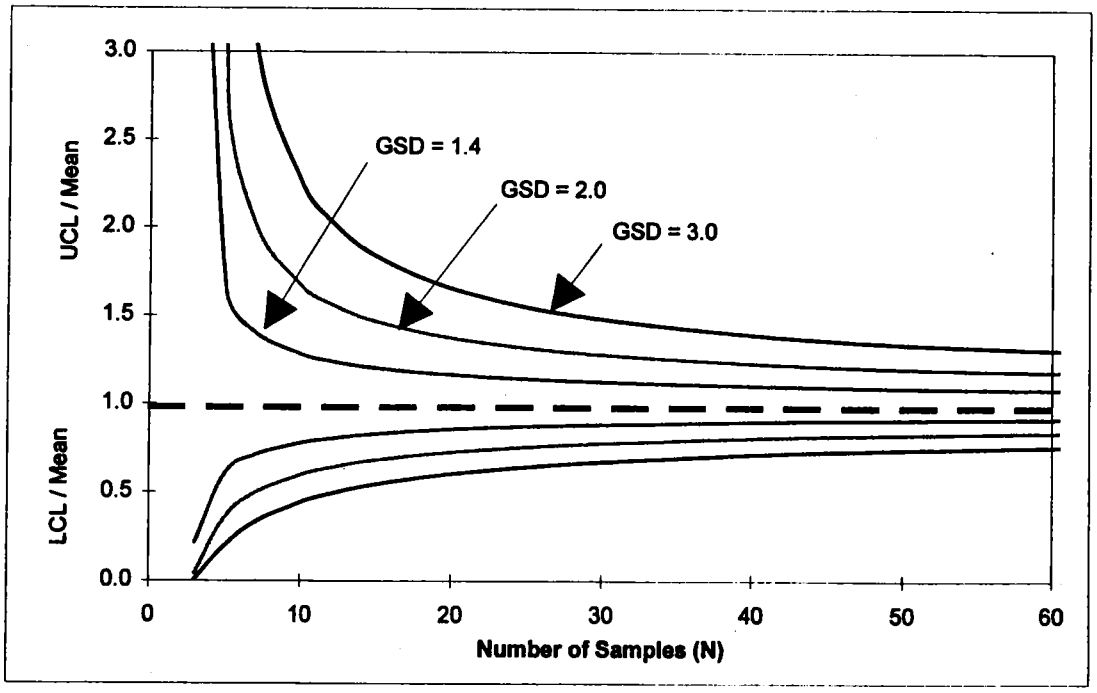


Figure adapted from EPA (1996)

UCL – Upper confidence limit on the mean concentration.

LCL – Lower confidence limit on the mean concentration.

Note: A value of 1.0 represents the point at which both the UCLs equal the mean concentration.

uncertainty in the estimate of the mean concentration decreases with more samples, regardless of the GSD, and uncertainty is higher for data sets with high variability (GSD) than lower variability. From a practical standpoint, it is also important to note that, after a certain point, taking more samples does not appreciably reduce uncertainty. It is not cost effective to attempt to reduce the uncertainty by more than a factor of 1.2 to 1.3 by collecting more samples (flat part of the curve in Figure 3.1). It is imperative to collect enough samples to accurately estimate exposure point concentrations in all lead risk assessments because the effect of the calculated P10 is very sensitive to small changes in the average soil concentration. Table 3.4 shows the

sensitivity of the average soil lead concentration as a factor of variability (or range of concentrations). Confidence intervals around the value of P10 are much larger than the confidence intervals around the value of the mean soil concentration. This range can span the decision threshold (P10<5%) when soil concentrations are between 300 and 600 ppm, which is close to the *default* decision threshold for risk management decision (site-specific conditions may increase the acceptable lead soil concentrations). In this range of soil lead concentrations; it is very important to collect sufficient samples to accurately estimate the PbB level.

Table 3.4 shows the number of samples required to estimate the average lead concentration within a factor of 1.3 to 2.0 for sites having low, medium, and high variability. For example the number of samples required at a relatively heterogeneous site (where the data variability is high; GSD = 3.0) will be 60 and 12 samples when it is required that the average concentration be estimated within a factor of 1.3 and 2.0, respectively. It is not practical to define the mean concentration more accurately than within a factor of about 1.2 to 1.3. When insufficient data are available to make an *a priori* determination about the variability of the sites, EPA Region 8 (1998) recommends using a default GSD of approximately 2.0. This would require approximately 30 samples from each exposure unit, but costs may be reduced by samples across the exposure area. Compositing samples is appropriate because the calculated mean concentration of *n* samples is expected to approximate the single measured value for a composite of those same *n* samples.

TABLE 3.4

NUMBER OF SAMPLES REQUIRED TO ESTIMATE MEAN SOIL LEAD CONCENTRATION

	NUMBER OF SAMPLES REQUIRED		
Variability	**Estimating The Mean Within A Factor Of 1.3**	**Estimating The Mean Within A Factor Of 1.5**	**Estimating The Mean Within A Factor Of 2.0**
Low Variability (GSD=1.5)	**10**	**7**	**5**
Medium Variability (GSD=2.0)	**30**	**15**	**7**
High Variability (GSD=3.0)	**60**	**30**	**12**

Depth of soil sampling should represent that portion of soil where exposure is expected to occur. Although there is no regulatory standard or formal definition for surface soil, soil collected at depths from 0.5 to 2 inches below ground surface is typically used to represent residential exposure (EPA 1991, 1994, and 1995).

Two sampling strategies should be considered for collecting multiple soil samples within a residential exposure unit. In the first strategy, discrete samples are collected and analyzed individually. This approach should be followed when hot spots are thought to exist within the exposure area (however, hot spot data should only be used to estimate PbB levels when it is located within the exposure area). Additionally, it can reveal information on soil variability across the exposure area. However, the cost for discrete sampling and analysis can be high and yield little useable information when lead concentrations are relatively *homogeneous*. Before implementing a discrete sampling and analysis approach, the site conceptual model should be developed together with a cost-benefit analysis to determine whether additional costs are warranted.

The second sampling strategy involves combining or compositing individual soil samples into a single sample that is subsequently analyzed. For most sites, this approach will significantly reduce sampling and analysis costs with no loss of site information. The single composite sample concentration can be used directly in the lead risk assessment to represent a best estimate of the average exposure point concentration across the exposure unit. The only disadvantage of the composite sampling approach is that it may not reveal the presence of hot spots. However, for fairly homogeneous sites having only one source of lead, this is the preferred approach.

When composited sampling is conducted, the results of the risk assessment should not be used to automatically force an "all or none" remedial decision at a particular residence. Subsequent discrete sampling should always be conducted to determine whether remediation of the entire site or only a small portion is necessary. This two-step sampling approach can save on sampling costs.

The number of samples combined in a composite sample should be at least three and no more than 10 (USEPA 1994). Samples should always be composited to represent discreet portions of the exposure unit and not be composited randomly. Compositing in this manner will allow small areas within each exposure unit to be identified if subsequent remediation is warranted. Other sampling strategies intermediate between discreet and compositing sampling should be

considered if they yield the necessary data for risk assessments. For non-residential sites, samples must also be collected in a manner that will yield the *average* exposure point concentration (EPC) for long-term exposures. USEPA (1994) defines the EPC as "the portion of soil to which adults are most likely exposed." Exposures are also assumed to occur on a regular or daily basis randomly across the exposure area over the year(s). Under both current and future exposure scenarios, an arithmetic mean concentration should be estimated based on the specific exposure area that a worker would plausibly be expected to contact on a regular basis. It is important to collect data from all areas that are known to be affected, as well as areas where lead releases have not occurred, since the average exposure is assumed to be random across the entire site. USEPA suggests using half an acre as a reasonable default exposure area for outdoor workers; however, site-specific information or conditions may suggest that workers are exposed to a greater area (e.g., lineman) or a smaller area (e.g., small commercial facility site).

As with residential sites, background conditions should be evaluated with non-residential sites to develop a practical, cost-effective remediation strategy. Recent geochemical analytical methods have been developed to provide not only site-specific background information, but also background information on a sample-by-sample basis (DON 2000).

Dust Lead

After soil, indoor house dust is the next-most important environmental medium requiring that site-specific data be collected. However, determining dust lead concentrations is not an absolute requirement. Unlike soil lead data, for which there are no default options, there is a conservative default approach for estimating indoor dust lead concentrations.

Site-specific dust lead concentrations should be determined when exposure to indoor dust lead is expected to be significant. However, dust measurements may not be possible under some circumstances, and a default approach must be used. The default assumption (USEPA 1994) is that 70% of indoor dust lead is contributed by outdoor soil lead. This relationship is expressed as:

$$\mathbf{C}_{dust} = \mathbf{0.70} * \mathbf{C}_{soil}$$

This default proportionality is based on empirical data collected at a number of *residences* and may be an appropriate value for many risk assessments. At other sites, the contribution of soil lead is substantially lower than the 70% default, in which case, PbB levels could be overestimated. A major factor contributing to residential dust lead levels is the normal behavior

of children and pets, which physically transport soil lead particles into houses. Consequently, this default relationship should only be used at residential sites.

For non-residential sites, the default dust value of 70% will likely overestimate the "true" site-specific indoor dust lead concentrations for occupational exposures. This could result in exceeding some health-based target for indoor workers or triggering unnecessary remediation. The primary reason is that children and family pets (responsible for transporting soil lead into homes) are not present at office buildings. The contribution of resuspended soil lead to dust lead will be even lower in office buildings that are climate controlled (where windows are shut) and/or the site has landscaped ground cover. Consequently, residential default values for dust lead should not be used (unless there is no practical alternative) to evaluate non-residential exposures. In the long term, it will usually be cost-effective to collect indoor dust lead samples because dust samples may be the only data requirement to estimate non-residential PbB levels (assuming there is no direct contact with outdoor soil). If soil concentrations are used to calculate dust concentrations, risks will be overestimated at many sites.

Paint Lead

Interior or exterior leaded paint can be an important source of lead exposure that can occur directly (ingesting paint chips) or indirectly (ingesting soil contaminated by lead chips). Measuring the fraction of lead in paint may, therefore, be important. Evaluating the condition of the paint is equally important in order to determine if the paint is tight, weathered, chipping, peeling, or flaking.

Although leaded paint data may be useful for making risk management decisions, it is not necessary for estimating PbB levels in lead risk assessments for several reasons. First, none of the risk assessment models can directly evaluate paint chip ingestion. Direct ingestion of paint chips is expected to be intermittent and not chronic (EPA 1998), resulting in temporary "spikes" in PbB levels that cannot be handled with current risk assessment paradigms. Although direct paint ingestion may be an acute hazard, few studies have measured the toxic effects from lead paint chip ingestion, and it is not currently possible to include this particular type of exposure in risk assessments. For example, while it is presumed that ingesting an occasional paint chip will cause a relatively large increase in PbB levels, it is not known how long the PbB levels remain high or what the corresponding toxic effect will be. Inorganic lead is not metabolized but is directly absorbed, distributed, and excreted. Once in the blood, lead is distributed primarily

among three compartments: blood, soft tissue (kidney, bone, marrow, liver, and brain), and mineralizing tissue (bones and teeth). Mineralized tissue contains about 95% of the total body burden of lead in adults (ATSDR 1990). Additionally, it is not known whether a small but transient spike in PbB levels can produce toxic effects similar to those of PbB levels that remain chronically high (exceeding 10 μg/dL). In blood, 99% of the lead is bound to erythrocytes (red blood cells). Only 1% is in plasma and available for tissue transport. In adults, PbB levels have a half-life (the amount of time for the concentration to be reduced to one-half the original concentration) of approximately 25 days. In soft tissue and bone, the half-life is approximately 40 years and 25 years, respectively (ATSDR, 1992).

Second, when soil and dust lead levels are measured and used in the risk assessment to predict PbB levels, the contribution of leaded paint to overall exposure is *already* accounted for. Thus, there is no need to measure lead levels in paint, at least for risk assessment purposes. The only reason to sample for leaded paint and determine the condition of the painted surface is to determine if it is currently an important source of lead loading to other environmental media or will likely become an important source in the future. Risk management decisions may be influenced by such site-specific information regarding lead sources.

Drinking Water Lead

Based on the volume of water ingested each day and the bioavailability of soluble forms of lead, lead in drinking water can contribute significantly to PbB levels. Lead in drinking water can arise from the lead in water (private well or municipal supply) or from indoor plumbing. Assuming that the main purpose of the risk assessment is to focus on risks from lead released to the environment from a site-related activity, in most circumstances it will only be necessary to analyze lead levels in source water (EPA 1989). When the water for the site under investigation is a municipal supplied water source, it is conventional to assume the municipality is in compliance with regulatory drinking water standards (maximum contaminant levels; MCLs) unless unusual site-specific conditions exist.

Airborne Lead

The physical properties of lead limit the amount and physical form of lead that can be inhaled. Lead does not exist in vapor form and, in most cases, is adsorbed to small dust particles, which can reach the lung only if they are sufficiently small. It is generally assumed that lead-bound particles must be smaller than 10 microns (μm) in diameter to enter the lungs. However, the

inhalation pathway is relatively insignificant compared with soil, dust, and food ingestion, so it may not be cost-effective to spend time or money collecting airborne lead data. Using the default exposure assumptions in the *IEUBK* model for a child aged 2 to 3 years and the default assumption regarding the amount of soil that exists as respirable particles in air, the ratio of the lead dose from inhalation of PM_{10} (particulate matter that is 10μm in diameter) to the dose from ingestion of soil and dust is as follows (EPA 1998):

$$\frac{DIair}{Disoil} = \frac{C_{air} * BR}{C_{soil}(IRs + 0.7IR_d}$$

Where:

DI_{air} = Daily intake of lead from air (μg/day);

DI_{soil} = Daily intake of lead from soil and dust (μg/day);

C_{air} = Concentration of lead in air (μg/day), estimated as $C_{air} = C_{soil}$ * **PEF** (particle emission factor; 2E-4 mg/m^3);

BR = Breathing rate (5 m^3/day)

IR_s = Ingestion rate for soil (61 mg/day); and

IR_d = Ingestion rate for dust (74 mg/day).

Using these default values, the inhaled dose of lead from soil suspended in air is less than 0.001% of the daily-ingested dose of soil and dust lead. Therefore, there is generally no need to collect site-specific air lead data for risk assessment purposes. Instead, regional yearly average airborne concentrations should be used to estimate risk.

The Clean Air Act requires EPA to set National Ambient Air Quality Standards for pollutants considered harmful to public health and the environment. The Act established two types of national air quality standards. *Primary standards* set limits to protect public health, including the health of "sensitive" populations, such as asthmatics, children, and the elderly. *Secondary standards* protect public welfare, including protection against decreased visibility, damage to

animals, crops, vegetation, and buildings. The EPA Office of Air Quality Planning and Standards (OAQPS) has set National Ambient Air Quality Standards for lead, which is one of the "criteria" pollutants. The primary and secondary standard for lead is 1.5 $\mu g/m^3$, based on a quarterly average. As a priority pollutant, ambient air levels of lead are continuously measured at all monitoring stations throughout the United States. The ambient concentration for most sites can be found in the AIRS*Data* database (previously discussed). It provides annual summaries of lead concentrations measured at individual monitoring stations and tells where monitoring stations are located relative to the site under investigation.

3.3 Evaluating Lead Bioavailability

Lead exists in the environment in many different chemical and physical states. It is important to determine the site-specific form of lead in order to make accurate PbB level predictions. This information is necessary, regardless of the lead model used or the type of receptor at the site. Lead bioavailability directly influences the PbB levels and lead toxicity.

Bioavailability is generically defined as the absorption from the gastrointestinal tract (or lung) into the body. It is a key element in predicting PbB levels because lead with low bioavailability will pose much less of a hazard than does the same dose of lead with high bioavailability. Lead that is ingested, but not absorbed, passes harmlessly through the body (eliminated in the feces). Unlike risk assessments for other chemicals where the total amount of chemical "ingested" is simply calculated and used to predict human health risks, lead risk assessments require that the fraction of lead actually absorbed into the body be determined.

Specific terminology referring to the "availability" and "absorption" of lead into the body has been defined by USEPA (1994). It is important to note that lead must first be dissolved and in a soluble state before any absorption into the body can occur. This means that lead bioavailability must be evaluated as a two-step process, which is as follows:

- **Step 1:** Determine the fraction of lead (i.e., soil and dust lead) that is soluble or can be made soluble in the gastrointestinal tract.

- **Step 2:** Determine how much of the soluble fraction can be absorbed.

The term "bioaccessability" is frequently used to describe the fraction of ingested lead that becomes solubilized in the gastric fluid. However, bioaccessability is related to bioavailability, not simply as the total amount that is soluble, but also the *rate* at which lead becomes soluble.

Though the general term "bioavailability" refers to *"the fraction of the total amount of material in contact with a body portal-of-entry such as the lung, gut, and skin that enters the blood"* (USEPA 1994), there are different types of bioavailability. Bioavailability is also described as absolute or relative. Absolute bioavailability is the amount of lead entering the circulatory system (blood) following ingestion, divided by the total amount administered. For practical reasons, absolute bioavailability is typically calculated as the percent of fractional uptake of lead following ingestion of an injected dose, where the injected dose represents 100% absorption. In contrast, *relative* bioavailability represents the fractional bioavailability of a particular form of lead relative to the bioavailability of a soluble form of lead, such as lead acetate.

Studies have demonstrated that there is great variability in bioavailability associated with different soil and dust matrices (Casteel *et al.* 1997; Henningsen *et al.* 1998; Steele *et al.* 1990). They have identified the following three-physical/chemical aspects that strongly influence bioavalability and which must be considered in lead risk assessments:

- Soil and dust particle size;
- Mineralogical or chemical form; and
- Lead speciation and physical matrix (extent to which lead is encased in inert mineral material).

Table 3.5 presents a summary of the relative bioavailability of different forms of lead, as determined by Henningson *et al.* (1998). As indicated, the relative bioavailability of different mineral lead forms can vary considerably. USEPA (Region 8) has conducted *in vivo* animal experiments that show a general pattern of relative bioavailability for certain lead salts. Lead speciation has been identified as a key factor influencing bioavailability. This archival information can be used to compare bioavailability based on the site-specific lead minerological form to that which is used as the default value. If the lead form is significantly different from the form that the default value is based on, then the site-specific form should be used instead of the default value (assuming supporting information is available or can be gathered).

TABLE 3.5

RELATIVE BIOAVAILABILITY OF DIFFERENT MINERAL FORMS OF LEAD

	RELATIVE BIOAVAILABILITY		
	Low (Less Than 25%)	**Medium (Between 25 and 75%)**	**High (More Than 75%)**
Mineral Form Of Lead	**Galena (PbS)**	**Pb Oxide**	**Cerrusite (PbCO3)**
	Anglesite (PbSO4)	**Pb Fe (metal) Oxides**	**Pb Mn (metal) Oxides**
	Pb (metal) Oxides	**Pb Phosphate Slags**	
	Pb Fe (metal) Sulfates		
	Native Pb		

Source: Adapted From Henningsen *et al.* (1998)

Geochemical analysis also provides information about different lead sources at a site. For example, lead speciation data can be used to differentiate the fraction of soil and dust lead attributable to paint chips or flakes, naturally occurring background, and anthropogenic background conditions. EPA Region 8 suggests that at least a limited soil characterization study be conducted for lead risk assessments. Although some sites may require detailed analyses, it may be possible to identify paint chips or flakes with a light microscope. This circumvents costly analysis with electron microscopic or microprobe analysis.

The rate and amount of soluble lead absorbed in the gastrointestinal tract is dependent on the following two components:

- Passive absorption; and
- Facilitated or active absorption.

The *passive* component refers to the type of absorption that does not depend on lead concentration in the gastrointestinal tract and is not saturable. In other words, there is no limit to the amount of lead that can be passively absorbed. The *facilitated or active* component may become saturated and rate limiting when the total concentration of lead in the gut is sufficiently

large. In other words, there is a limited amount that can be actively absorbed. The importance of these components in the risk assessment is that there is a finite amount of lead that can be absorbed by the body at one time. Absorption will not always be proportional to the amount of lead ingested or the amount of lead solubilized in gastric fluid.

As Table 3.6 shows, as the mass of soil ingested increases, the relative bioavailability decreases.

TABLE 3.6

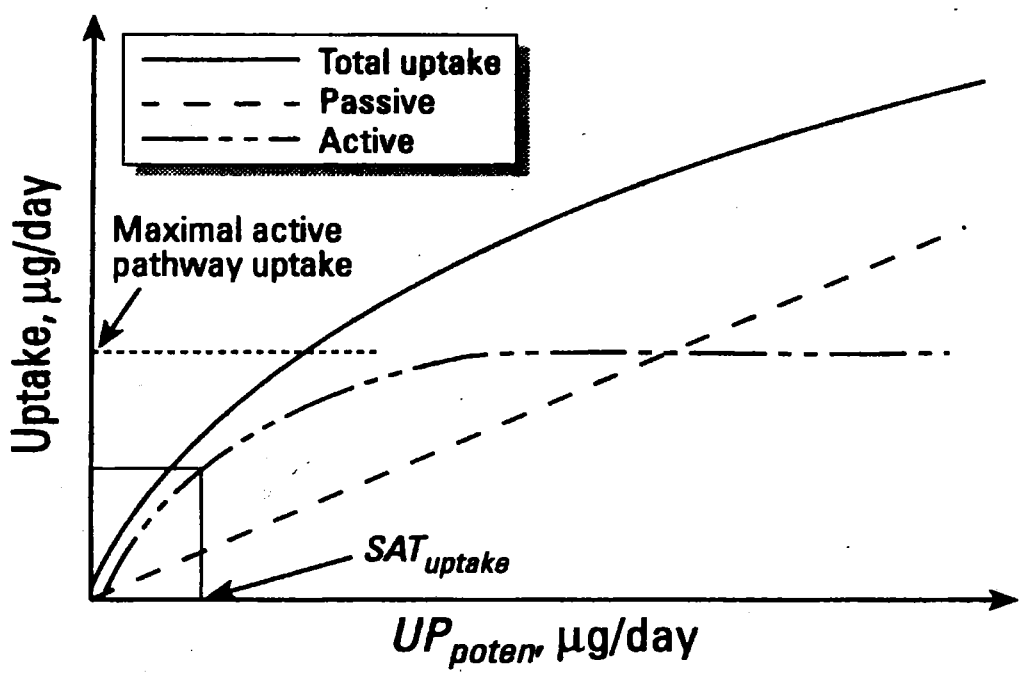
RELATIVE BIOVAILABILITY IS DEPENDENT ON THE AMOUNT OF LEAD INGESTED – IT DECREASES WITH INCREASED INGESTION

PbB Levels For Calculating Relative Bioavailibility (µg/dL)	Dose Of Soluble Lead To Achieve PbB Level (mg/kg/day)	Dose Of Soil Lead To Achieve PbB Level (mg/kg/day)	Relative Bioavailability
1.0	0.03	0.04	0.78
2.0	0.07	0.10	0.71
3.0	0.11	0.17	0.65
4.0	0.15	0.27	0.58
5.0	0.20	0.40	0.50
6.0	0.25	0.60	0.42
7.0	0.30	0.93	0.33
8.0	0.36	1.60	0.23

This effect is also shown graphically in Figure 3.2, where the total lead absorption tapers off when lead intake exceeds the amount of lead that can be actively absorbed following ingestion. The point noted as *Maximal Active Pathway Uptake* shows the saturating effect.

FIGURE 3.2

ILLUSTRATION OF SATURATING ACTIVE ABSORPTION ON TOTAL LEAD UPTAKE



Source: White *et al.* (1998)

Note:

UP_{poten} represents the amount of lead that would be absorbed without saturation effects

SAT_{uptake} represents the UP_{poten} point at which the active transport is one-half saturated.

The current Agency position is that *in vivo* animal bioassays using actual site soil or dust constitute the only way to confirm site-specific bioavailability. EPA Region 8 (1996) suggests the following three possible approaches for investigating site-specific bioavailability:

- Measure the bioavailability of lead in an appropriate *in vivo* animal study;
- Measure the solubility of lead in an *in vitro* test system, and estimate the bioavailability by extrapolation; and
- Characterize the physical and chemical forms of lead present by light or electron microscopy.

The first option is the most direct and scientifically tenable approach. However, the type of animal experiments may be costly and complex in design and interpretation. This option should only be considered after conducting a cost-benefit analysis in which the cost of remediation is weighed against the cost of the animal study.

The second option is an *in vitro* ("test tube") study. Some fast and cost-effective *in vitro* tests have been developed, but they have not been verified. Moreover, *in vitro* assays do not directly measure bioavailability. They only provide information on potential bioaccessibility (or solubility). The results can be influenced by slight changes in pH, time, temperature, volume, other solutes, and agitation. However, if an *in vitro* test indicates that soil or dust has very low solubility, this can be used as supporting information.

The third option involves electron microscopic analysis. EPA (1996) has conducted lead bioavailability measurements on a number of different soils from contaminated sites across the country. These soils were geochemically analyzed with electron microprobe analysis, so it may be appropriate to extrapolate results to other soils with similar geochemical composition. It will only be possible to extrapolate after the geochemical composition of the reference test material is confirmed to be similar.

According to USEPA (1999), soil and dust samples that are tested for *in vivo* bioavailability or *in vitro* bioaccessibility should be representative. The top 2 inches of surface soil from residential yards should be composited for testing and sieved to less than 250 μm to closely represent the size of soil particles that would be expected to adhere to children's hands.

4 USEPA INTEGRATED EXPOSURE UPTAKE BIOKINETIC MODEL

4.1 Background Information

Prior to developing the *IEUBK* model, USEPA relied on a simple mathematical model based on a slope factor approach to estimate health effects. EPA's Office of Air Quality Planning and Standards used this mathematical approach as a tool for setting air lead standards. The relationship between PbB levels and environmental lead concentrations in different environmental media was estimated using a linear relationship. The linear relationship between PbB levels and lead in each of the environmental media became known as the slope factors. However, as more studies were conducted, it became apparent that the slope factor approach oversimplified the toxicological aspects of lead and should not be regarded as universal constants applicable to all exposure situations, sites, and child populations. The following summarizes USEPA (1994) findings:

- *"Slope factors are a function of many factors: media ingestion rates; bioavailability and absorption of lead from the medium; and biological kinetics of lead retention and elimination in the child. Biological and physical differences between sites and study populations cannot be incorporated explicitly and quantitatively into regression slope factors from different studies."*

- *"Slope factors for a single medium, such as lead in air or lead in soil, may provide only a very incomplete picture of total lead exposure from a particular source, even if the source is identified with the medium. A single medium such as household dust may contain lead from many sources, and lead from a single source such as exterior leaded paint may contribute to several exposure media pathways to the child."*

For these fundamental reasons, a slope factor approach is considered by USEPA to be inadequate for estimating PbB levels in children (it should be noted that, although USEPA regards the slope factor approach inappropriate, this approach is used in the *AL* and Ca*LS* models).

In 1985, EPA's OAQPS began developing the Uptake-Biokinetic (UBK) model. This model was used to predict PbB levels based on different input concentrations from lead in air, soil, and dust. This model was based on the biokinetic model developed by Harley and Kneip (1985), and on

long-term feeding studies of infant and juvenile baboons, human autopsy data, and human infant feeding studies. USEPA validated this model according to the following criteria (USEPA 1994)

- *"The model is biologically and physically plausible and incorporates the best available empirical data on parameters";*
- *"The model uses numerically accurate algorithms and the accuracy of the computer codes for these algorithms has been verified";* and
- *"The model provides some satisfactory empirical comparisons of model output with real-world data."*

Although they have concluded that the "computational correctness" is sound and that the *IEUBK* model provides *"some satisfactory empirical comparisons"* with which to measured PbB levels, the following three points must be stressed:

- The *IEUBK* computer code has never been released for external review or public comment to verify the computer code or algorithms; and
- Although USEPA has concluded that the *IEUBK* model provides "some satisfactory" PbB predictions when compared with actual "real-world data," other studies have shown that the model significantly overpredicts lead risks when compared to measured PbB levels.

USEPA has intentionally developed the *IEUBK* model to be health protective at all lead-contaminated sites. That is, the conservatism introduced into the risk estimate and subsequent risk management decisions based solely on the *IEUBK* results will always protect the general public (under default assumptions, it is implausible that the *IEUBK* model will ever under predict PbB levels). However, it is not clear how often, to what degree, and under what circumstances the *IEUBK* model will over predicts risks. True model validation and verification can only be accomplished when blood samples are collected from the child population and PbB levels are determined in exposed children. A strong agreement between the predicted and measured PbB levels would validate the model. Without verification, the *IEUBK* could result in significantly overestimating PbB levels and automatically trigger expensive and unnecessary remediation, as well as needlessly alarming the targeted population. Nevertheless, USEPA (1994) believes "the

computational correctness of the *IEUBK* model is sound and that the *IEUBK* model provides valid prediction of observed PbB levels from representative populations of children with typical exposure."

In situations where the empirical comparisons do not validate the model, USEPA has concluded that it is due to incorrect or inappropriate input parameters that are not site specific. Although this point correctly emphasizes the need for collecting relevant site-specific information (instead of relying on default values), it does not address the inherent mathematical problem of a deterministic approach where single input parameters are used to predict PbB levels.

Recent validation studies conducted by EPA Region 8 have shown that the *IEUBK* model over predicted risk at several sites. Although these studies are limited, they strongly indicate that the *IEUBK* model tends to significantly over predict PbB levels (see Chapter 7.0).

There are four possible explanations for discrepancies between measured and predicted PbB levels using the *IEUBK* model, which are as follows:

- Default input parameters are not appropriate and representative;
- The *IEUBK* model, which is deterministic, does not address normal variability; and
- PbB levels data is not being collected from a "truly representative population" (measured PbB levels are not representative).

Default input parameters to predict PbB levels should only be used as a first approximation of "plausible" PbB levels. Moreover, they should only be used during the initial screening of the site. Considerable conservatism has been built into developing default parameters, and they will (under most circumstances) significantly overestimate PbB levels. Likewise, PbB levels can be overestimated when non-representative input parameters are unknowingly used. In addressing this error, USEPA (1994) notes:

> *"The empirical comparisons in which there are differences between observed and predicted blood lead concentrations underscore the importance of valid exposure scenarios as input."*

Another possible reason the *IEUBK* tends to over predict PbB levels is that it is a deterministic model. As will be extensively discussed in Section 7.0, single variables are used to represent a

population of possible values in a deterministic model. Combining single input variables (also referred to as point estimates) can result in "compounding conservatism," in which the predicted PbB is not only excessively high, but unrealistic. Although deterministic approaches are simple and easy to use, they provide little information on the variability or uncertainty of the results. USEPA has acknowledged these shortcomings and problems inherent in deterministic risk assessments for several years. To address these limitations, they have recently developed policy (USEPA 1998) and guidance (USEPA 1999) for conducting probabilistic risk assessments. In contrast to deterministic risk assessments where single variables are combined to estimate risks for the RME, probabilistic risk assessments use the entire population of possible values.

The final reason for the discrepancy between *IEUBK predicted* PbB levels and *measured* PbB levels of individuals in the exposed population is that the individuals may *not* be exposed to the assumed lead levels. Empirical blood data show a strong positive correlation between soil and dust lead concentrations, and PbB levels. Generally, PbB levels increase 3 to 7 μg/dL for every 1000 ppm increase in soil or dust lead concentrations. Actual site-specific exposure to soil, type of ground cover, behavior patterns, seasonal variation in exposure conditions, and other factors are responsible for population variability.

Despite these potential problems, the *IEUBK* model has been recommended as the risk assessment tool to support the implementation of the July 14, 1994, Office of Solid Waste and Emergency Response Interim Directive on Revised Soil Lead Guidance for CERCLA Sites and RCRA Facilities. The most current version, Version 0.99D, of the *IEUBK* model is used in this risk analysis.

The *IEUBK* model is used to predict blood-lead concentrations only for children. It is not appropriate for modeling lead exposures in adults. Using relevant input parameters, the *IEUBK* rapidly calculates the PbB level by solving a complex set of equations to estimate PbB levels for a hypothetical child or population of children (aged 6 months to 7 years).

The *IEUBK* model is a stand-alone, personal computer (PC)-compatible software package. It calculates a plausible distribution of PbB levels centered on the geometric mean PbB level. From this distribution, the model calculates the probability that children's PbB levels will exceed the 95 percentile PbB levels. As discussed in Chapter 1.0, USEPA and CDC have determined that childhood PbB levels at or above 10 μg/dL may present risks to children's health. Accordingly, the Agency's risk management strategy focuses on reducing the likelihood or probability that

PbB levels do not exceed this health-based bright line. This strategy is based on the results of the *IEUBK* model, which calculates the *probability* that childhood PbB levels will exceed 10 μg/dL. Specifically, the current USEPA (1998) risk management goal is to limit exposure so that there is a less-than-5% probability that PbB levels will exceed 10 μg/dL. The probability that the PbB level of 10 μg/dL will be exceeded is often referred to as the "P10."

It should be noted that USEPA (1999) recognizes some limitations with the *IEUBK* model. The *IEUBK* model should not be used for exposure periods of less than three months or when exposures are intermittent (exposures occur significantly less than 7 days per week). Finally, the Agency cautions against interpreting the results of the *IEUBK* model as matching the PbB levels for a *specific* child. The model is designed to predict an average PbB concentration for an entire population or the probability that a child with a specific exposure scenario would have an elevated PbB.

4.2 Technical Description—Model Overview

The *IEUBK* model is designed to predict current or future probable PbB levels for children between 6 months and 7 years of age who are, or have been, exposed to lead through all environmental media (air, water, soil, dust, and diet). The model has the following four functional components:

- **Exposure Component:** Compares lead concentrations in environmental media with the amount of lead intake. The exposure component utilizes environmental media-specific intake rates and lead concentrations in each environmental medium to estimate media-specific lead intake.

- **Uptake Component:** Compares lead intake into the lungs or digestive tract with the amount of lead absorbed into the child's blood.

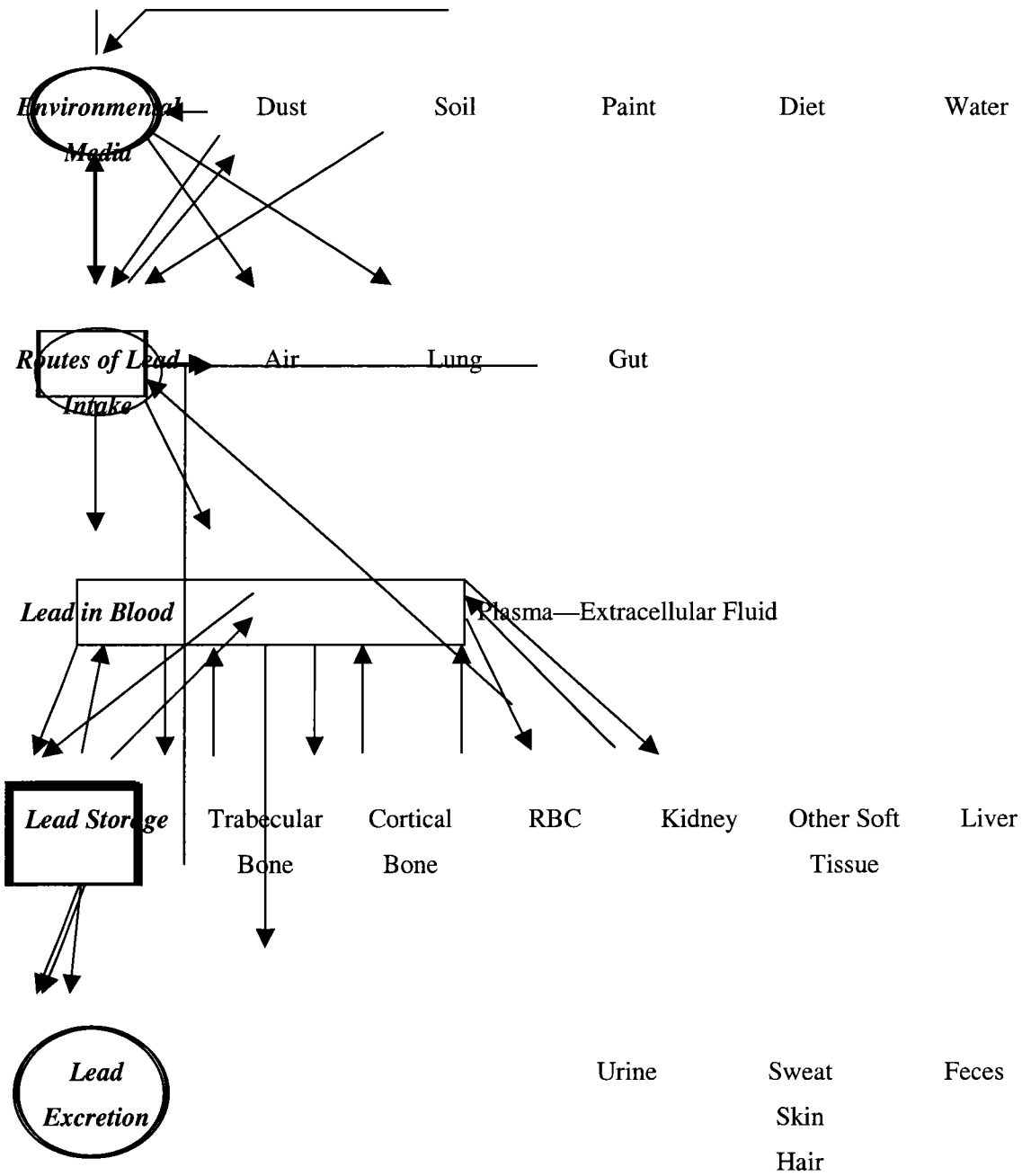
- **Biokinetic Component:** Evaluates transfer of lead between blood and other body tissues, and the elimination of lead from the body altogether.

- **Probability Distribution Component:** Reveals the probability that PbB levels will exceed 0 μg/dL in an exposed child based on default or site-specific parameters used in the model.

Figure 4.1 shows the interrelationships between the four components and the complexity represented by the *IEUBK* model.

FIGURE 4.1

CONCEPTUAL DIAGRAM OF THE MOVEMENT OF ENVIRONMENTAL LEAD INTO AND THROUGH THE HUMAN BODY



Source: USEPA 1994

The *IEUBK* model has been developed to predict PbB levels under steady-state conditions where exposures are relatively long-term and uniform. The model cannot accurately predict PbB levels for short, occasional, or transitory lead exposures. For example, the model does not predict PbB levels associated with direct ingestion of paint chips. However, under conditions where leaded paint is deteriorating and soil and dust lead loading is occurring, the *IEUBK* model indirectly estimates the leaded paint by incorporating soil and dust lead levels directly into the risk assessment. Thus, at poorly maintained homes, where deteriorating paint conditions could have resulted in significant lead loading to soil and dust, the predicted PbB levels do take into account leaded paint. The *IEUBK* model also evaluates naturally occurring and anthropogenic contributions of lead exposure unless steps are taken to differentiate site-specific and background lead concentrations. It may be possible to winnow the relative contribution of leaded paint by conducting an independent chemical analysis of the different types of lead present in samples.

The *IEUBK* model standardizes lead exposure by using age-weighted parameters for intake of food, water, soil, and dust. The model simulates continual growth in the average exposed child under constant exposure levels (on a year-to-year basis). Simultaneously, the model also simulates lead uptake, distribution within the body, and elimination from the body.

Although the *IEUBK* model can be used to predict the average PbB level for an entire community, there may be significant variability within the exposed population between different homes within a single community. At these sites, it would be prudent to first apply the *IEUBK* model to predict PbB levels for individual homes or homogeneous areas, then to combine the results to derive the mean or average PbB levels for the neighborhood or community.

According to USEPA (1994), the *IEUBK* model is intended to:

- Evaluate a typical child's *long-term* exposure to lead in and around the residence;
- Predict a plausible estimate of the geometric average PbB level for a typical child aged 6 months to 7 years;
- Estimate the *risk* of elevated PbB levels for a hypothetical child;
- Evaluate the impact of *remediation* on the risk of elevated PbB levels by using proposed remediation target goals in soil, dust, water, or air in the model;

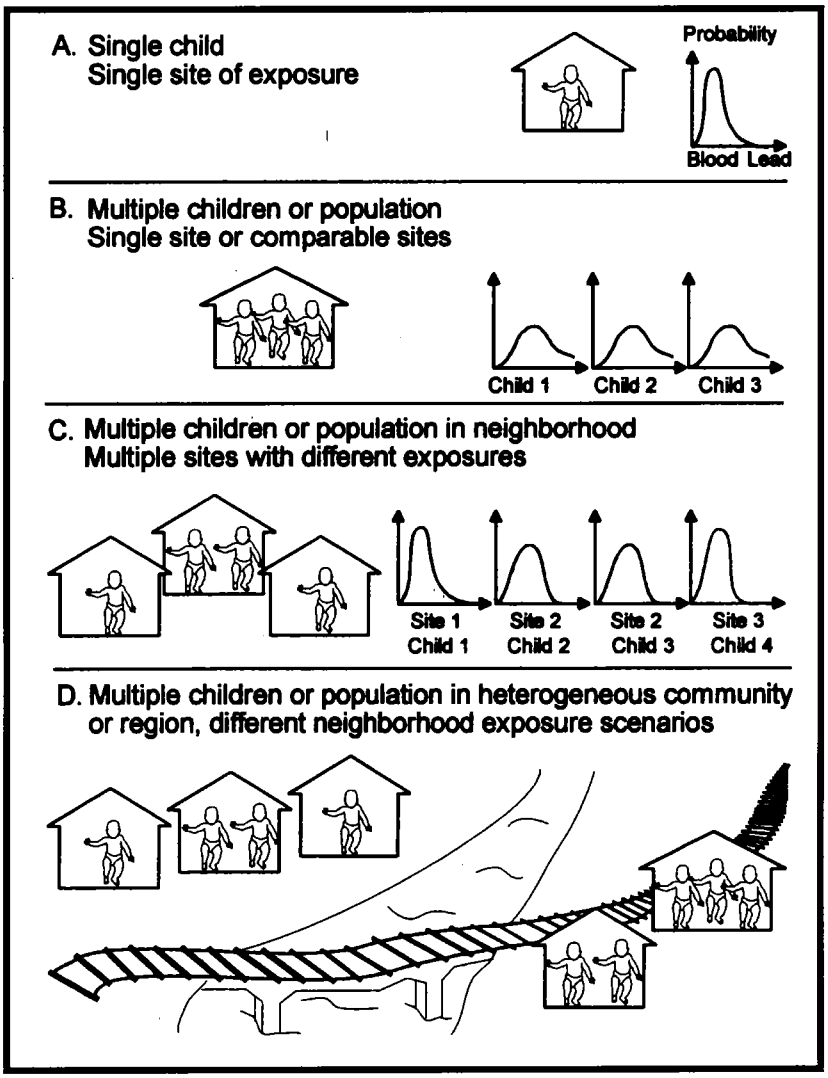
- Determine final target cleanup levels at specific residential sites for soil or dust containing high amounts of lead; and

- Provide support assistance in estimating PbB levels associated with the Pb concentration of soil or dust at undeveloped sites that may be developed at a later date.

The *IEUBK* model can be applied to evaluate individuals or populations, and each result must be interpreted accordingly. Typically, the model will be used to evaluate risk assuming that children stay within the exposure unit, which will yield information that will be used to make remedial decisions. The scale will typically represent a residential yard with a single residence or an equivalent area for multi-unit buildings. For undeveloped areas that have the potential to become residential housing, the *IEUBK* can be used to subdivide the property into areas that are representative (e.g., a quarter of an acre) of future residential lots. The home and its surrounding yard is the basic unit for risk analysis because lead exposure for preschool children primarily occurs there. Figure 4.2 illustrates the type of target receptor(s) the *IEUBK* model can evaluate

FIGURE 4.2

CATEGORIES OF TARGET RECEPTOR THAT CAN BE EVALUATED WITH THE *IEUBK* MODEL



Source: USEPA 1994

In Category A, risk is calculated for a single child (the most frequent target population) at a single residence. The *IEUBK* model output is interpreted as - the probability that a child's PbB level will exceed the PbB level of concern (10 μg/dL). The probability distribution describes the likely variability in PbB levels for the child, based on the site conceptual model and current or expected exposure conditions. The best single-number prediction of PbB levels is the geometric mean of the distribution of plausible concentrations that *may* result from the specified exposure.

Categories B, C, and D represent multiple children or multiple populations of children typified by the following:

- **Category B:** Site where more than one child currently resides;
- **Category C:** Multiple children at multiple locations (typified by an apartment complex); and
- **Category D:** Community-wide lead risks.

It should be emphasized that, regardless of the receptor or population of receptors, the *IEUBK* model is intended to provide a best estimate of geometric *mean* PbB levels. The *IEUBK* model should not be used in a worst-case scenario, as the model does not apply any uncertainty factors or modifying factors in predicting PbB levels. When uncertainty about model parameters exists, these should be evaluated using sensitivity analyses.

A site-specific risk assessment requires gathering exposure information on lead from all possible environmental media for the site. For example, information on lead exposure from soil and dust include soil-to-indoor dust transfer; ingestion parameters for soil and dust (i.e., how much soil or dust a typical child may ingest over the exposure duration); and the amount of lead that can be absorbed from the soil and dust. Risk estimates are very sensitive to these input parameters. That is, changing a single input parameter for a variable can significantly affect the predicted PbB levels.

Although the *IEUBK* model is primarily designed to calculate the risk of elevated PbB levels, it can also be used to determine how a specific remedial action may reduce site PbB levels to acceptable levels. By entering the target remediation levels or projected cleanup goals, the *IEUBK* model can be used to predict PbB levels following remediation. Used iteratively in this

manner, the model can narrowly focus risk management decisions on efforts to mitigate lead risks that will be truly effective.

Although the *IEUBK* model requires input for all potential lead exposure pathways associated with all lead-impacted environmental media, the only absolute requirement for *site-specific* input is soil lead. For all other environmental media, default parameters have been developed by USEPA. Before automatically using default parameters, a careful evaluation of the default parameters should be conducted for two reasons: first, to determine whether default assumptions truly represent site-specific conditions and, second, to focus data collection and information gathering. At many sites, relying on numerous default assumptions will result in overestimated PbB levels and predicted risk. Obviously, unknowingly overestimating risk can trigger unnecessary remediation. For this reason, it is desirable to use default parameters in the *IEUBK* model only during a *screening* risk assessment. Sites that fail the initial screen should then be further investigated by collecting site-specific data to re-run the *IEUBK* model.

As discussed in Section 3.1, for each potential exposure medium (i.e., soil, dust, food, water, air) at a site, several possible sampling strategies should be evaluated to provide a cost-effective means to estimate lead risks. Although many different sampling strategies are possible, all must satisfy minimum requirements for the data sets to be used in the risk assessment. For this reason, risk assessors should be involved in all stages of the investigation and development of the sampling strategy. When risk assessors are not involved in developing a sampling plan at the earliest stage, the datasets often lead to significantly overestimating risk. This frequently occurs when the investigation team (lacking a risk assessor) implements a sampling strategy to determining the "nature and extent" of lead contamination. Frequently, the investigation team will focus on identifying hot spots or areas of high concentrations of lead. These data are often given to the risk assessor, who automatically uses them as input data without confirming that the *average exposure* will occur exclusively in the hot spots, which is implausible and contrary to risk assessment guidance. According to USEPA (1989), the underlying assumption for exposure is that contact occurs with all areas within the exposure unit in a random manner. Factors that need to be evaluated include sample size, sample location, sample type, temporal and meteorological factors, field analyses, and cost of sampling.

Because the *IEUBK* model is only a mathematical model used to *predict* PbB levels, and, therefore, is only as accurate as the site-specific input data collected (which is in many cases limited), blood samples should be collected wherever possible to determine actual site PbB levels

in order to verify the *IEUBK* results. Without this information, all risk management decisions must rest on the mathematical results. Additionally, blood samples should always be collected where it is suspected a current health hazard exists. When planning biomonitoring to assess current and/or historical exposures, ATSDR should be consulted in conducting these studies to ensure that any human site-specific data collected are of sufficiently high quality to be used for human health risk assessment.

Following sampling, data quality must be assessed. The data quality may depend on the analytical method used and sample quantitative limits. Only data of sufficiently high quality should be used in the risk assessment. This may involve selecting a subset of data to be used in the risk assessment.

Exposure Assessment - In a lead risk assessment, exposure is defined as contact of a receptor with lead in all environmental media. Exposure assessment is the step in which magnitude; frequency, duration, and route of exposure are quantified. The exposure assessment determines not lead intake, but quantifies the fraction of intake that is actually taken up and into the body. Under existing guidance, exposure assessments should evaluate current exposed population as well as potential future populations. In practice, these two populations may be identical. That is, current exposures may be a good predictor of future exposures.

Toxicity Assessment - The toxicity assessment weighs all the available evidence and estimates the potential for the occurrence of adverse health effects. For lead, the toxicity assessment is based on exceeding a PbB level of 10μg/dL. Under normal conditions, when predicted PbB levels are below this health-protective bright line, no adverse health effects are expected to develop. This level can be considered a *de minimus* risk level.

Risk Characterization - Risk characterization is the final step in the risk assessment. Risk management decisions are based on the final predicted PbB levels. Risk characterization is a combination of all the information gathered during the risk assessment and relates toxicity and exposure assessments, and can include developing preliminary remediation goals.

The risk assessment must clearly identify and communicate all the assumptions and uncertainties associated with the predicted PbB levels. When there is considerable uncertainty in the lead risk assessment, cost-effective recommendations should be made to eliminate or reduce uncertainty to the extent possible. This is particularly true for the input parameters to which the *IEUBK* model is very sensitive. It is as important to identify the key site-related variables and assumptions that

contribute most to the uncertainty, as it is to precisely quantify the degree of uncertainty in predicted PbB levels.

4.3 Default Input Parameters

Default input parameters are descriptive statistics that are based on U.S. population census data and scientific studies representing the general childhood population. These generic default parameters can be used to predict the PbB level for a hypothetical child. Although some exposure information may be available for predicting PbB levels for specific children, most exposure, uptake, and biokinetic parameters have been derived as group statistics from population studies. For example, it is impossible to precisely determine the amount of soil and dust a child ingests; how much is actually absorbed into the body; and how the lead is distributed, stored, and excreted on a daily basis. For this reason, the *IEUBK* model cannot accurately predict the PbB level for a specific child, but rather makes predictions for the average child under the specified conditions. Assumptions made about the target population distribution and variability within the population can then be used to generate a PbB levels for the childhood population in the area under investigation.

Table 4.1 presents the age-adjusted, USEPA-derived default parameters used to predict lead risks with the *IEUBK* model.

TABLE 4.1

DEFAULT EXPOSURE ASSUMPTIONS FOR USEPA *IEUBK* MODEL

Medium	Parameter	Age (years)						
		0-1	1-2	2-3	3-4	4-5	5-6	6-7
Air	Breathing Rate (m^3/hr)	2	3	5	5	5	7	7
	Time Outside (hr/day)	1	2	3	4	4	4	4
	Concentration In/Out	0.3	0.3	0.3	0.3	0.3	0.3	0.3
	Absorption Fraction	0.32	0.32	0.32	0.32	0.32	0.32	0.32
	Default Concentration (μg/ m^3)	0.1	0.1	0.1	0.1	0.1	0.1	0.1
Diet	Daily Lead Intake (μg/day)	5.53	5.78	6.49	6.24	6.01	6.34	7.00
	Absorption Fraction	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Drinking Water	Ingestion Rate (L/day)	0.2	0.5	0.52	0.53	0.55	0.58	0.59
	Absorption Fraction	0.5	0.5	0.5	0.5	0.5	0.5	0.5
	Default Concentration (μg/L)	4	4	4	4	4	4	4
Soil/Dust Ingestion	Total Daily Intake (mg/day)	85	135	135	135	100	90	85
	Soil Fraction	0.45	0.45	0.45	0.45	0.45	0.45	0.45
	Dust Fraction	0.7	0.7	0.7	0.7	0.7	0.7	0.7
	Absorption Fraction	0.3	0.3	0.3	0.3	0.3	0.3	0.3
All	Geometric Standard Deviation	1.6	1.6	1.6	1.6	1.6	1.6	1.6

Source: USEPA 1994

As previously discussed, the only absolute site-specific data required to run the *IEUBK* model is the average soil lead concentration. However, using site-specific information for the following variables is highly recommended to avoid over estimating lead risk:

- Dust lead concentrations;
- Lead in diet;
- Drinking water lead concentrations;
- Ambient air lead concentrations;
- Maternal/fetal exposure; and
- Lead bioavailability.

When exposure and uptake parameter values are not specified, the *IEUBK* model program automatically provides default values. Most input parameters are age-adjusted. That is, the input values used in the model correspond with behavioral and physiological childhood changes in a hypothetical child. The following brief sections provide an overview of the parameters used in the *IEUBK* model.

Exposure Rates - The age-weighted dust and soil ingestion rates used as defaults in the model (85 to 135 mg/day) represent central tendency values within the range of values seen in different studies. The default proportion (45%) of total dust and soil ingested that is derived from soil is based primarily on a study of Dutch children in daycare centers (USEPA, 1994) in which dust plus soil ingestion on days with good weather was contrasted with dust ingestion on days with rainy weather (presumably little outdoor activity on those days).

Exposure Concentrations - Default diet values (5.53 to 7.00 mg/day) are based on data from the U.S. Food and Drug Administration (USFDA 1989). Model default water values were considered adequate for communities without a particular problem with lead in water. The default air lead concentration (0.1 $\mu g/m^3$) is approximately equal to the average 1990 urban air lead concentration.

Uptake of Ingested Lead - Lead bioavailability varies across the chemical forms in which lead can exist. Many factors complicate estimating bioavailability, including nutritional status and

timing of meals relative to lead intake (lead uptake generally increases as dietary levels of calcium, iron, phosphate, vitamin D, fats, etc., decrease), age, and magnitude of exposure. The default media-specific bioavailability in the *IEUBK* model is central tendency estimates.

Biokinetic Parameters - The data on which these parameter values are based originate from a variety of separate investigations, including as much clinical data as were available (USEPA, 1995). Risk assessors cannot change the biokinetic parameters.

Variability In PbB Levels - A variety of factors may cause children exposed to similar environmental lead concentrations to have varying PbB levels. These include differences in children's tendency to ingest soil or dust, hygiene habits, the potential for soil or dust to be deposited on food, and biological factors that may affect the absorption and processing of lead. The complexity of these factors suggests that the overall variability represented by the GSD cannot be determined by aggregating the variability in each of these factors into an overall GSD estimate. Instead, an empirical estimate of the variability in PbB levels, a GSD of 1.6, was estimated from residential community blood lead studies (USEPA, 1994).

4.4 Revised Default Input Parameters

Revised default values presented in this section should be used in to:

1) Estimate PbB levels and calculate lead risks; and

2) Calculate acceptable soil lead levels as cleanup goals.

Default values presented in USEPA guidance (1994) are based on various studies and were considered by USEPA to be, at the time, the best available estimates for urban residents with no unusual lead exposure (USEPA 1994). As additional studies become available, however, it is important to ensure that default values represent current conditions. Up-to-date information using the most recent values representing *current* conditions should always be used as default values. Default values that were appropriate and representative six years ago may not be applicable today. For example, default values for ambient air lead levels developed in the early 1990s will not be applicable or represent current conditions because lead concentrations in many environmental media have been decreasing dramatically.

As noted in Section 1.2, the ban on leaded gasoline has resulted in, and will continue to directly and indirectly lead to decreases in environmental lead concentrations, as well as baseline PbB

levels in the U.S population. A detailed analysis of all default input parameters was conducted for the *IEUBK* model to determine whether there was new data or information that should be used to replace existing default assumptions. Although environmental lead concentrations need to be modified to reflect decreases, no default biological or exposure values (i.e., intake rates, absorption, ventilation rates, etc.) were found to be inappropriate. That is, biological systems described by default values do not need to be significantly refined. It should be stressed, however, that, although national population statistics have not significantly changed, they might not represent site-specific conditions. An evaluation of default values should always be conducted to determine whether they are appropriate for the site under investigation. Site-specific values should always be used preferentially.

The following brief sections highlight only those default values that need to be changed based on more current data that is relevant to risk assessments conducted today.

Environmental Lead Concentrations - As mentioned in Section 1.2, the most recent NHANES III report (Phase 2, 1991-1994) revealed a marked decrease in PbB levels that USEPA primarily attributes to reduced leaded gasoline use. Overall lead emissions from highway vehicles have decreased the concentration of airborne lead and lead loading to soil. According to USEPA (1994), the default air lead concentration is 0.1 $\mu g/m^3$, which is approximately the average 1990 urban air lead concentration (USEPA 1991). According to the California Air Board (1997), the airborne lead concentration has markedly declined throughout the state of California. According to the latest available data (California Air Resources Board 1997), the average airborne lead concentration in that state is now 0.028 $\mu g/m^3$. This concentration should be used as the default concentration when conducting lead risk assessments in the State of California.

Maternal PbB Levels - The maternal PbB level is used in the *IEUBK* model to establish a baseline PbB level in the neonate. The previous default value based on NHANES II was 2.5 $\mu g/dL$. As ambient levels of lead in the environment have decreased and so has the baseline PbB level in women of childbearing age. According to the results of NHANES III, Phase 2, this value should be revised to 1.4 $\mu g/dL$ for women living in the western United States (CDC 1994; Bowers and Cohen 1998).

Lead In Food - The lead concentration in food has decreased due to the ban on lead soldering used in canned goods and the overall reduction of lead in the environment. The reduction is

estimated to be 30% from the age-adjusted default values derived by USEPA (1994) based on recent USFDA Market Basket surveys (Bolger *et al.* 1996; Griffin 2000).

For convenience, Table 4.2 presents a work sheet with the age-adjusted default input values for the *IEUBK* model and the revised default parameters based on more current data and information that can be used to estimate lead risk assessments and cleanup goals. However, site-specific information collected and used to predict PbB levels will yield more accurate PbB level predictions and site-specific remedial target goals. Risk estimates and cleanup goals based solely on these default values should only be considered screening levels.

TABLE 4.2

***IEUBK* MODEL REVISED DEFAULT WORKSHEET FOR RISK ASSESSMENTS**

PARAMETER	PREVIOUS DEFAULT VALUE	REVISED DEFAULT VALUE	UNITS
AIR (constant)			
Outdoor Air Lead Concentration	0.10	0.028	$\mu g/m^3$
Ratio Of Indoor To Outdoor Air Lead Concentration	30	30	%
AIR (by year)			
Air Concentration			
Age = 0-1 Year (0-11 Months)	0.10	0.028	$\mu g/m^3$
1-2 Years (12-23 Months)	0.10	0.028	$\mu g/m^3$
2-3 Years (24-35 Months)	0.10	0.028	$\mu g/m^3$
3-4 Years (36-47 Months)	0.10	0.028	$\mu g/m^3$
4-5 Years (48-59 Months)	0.10	0.028	$\mu g/m^3$
5-6 Years (60-71 Months)	0.10	0.028	$\mu g/m^3$
6-7 Years (72-84 Months)	0.10	0.028	$\mu g/m^3$
Time outdoors			
Age = 0-1 Year (0-11 Months)	1	1	h/day
1-2 Years (12-23 Months)	2	2	h/day

2-3 Years (24-35 Months)	3	3	h/day
3-7 Years (36-83 Months)	4	4	h/day
VENTILATION RATE			
Age = 0-1 Year (0-11 Months)	2	2	m^2/day
1-2 Years (12-23 Months)	3	3	m^2/day
2-3 Years (24-35 Months)	5	5	m^2/day
3-4 Years (36-47 Months)	5	5	m^2/day
4-5 Years (48-59 Months)	5	5	m^2/day
5-6 Years (60-71 Months)	7	7	m^2/day
6-7 Years (72-84 Months)	7	7	m^2/day
Lung Absorption	32	32	%
DIET INTAKE			
Dietary Lead Intake			
Age = 0-1 Year (0-11 Months)	5.53	3.87	µg Pb/day
1-2 Years (12-23 Months)	5.78	4.04	µg Pb/day
2-3 Years (24-35 Months)	6.49	4.54	µg Pb/day
3-4 Years (36-47 Months)	6.24	4.37	µg Pb/day
4-5 Years (48-59 Months)	6.01	4.21	µg Pb/day
5-6 Years (60-71 Months)	6.34	4.44	µg Pb/day
6-7 Years (72-84 Months)	7.00	4.90	µg Pb/day
ALTERNATE DIET SOURCES			
Concentration:			
Home-Grown Fruits	0	0	µg Pb/g
Home-Grown Vegetables	0	0	µg Pb/g
Fish From Fishing	0	0	µg Pb/g
Game Animals From Hunting	0	0	µg Pb/g
Percent Of Food Class			
Home-Grown Fruits	0	0	%

Home-Grown Vegetables	0	0	%
Fish From Fishing	0	0	%
Game Animals From Hunting	0	0	%
DRINKING WATER			
Lead Concentration In Drinking Water	4	4	µg/L
Ingestion Rate			
Age = 0-1 Year (0-11 Months)	0.20	0.20	Liters/day
1-2 Years (12-23 Months)	0.50	0.50	Liters/day
2-3 Years (24-35 Months)	0.52	0.52	Liters/day
3-4 Years (36-47 Months)	0.53	0.53	Liters/day
4-5 Years (48-59 Months)	0.55	0.55	Liters/day
5-6 Years (60-71 Months)	0.58	0.58	Liters/day
6-7 Years (72-84 Months)	0.59	0.59	Liters/day
DRINKING WATER SOURCES			
Concentration:			
First-Draw Water	4	4	µg/L
Flushed Water	1	1	µg/L
Fountain Water	10	10	µg/L
Percentage Of Total Intake			
First-Draw Water	50	50	%
Flushed Water (not a user entry; calculated based on entries for first-draw and fountain percentages)	100 minus first draw and fountain	100 minus first draw and fountain	%
Fountain Water	15		%
SOIL/DUST LEAD (constant)			
Concentration:			
Soil	200	530	µg /g
Dust	200	374	µg /g
Soil Ingestion As Percent Of Total Soil And Dust Ingestion	45	45	%

SOIL/DUST INGESTION			
Soil/Dust Ingestion Rate			
Age = 0-1 Year (0-11 Months)	0.085	0.085	g/day
1-2 Years (12-23 Months)	0.135	0.135	g/day
2-3 Years (24-35 Months)	0.135	0.135	g/day
3-4 Years (36-47 Months)	0.135	0.135	g/day
4-5 Years (48-59 Months)	0.100	0.100	g/day
5-6 Years (60-71 Months)	0.090	0.090	g/day
6-7 Years (72-84 Months)	0.085	0.085	g/day
SOIL LEAD			
Soil Lead Concentration			
Age = 0-1 Year (0-11 Months)	200	530	µg/g
1-2 Years (12-23 Months)	200	530	µg/g
2-3 Years (24-35 Months)	200	530	µg/g
3-4 Years (36-47 Months)	200	530	µg/g
4-5 Years (48-59 Months)	200	530	µg/g
5-6 Years (60-71 Months)	200	530	µg/g
6-7 Years (72-84 Months)	200	530	µg/g
DATA ENTRY FOR DUST			
Dust Lead Concentration			
Age = 0-1 Year (0-11 Months)	200	374	µg/g
1-2 Years (12-23 Months)	200	374	µg/g
2-3 Years (24-35 Months)	200	374	µg/g
3-4 Years (36-47 Months)	200	374	µg/g
4-5 Years (48-59 Months)	200	374	µg/g
5-6 Years (60-71 Months)	200	374	µg/g
6-7 Years (72-84 Months)	200	374	µg/g
SOIL/DUST MULTIPLE SOURCE ANALYSIS (constant)			

Ratio Of Dust Lead Concentration To Soil Lead Concentration	0.70	0.70	Unitless
Ratio Of Dust Lead Concentration To Outdoor Air Lead Concentration	100	100	µg Pb/g dust per µg Pb/m^3 air
SOIL/DUST MULTIPLE SOURCE ANALYSIS WITH ALTERNATIVE HOUSEHOLD DUST LEAD SOURCES (constant)			
Concentration			
Household Dust (Calculated)	Site-Specific	Site-Specific	µg/g
Secondary Occupational Dust	Site-Specific	Site-Specific	µg/g
School Dust	Site-Specific	Site-Specific	µg/g
Daycare Center Dust	Site-Specific	Site-Specific	µg/g
Second Home	Site-Specific	Site-Specific	µg/g
Interior Lead-Based Paint	Site-Specific	Site-Specific	µg/g
Percentage			
Household Dust (Calculated)	100 minus all other	100 minus all other	%
Secondary Occupational Dust	0	0	%
School Dust	0	0	%
Daycare Center Dust	0	0	%
Second Home	0	0	%
Interior Lead-Based Paint	0	0	%
BIOAVAILABILITY FOR ALL GI ABSORPTION PATHWAYS			
Total lead absorption (at low intake)			
Diet	50	50	%
Drinking Water	50	50	%
Soil	30	30	%
Dust	30	30	%
Alternate Source	0	0	%
Fraction Of Lead Absorbed Passively At High Intake			

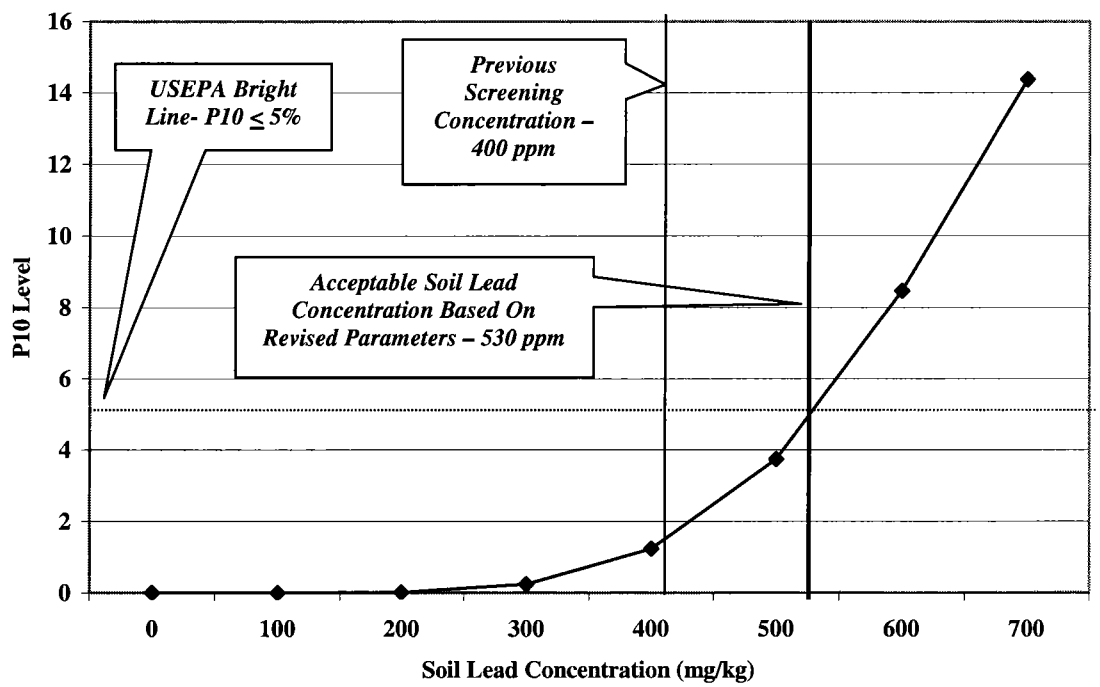
Diet	0.2	0.2	Unitless
Drinking Water	0.2	0.2	Unitless
Soil	0.2	0.2	Unitless
Dust	0.2	0.2	Unitless
Alternate Source	0.2	0.2	Unitless
ALTERNATE SOURCES (by year)			
Total Lead Intake			
Age = 0-1 Year (0-11 Months)	0	0	µg/day
1-2 Years (12-23 Months)	0	0	µg/day
2-3 Years (24-35 Months)	0	0	µg/day
3-4 Years (36-47 Months)	0	0	µg/day
4-5 Years (48-59 Months)	0	0	µg/day
5-6 Years (60-71 Months)	0	0	µg/day
6-7 Years (72-84 Months)	0	0	µg/day
MATERNAL-TO-NEWBORN LEAD EXPOSURE			
Mother's Blood Lead Level At Time Of Birth	2.5	1.4	µg/dL
PLOTTING AND RISK ESTIMATION			
Geometric Standard Deviation For Blood Lead, GSD	1.6	1.4	Unitless
Blood Lead Level Of Concern, Or Cutoff	10	10	µg/dL
COMPUTATION OPTIONS			
Iteration Time Step For Numerical Integration	4	4	h

Estimating PbB levels requires the *IEUBK* model to be used in based on revised input values. These values are entered directly into the model and the model calculates the geometric mean and the P10 level. Figure 4.3 presents P10 levels corresponding to increasing soil lead concentrations. It is interesting to note that predicted P10 levels are curvilinear with the slope increasing with increased concentrations.

To calculate cleanup goals, the same revised input values are entered into the model and the model is used iteratively until the target acceptable P10 level (where the P10 is equal to 5 percent) is calculated. The default value of 530 ppm is shown in Figure 4.3. Site-specific conditions, rather than default assumptions, should be used to calculate soil lead concentrations corresponding to the P10 levels. This concentration should then be used as the target remediation goal. It is emphasized that site-specific information should always be used instead of default values to estimate both lead risks and acceptable soil/dust cleanup goals. The revised default values presented in this section should only be used when site-specific values are not available.

FIGURE 4.3

***IEUBK*-PREDICTED P10 LEVELS CORRESPONDING TO INCREASED SOIL LEAD CONCENTRATION BASED ON *REVISED* DEFAULT PARMETERS**



4.5 Sensitivity Of Input Parameters

It should be noted that a sensitivity analysis was implemented in an attempted to identify the most important input parameters for the *IEUBK* model. Because the *IEUBK* model is a deterministic model, it was necessary to change one parameter at a time while keeping all other parameters

constant. However, after many trials it was ultimately determined that the analysis would not yield meaningful data unless bounding conditions could be placed on site-specific conditions. That is, the importance of a specific parameter is dependant on the overall relative contribution for the pathway. For example, at low soil lead levels the predicted PbB levels would be largely based on other pathways such as food and drinking water ingestion. It was concluded that the only approach to evaluate the sensitivity was through probabilistic simulations. Examples of these are presented in Chapter 7.0.

Although a robust sensitivity analysis of all parameters could not be conducted, Table 4.3 shows the importance of collecting site-specific information for key input parameters. Using the revised input parameters presented in Table 4.2 the revised default cleanup level for soil lead is 530 ppm. However, when the default value for percent absorption of soil lead is doubled or halved, the P10 values and cleanup levels can change significantly. This demonstrates the necessity of developing a site-specific set of data to accurately predict PbB levels. The output data and graph results from the *IEUBK* model for this example are presented in Appendix A.

Other input parameters, such as the soil ingestion rate, were identified as very sensitive parameters. However, a methodology does not exist for developing and substituting site-specific input values. For these parameters the only solution is to apply a probabilistic approach such as the *ISE* model that uses the entire range of possible input values. This model is detailed in section 7.0.

TABLE 4.3

EXAMPLE OF THE SENSITIVITY OF SOIL LEAD BIOAVAILABILITY ON PREDICTED PbB LEVELS

SITE-SPECIFIC CONDITION	P10 LEVEL	SOIL LEAD BIOAVAILABILITY	CLEANUP LEVEL BASED ON SOIL LEAD BIOAVAILIBILITY
One-half Default Bioavailability	0.11 %	15 %	1075 ppm
Default Bioavailability	5.0 %	30 %	530 ppm
Doubling Default Bioavailability	43.14 %	60 %	265 ppm

4.6 Validating the IEUBK Model

The *IEUBK* model has been shown to over predict PbB levels at numerous sites, which can (unknowingly) lead to costly and unnecessary remediation. Unnecessary remediation can occur when there are no data for actual measured PbB levels with which the *IEUBK*-predicted results can be compared. At these sites risk management decisions must rest solely on the results of the *IEUBK*. Several recent studies highlight this problem.

For example, in a recent study by EPA Region 8 at Jacobs Smelter Site in Stockton, Utah, measured PbB levels were significantly lower that those predicted with the *IEUBK* model (EPA 1999). The state of Utah Department of Environmental Quality (UDEQ) collected 29 soil samples from the affected area in 1997. Analysis of these samples revealed that lead levels in soil were significantly elevated, with a maximum lead soil concentration of 68,400 ppm. Because the soil concentrations were much higher than levels generally regarded as health protective for residential exposure (a screening level of 400 ppm was exceeded), subsequent sampling for lead in soil and dust was conducted by EPA Region 8. According to EPA, the purpose of this follow-up study was to identify current residences where soil lead concentrations were higher than 3,000 ppm, which was considered sufficiently high to warrant immediate removal and replacement of the residential soil.

A total of 487 surface soil samples (0 to 2 inches below the surface) were collected from 248 properties. House lead dust was collected from 23 homes within the area of concern. A summary of the sampling results is presented in Table 4.4.

TABLE 4.4

SUMMARY SOIL/LEAD DATA
JACOBS SMELTER SITE IN STOCKTON, UTAH

Environmental Medium	Minimum Concentration (ppm)	Maximum Concentration (ppm)	Average Concentration (ppm)
Soil Lead	13	41,537	1,474
Dust Lead	103	1,370	455

Risks associated with these elevated levels of lead were evaluated subdividing the site into eight zones and using the *IEUBK* model to predict PbB levels for the population of children residing within each zone. The *IEUBK* modeling results for *predicted* PbB levels are presented in Table 4.5.

TABLE 4.5

***IEUBK*-PREDICTED PbB LEVELS FOR PROPERTIES IN EACH STUDY ZONE**

Zone	Number of Properties	Range of *Predicted* PbB Levels	Mean *Predicted* PbB Level	Number of Properties Exceeding USEPA Acceptable *Predicted* PbB Levels (1)
1	16	4-16	8	13
2	47	4-100	22	42
3	67	2-22	7	30
4	28	2-42	7	7
5	13	4-21	7	9
6	40	2-51	14	30
7	8	5-32	15	7
8	25	2-16	6	8

(1) USEPA Acceptable Levels: The level at which there exists no more than a 5% chance that a child in the target population will have a PbB level exceeding 10 µg/dl.

Because the soil lead levels and corresponding *IEUBK*-predicted PbB levels were so extraordinarily high, the Tooele County Health Department in 1998 conducted a biomonitoring investigation to measure blood levels (primarily in residential children) for those exposed to high soil lead concentrations. Blood samples were collected from 26 residents, ranging from 1 to 21 years of age. The measured PbB levels were surprising low. Despite the very high lead concentrations detected in soil and dust, and the elevated PbB levels *predicted* with the IEUBK model for residential properties, the *actual* measured PbB levels in the sample population of residents indicated that *no* resident had a PbB level exceeding 10 µg/dL. This was in stark contrast to the predicted PbB levels, which were as high as 100 µg/dL which could have precipitated an emergency response since it is a lethal concentration. It should also be noted that

all other lead risk assessment models would have similarly exaggerated PbB levels as well. For example, at an *average* soil lead concentration of 1,474 ppm, the Ca*LS* model predicts a PbB level of 60 μg/dL (99th percentile, which is more than 60 times the actual measured PbB level), and at the maximum soil lead concentration of 64,200 ppm the Ca*LS* predicted PbB level is approximately 2,600 μg/dL, which certainly would have resulted in death.

Based on this limited study of predicted versus actual PbB levels, the IEUBK model (as well as other models) appears to greatly over predict risks. Obviously, if measured PbB levels were not available with which to check the results of the *IEUBK* model, an unfortunate public crisis and possible unnecessary remediation could have been triggered. EPA concludes, *"the data do not suggest that current residents are exposed to excessive levels of lead."* The discrepancy between predicted and observed PbB levels has not been identified; however, it appears that over predicting PbB levels with the IEUBK model is the rule and not the exception at many sites. In addition to the Jacobs Smelter site, the *IEUBK* model over predicted lead risks at numerous other Western mining or smelting sites, including California Gulch, Sand Smelter, Murray Smelter, Bingham Creek, and Herriman. It is not known how many other sites throughout the U.S. have been unnecessarily remediated based solely on the results of the *IEUBK* model because biomonitoring data are not oftentimes available to verify the modeling results.

5 USEPA ADULT LEAD MODEL

5.1 Background Information

In December 1996, the USEPA Technical Review Workgroup prepared a guidance document titled *"Recommendations of the Technical Review Workgroup for Lead for an Interim Approach to Assessing Risks Associated with Adult Exposures to Lead in Soil,"* which presents tools that can be used in a risk assessment to provide an evaluation of risk for the adult population. This risk assessment methodology is referred to as the interim Adult Lead Methodology and is based on the Adult Lead (*AL*) model (USEPA 1996).

Although the *AL* model is described as a risk assessment approach for "assessing risks associated with adult exposures to lead in soil" (USEPA 1996), the actual receptor is not a potential non-residential *adult* receptor, but a *fetus*. That is, the approach developed in the *AL* Model for predicting PbB levels for non-residential receptors relates the amount of soil lead ingested by a hypothetical pregnant woman to a corresponding PbB level that then forms the basis of the predicted PbB level in her fetus. Thus, the default assumption is that all non-residential sites will have worker populations with at least one woman who will become pregnant while employed at the site. She will continue to regularly work at the site through her pregnancy for at least three continuous months. During the gestational period, the fetus will be exposed to lead in soil as a result of the woman coming into direct contact with lead and the mother's PbB levels will reach a "quasi-steady state"

Similar to USEPA policy regarding childhood exposures to lead, in which the *IEUBK* model is used to predict the PbB level in children who are between 0 and 64 months of age, the *AL* model is used to predict the PbB level in the fetus as a result of *in utero* lead exposure. As a health-based goal, USEPA policy has established a safe PbB level of less than 10 µg/dL in the fetus (although no supporting empirical data on safe PbB levels exist).

The *AL* model is used to estimate the relationship between the PbB level in adult women (PbB_{adult}) and the corresponding 95th percentile fetal PbB level ($PbB_{fetal,\ 0.95}$). USEPA believes this approach will achieve USEPA's goal of limiting the risk of elevated fetal PbB levels resulting from site-specific lead exposures to women of childbearing age. In summary, USEPA has concluded (1999):

> *"Based on the available scientific information, a fetus is believed to be more sensitive to the adverse affects of lead than an adult. Thus, preliminary remediation goals (PRGs) that are protective of a fetus should also afford protection for adults."*

Although this conclusion appears reasonable, it is also reasonable to conclude that conditions that protect the fetus are will be overprotective of the adult worker population where the likelihood of fetal exposure is negligible.

5.2 Technical Description—Model Overview

The *AL* model is a simple lead model based on a slope factor approach. It does not attempt to evaluate important biokinetic aspects of lead exposure (as does the *IEUBK* model for children). Instead of estimating PbB levels based on empirical information on lead biokinetics, which includes absorption, distribution, transformation, and excretion—it simply relates PbB levels to the amount of lead ingested. In estimating PbB levels for a pregnant woman (assumed to be directly exposed to site-specific soil lead concentrations), the incremental increase in the PbB level resulting from site-specific conditions is simply added to the "baseline" PbB level assumed to already exist in the pregnant woman as a result of off-site exposures. It is important to note that the *AL* model has not yet been validated by comparing predicted fetal PbB levels to measured fetal PbB levels (which are represented by umbilical cord PbB levels).

The *AL* model for predicting PbB levels in the developing fetus under a non-residential exposure scenario is a two-step process, which is as follows:

- **Step 1:** Calculate PbB levels in an occupationally exposed pregnant woman.
- **Step 2:** Extrapolate the PbB level in the pregnant woman to her fetus.

In the first step, the PbB level for a hypothetical pregnant women is estimated. The predicted PbB level for the pregnant women is made up of the following two components:

- **Non-site Related Background (or Baseline Lead Sources):** Store-bought food, ambient air, home tap water, etc.; and
- **Site-related Sources of Lead (Site Exposures):** Site-specific lead in soil and dust.

The following equation is used to estimate PbB levels in an occupationally exposed pregnant woman:

$$PbB_{adult,central} = PbB_{adult,0} + \frac{PbS \cdot BKSF \cdot IR_S \cdot AF_S \cdot EF_S}{AT}$$

Where:

$PbB_{adult,\ central}$	=	Average PbB level (µg/dL) in a hypothetical occupationally exposed pregnant woman who contacts lead at the site.
$PbB_{adult,\ 0}$	=	Background (or baseline) PbB level (µg/dL) in the pregnant woman (representing lead exposures away from the site being assessed).
Pb_S	=	Site-specific soil lead concentration (µg/g; average concentration contacted daily).
$BKSF$	=	Biokinetic slope factor relating the increase in PbB level in the pregnant woman to average daily lead uptake (µg/dL PbB increase per µg/day lead uptake).
IR_S	=	Soil intake rate by a pregnant woman (g/day; including both outdoor soil and indoor soil-derived dust).
AF_S	=	Absolute gastrointestinal absorption fraction for ingested lead in soil and dust.
EF_S	=	Exposure frequency for soil and dust contact (days of exposure during the averaging period).
AT	=	Averaging time; the total period during which soil contact may occur; 365 days/year for continuing long-term exposures.

The second step is to relate the calculated PbB level in the pregnant woman (calculated above; $PbB_{adult,\ central}$) to the fetus. It is assumed that the fetus will be carried to term while the pregnant mother is exposed to site lead in soil and dust. In other words, the PbB level have reached a

quasi-steady state. The following equation is used to predict how much lead is transferred from the mother's blood into the fetus.

$$PbB_{fetal,\ 0.95} = PbB_{adult,\ central} * GSD_{i,\ adult} * R_{fetal/maternal}$$

Where:

$PbB_{adult,\ central\ goal}$ = Goal for average PbB levels (µg/dL) in pregnant women. The goal is intended to ensure that $PbB_{fetal,\ 0.95}$, does not exceed 10 µg/dL.

$PbB_{fetal,\ 0.95,\ goal}$ = Goal for the 95th percentile PbB level (µg/dL) among exposed fetuses. This is interpreted to mean that the likelihood of a fetal PbB level greater than 10 µg/dL would be less than 5%.

$GSD_{i,\ adult}$ = Estimated value of the geometric standard deviation among women of childbearing age. The exponent, 1.645, is the value of the standard normal deviate used to calculate the 95th percentile from a lognormal distribution of PbB level.

$R_{fetal/maternal}$ = Ratio between fetal PbB levels ($PbB_{fetal,\ 0.95}$) at birth and maternal PbB levels ($PbB_{adult,\ central}$; unitless).

The scientific veracity of predicting fetal PbB levels with the *AL* model and the appropriateness of USEPA policy for evaluating non-residential lead exposure are based on the following assumptions:

- Within each non-residential worker population, at least one woman will be employed who will become pregnant and continue to work at the site during her pregnancy.
- It is scientifically correct to estimate the PbB level in a pregnant woman as the sum of an expected starting PbB level in the absence of site exposure ($PbB_{adult,\ 0}$) and an expected site-related increase resulting from exposure to the site.
- The site-related increase in PbB levels is linear over the entire exposure range and can be estimated using a linear biokinetic slope factor.

- Lead uptake in the pregnant woman is *directly* related to the estimated soil lead concentration (Pb_S), the overall rate of daily soil ingestion (IR_S), and the estimated fractional absorption of ingested lead (AF_S).

- The distribution of PbB levels in the subpopulation of pregnant women in the United States is lognormal and is appropriate to use at any U.S. site.

- The expected fetal PbB levels are *directly proportional* to maternal PbB levels in all cases, and they are lognormally distributed with a standard deviation identical to the subpopulation of PbB levels among women of childbearing age.

USEPA has concluded that a health-protective, non-residential, risk-based remediation goal for soils should be protective of the developing fetus (or neonate) because they are the most sensitive subpopulation. As a general policy, the Agency has concluded that protecting the most sensitive subpopulation (fetuses) will be protective of all other non-residential receptors.

As with young children, the acceptable PbB level in neonates is assumed to be 10 µg/dL. Although the primary use of the *AL* model is to evaluate the risk for fetal exposures, USEPA notes that, in some circumstances, it may be appropriate to modify the methodology to estimate PbB levels for non-residential adult exposures (for a target receptor other than a fetus) and to estimate RBRGs for different receptors. For example, a RBRG can be estimated for risks to adults by substituting an appropriate adult PbB levels benchmark corresponding to a health-based benchmark, such as hypertension.

The *AL* model also presents a method for calculating site-specific RBRGs. The RBRG is a health-protective lead concentration in soil that can be used to guide remediation during risk management. The following equation can be used to estimate the acceptable concentrations:

$$RBRG = PbS = \frac{(PbB_{adult,central,goal} - PbB_{adult,0}) \cdot AT}{(BKSF \cdot IR_S \cdot AF_S \cdot EF_S)}$$

The RBRG is the health-protective soil lead concentration (PbS) that would be expected to result in a specified PbB level in a pregnant woman ($PbB_{adult,\ central\ goal}$) that, in turn, corresponds to the 95th percentile fetal PbB level ($PbB_{fetal,\ 0.95,\ goal}$).

5.3 Default Input Parameters

As indicated in the above section, the *AL* model is a simplistic risk assessment model that simply adds the PbB level resulting from one exposure pathway, namely soil ingestion, to the baseline PbB levels that account for all other non-site related exposures. Based on new information, some default values need to be updated. Default values are presented in Table 5.1

TABLE 5.1

SUMMARY OF DEFAULT *AL* MODEL INPUT PARAMETERS

INPUT PARAMETER	DEFAULT VALUE	PARAMETER DESCRIPTION
$PbB_{fetal,\ 0.95,goal}$	10 µg/dL	***Target PbB:*** PbB goal of likelihood of a fetal PbB level greater than 10 µg/dL would be less than 5%.
$GSD_{i,adult}$	1.8 or 2.1	***Geometric Standard Deviation***
$R_{fetal/maternal}$	0.9 µg/dL	***Ratio Between Fetal and Maternal Blood***
$PbB_{adult,0}$	1.7-2.2 µg/dL	***Background/Baseline PbB Levels***
BKSF	0.4 µg/dL per µg/day	***Biokinetic Slope Factor***
IR_S	0.05 g/day	***Ingestion Rate***
EF_S	219 day/yr	***Exposure Frequency***
AF_S	0.12 (unitless)	***Absorption Factor***

5.4 Revised Default Input Parameters

It is important to note that default parameters are based on U.S. population statistics and should not be considered site-specific values. Consequently, predicted PbB levels based on default values should be considered "plausible" not site-specific. Individual default parameters may or may not be applicable and appropriate for estimating PbB levels under site-specific conditions. It is highly recommended that site-specific information be collected and used to precisely predict PbB levels.

The following brief section provides supporting rationale for revising some input parameters suggested in previous USEPA (1996) guidance. The suggested changes are based on recent studies and information that has become available since the time the original guidance was prepared. As mentioned previously, there has been a marked decrease in lead levels in all environmental media (as a direct result of banning leaded gasoline), which has produced a corresponding decrease in PbB levels in all segments of the U.S. population. Revising the input parameters to reflect these changes will provide for more precise PbB level predictions.

Geometric Standard Deviation - The GSD represents inter-individual variability in PbB levels between individuals in the target population. Although it is assumed that all members are exposed to the same concentrations of lead in soil and dust, differences in PbB levels arise from behavioral and biological differences. Factors that contribute to natural variability within the population include differences primarily in activity-weighted ingestion rates and physiologic lead biokinetics.

Lower GSD values represent homogeneous populations (e.g., individuals with similar socioeconomic and ethnic characteristics living within a relatively small geographic area). These populations are exposed to similar chemical forms and concentrations of lead. In contrast, higher GSD values are expected from a national survey in which many different subpopulations are pooled. Although lead exposures among the general U.S. population are likely to be more greatly affected by diet than soil, the national population is very heterogeneous in that it includes individuals with different socioeconomic and ethnic characteristics living in distinct geographic areas (USEPA 1996).

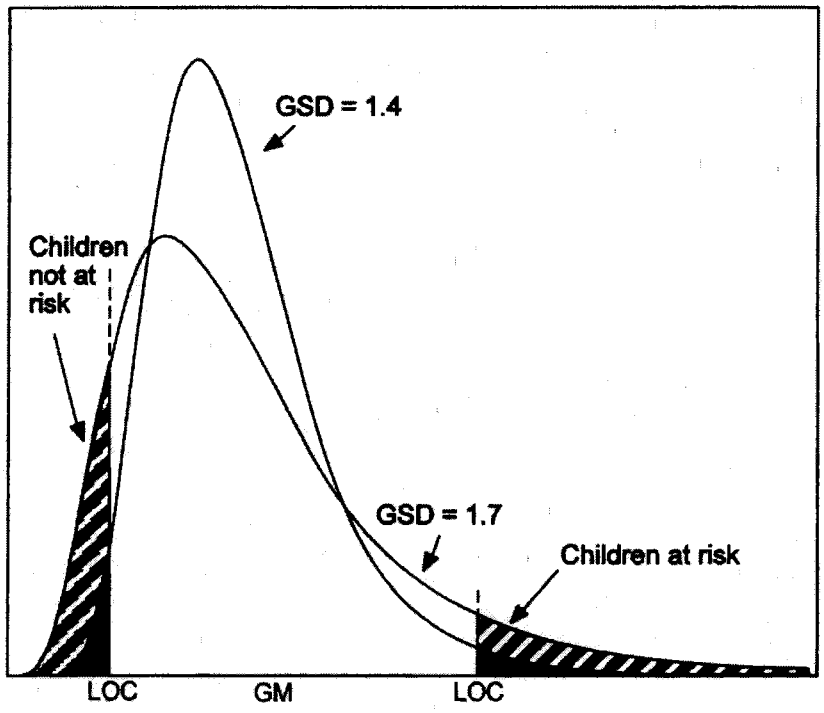
It is important to correctly estimate or define the GSD when predicting PbB levels in the fetus because it is used directly to estimate $PbB_{fetal,95}$, which is defined as the 95th percentile PbB levels among fetuses born to women exposed to site-specific lead concentrations. The $PbB_{fetal,95}$ is estimated with the following equation:

$$PbB_{fetal,0.95} = R_{fetal/maternal} * PbB_{adult,central} * GSD^{1.645}$$

A small change in the GSD can translate to a significantly different $PbB_{fetal,0.95}$ level. Figure 5.1 demonstrates the relative increase in the predicted number of children "at risk" when the GSD for the population increases from 1.4 to 1.7, even when both populations have the same geometric mean.

FIGURE 5.1

IMPORTANCE OF THE USING THE CORRECT GEOMETRIC STANDARD DEVIATION



The curve with a GSD=1.7 has substantially more children at risk (as shown by the hatched shaded area) compared to the curve with a GSD=1.4 (children at risk are shown as solid shaded area).

This figure shows that the number of children who are "at risk," defined as those children in the population exceeding the Level of Concern (LOC), is significantly higher for the population with a GSD of 1.7 compared with the population having a GSD of 1.4.

The previous GSD values of 1.8 to 2.1 were based on the results of the NHANES III, Phase 1 study. According to White *et al.* (1998), the previous default GSD values of either 1.8 or 2.1 should be revised to 1.6. They authors state:

> *"The recommended default GSD for the IEUBK model is 1.6, which is intended as a broadly applicable, not a conservative, value."*

A value of 1.6 is the same GSD value that DTSC recommends for evaluating lead exposures for both children and adults in the recently released Lead Spread Model. (Version 7). It should be emphasized that even a GSD value of 1.6 may overestimate PbB levels because it is derived from a large cross-section of the U.S. population. Since the GSD represents variability within the population, a GSD of 1.6 (which is based on diverse U.S. populations) will tend to overestimate PbB levels associated with exposure to lead within a relatively small geographical region where exposures are expected to be similar (like a single Navy installation). When possible, the GSD should be estimated based on empirical data. For Western states (including California), a GSD of 1.4 is more representative than 1.6 and should be used were appropriate (see sections below)

Baseline PbB Levels - The baseline PbB level ($PbB_{adult,0}$) is intended to represent the best estimate of the average PbB level in women of childbearing age who are not exposed to lead at the site. The baseline PbB level can be considered the background level in the population. In other words, the baseline PbB level is a preexisting level that a woman would normally have prior to being employed at the site. It is important to accurately define $PbB_{adult,0}$ in predicting PbB levels for a non-residential lead exposure scenario because the predicted PbB_{adult} is defined as the sum of PbB levels corresponding to baseline (from background sources) and site-specific sources of lead:

$$PbB_{Total} = Pb_{Adult,0} + Pb_{Site\text{-}Specific}$$

The value used to represent $PbB_{adult,0}$ should be based on an estimate of the target population at the site. However, this information is not always available. The best estimate of $PbB_{adult,0}$ would be based on a representative population of adult women not exposed to site soil or dust, but who are exposed to naturally occurring and ubiquitous background lead. Exposures would occur similar in magnitude to exposures experienced by the population of concern at the site and would have similar diets and drinking water sources. Like all parameters used in the *AL* model, average values must be used because the GSD is already built into the model. In cases where site-specific extrapolations from surrogate populations are not possible, USEPA previously recommended a GSD of 1.7 to 2.2 µg/dL as a plausible range, based on the results of Phase 1 of the NHANES III, as reported by Brody *et al.* (1994). Based on the results of NHANES III, Phase 2, this value should be revised to 1.4 µg/dL for women living in the western United States (CDC 1994;

Bowers and Cohen 1998). Table 5.2 presents a summary comparison of Phase 1 and 2 NHANES III data for women of childbearing age.

TABLE 5.2

SUMMARY BASELINE PbB LEVELS FOR WOMEN OF CHILDBEARING AGE IN DIFFERENT REGIONS OF THE UNITED STATES

	PHASE-1 NHANES III (1)		PHASE-2 NHANES III (2)	
U.S. REGION	GEOMETRIC MEAN	GEOMETRIC STANDARD DEVIATION	GEOMETRIC MEAN	GEOMETRIC STANDARD DEVIATION
Midwest	1.84	1.94	1.48	1.89
Northeast	2.39	1.82	1.74	1.76
South	1.54	1.88	1.42	1.77
West	1.77	1.83	1.36	1.81

(1) Phase-1 NHANES III data represent baseline PbB levels during years 1988-1991.
(2) Phase-2 NHANES III data represent baseline PbB levels during years 1991-1994.

Ingestion Rate - The ingestion rate represents the *average* amount (gm/day) of soil and dust (derived from soil) ingested by women of childbearing age. USEPA (1996) recommends a default value of 0.05 g/day as a plausible point estimate of the central tendency for daily soil intake from all occupational sources, including soil in indoor dust, resulting from non-contact-intensive activities. The Agency suggests that site-specific data on soil contact intensity, including potential seasonal variations, be considered in evaluating whether or not the default value is applicable to the population of concern and, if not, that activity-weighted estimates of IR_S that more accurately reflect the site be developed.

Little empirical information is available to estimate adult ingestion rates because most soil ingestion studies have been conducted for children. A recent study by Stanek and Calabrese (1995) indicates that the average ingestion rate for a child is 0.04 g/day. Based on the assumption

that children have a much higher ingestion rate than adults (due to hand-to-mouth behaviors), it is reasonable to assume that, for normal indirect contact with soil, an adult would ingest approximately 50% of the amount ingested daily by a child (Bowers and Cohen 1998). Based on this proportionality, an average daily ingestion rate of 0.02 g/day for an adult woman of childbearing age who works primarily indoors is appropriate. However, for higher-intensity exposures for outdoor workers who directly contact soil, the USEPA default value of 0.05 g/day likely represents the appropriate average daily ingestion rate.

Additional Adjustments - There are two additional adjustments to the *AL* model are necessary to estimate site-specific PbB levels for a non-residential indoor worker. They are as follows:

- Converting external soil concentrations to indoor dust concentrations; and
- Adjusting the daily soil ingestion rate to differentiate soil ingested from the site from soil ingested off-site.

Developing Indoor Dust Concentrations for Indoor Workers - In the past, USEPA has grouped all non-residential exposures under the general heading of occupational scenarios without making important distinctions about potential differences in exposures based on specific work-related activities. For example, a clerical worker who spends the entire workday in a climate-controlled office would be exposed to far less soil lead than a construction worker or landscaper. When soil lead is the only source of lead exposure, indoor workers would be exposed to indoor dust.

Recent USEPA (1999) guidance now provides an approach for evaluating risks associated with different types of occupational exposures. As presented in *"Supplemental Guidance for Developing Soil Screening Levels for Superfund Sites,"* health-protective screening levels for numerous chemicals can be developed for two general non-residential classifications based on different work-related activity patterns for the following groups:

- Indoor workers; and
- Outdoor worker/landscapers.

According to USEPA (1996), an indoor worker is defined as:

> ***Indoor Worker:*** *This receptor spends most, if not all, of the workday indoors. Thus, an indoor worker has no direct contact with outdoor soils. This worker may, however, be*

exposed to contaminants through ingestion of contaminated soils that have been incorporated into indoor dust, ingestion of contaminated ground water, and the inhalation of contaminants indoors through vapor intrusion. SSLs calculated for this receptor are expected to be protective of both workers engaged in low intensity activities such as office work and those engaged in more strenuous activity (e.g,. factory or warehouse workers.

Outdoor Worker: *This is a long-term receptor exposed during the work day who is either: (1) a full time employee of the company operating on-site who spends most of the workday landscaping or conducting other maintenance activities outdoors; or (2) who is assumed to return regularly to the site for grounds-keeping activities. The activities for this receptor (e.g,. moderate digging, gardening) typically involve on-site exposures to surface and shallow subsurface soils (at depths of zero to two feet). The outdoor worker/landscaper is expected to have a high soil ingestion rate and is assumed to be exposed to contaminants via the following pathways: dermal contact, inhalation of volatiles outdoors, inhalation of fugitive dust, incidental ingestion of soil, and ingestion of ground water contaminated by leachate. The outdoor worker/landscaper is expected to be the most highly exposed receptor in the outdoor environment under commercial/industrial conditions. Thus SSLs for this receptor are protective of other reasonably anticipated outdoor activities at commercial/industrial facilities.*

For office workers exposed to indoor dust at sites with no separate indoor source of lead contamination, it can be assumed that dust lead is derived entirely from outdoor soil. Dust lead loading occurs either through-resuspended soil in air or by being directly transported into the building on contaminated clothing or shoes. At many sites, the dust lead concentration indoors is only a fraction of the outdoor soil concentration. Using the soil lead concentration to estimate lead risks for indoor workers significantly overestimates exposure and PbB levels. To make accurate PbB level estimates for indoor workers, it is necessary to base predictions on the amount of lead ingested from dust lead.

USEPA has found that the physical relationships between soil and dust are complex and may or may not be related. Their results, presented in *"Data Analysis of Lead in Soil and Dust"* (USEPA 1993) suggest that the expected correlation between soil and dust are not always empirically observed. Nonetheless, it is imperative to base PbB level predictions on accurate site-

TABLE 5.2

SUMMARY DEFAULT AND REVISED *AL* MODEL INPUT PARAMETERS AND CORRESPONDING PRG LEVELS

INPUT PARAMETER	PREVIOUS DEFAULT VALUE	REVISED DEFAULT VALUE	PARAMETER DESCRIPTION
$PbB_{fetal,\ 0.95,goal}$	10 µg/dL	*NC*	***Target PbB:*** PbB goal of likelihood of a fetal PbB level greater than 10 µg/dL would be less than 5%.
$GSD_{1,adult}$	1.8 or 2.1	1.6	***Geometric Standard Deviation:*** Value of 1.6 is now recommended (White *et al.* 1998; DTSC 1999.)
$R_{fetal/maternal}$	0.9 µg/dL	*NC*	***Ratio Between Fetal and Maternal Blood:*** Based on Goyer (1990) and Graziano *et al.* (1990).
$PbB_{adult,0}$	1.7-2.2 µg/dL	1.4 µg/dL	***Background/Baseline PbB Levels:*** Point estimate should be selected based on site-specific demographics. The value 1.4 is based on NHANES III, Phase 2 (1991-1994).
BKSF	0.4 µg/dL per µg/day	*NC*	***Biokinetic Slope Factor:*** Based on analysis of Pocock *et al.* (1983) and Sherlock *et al.* (1984) data.
IR_S	0.05 g/day	0.02-0.05 g/day	***Ingestion Rate:*** The value 0.02 represents occupational exposures to indoor soil-derived dust, while 0.05 represents high outdoor direct contact with soil (Stanek and Calabrese 1995.)
EF_S	219 day/yr	*NC*	***Exposure Frequency:*** Based on USEPA (1993) guidance for average time spent at work by both full-time and part-time workers.
AF_S	0.12 (unitless)	0.048	***Absorption Factor:*** Based on an absorption factor for soluble lead of 0.08 and a relative bioavailability of 0.6 soil/soluble (Bowers and Cohen 1998.)
SOIL LEAD PRG CONCENTRATION	**888-1,545 ppm**	**6,473 ppm**	***Preliminary Remediation Goal***

NC – No change

6 CALIFORNIA DTSC LEAD SPREAD MODEL

6.1 Background Information

Like USEPA lead risk assessment models, the purpose of the California Department of Toxic Substance Control (DTSC) *LeadSpread* model (Ca*LS*) is to predict PbB levels in potentially exposed receptors. The Ca*LS* model has been developed to predict PbB levels in both children and adults, as follows:

- Children:
  - Average residential childhood exposure; and
  - Pica child (abnormal soil ingestion).
- Adults:
  - Residential exposure; and
  - Occupational exposure.

DTSC recently (March 2000) released a beta Version 7 Ca*LS* model that replaces Version 6. Both models share the same structural elements used to estimate PbB levels, but Version 7 has been updated to include more recent default parameters. It is important to evaluate these default values carefully to determine whether they represent site-specific conditions. Unlike the *IEUBK* model, with which USEPA strongly encourages using site-specific input parameters to accurately predict PbB levels, California DTSC's risk assessment/management policy is just the reverse. The Agency's policy is to preferentially use default values unless compelling evidence and justification is available to permit using alternate values.

The Ca*LS* model relies on a slope factor approach, which, as discussed in Section 4.1, oversimplifies the toxicological aspects of lead and should not be regarded as a highly accurate model. It also may not be applicable to all exposure situations, sites, and child populations (1994). As previously discussed, the relationship between lead exposure and PbB levels is not always linear. That is, PbB levels do not always increase in direct proportion to exposure levels. For these reasons, USEPA altered its approach, developed the *IEUBK* model, and no longer uses

a slope factor approach to evaluate lead risks. The Ca*LS* should be regarded only as a screening level tool that can be used to identify sites that warrant further investigation.

Comparing USEPA and California CaLS Models

The following brief sections highlight the important similarities and differences between the Ca*LS* and USEPA lead models in predicting PbB levels in exposed receptors. Although there are considerable technical differences between the models, the predominant difference between USEPA and California lead risk assessments is in how the results are interpreted. California's health-protective benchmark used to make risk management decisions is considerably more conservative than that of USEPA. That is, in addition to the conservatism introduced into the Ca*LS* model itself, the risk management decisions are based on a more conservative policy than USEPA lead risk assessment/management policy.

As discussed earlier, USEPA's lead risk assessment/management policy has set a PbB level of 10 μg/dL as the acceptable biological level of exposure. Due to the statistical approach and conservatism knowingly introduced into both *IEUBK* and *AL* risk assessment models, USEPA has defined a statistical value as the acceptable *predicted* PbB level. This bright line has been set to protect a hypothetical child and fetus, respectively. The Agency initially set and reconfirmed an acceptable risk level that corresponded to an exposure where the probability of a childhood or fetal PbB level exceeding 10 μg/dL was less than 5%. According to a 1994 OSWER Directive (USEPA 1994):

> *"Development of the residential screening level in this interim directive required two important OSWER decisions. 1) OSWER determined that it would seek to achieve a specific level of protectiveness in site cleanups; generally, OSWER will attempt to limit exposure to soil lead levels such that a typical (or hypothetical) child or group of similarly exposed children would have an estimated risk of no more than 5% exceeding the 10 μg/dl blood lead level".*

This health-protective bright line was confirmed in the subsequent 1998 OSWER Directive (USEPA 1998):

> *"The directive describes OSWER's risk reduction goal as "...generally, OSWER will attempt to limit exposure to soil lead levels such that a typical (or hypothetical) child or group of similarly exposed children would have an estimated risk of no more than 5% exceeding a 10 μg/dl blood lead level." The directive also states that "... EPA recommends that a soil lead concentration be determined so that a typical child or group of children exposed to lead at this level would have an estimated risk of no more than 5% of exceeding a blood lead of 10 ug/dl...* And finally *" This approach helps achieve OSWER'S recommended health protection goal that an individual child or group of similarly exposed children would have < 5 % chance of exceeding a blood-lead concentration of 10 μg/dL."*

USEPA (1994) set a similar health-protective level for a hypothetical fetus:

> *"Current Office of Solid Waste and Emergency Response (OSWER) guidance calls for the establishment of cleanup goals to limit childhood risk of exceeding 10μg/dL to 5% (U.S. EPA, 1994a). Goal for the 95th percentile blood lead concentration (μg/dL) among fetuses born to women having exposures to the specified site soil concentration. This is interpreted to mean that there is a 95% likelihood that a fetus, in a woman who experiences such exposures, would have a blood lead concentration no greater than PbB fetal, 0.95, goal (i.e., the likelihood of a blood lead concentration greater than 10 μg/dL would be less than 5%."*

In contrast, California's health-protective level is much more conservative (DTSC 1997):

> *"The Pb concentration of concern in children and adults is ten micrograms (μg) per deciliter (dL) of whole blood. The point of departure for risk management is a 0.01 risk of exceeding this value."*

Simply stated, California's *de minimus* lead risk policy for children and adults is to limit the *predicted* probability of exceeding the PbB level of 10 μg/dL to less than *1%* (instead of 5%). Although this may not appear to be a significant difference, this difference translates to an acceptable soil and dust lead concentration in California that is several hundred ppm *lower* than USEPA's acceptable concentration.

It should be emphasized that neither USEPA's nor California's lead risk policy applies to *measured* PbB levels (intervention may be required when a measured PbB level for a specific child exceeds 10 μg/dL). Both California and USEPA policies are based simply on *predicted* PbB levels and the *probability* that a bright line will be exceeded. Confirming the accuracy of any model prediction requires biomonitoring by collecting actual blood samples from exposed receptors, a step not normally taken in lead investigations.

Finally, it should be emphasized that DTSC has not validated the model by measuring PbB levels in exposed populations. Based on the information of numerous studies at lead-contaminated sites, where soil and dust lead concentrations have been measured and compared with PbB levels measured in the exposed population, it appears that the Ca*LS* model yields implausibly high predicted PbB levels. The utility of the Ca*LS* model in risk assessments is unclear. Until well-designed studies are designed and implemented, the model should be considered a regulatory policy tool that DTSC may use to make internal risk management decisions.

Childhood Exposures: Comparing IEUBK and CaLS Models

The *IEUBK* and Ca*LS* models can both be used to predict PbB levels in exposed children. However, the underlying mathematical structures of the models are very different. Whereas the *IEUBK* model is a complex multi-compartment biokinetic model that integrates age-adjusted lead exposures throughout childhood, the Ca*LS* models is a simple linear model, based on empirical relationships between intake and PbB levels under steady-state assumptions. That is, it lacks a biological component and attempts to predict PbB levels just based on intake rates. The *IEUBK* predicts PbB levels from knowledge about maternal blood lead concentration, lead concentrations in all environmental media, behavioral activities, and bioavailability. In contrast, the Ca*LS* model does not evaluate these aspects nor does it predict PbB levels throughout the entire childhood exposure. The *IEUBK* estimates PbB levels lead for children from birth to 7 years old, while the Ca*LS* model provides predicted PbB levels only for 1- to 2-year-old children, with or without pica.

Perhaps the greatest difference between the *IEUBK* and Ca*LS* models is that the latter relies on a slope factor and is based on the assumption of linearity, which may not be appropriate for all types of exposures. As previously noted, USEPA used to rely on a similar approach until it concluded that a slope factor approach oversimplified the toxicological aspects of lead exposure and did not provide accurate PbB level estimates. According to USEPA (1994), slope factors

should not be regarded as universal constants applicable to all exposure situations, sites, and child populations. Biological and physical differences between sites and study populations cannot be incorporated explicitly and quantified into regression slope factors from different studies. Slope factors for a single medium, such as lead in air or lead in soil, may provide only a very incomplete picture of total lead exposure from a particular source. For these fundamental reasons, a slope factor approach is considered by USEPA to be inadequate for estimating PbB levels. USEPA (1999) has recently summarized these issues:

> *"Prior to the development of the IEUBK model, a single slope factor constant had been used to predict risk from exposure to lead, as is done for other chemicals. The slope factor approach assumed a linear relationship between environmental concentrations and risk levels. Although, for Pb, the rate relationship is close to linear at lower PbB levels, it is non-linear at higher levels, invalidating the linear approach. Additionally, the linear approach did not adequately address the site-specific variability and multi-media nature of exposure to lead. The IEUBK model is the primary tool used in determining risk-based cleanup levels at Pb contaminated sites. The following modules are utilized in predicting PbB concentrations and risks in the IEUBK model: Exposure, Uptake, Biokinetic and Probability Distribution."*

For these reasons, any mathematical model based on a slope factor should be considered a rough approximation of actual lead exposures and the results as information used to focus subsequent investigations or for screening.

Like the *IEUBK* model, the Ca*LS* model is a deterministic model where a single value is used to represent an entire population of values for each input parameter. Using the wrong value or a non-representative value can significantly overestimate lead risk. For example, when a single soil/dust concentration is used to represent chronic exposure to soil/dust lead with the *CaLS* model, it is automatically assumed that the child will continuously ingest soil lead at that particular concentration 24 hours per day 7 days a week for the 1- to 2-year exposure duration. In other words, the child essentially never leaves its property. Moreover, using the soil concentration to predict PbB levels with the Ca*LS* model can significantly overestimate risks. This is because the model assumes (by default) that children 1 to 2 years old spend most of their time outside directly exposed to soil lead, when, in fact, young children spend minimal time outdoors at this age. According to USEPA (1994), children 1 to 2 years of age only spend approximately 1 to 2 hours outdoors. So they do not directly contact soil lead, but, rather, come

in contact with dust lead while playing *inside* the home. Accordingly, the soil/dust lead intake for these children should be based primarily on indoor dust concentrations. As discussed previously, the dust lead (in the absence of indoor leaded paint) concentration comprises soil lead, but at only fraction of the soil concentration. Dust concentration can range from about 20% to 70% of the soil lead concentration (default is 70%). To predict PbB for childhood exposures with the Ca*LS* model requires the appropriate input data and environmental concentrations based on the areas of the home where exposures will actually occur. There are other explicit and implicit assumptions underlying the default input parameters that should be carefully evaluated when using the Ca*LS* model to avoid unintentionally overestimating risk.

DTSC has compared the results from the *IEUBK* and Ca*LS* (V.7) models using default parameters. They have concluded the following:

- *IEUBK* describes the pharmacokinetics of the absorption and distribution of lead in greater detail than LeadSpread 7. However, LeadSpread 7 is easier to use.

- At high concentrations of lead in soil, the two models diverge significantly, because *IEUBK* has a saturable component for uptake of lead, while LeadSpread 7 does not.

- LeadSpread 7 predicts generally lower blood lead than *IEUBK* for the 1-2 year old child, because it incorporates defaults reflecting decreases in ambient levels of lead in food, water, and air. Differences between predictions from the two models become much smaller when the recommended defaults for LeadSpread are used in *IEUBK*.

- Predictions from both LeadSpread and *IEUBK* are in agreement with NHANES III, when data are limited to children living in post-1973 housing.

These conclusions, while factually correct, appear to be somewhat misleading. One advantage of the *IEUBK* model is that it is not a linear model and that it has the capability to represent site-specific conditions. The fact that the Ca*LS* model is "easier to use" may be true, but scientific veracity should not be sacrificed for expedience unless the model is to be truly a screening tool. To be truly representative and yield accurate PbB level predictions, a model should be as complex as required by biological and behavioral differences between populations and site-specific conditions.

Although DTSC states that the Ca*LS* model produces roughly the same results as the *IEUBK* model, the comparison appears to be irrelevant to the central goal of all lead risk assessments. The goal should not necessarily be to reproduce the result of another model, but to yield *predicted* PbB levels that are consistent with actual site-specific measured PbB levels. That is, the model has not been verified as a good predictive tool with biomonitoring data. Furthermore, comparing the Ca*LS* model with the *IEUBK* model ignores the fact that, under many site-specific conditions, the *IEUBK* model itself (see Chapter 7.0) significantly overestimates PbB levels. The *IEUBK* model should not be considered the "gold standard" with which all lead models are compared. Comparing the Ca*LS* model to another model that has been shown to be unreliable appears misdirected. Furthermore, the Ca*LS* and *IEUBK* models were only compared based on the *mean concentrations,* even though neither DTSC nor USEPA make risk management decisions based on the mean. Risk management decisions are based on the 95th percentile within USEPA, while DTSC makes decisions based on the 99th percentile. Accordingly, the models should be compared based on the PbB level percentile upon which risk assessment/management decisions are made, not a central point along the curve. Additionally, it is misleading to base comparisons on the means, which are fairly insensitive to input parameters. The tails of the curves are most sensitive to small changes and should be used for all comparisons. Before the Ca*LS* model is accepted as a robust scientific tool, biomonitoring studies need to be performed to determine whether the predicted PbB levels are equivalent to actual measured PbB levels.

Finally, DTSC has concluded that, based on a comparison of the *mean* PbB level estimated with the Ca*LS* model and the mean National average reported in the NHANES III report, the Ca*LS* model is a good predictive tool. This comparison, however, rather than verifying the Ca*LS* model, indicates the Ca*LS* model is *not* a good predictive tool. The predicted PbB levels are based on the assumption (default values) that the individuals in the NHANES III study were exposed to 20 ppm lead in soil and 15 ppb lead in drinking water. However, as was discussed in Chapter 2, because a very high percentage of individuals in the NHANES III studies lived in urban environments where the ambient anthropogenic lead soil concentrations can be many 1000's ppm (see Table 2.2) and the drinking water lead concentration much higher than 15 ppb (due to lead solder in plumbing), it is unlikely that their exposure matches the default exposure conditions represent in the Ca*LS* model. If the actual site conditions were used as input data for the Ca*LS* model, it is likely the model would have predicted PbB levels much higher than the measured results in the NHANES III study. As noted in a recent USEPA document:

> *"A plausible urban background is 75 to 200 μg/g (U.S. Environmental Protection Agency, 1989a; HUD, 1990)."*

The Ca*LS* model should be calibrated not using 20 ppm as the "average soil lead concentration" but the actual soil lead concentrations that the population in the NHANES III study was exposed. Until the lead concentrations of all the environmental media to which the population of the NHANES III were exposed are defined, it is untenable to conclude that the Ca*LS* model is a good predictive tool.

Figure 6.1 compare the *mean* results from the Ca*LS* and *IEUBK* models based on a variety of default parameters. They appear to show that both models produce comparable results, however, the *IEUBK* predicted PbB levels based on revised default parameters are significantly less than both Ca*LS* model results and the *IEUBK* based on previous default values. It should be noted, however, that simply comparing models diverts attention from the central question: *How well do the models predicted PbB levels match actual measured PbB levels?*

Note also that the model results are presented as mean PbB levels and not the 99th percentile PbB level, which is used by DTSC to make risk management decisions. Presenting predicted PbB levels as the mean values can be misleading. For example when the 50th, 95th, and 99th percentile values are *all* juxtaposed as in Figure 6.2, the 99th percentile PbB level, which is DTSC's acceptable bright line, would correspond to a soil lead concentration of approximately 146 ppm. The acceptable mean (50th percentile) PbB level is 3.3 μg/dL. Note also that there is greater divergence between different percentiles with increased concentration. That is, the slope of the 99th percentile predicted PbB level is steeper than the 50th percentile. By comparison, the USEPA 95th percentile level (the acceptable bright line) corresponds to a soil lead level of 530 ppm and with a mean PbB level of 5.8 μg/dl.

FIGURE 6.1

COMPARING USEPA *IEUBK* AND CA*LS* MODEL PREDICTED PbB LEVELS AT LOW SOIL LEAD CONCENTRATIONS

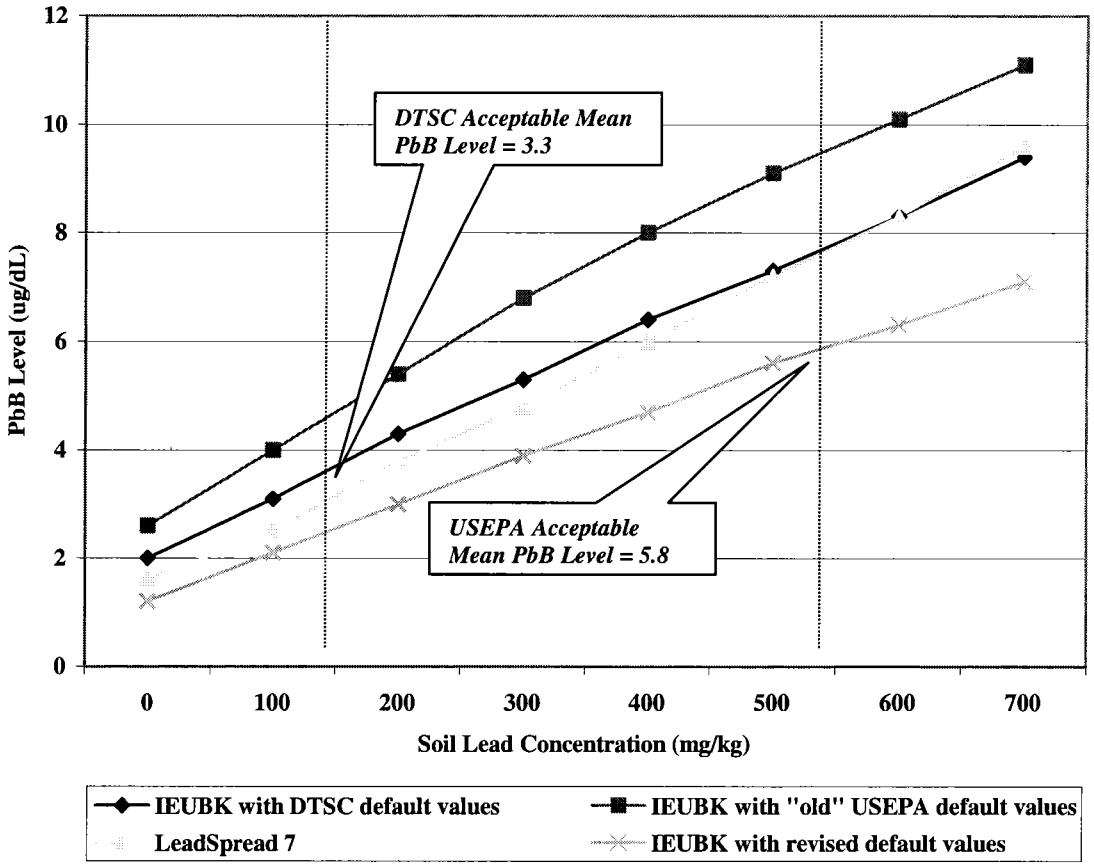


FIGURE 6.2

LEAD SPREAD PREDICTED 50TH, 95TH, 99TH PERCENTILE PbB LEVELS

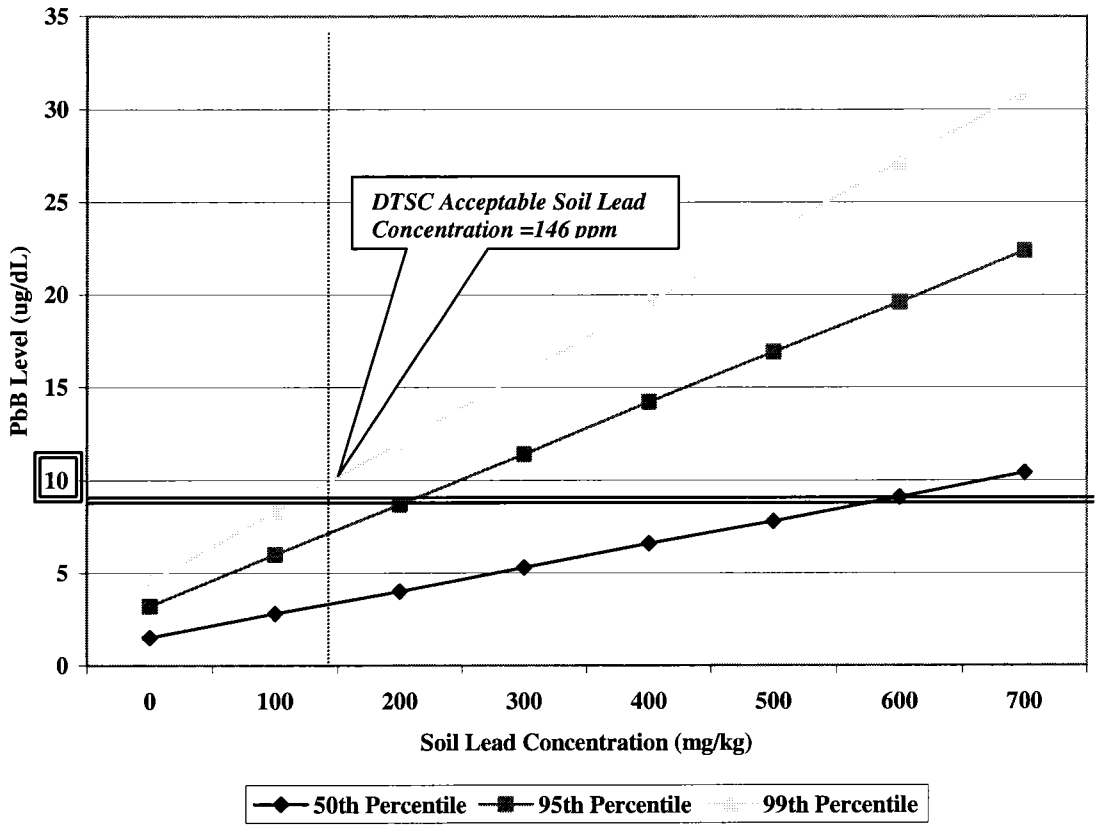


Figure 6.3 presents the Ca*LS* and *IEUBK* model predicted PbB levels for high soil lead concentrations. It is important to emphasize the plotted values are all mean PbB levels. Even so, they likely are significant overestimates of actual PbB levels. As discussed in chapter 7, even when soil lead concentrations are detected in thousands of ppm, actual, measured PbB levels are often below 10 µg/dl. For example, based on the *mean* PbB levels predicted with the Ca*LS* model it would be assumed that many in the community would die from such exposures. Figure 6.3 also shows the problem with the simplistic Ca*LS* slope factor approach. Even though it is well known that lead uptake from the gastrointestinal tract is saturable (no more lead can be absorbed after a certain point), the Ca*LS* model remains linear at any concentration contradicting

the well-known saturation phenomenon. By comparison, the *IEUBK* curve shows saturation effects which is built into the model.

FIGURE 6.3

PREDICTED MEAN PbB LEVELS CORRESPONDING TO INCREASED SOIL LEAD AT HIGH SOIL LEAD CONCENTRATIONS

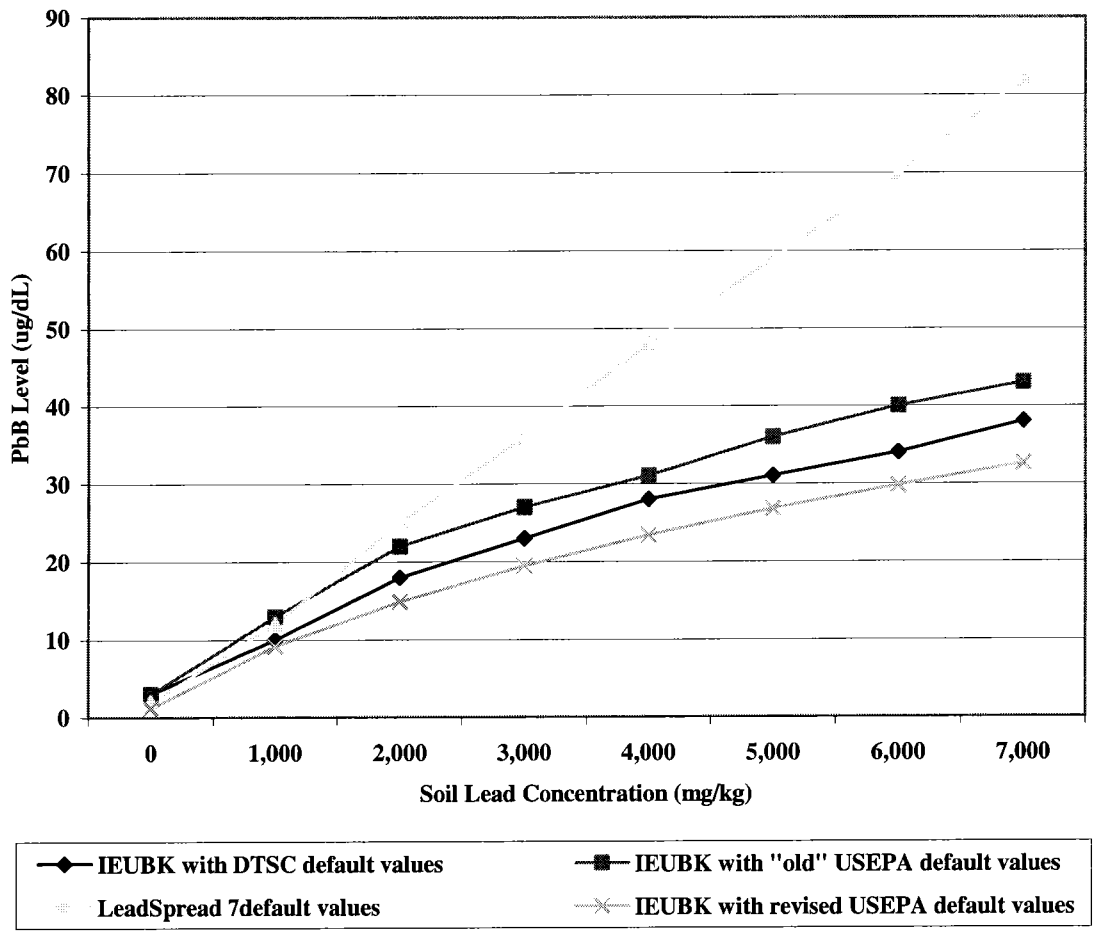


FIGURE 6.4

CHANGES IN MEAN PbB LEVELS WITH CHANGES IN CONCENTRATION OF LEAD IN DRINKING WATER

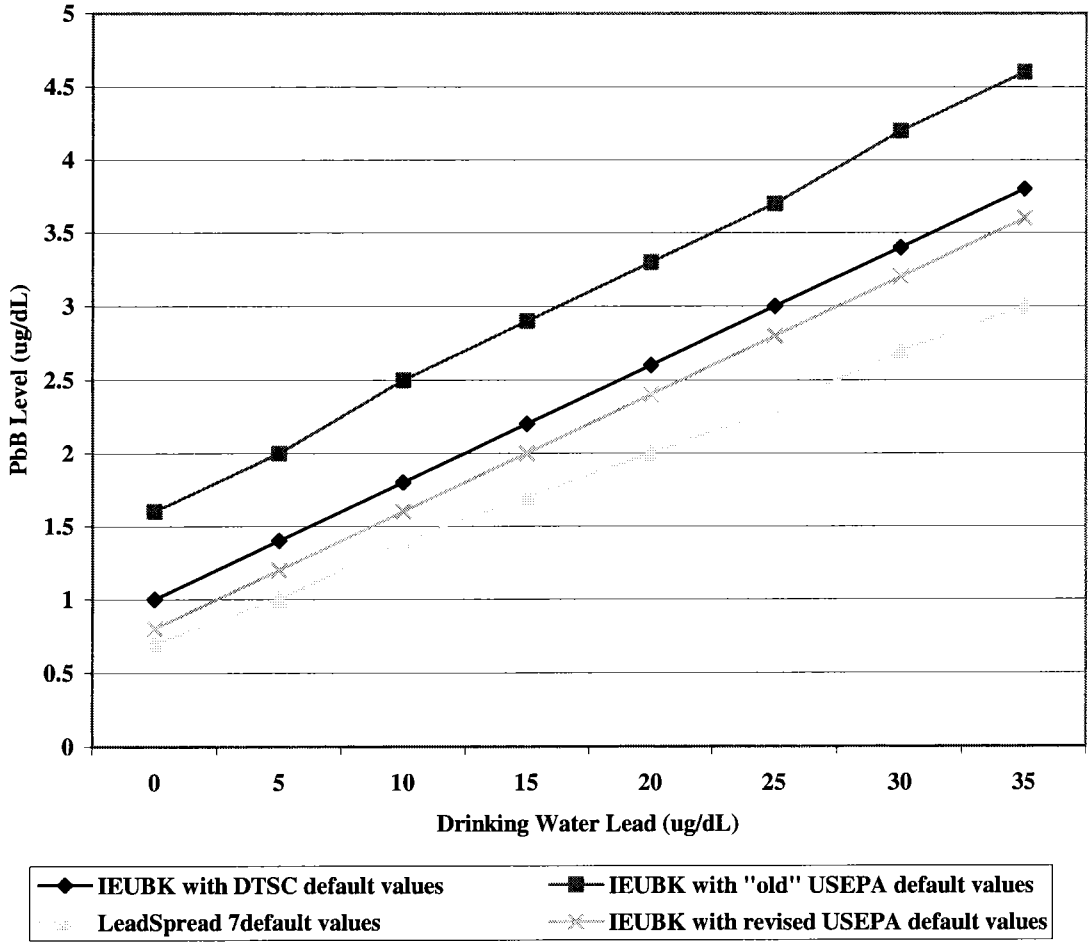
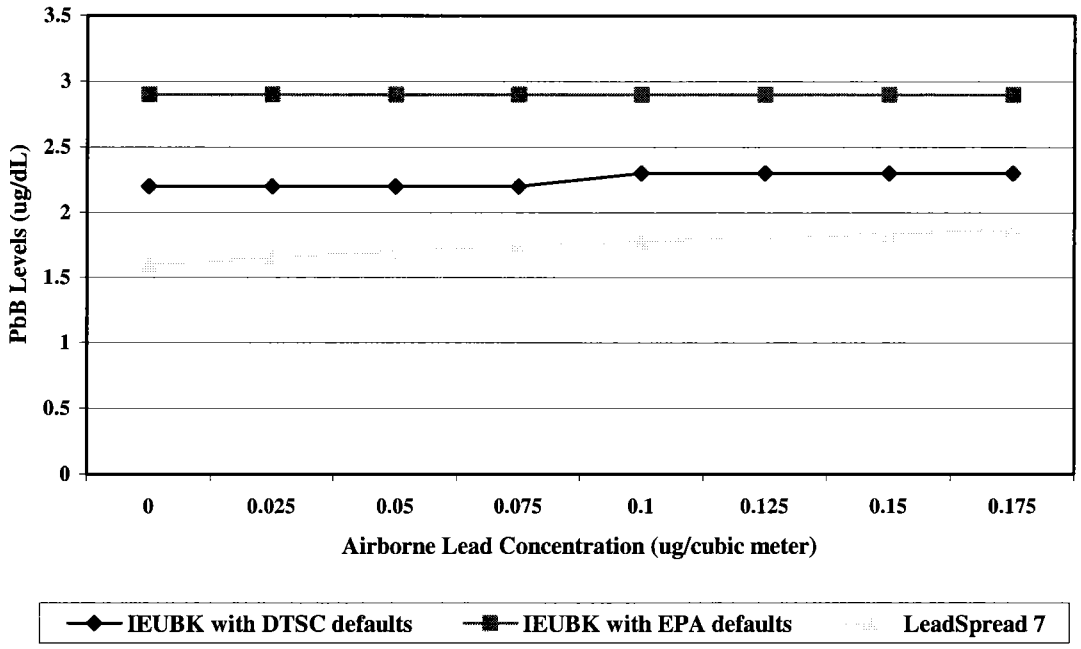


FIGURE 6.5

CHANGES IN MEAN PbB LEVELS WITH CHANGES IN LEAD IN AIR



Figures 6.4 and 6.5 shows the effect on PbB levels resulting in increased lead concentrations in food and air. It is noteworthy to point out that the inhalation pathway has a negligible effect on PbB levels as the air lead concentration is increased. That is, even when air concentrations increase significantly PbB levels remain relatively constant. Consequently, little effort should be expended in collecting site-specific data for the inhalation pathway.

Adult Exposures: Comparing AL and CaLS Models

The Ca*LS* model can be directly used without modification to estimate PbB levels in adults. As discussed in Chapter 5.0, USEPA has developed the Adult Lead (*AL*) model but the actual receptor is not an adult but a *fetus* that is exposed during gestation via intake by the mother. Although the *AL* model can be slightly modified to predict adult PbB levels, that was not the intended purpose.

Both the Ca*LS* and the *AL* models are simple models based on slope factors, an approach that has several technical shortcomings, as noted in the previous section. The major difference between the Ca*LS* and *AL* models is in the number of pathways evaluated. As previously discussed, the

Ca*LS* model is based on summing the incremental increases in PbB levels associated with five routes of exposure. In comparison, the *AL* model is limited to direct evaluation of only one route—namely, soil and dust ingestion. The other routes of exposure are indirectly evaluated by establishing a baseline (or background level not associated with the site) PbB level and adding to that the incremental increase in the PbB level associated with ingesting soil and dust at the site. In other words, every U.S. citizen has a baseline PbB that corresponds to intake from background levels of lead in air, drinking water, soil, and in food grown in the United States. For all practical purposes, the *AL* model is an approximation of the Ca*LS* model because four of the five routes of exposure are either directly represented by baseline PbB levels (food ingestion, drinking water ingestion, ambient air inhalation) or are relatively insignificant (dermal contact with inorganic lead). The major difference between the two models is that the baseline PbB level is a single value (based on the national population) that is the sum of all background exposures, while the Ca*LS* model allows baseline levels to be estimated based on regional information. Where regional information is not available and default input parameters must be used in the Ca*LS* model, the *AL* and Ca*LS* models should yield approximately the same results.

6.2 Technical Description—Model Overview

With the *CaLS* model, the predicted PbB level is an integrated measure of internal dose reflecting total intake from both site-related and background sources. Total lead sample concentration is generally used as the measure of lead in all environmental media and input with the Ca*LS* model. As mentioned in Chapter 2.0, it may be prudent to winnow site-specific sources from the total lead concentration to identify naturally occurring or anthropogenic background contributions to PbB levels.

The Ca*LS* model is a model that simply adds the incremental increase in PbB levels associated with the following five intake routes:

- Dietary intake;
- Drinking water intake;
- Soil/dust ingestion intake;
- Inhalation intake; and
- Dermal contact intake.

The total blood lead level is the sum of these five intake exposure routes:

$$\textit{Total PbB Level} = \textit{Pb Level}_{diet} + \textit{Pb Level}_{water} + \textit{Pb Level}_{soil/dust} + \textit{Pb Level}_{air} + \textit{Pb Level}_{dermal}$$

The algorithms used to derive PbB intake for each exposure route and the input parameters are briefly described below:

- **DIETARY INTAKE EQUATION**

$$\textit{Pb Level}_{diet} = \textit{Dietary Pb Concentration} * \textit{Intake Rate} * \textit{Dietary Slope Factor}$$

Where:

Pb Level$_{diet}$	=	PbB level associated with diet.
Dietary Pb Concentration	=	Assumes that 5.5% of the diet consists of home-grown produce (assumed to contain 0.045% of the soil lead concentration), with the other 94.5% supplied by a homogeneous source with a lead content of 1 μg/kg. Sites having no garden should assume 100% from 1 μg/kg source.
Intake Rate	=	Amount of food ingested per day (kg/day).
Dietary Slope Factor	=	Increase in PbB level per amount lead ingested [(μg/dL)/(μg/day)].

- **DRINKING WATER INTAKE EQUATION**

$$\textit{Pb Level}_{water} = \textit{Water Pb Concentration} * \textit{Intake Rate} * \textit{Drinking Water Slope Factor}$$

Where:

Pb Level$_{water}$	=	PbB level associated with drinking water.
Water Pb Concentration	=	Site-specific, measured value (μg/L).
Intake Rate	=	Volume of drinking water ingested per day (L).

Drinking Water Slope Factor = Increase in PbB level per amount lead ingested [(μg/dL)/(μg/day)].

- **SOIL AND DUST INGESTION INTAKE EQUATION**

$$Pb\ Level_{soil/dust} = Soil/Dust\ Pb * Intake\ Rate * Soil/Dust\ Slope\ Factor$$

Where:

Pb Level$_{soil/dust}$ = PbB level associated with soil/dust ingestion.

Soil/Dust Pb Concentration = Site-specific, measured value (mg/kg).

Soil/Dust Slope Factor = Increase in PbB level per amount lead ingested [(μg/dL)/(μg/day)].

- **INHALATION INTAKE EQUATION**

$$Pb\ Level_{air} = Atmospheric\ Pb * Inhalation\ Slope\ Factor$$

Where:

Pb Level$_{air}$ = PbB level associated with inhaling air.

Air Pb Concentration = Local or regional ambient level (μg/m^3).

Inhalation Slope Factor = Increase in PbB level per amount inhaled [(μg/dL)/(μg/m^3)].

- **DERMAL CONTACT INTAKE EQUATION**

$$Pb\ Level_{dermal} = Soil/Dust\ Pb\ Concentration * Contact\ Rate * Dermal\ Slope\ Factor$$

Where:

Pb Level$_{water}$ = PbB level associated with dermal absorption through the skin.

Soil/Dust Pb Concentration	=	Site-specific, measured value (mg/kg).
Contact Rate	=	Amount of soil/dust contact per day (gm/day).
Dermal Slope Factor	=	Increase in PbB level per amount absorbed [(μg/dL)/(μg/day)].

6.3 Default Input Parameters

DTSC has developed a set of default values for the Ca*LS* model. Based on new scientific information, the default values have been revised. For comparison purposes, Version 6 (previous values) and Version 7 default values are presented in Table 6.1. It is important to note that, while lead concentrations have been dramatically decreasing in all environmental media, the acceptable soil lead concentration, as represented by the preliminary remediation goal, has been lowered not increased. This appears counterintuitive, since the PbB level is simply the sum of all potential lead exposures from all environmental media. With decreasing lead in air, food, etc., it seems that the acceptable lead soil concentration would actually increase, not decrease. DTSC provides no explanation to reconcile the apparent paradox created in lowering the acceptable soil lead concentration.

TABLE 6.1

CALIFORNIA DTSC *LEADSPREAD* PREVIOUS AND NEW RESIDENTIAL DEFAULT INPUT PARAMETERS

INPUT PARAMETER	UNITS	PREVIOUS VALUE (V. 6) (1)	CURRENT VALUE (V.7) (2)	REFERENCE
GENERAL				
Geometric Std. Deviation	unitless	1.42	1.60	White *et al.*, 1998
Background Airborne Lead	$\mu g/m^3$	0.18	0.028	CARB, 1999
Source-Specific Airborne Dust	$\mu g/m^3$	50	1.5	Cowherd, 1985
Lead In Drinking Water	µg/L	15	15	MCL
% Diet Home-Grown (Resident)	%	5.5	7	USEPA, 1997
% Diet Home-Grown (Worker)	%	0	0	
Daily Food Consumption	kg/day	1.3	1.1	Bolger, 1996
RESIDENTIAL CHILD				
Dietary Lead	***µg/kg***	***10***	***2.8***	***USFDA, 1996-97***
Soil Ingestion	***mg/day***	***55***	***100***	***USEPA, 1997***
Soil Ingestion, Pica Child	***mg/day***	***790***	***200***	***USEPA, 1997***
Ventilation Rate	***m3/day***	***10***	***6.8***	***USEPA, 1997***
Exposed Skin Area	***cm2***	***2,800***	***2,900***	***USEPA, 1997***
Soil-To-Skin Adherence	***mg/cm2***	***1***	***0.2***	***USEPA, 1998***
Preliminary Remediation Goal-Soil Lead Concentration (PRG)	***ppm***	***247***	***146***	***DTSC***
RESIDENTIAL ADULT				
Daily Food Consumption	kg/day	2.2	1.9	Bolger, 1996
Dietary Lead	µg/kg	10	1.3	USFDA, 1996-97
Soil Ingestion	mg/day	25	50	USEPA, 1997
Exposed Skin Area, Resident.	cm^2	3,700	5,800	USEPA, 1997
Soil-To-Skin Adherence	mg/cm^2	1	0.07	USEPA, 1998
Preliminary Remediation Goal-Soil Lead Concentration	ppm	1062	676	DTSC

The relative contributions to the overall PbB level associated with each pathway for the following receptor types are presented in Tables 6.2 and 6.3:

- Child resident;
- Pica child;

- Adult resident; and
- Occupational worker.

The PbB levels presented in the tables should be considered the average PbB levels resulting from exposure to lead in baseline or background conditions that are not associated with any site release. For example, exposure to background drinking water and food ingestion (from municipal sources and national food supply, respectively) represents 84% and 91% of the predicted PbB level for child and adult residents. This is based on the assumption that the average soil lead background concentration is 20 ppm. However, for urban areas or areas near anthropogenic lead sources such as highways or heavily trafficked streets, the background soil lead will be much higher than 20 ppm. This should be taken into account in all risk assessments because the background soil lead may be the predominate contributor to PbB levels.

TABLE 6.2

RELATIVE CONTRIBUTIONS OF EXPOSURE PATHWYS TO TOTAL PbB LEVELS BASED ON DEFAULT INPUT PARAMETERS RESIDENTIAL CHILD AND PICA CHILD RECEPTORS

EXPOSURE PATHWAYS				
EXPOSURE PATHWAYS	**RESIDENTIAL CHILD**		**PICA CHILD**	
	PATHWAY CONTRIBUTION		**PATHWAY CONTRIBUTION**	
	PbB Level (µg/dL)	**Percent Contribution**	**PbB Level (µg/dL)**	**Percent Contribution**
Soil Contact	0.00	0%	0.00	0%
Soil Ingestion	0.14	8%	0.28	15%
Inhalation	0.04	2%	0.04	2%
Water Ingestion	0.96	55%	0.96	51%
Eating Produce Grown Nationally	0.50	29%	0.50	27%
Eating Homegrown Produce	0.11	6%	0.11	6%
TOTAL PbB LEVEL	**1.75**		**1.89**	

TABLE 6.3

RELATIVE CONTRIBUTIONS OF EXPOSURE PATHWAYS TO TOTAL PbB LEVELS BASED ON DEFAULT INPUT PARAMETERS RESIDENTIAL AND OCCUPATIONAL RECEPTORS

EXPOSURE PATHWAYS				
EXPOSURE PATHWAYS	**RESIDENTIAL**		**OCCUPATIONAL**	
	PATHWAY CONTRIBUTION		**PATHWAY CONTRIBUTION**	
	PbB Level (μg/dL)	**Percent Contribution**	**PbB Level (μg/dL)**	**Percent Contribution**
Soil Contact	0.00	0%	0.00	0%
Soil Ingestion	0.02	2%	0.01	1%
Inhalation	0.05	4%	0.03	3%
Water Ingestion	0.84	72%	0.84	75%
Eating Produce Grown Nationally	0.22	19%	0.23	21%
Eating Homegrown Produce	0.05	4%		0%
TOTAL PbB LEVEL	**1.18**		**1.11**	

It should be noted that the above tables represent examples using DTSC default parameters. The *relative* sensitivity of each parameter will change as more site-specific information is used and the more the values depart from default parameters. For example, Tables 6.4 and 6.5 show how the relative contribution of each pathway changes when the lead soil concentration is 1,000 ppm with and without homegrown food, respectively. It is important to note that the predicted PbB levels (99th percentile) based on the Ca*LS* model are highly unlikely to represent site-specific conditions. As will be discussed in Chapter 7, there are numerous sites where the detected soil lead concentration is 1,000 ppm or greater and the measured PbB levels in exposed individuals are well below the bright line of 10 μg/dL. At the predicted PbB levels of 42.3 and 63.3 for a normal and pica child, respectively, it would be expected that they would exhibit frank

toxicological symptoms that could end in death. The reality is that these lead-induced toxicological symptoms are not observed. Instead, few if any symptoms are manifest.

TABLE 6.4

RELATIVE CONTRIBUTIONS OF EXPOSURE PATHWAYS TO TOTAL PbB LEVELS AT 1,000 PPM SOIL LEAD RESIDENTIAL CHILD AND PICA CHILD RECEPTORS

EXPOSURE PATHWAYS	RESIDENTIAL CHILD		PICA CHILD	
	PATHWAY CONTRIBUTION		PATHWAY CONTRIBUTION	
	PbB Level (μg/dL)	Percent Contribution	PbB Level (μg/dL)	Percent Contribution
Soil Contact	0.06	0%	0.06	0%
Soil Ingestion	7.04	50%	14.08	66%
Inhalation	0.04	0%	0.04	0%
Water Ingestion	0.96	7%	0.96	5%
Eating Produce Grown Nationally	0.50	4%	0.50	2%
Eating Homegrown Produce	5.54	39%	5.54	26%
Mean PbB Level (μg/dL)	**14.1**		**21.2**	
99 Percentile PbB Level (μg/dL)	**42.3**		**63.3**	

TABLE 6.5

RELATIVE CONTRIBUTIONS OF EXPOSURE PATHWAYS TO TOTAL PbB LEVELS AT 1000 PPM SOIL LEAD WITHOUT HOME GROWN FOOD, RESIDENTIAL CHILD AND PICA CHILD RECEPTORS

EXPOSURE PATHWAYS	RESIDENTIAL CHILD		PICA CHILD	
	PATHWAY CONTRIBUTION		PATHWAY CONTRIBUTION	
	PbB Level (μg/dL)	Percent Contribution	PbB Level (μg/dL)	Percent Contribution
Soil Contact	0.06	1%	0.06	0%
Soil Ingestion	7.04	81%	14.08	90%
Inhalation1	0.00	0%	0.00	0%
Inhalation	0.04	0%	0.04	0%
Water Ingestion	0.96	11%	0.96	6%
Eating Produce Grown Nationally	0.54	6%	0.54	3%
Eating Homegrown Produce	0.00	0%	0.00	0%
Mean PbB Level (μg/dL)	**8.6**		**15.7**	
99 Percentile PbB Level (μg/dL)	**25.8**		**46.9**	

Table 6.5 shows the relative contribution with the same soil lead concentration (1000 ppm), but under the assumption that produce will not be grown and eaten at the site. As can be seen by comparing Tables 6.4 and 6.5, this pathway represents a significant exposure route because the PbB levels for a residential child who eats or does not eat homegrown produce are 42.3 and 25.8, respectively. It should also be noted that there appear to be discrepancies in the default values for the lead content of produce grown nationally. DTSC presents several different values for this important parameter (in the Ca*LS* model and supporting documentation), including 1.3, 3.1, 2.8, 1.1, and 1.6. It is not clear from these sources whether an agency consensus has yet to be reached or whether there are typographical errors.

Default values should only be used in a screening assessment or when site-specific values are not available because relying on default values exclusively can lead to significantly overestimating PbB levels (when they do not represent site-specific parameters). Identification of site-specific data needed to accurately predict PbB levels is based on a well-developed site conceptual model and the results of a "sensitivity" analysis. The purpose of a sensitivity analysis is to identify specific parameters that significantly influence the predicted PbB level. That is, the most sensitive parameters will produce the largest change in the result, while non-sensitive parameters can be altered without any appreciable changes. This information can be used to implement a cost-effective sampling plan. Obviously, little time and effort should be spent on collecting site-specific data that will have a negligible effect on the final outcome. In contrast, highly sensitive parameters should be the primary focus. A sensitivity analysis can be applied to the Ca*LS* model because it is a linear model (unlike other models like the IEUBK). The key input parameters can be identified by iteratively running the model. The most sensitive parameters can be identified by keeping all values constant except for a single parameter during each run. Sensitive parameters should be considered *relative* to the input parameters. Tables 6.6 – 6.9 show the results of this simple sensitivity analysis.

There are two notable features that standout in all the tables. The first is that model is sensitive to changes in soil/dust levels. When soil/dust concentrations are increased to 1000 ppm, predicted PbB levels are increased dramatically. The second is the drinking water concentrations appear to greatly influence predicted levels. This is because the default assumption regarding absorbance for water-soluble lead is extremely high. The default assumption of lead in drinking water sources is 15 ppm. However, USEPA (1994) has shown lead (through surveys) to be present in drinking water at approximately 4 ppm, which is far less than the Ca*LS* model assumption. Consequently, site-specific information should always be collected for drinking water and the

average soil lead concentration should be used with the Ca*LS* model. The remaining exposure routes will be, for most sites, relatively insignificant.

TABLE 6.6

CHILD RESIDENT
INPUT PARAMETER SENSITIVITY OF CA*LS* MODEL

INPUT VALUES					PbB LEVELS			
Soil/Dust Lead (mg/kg)	Homegrown Food (% Diet)	Drinking Water Lead (µg/L)	Airborne Lead (µg/m^3)	PM_{10} (µg/m^3)	PbB Levels (µg/dL)		Soil/Dust Lead Concentration Corresponding to 10 µg/dL	
					95th Percentile	99th Percentile	95th Percentile	99th Percentile
20	7%	15	0.028	1.5	3.8	5.2	247	146
1000	7%	15	0.028	1.5	30.6	42.3	247	146
20	**0%**	15	0.028	1.5	3.6	5.0	435	255
20	7%	**5**	0.028	1.5	2.4	3.3	298	197
20	7%	15	**0.1**	1.5	4.0	5.5	240	139
20	7%	15	0.028	**50**	3.8	5.2	246	145

Note: Solid shaded cells are changed input values. Crosshatched cells show significant departure from default assumptions.

TABLE 6.7

PICA CHILD
INPUT PARAMETER SENSITIVITY OF CA*LS* MODEL

INPUT VALUES					PbB LEVELS			
Soil/Dust Lead (mg/kg))	Homegrown Food (% Diet)	Drinking Water Lead (μg/L)	Airborne Lead (μg/m^3)	PM_{10} (μg/m^3)	PbB Levels (μg/dL)		Soil/Dust Lead Concentration Corresponding to 10 μg/dL	
					95th Percentile	99th Percentile	95th Percentile	99th Percentile
20	7%	15	0.028	1.5	4.1	5.7	159	94
1000	7%	15	0.028	1.5	45.8	63.3	159	94
20	**0%**	15	0.028	1.5	3.9	5.4	218	128
20	7%	**5**	0.028	1.5	2.4	3.3	191	126
20	7%	15	**0.1**	1.5	4.3	5.9	154	89
20	7%	15	0.028	**50**	4.1	5.7	158	94

Note: Solid shaded cells are changed input values. Crosshatched cells show significant departure from default assumptions.

TABLE 6.8

ADULT RESIDENT
INPUT PARAMETER SENSITIVITY OF CA*LS* MODEL

INPUT VALUES					PbB LEVELS			
Soil/Dust Lead (mg/kg)	Homegrown Food (% Diet)	Drinking Water Lead (µg/L)	Airborne Lead (µg/m^3)	PM_{10} (µg/m^3)	PbB Levels (µg/dL)		Soil/Dust Lead Concentration Corresponding to 10 µg/dL	
					95th Percentile	99th Percentile	95th Percentile	99th Percentile
20	7%	15	0.028	1.5	2.5	3.5	1062	676
1000	7%	15	0.028	1.5	9.6	13.2	1062	676
20	**0%**	15	0.028	1.5	2.5	3.4	3793	2407
20	7%	**5**	0.028	1.5	1.3	1.8	1230	844
20	7%	15	**0.1**	1.5	2.8	3.8	1026	640
20	7%	15	0.028	**50**	2.5	3.5	1037	660

Note: Solid shaded cells are changed input values. Crosshatched cells show significant departure from default assumptions.

TABLE 6.9

OCCUPATIONAL WORKER
INPUT PARAMETER SENSITIVITY OF CA*LS* MODEL

INPUT VALUES				PbB LEVELS			
Soil/Dust Lead (mg/kg)	**Drinking Water Lead (μg/L)**	**Airborne Lead (μg/m³)**	**PM_{10} (μg/m³)**	**PbB Levels (μg/dL)**		**Soil/Dust Lead Concentration Corresponding to 10 μg/dL**	
				95th Percentile	**99th Percentile**	**95th Percentile**	**99th Percentile**
20	15	0.028	1.5	2.4	3.3	5,452	3,468
1000	15	0.028	1.5	3.8	5.2	5,452	3,468
20	**5**	0.028	1.5	1.2	1.7	6,320	4,335
20	15	**0.1**	1.5	2.6	3.6	5,322	3,337
20	15	0.028	**50**	2.4	3.3	5,011	3,187

Note: Solid shaded cells are changed input values. Crosshatched cells show significant departure from default assumptions.

Collecting the correct soil and dust data to predict PbB levels with the Ca*LS* model is a pivotal step in the lead risk assessment. The sampling design should yield an exposure point concentration that represents the average concentration of soil/dust contacted over a relatively long exposure period. Although DTSC guidance recommends using the 95 UCL on the mean soil lead concentration, the average concentration should be used to be consistent with the structure of the model as stated:

> *"The model assumes a log-normal distribution with a GSD of 1.42 and uses this information to estimate the fiftieth, ninetieth, ninety-fifth, ninety-eighth, and ninety-ninth percentile blood Pb concentration for a set of inputs. Since this distribution reflects the physiologic and behavioral variables including soil consumption, using upper bound values for contact rates would distort the percentiles corresponding to blood Pb concentrations."*

Only in circumstances where there is great uncertainty due a lack of data should the 95 UCL be used in the Ca*LS* model.

Additionally, the EPC should represent the average exposure within the exposure unit for the environmental media that will be contacted. For a normal child in the Ca*LS* model, this would primarily be dust lead, not soil lead. According to USEPA (1994), the 1- to 2-year-old child for whom the Ca*LS* model is based only spends 1-2 hours outdoors in direct contact with soil. The remaining hours are spent indoors, where the child is in contact with dust lead. As discussed in Chapter 3.0, this is significant because indoor dust lead concentrations will be only a fraction of the outdoor soil lead concentration (assuming there are no indoor lead sources). Using the soil lead concentration to estimate PbB levels for the child will overestimate lead risk. For this reason, dust lead concentrations should be used to estimate lead risk for a residential child (the PRG for soil lead should also be modified accordingly). Similar site-specific information should be gathered and used in lead risk assessments where the exposure scenario involves an indoor worker.

The default assumption that all sites will have a garden of sufficient size and nutrient quality to provide a significant portion of the diet may be incorrect for most sites. If site-specific conditions preclude an on-site garden, this lead source and exposure route can be excluded from the Ca*LS* model risk assessment. Where eating homegrown produce cannot be eliminate from the risk assessment for future exposures, care should be exercised to use the soil lead concentration in the

area where the garden could reasonably be located. For example, soil samples collected near the drip-line should not be used to estimate PbB levels associated with eating homegrown produce because it is not reasonable to assume a garden will be planted so near the house.

The soil ingestion pathway also assumes a default value for lead bioavailability that is based on a comparison of the absorption of soil lead and lead acetate incorporated into the diets of rats Chaney *et al* 1990). While the authors found a direct relationship between the Pb concentration in the soil and Pb bioavailability, the data did not define the shape of the concentration/bioavailability curve sufficiently to allow extrapolation beyond the range studied. The highest observed bioavailability for soil lead concentrations less than 1000 ppm was 44% of that observed for Pb acetate, and the Ca*LS* model uses this value as a conservative estimate of bioavailability. Additionally, USEPA has concluded the rat experimental model is *not* appropriate and has developed a default bioavailability value of 30%, based on more relevant and representative physiological studies. DTSC suggests that, to accurately assess the matrix effect, a variety of variables, including lead species, particle size, and soil type need to be evaluated at various soil lead concentrations. As presented in Section 3.2, site-specific bioavailability information that is applicable to the Ca*LS* model should be used to provide the most accurate estimates of PbB levels.

For inorganic lead exposures, dermal absorption is negligible and can essentially be dropped from the risk assessment. However, for sites where organic lead has been detected (i.e., petroleum sites), it should be evaluated because it can be absorbed through the skin. However, because it is less stable in the environment, it usually represents a minor source of exposure.

6.4 Revised Default Input Parameters

Table 6.10 presents default input parameters used in Ca*LS* Version 6 model and the updated values used in the Version 7 (V.7) model. However, many of the values used in the V.7 still conflict with default values developed by USEPA, which are currently used in both *IEUBK* and *AL* models, as well as updated peer review studies. Table 6.11 compares Ca*LS* (V.7) default input parameters with those developed by USEPA and other scientists. It is interesting to note that Ca*LS* default parameters are even more conservative than USEPA, which are themselves generally regarded as conservative. Although numerous inconsistencies exist between Ca*LS* and USEPA model default assumptions and input parameters, only those values that make a significant difference in the predicted result are presented.

It should also be noted that risk assessment assumptions in the Ca*LS* model are fundamentally different from USEPA. For example, USEPA suggests evaluating lead ingestion from homegrown gardens based on site-specific information, whereas DTSC requires a default assumption that a homegrown garden will not only be at every site, but that the fraction of lead uptake by plants and consumption by 1-2 year old children will be significant and long-term representing 7% of the diet every day of the year. Although this may be possible at some sites, it almost certainly does not represent the average situation. Before the pathway can be eliminated, DTSC typically requires substantial "proof" that home grown produce will not be consumed.

TABLE 6.10

COMPARING DTSC CA*LS* MODEL INPUT PARAMETERS PREVIOUS AND NEW RESIDENTIAL DEFAULT VALUES

INPUT PARAMETER	UNITS	PREVIOUS VALUE (V.6) (1)	CURRENT VALUE (V.7) (2)	REFERENCE
GENERAL				
Geometric Std. Deviation	unitless	1.42	1.60	White *et al.*, 1998
Background Airborne Lead	$\mu g/m^3$	0.18	0.028	CARB, 1999
Source-Specific Airborne Dust	$\mu g/m^3$	50	1.5	Cowherd, 1985
Lead In Drinking Water	µg/L	15	15	MCL
% Diet Home-Grown (Resident)	%	5.5	7	USEPA, 1997
% Diet Home-Grown (Worker)	%	0	0	
Daily Food Consumption	kg/day	1.3	1.1	Bolger, 1996
RESIDENTIAL CHILD				
Dietary Lead	***µg/kg***	***10***	***2.8***	***USFDA, 1996-97***
Soil Ingestion	***mg/day***	***55***	***100***	***USEPA, 1997***
Soil Ingestion, Pica Child	***mg/day***	***790***	***200***	***USEPA, 1997***
Ventilation Rate	***m3/day***	***10***	***6.8***	***USEPA, 1997***
Exposed Skin Area	***cm2***	***2,800***	***2,900***	***USEPA, 1997***
Soil-To-Skin Adherence	***mg/cm2***	***1***	***0.2***	***USEPA, 1998***
Preliminary Remediation Goal-Soil Lead Concentration (PRG)	***ppm***	***247***	***146***	***DTSC***
RESIDENTIAL ADULT				
Daily Food Consumption	kg/day	2.2	1.9	Bolger, 1996
Dietary Lead	µg/kg	10	1.3	USFDA, 1996-97
Soil Ingestion	mg/day	25	50	USEPA, 1997
Exposed Skin Area, Resident.	cm^2	3,700	5,800	USEPA, 1997
Soil-To-Skin Adherence	mg/cm^2	1	0.07	USEPA, 1998
Preliminary Remediation Goal-Soil Lead Concentration	ppm	1062	676	DTSC

TABLE 6.10

COMPARING CA*LS* MODEL AND REVISED VALUES FOR SENSITIVE (SIGNIFICANT) INPUT PARAMETERS

INPUT PARAMETER	Ca*LS* MODEL VALUE (V.7)	REVISED VALUES	REFERENCE
GENERAL			
Drinking Water Lead	15	4 ppm	USEPA 1994
GSD	1.6	1.4	NHANES III Phase 2
Soil Ingestion Rate	50 mg/day	20 mg/day	USEPA 1998
Dust/Soil Ratio	70%	70%	USEPA 1994
Bioavailability	44%	4.8%	Bowers and Cohen (1996)
Bioavailability	44%	12%	USEPA 1998
Bioavailability	44%	30%	USEPA 1994

Tables 6.11 and 6.12 present estimated PRGs results from the Ca*LS* model (V.7) based on default DTSC input parameters for the 95th and 99th percentile individual as well as the results from a combination of DTSC default parameters and revised parameters that better represent most site conditions. With one exception, all the revised parameters have been developed by USEPA and are recommend as the best estimates for predicting PbB levels and health-protective cleanup goals for both childhood and adult exposures. A comparing the two results, it is interesting to note that significant differences are seen by replacing only a few input parameters. It is also apparent that the default assumption that all residential sites will have homegrown gardens that will yield sufficient produce to eat throughout the year has a major impact on the results. Another questionable default parameter is the background drinking water lead concentration. Although *all* input parameters are supposed to represent the average or mean value (because the GSD is subsequently applied to the mean PbB level and used to protect the 95th or 99th percentile individual) the default assumption is that all municipal drinking water sources will be maintained at an *average* corresponding to the Maximum Contaminant Level (MCL; 15 μg/L). However, the MCL represents the *upper limit* of drinking water concentrations that should not be exceeded. The MCL does not represent the average drinking water lead concentration. Furthermore, the latest USEPA survey of municipal drinking water supplies showed the average lead concentration

far below the MCL (the mean concentration was approximately 4 ppm) with lead not detected in many samples.

A final adjustment could have been made (but was not) to the soil lead PRGs for childhood exposure that would have the effect of increasing the PRG concentration. As discussed previously, the Ca*LS* model is based on exposures to children 1-2 years of age that, USEPA (1994) has shown spend only 1-2 hours outside in direct contact with soil (this is a default assumption built into the *IEUBK* model). The remaining time is spend indoors where the child contacts lead in *dust*. The conservative default assumption (which has been shown to lead to overestimated risk as discussed in Chapter 7) is that indoor dust is derived from the outdoor soil described by $C_{dust} = 0.7 * C_{soil}$. That is, since it is presumed that indoor dust is only 70% of the outside soil concentration and children primarily contact dust lead, rather than soil lead, the PRG for *soil* lead should be based on its contribution to indoor dust lead. Consequently, the PRGs in Table 6.11 corresponding to soil PRGs based on childhood exposures could have been increased by slightly less than 30% (since the 1-2 hours spent outside would be adjusted as a time-weighted average). Although it was ultimately decided not to make the final adjustment, the "revised" PRGs that are presented should still be considered conservative and could be increased if necessary and still be provide health-protective conditions. Additionally, the PRGs in Table 7.11 should only be considered "*Preliminary* Remediation Goals" used to screen sites. A final decision on whether they are health protective or overly-health protective can only be made with site-specific investigations.

TABLE 6.11

RESIDENTIAL EXPOSURES - COMPARING DEFAULT AND REVISED INPUT PARAMETERS ON PRELIMINARY REMEDIATION GOALS

EXPOSED INDIVIDUAL	INPUT PARAMETER	Default Input Value	Revised Input Value	PRELIMINARY REMEDIATION GOAL			
				DTSC Default PRG		Revised PRG	
				95th Percentile	99th Percentile	95th Percentile	99th Percentile
RESIDENTIAL EXPOSURES							
Child							
DTSC-Child Ingesting Garden Produce				247 ppm	146 ppm		
DTSC-Child Not Ingesting Garden Produce				435 ppm	255 ppm		
Child Ingesting Garden Produce	*Drinking Water Lead*	15 ppm	4 ppm			369 ppm	245 ppm
	Bioavailability	44%	30%				
Child Not Ingesting Garden Produce	*Drinking Water Lead*	15 ppm	4 ppm			783 ppm	519 ppm
	Bioavailability	44%	30%				
Adult							
Adult Ingesting Garden Produce				1,062 ppm	676 ppm		
Adult Not Ingesting Garden Produce				3,793 ppm	2,407 ppm		
Adult Ingesting Garden Produce	*Drinking Water Lead*	15 ppm	4 ppm				
	GSD	1.6	1.4				
	Bioavailability	44%	4.8%			2,111 ppm	1,634 ppm
	Bioavailability	44%	12%			1,991 ppm	1,540 ppm
Adult Not Ingesting Garden Produce	*Drinking Water Lead*	15 ppm	4 ppm				
	GSD	1.6	1.4				
	Soil Ingestion Rate	50	20				
	Bioavailability	44%	4.8%			115,623 ppm	89,374 ppm
	Bioavailability	44%	12%			47,801 ppm	36,949 ppm

TABLE 6.12

NONRESIDENTIAL EXPOSURES-COMPARING DTSC AND REVISED PRELIMINARY REMEDIATION GOALS (PRGS) BASED ON DEFAULT VALUES

EXPOSED INDIVIDUAL	INPUT PARAMETER	Default Input Value	Revised Input Value	PRELIMINARY REMEDIATION GOAL			
				DTSC Default PRG		Revised PRG	
				95th Percentile	99th Percentile	95th Percentile	99th Percentile
NON-RESIDENTIAL EXPOSURES							
DTSC-Outdoor Worker				5,452 ppm	3,468 ppm		
Outdoor Worker High And Low Bioavailability	***Drinking Water Lead***	15 ppm	4 ppm				
	GSD	1.6	1.4				
	Bioavailability	44%	4.8%			70,719 ppm	54,704 ppm
	Bioavailability	44%	12%			20,696 ppm	15,998 ppm
DTSC-Indoor Worker [1] ***(Adjusted)***				7,087 ppm[1]	4,508 ppm[1]		
Indoor Worker High And Low Bioavailability	***Drinking Water Lead***	15 ppm	4 ppm				
	GSD	1.6	1.4				
	Soil Ingestion Rate	50	20				
	Dust/Soil Ratio	70%	70%				
	Bioavailability	44%	4.8%			132,088 ppm	170,758 ppm
	Bioavailability	44%	12%			54,704 ppm	70,719 ppm

[1] The default indoor worker PRG for soil was derived from the outdoor worker PRG soil by applying the default relationship between soil and dust described by $C_{dust} = 0.7 * C_{soil}$. That is, since it is presumed that indoor dust is only 70% of the outside soil concentration and indoor workers contact dust lead, rather than soil lead, the PRG for soil lead should be based on its contribution to indoor dust lead.

7 INTEGRATED STOCHASTIC EXPOSURE MODEL

7.1 Background Information

Shortly after initiating this project, it was learned that Dr. Susan Griffin at EPA Region 8 (collaborating with Dr. Philip Goodrum) was developing a new technical approach and risk assessment model for evaluating lead risks for children. This new approach was termed the *Integrated Stochastic Exposure* model and was based on probabilistic methodology.

The *ISE* model can be considered a next-generation risk assessment tool for predicting PbB levels and estimating lead risk, and provides far more information than models currently available. The *ISE* model extends and refines the scientific approaches developed by USEPA for the UBK paradigm (which was based on a simple slope factor) and the current IEUBK model (which was based on biokinetic parameters but is a deterministic model). Although USEPA has not yet formally approved the ISE itself, the probabilistic approach upon which it is based has been approved, and headquarters has developed draft supporting guidance. The advantages of the *ISE* model are numerous; however, the principle advantage is that it yields more accurate PbB level predictions. That is, the *ISE*-predicted PbB levels more accurately match measured PbB levels in exposed populations. For this reason alone, it will likely be used in conjunction with—or as a replacement for—the IEUBK model in making accurate and precise lead risk estimates in the future.

7.2 Technical Description—Model Overview

As noted in numerous sections of this report, existing lead risk assessment mathematical models often over predict actual site-specific PbB levels, which can lead to unnecessary and costly remediation. Although this problem is inherent in all models, recent biomonitoring studies have provided empirical evidence that, at many sites, *IEUBK*-predicted PbB levels are greatly exaggerated and far in excess of PbB levels actually measured. Although the *IEUBK* model is fundamentally correct, it appears the current mode of application introduces conservatism into the predictions. This is because the *IEUBK* model is used in a deterministic manner in which single input variables are used to represent "best guess" statistics for a population of possible values. Combining these values can lead to compounding conservatism. Although each single value may appear to represent the "best" available value, the combination of many conservative (sometimes

referred to as "health protective") values for each parameter for each environmental medium results in implausible results that are not empirically observed.

In contrast, the *ISE* model circumvents the limitations of a deterministic approach by implementing a probabilistic method. Detailed guidance for conducting probabilistic risk assessments is presented in "*Risk Assessment Guidance For Superfund: Volume 3 -Part A, Process For Conducting Probabilistic Risk Assessment*" (USEPA 1999).

Probabilistic risk assessments model exposure and risks to a population of human receptors by iteratively calculating risk for each person in an exposed population. The procedure involves iteratively solving the same equation (representing risk) using a randomly chosen set of parameters to represent an individual's exposure. Thus, the risk result from each iteration represents a single individual. Each subsequent iteration adds another person to the population, and combining the results presents a statistical model of the entire exposed population. Iterations are typically conducted 5,000 to 10,000 times to represent a relatively large exposed population. This process allows any individual risk, such as the 95th percentile individual, to be easily identified and quantified within the population.

Until recently, probabilistic risk assessments were only recommended for chemicals other than lead. However, recent work by EPA Region 8 in developing the *ISE* model have now provided preliminary evidence that a probabilistic approach is not only appropriate for lead risk assessments but can yield a more precise risk estimate compared with the *IEUBK*, *AL*, and *CaLS* lead risk assessment models, which are all deterministic models. Currently, the *ISE* model has only been developed to predict lead levels and risks for childhood exposures. However, since it is essentially an exposure module added on to the existing *IEUBK* model, it could readily be added onto any other lead risk assessment model (*AL* or *CaLS* models) to produce the same results.

Under some circumstances, the *IEUBK* model produces results that are implausible and unrealistic regardless of whether default or site-specific input parameters are used to predict PbB levels. The *IEUBK* model regularly predicts PbB levels far in excess of levels actually measured in exposed individuals, even when considerable site-specific information is used in the risk assessment. An example was presented in Section 4.6 where EPA Region 8 recently conducted a lead risk assessment at Jacobs Smelting site in Stockton, Utah (EPA 1999), where predicted risks were far in excess of measured levels.

Largely prompted by the inability of the *IEUBK* model to accurately predict PbB levels, EPA Region 8 developed the *ISE* model. Dr. Griffin (Griffin *et al.* 2000) recently conducted a detailed investigation in collaboration with other scientists to determine the predictive power of the *ISE* model and to compare the performance of the model under actual exposure conditions at another Superfund site. The remainder of this chapter presents the results of the study. However, it should be noted that a collaborative arrangement was also developed between Dr. Susan Griffin, Mr. David McConaughy (Navy Environmental Health Center [NEHC]), and Scientia Veritas LLP to locate a Navy data set of measured PbB levels with corresponding soil and dust lead data to conduct a similar study in which the predictive power of both the *ISE* and *IEUBK* models would have been made. After several months and much effort attempting to locate an existing representative Navy data set, it was concluded that none was currently available. It was also concluded that the current project could not be further delayed. Although it was necessary to abort this collaboration in order to prepare this report, the collaborative arrangement remains intact for a possible future study with Dr. Griffin. It is highly recommended that the Navy take full advantage of this unique opportunity.

In lieu of an original collaborative study, it was concluded that a recent lead risk assessment study by Dr. Griffin, using the *ISE* model, be presented (with permission and encouragement from Dr. Griffin). The purpose is to demonstrate how this new risk assessment tool performs in the field and is better able to predict PbB levels than any of the existing risk assessment models.

7.3 Case Study-Comparing ISE and IEUBK Models

Dr. Susan Griffin and her colleagues have recently conducted an evaluation of lead exposure of children at the Murray Smelter Superfund site. The purpose of the investigation was to evaluate potential health risks as estimated with the *IEUBK* and *ISE* models.

As discussed in Chapter 4.0, the *IEUBK* model has four components, which are as follows:

- Exposure component;
- Uptake component;
- Biokinetic component; and
- Probability distribution output component.

The *ISE* model is identical with the *IEUBK* model, except that the exposure component in the *ISE* model is probabilistic rather than deterministic. That is, a probabilistic exposure module is linked to the *IEUBK* model that allows variability and uncertainty estimates to be simulated. Site-specific data were used to develop probabilistic density functions (PDFs) to represent inter-individual variability in lead exposures and uptake. The *ISE* model also allows a detailed sensitivity analysis to be conducted to identify those predominant exposure variables that contribute most to variability and uncertainty. Compares lead concentrations in environmental media with the amount of lead intake. The exposure component is based on environmental media-specific intake rates and lead concentrations in each environmental medium in order to estimate media-specific lead intake. To evaluate and compare the *IEUBK* and *ISE* model both models were used to predict PbB levels at Murray Smelter, which is a Superfund site. These levels were ultimately compared to actual measured PbB levels in exposed individuals.

The Murray Smelter Site is located near Salt Lake City. The facility is surrounded by residential properties where children and adults are exposed to lead. Exposure pathways of concern for this site included soil, dust, and drinking water ingestion, as well as inhalation of lead particulates. Prior to sampling, the off-site area was divided into eight *Initial Study Zones* (ISZ) that were approximately 700 square feet, based on the results of air dispersion modeling. Each ISZ was considered an appropriate exposure area where a individual child could conceivably come into daily contact with soil and dust over the 7-year exposure duration. Composite samples representing 4 to 6 locations were collected, to represent average soil lead exposures, and sieved at 250 μm because smaller particles more readily adhere to hands.

The results of the soil lead sampling are presented in Table 7.1. As discussed in Chapter 4.0, the default assumption for dust lead concentration is that it is 70% of the outdoor soil concentration. EPA (Griffin *et al.* 2000) notes, however, *"this has been shown to be a highly conservative assumption that can lead to an overestimation of exposure."* To determine if the default relationship was representative of the Murray site, dust samples were collected. Using linear regression, dust and soil lead were found to be correlated and related according to the following the mathematical expression described by:

$$C_{dust} = 174 + 0.19 * C_{soil}$$

The slope of 0.19 represents the average fraction of indoor dust that is attributable to soil lead. That is, the amount of dust lead is only 19% of soil lead (this is the reason PRGs developed for indoor exposures should be adjusted when the PRGs pertain to soil lead concentrations as discussed in Chapter 6). The intercept of 174 represents the contribution of lead to dust from sources other than soil. That is when C_{soil} is equal to zero, C_{dust} is 174 ppm. This relationship was used to derive dust lead levels in each of the zones and is presented in Table 7.1.

TABLE 7.1

SUMMARY STATISTICS FOR OUTDOOR SOIL AND INDOOR DUST LEAD BY STUDY ZONE

SUMMARY STATISTIC	MURRAY SITE INITIAL STUDY ZONE							
	ISZ-1	ISZ-2	ISZ-3	ISZ-4	ISZ-5	ISZ-6	ISZ-7	ISZ-8
SOIL								
Arithmetic Mean	1,299	241	768	391	426	657	1,222	925
Minimum	230	80	110	110	130	120	720	66
Maximum	3,200	410	1,600	780	640	1,800	1,800	7,300
Dust [(1)]								
Arithmetic Mean	421	220	320	248	255	299	406	350
Minimum	218	189	195	195	199	197	311	187
Maximum	782	252	478	322	296	516	516	1,561

Source:

[(1)] Calculated from simple linear regression relationship between soil and dust according to the equation

$$C_{dust} = 174 + 0.19 * C_{soil}$$

To calculate the predicted PbB level using the *IEUBK* model, the site-specific input values presented in Table 7.2 were used. These values represent the average or mean values for each input parameter. The GSD is a regional value based on an earlier study of 1,200 children (Griffin *et al.* 1998), and dietary lead was adjusted to represent 70% of default values (Elias 1999). All other values used in the *IEUBK* model were default values, as presented in Table 7.3.

TABLE 7.2

SITE-SPECIFIC INPUT VALUES USED IN THE *IEUBK* MODEL

EXPOSURE VARIABLE	MURRAY SITE INITIAL STUDY ZONE							
	ISZ-1	ISZ-2	ISZ-3	ISZ-4	ISZ-5	ISZ-6	ISZ-7	ISZ-8
C_{Soil} (ppm)	1,299	241	768	391	426	657	1,222	925
C_{Dust} (ppm)	421	220	320	248	255	299	406	350
C_{Water} [(1)] (μg/L)	2.5	2.5	2.5	2.5	2.5	2.5	2.5	2.5
C_{Air} (μg/m^3)	0.055	0.055	0.055	0.055	0.055	0.055	0.055	0.055
AF (%)	35	35	35	35	35	35	35	35
PbB GSD	1.4	1.4	1.4	1.4	1.4	1.4	1.4	1.4
Dietary Intake (μg/day)	70% of *IEUBK* Model Default Values							

(1) Site samples were all below detection limits. Values shown are one-half the detection limit.

TABLE 7.3

DEFAULT INPUT VALUES USED IN THE *IEUBK* MODEL

MEDIUM	PARAMETER	AGE (YEARS)						
		0-1	1-2	2-3	3-4	4-5	5-6	6-7
Air	Breathing Rate (m^3/hr)	2	3	5	5	5	7	7
	Time Outside (hr/day)	1	2	3	4	4	4	4
	Absorption Fraction	0.32	0.32	0.32	0.32	0.32	0.32	0.32
Diet	Daily Lead Intake (µg/day)	5.53	5.78	6.49	6.24	6.01	6.34	7.00
	Absorption Fraction	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Drinking Water	Ingestion Rate (L/day)	0.2	0.5	0.52	0.53	0.55	0.58	0.59
	Absorption Fraction	0.5	0.5	0.5	0.5	0.5	0.5	0.5
Soil/Dust Ingestion	Total Daily Intake (mg/day)	85	135	135	135	100	90	85
	Soil Fraction	0.45	0.45	0.45	0.45	0.45	0.45	0.45
	Dust Fraction	0.55	0.55	0.55	0.55	0.55	0.55	0.55

Table 7.4 presents the PbB levels predicted with the *IEUBK* model for each zone. These PbB levels were predicted based on the average soil and dust lead concentrations within each zone according to USEPA *IEUBK* guidance (USEPA 1994).

TABLE 7.4

***IEUBK*- PREDICTED PBB LEVELS IN EACH ZONE**

SUMMARY STATISTIC	MURRAY SITE INITIAL STUDY ZONE							
	ISZ-1	ISZ-2	ISZ-3	ISZ-4	ISZ-5	ISZ-6	ISZ-7	ISZ-8
GM PbB (µg/dL) [1]	10.1	4.1	7.3	5.1	5.3	6.7	9.7	8.2
P10 (%)	48	0	16	2	3	11	43	26

Note: Shaded cells show where "acceptable P10 levels" are predicted to exceed USEPA health-based criteria of 5%.

Based on the *IEUBK*-predicted PbB levels in Table 7.4, five zones (ISZ-1, 3, 6, 7, and 8) would require remediation. All of these zones significantly exceeded the acceptable 5% level in children.

To evaluate the performance of the *ISE* model and to compare with the *IEUBK* model, distributions for each exposure input parameter were developed. As discussed, distributions replace the single "best estimates" that are used in the *IEUBK* model and are presented in Table 7.5. Note that, by using the entire distribution or range of possible values in a probabilistic approach, the (single) values used in the *IEUBK* model are also used (as part of the distribution population).

TABLE 7.5

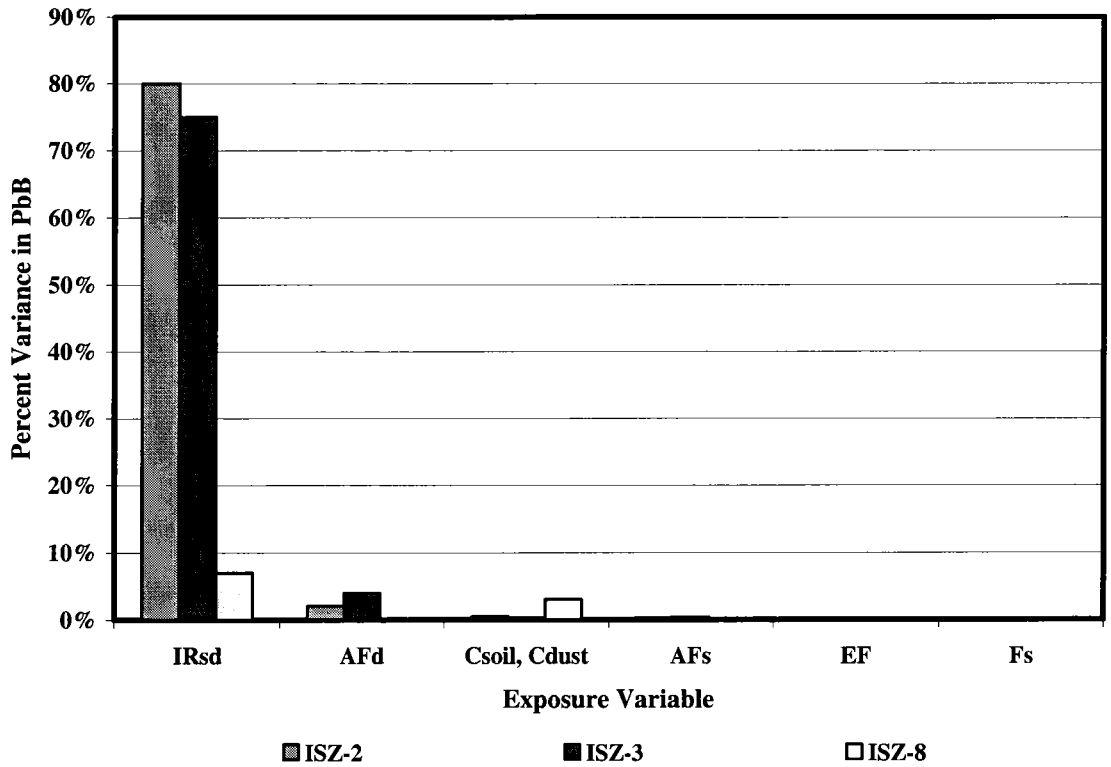
INPUT VALUES FOR THE *ISE* MODEL BY EXPOSURE PATHWAY

EXPOSURE PATHWAY	EXPOSURE VARIABLE		PROBABILITY DISTRIBUTIONS FOR EXPOSURE VARIABILITY		
	SYMBOL	DESCRIPTION	PDF	PARAMETERS	SOURCE
Soil/Dust Ingestion	C_{soil}	Soil Pb concentration (ppm)	Lognormal	Arithmetic mean, Standard deviation	ISZ site data
	C_{dust}, Regression A	Dust Pb concentration (ppm)	Point Estimate	174	ISZ site data
	C_{dust}, Regression B	Soil ingestion rate (mg/kg)	Point Estimate	0.19	ISZ site data
	$IR_{soil/dust}$	Weighting factor, age (unitless)	Empirical Continuous	(0,10,45,88,186,208,225,7 000) (0,0.25,0.5,075,0.9,.095,0. 99,1.0)	Stanek and Calabrese (1995)
	WF_{age}	Weighting factor, soil (unitless)	Point Estimate	*IEUBK*	USEPA (1994b)
	WF_{soil}	Weighting factor, soil (unitless)	Triangular	(min, mode, max) = (0.3, 0.45, 0.6)	Mode: UPEPA (1994b) min, max Pope (1985)
	$AF_{soil/dust}$	Absorption fraction (%)	Triangular	(min, mode, max) = (23, 36,48)	USEPA (1996)
Dietary Intake	$Intake_{diet}$	Intake rate (μgPb/day)	Point Estimate	70% * *IEUBK* default	Gunderson *et al.* (1995)
Water Ingestion	All exposure variables		Point Estimate	*IEUBK*	USEPA (1994b)
Air Inhalation	All exposure variables		Point Estimate	*IEUBK*	USEPA (1994b)
All	EF	Exposure Frequency (days/year)	Triangular	(min, mode, max) = (200, 234, 350)	USEPA (1993)

To determine the importance of each input parameter in the risk assessment, a sensitivity analysis was conducted for three of the study zones. The study zones were selected to represent low (ISZ-2), medium (ISZ-3), and high (ISZ-8) mean and GSD soil lead concentrations. The results of the sensitivity analysis show that the soil ingestion rate contributes the greatest amount of variability to the predicted PbB levels.

FIGURE 7.5

SENSITIVITY ANALYSIS OF INPUT VALUES FOR THE *ISE* MODEL PERCENT OF VARIANCE IN PREDICTED P10 ESTIMATE



Health-protective cleanup goals for soil lead (or any other environmental medium) can be calculated with the *IEUBK* or *ISE* models by running the model iteratively until the predicted P10 level is acceptable (less than 5% exceeding the 10μg/dL level). The cleanup level for the Murray Site, based on the *IEUBK* model, is 550 ppm. The results of the *ISE* model are presented in Table 7.6. As shown, the cleanup level based on the *ISE* model is between 1,300 and 1,500 ppm. Simulations were run with different soil lead concentrations and different numerical values for the GSD. Values between discreet points in the Table 7.6 can be extrapolated. For example, a

soil lead concentration of 657 ppm and a GSD of 2.1 would result in a P10 of less than 2%, which is below USEPA's unacceptable risk level of 5%.

Based on the *IEUBK*-predicted PbB levels in Table 7.0, five zones (ISZ-1, 3, 6, 7, and 8) would require remediation. All zones significantly exceeded the acceptable 5% level in children.

TABLE 7.6

ACCEPTABLE SOIL LEAD CONCENTRATIONS (REMEDIATION GOALS) BASED ON THE *ISE* MODEL

Mean C_{soil} (ppm)	PbB Levels (µg/dL)									
	GSD C_{soil}	GSD C_{soil}	GSD C_{soil}	GSD C_{soil}	GSD C_{soil}	GSD C_{soil}	GSD C_{soil}	GSD C_{soil}	GSD C_{soil}	GSD C_{soil}
	1.6	**1.8**	**2.0**	**2.2**	**2.4**	**2.6**	**2.8**	**3.0**	**3.2**	**3.4**
600	2.4	2.1	1.6	2.0	1.4	1.8	2.0	2.2	1.9	2.2
700	3.3	2.6	2.3	2.1	2.1	1.9	2.5	2.0	2.0	2.1
800	3.4	3.0	2.8	3.1	2.6	2.0	2.4	2.1	2.4	2.2
900	4.0	3.0	3.6	2.6	2.7	2.7	2.8	2.9	2.9	2.8
1,000	4.4	4.2	3.1	4.0	3.3	3.3	2.8	3.3	3.4	3.0
1,100	3.9	4.3	3.6	3.7	3.3	3.2	3.5	3.9	3.6	2.8
1,200	4.3	4.2	4.0	4.1	4.0	3.8	3.7	3.9	4.0	3.7
1,300	4.8	4.7	4.4	4.3	4.5	4.5	4.6	4.1	4.5	4.3
1,400	**5.1**	4.6	4.7	4.7	4.8	4.7	4.8	4.7	4.6	4.8
1,500	**5.2**	5.0	4.9	**5.4**	4.4	**5.5**	**5.2**	**5.6**	4.7	**5.4**
1,600	**5.3**	**5.7**	**5.5**	**5.5**	**5.4**	**5.7**	**5.9**	**5.3**	**6.3**	**5.8**
1,700	**5.7**	**5.6**	**6.3**	**5.8**	**6.2**	**6.6**	**6.7**	**7.2**	**6.2**	**6.7**
1,800	**6.4**	**7.0**	**6.8**	**6.9**	**6.9**	**6.9**	**3.5**	**7.4**	**6.6**	**7.1**
1,900	**7.5**	**6.5**	**7.5**	**7.5**	**7.6**	**7.4**	**7.1**	**7.7**	**8.5**	**7.3**
2,000	**7.7**	**8.6**	**7.6**	**8.0**	**8.4**	**8.4**	**8.7**	**8.5**	**7.5**	**8.3**

GSD C_{soil}: Geometric standard deviation for soil lead, which is unitless.

Based on Table 7.6 the *ISE* model supports acceptable cleanup goals ranging from 1300 to 1500 ppm. By contrast, the *IEUBK* model predicted a safe soil lead level was 550 ppm. EPA Region 8 ultimately made the risk management decision to define health-based cleanup levels as 1200 ppm. Without actual site-specific measured PbB levels in Murray Site residents exposed to lead, it would be impossible to evaluate the *IEUBK* and *ISE* models in order to determine which model more accurately predicts PbB lead. Fortunately, a limited blood lead study (n=9) was performed by ATSDR at the Murray facility. The results of the ATSDR study in which PbB levels were measured in children for who PbB levels were subsequently estimated with *ISE* and *IEUBK* model based on site-specific conditions are presented in Table 7.7.

TABLE 7.7

COMPARING *ISE* AND *IEUBK* MODEL PREDICTED PBB LEVELS WITH ACTUAL MEASURED PBB LEVELS FOR MURRAY SITE RESIDENTS

RISK ASSESSMENT METHOD	MEAN PBB LEVEL (µG/DL)
ATSDR – Actual Measured PbB Levels (n=9)	4.8 µg/dL
***ISE* – Predicted PbB Levels**	5.3 µg/dL
***IEUBK* – Predicted PbB Levels**	17.5 µg/dL

Table 7.7 shows that the *ISE* model closely predicted actual measured PbB levels very closely while he *IEUBK* model over estimated PbB levels. If the *ISE* and ATSDR results had not been available and risk management decisions were made based solely on the *IEUBK* results, it is likely that very costly, but unnecessary remediation and intervention measures would have been implemented. Furthermore, because the *IEUBK* -estimated PbB levels represent the mean PbB levels the overestimated PbB levels could have precipitated emergency medical treatment including chelation therapy for children. Instead, based on the results of the ATSDR study, no further action is required.

8 CONCLUSIONS AND RECOMMENDATIONS

8.1 Conclusions

The test of any mathematical model is how well it predicts the real physical world. With regard to lead risk assessment models the simple fundamental question is:

Do the model-predicted PbB levels match actual levels exposed ?

It is insufficient and short-sited to test one model's predictions against another as California DTSC has to "verify" the Ca*LS* model. In comparing the results of the Ca*LS* model to the *IEUBK* model, they have set the *IEUBK* model as the "gold standard" when, in fact, for most sites the *IEUBK* model significantly over predicts PbB levels. Lead model results should not be compared for verification purposes without first independently verifying each of the models with actual biomonitoring data (measured PbB levels in the exposed population). For that reason, the analysis presented in this study should be regarded as an evaluation of the underlying scientific principals for each model, what important environmental data and information needs to be gathered to use each model, and changes in default values for specific parameters based on the latest scientific information. The report does not attempt to verify the models because no Navy biomonitoring data sets were available even though considerable effort was initially expended to locate biomonitoring data so that an independent verification of each model could be conducted. Until each model is verified by comparing the modeling results with actual site-specific biomonitoring data no recommendation can be made as to what model is the best predictive tool and under what circumstances and site conditions.

Recent studies have now revealed that all current lead models, with the exception of the recently developed *ISE* model, will over predict PbB levels, *even* when site-specific information is used to run the model. This is because a fundamental flaw in all previous lead models is that they are deterministic in nature. That is, a *single* value is used to represent an entire population of values. This is in contrast to the *ISE* model, which uses the entire range of possible values to represent the range of values rather than a single value. When single (default) values do not represent actual site conditions or exposures, predicted PbB levels would not accurately represent actual PbB levels in the exposed population. For example, to predict PbB levels with each model it is required that the *average* value for each parameter be used. However, in many instances the average value may unknowingly represent an upper-bound value for the population under study.

Furthermore, the GSD, which is applied to the average predicted PbB level to generate an estimate of the "spread" of the population of values, may over predict the true variability of the population. This is because the GSD used in the model is based on national population statistics that represent more than one segment of the population. In contrast, it is likely that a smaller single population living in a small area or region will have significantly less variability than the general population simply because people would tend to have similar and perhaps shared exposure conditions.

It is highly unlikely that the models will ever *under predict* PbB levels. Consequently, lead models should be considered risk management tools to identify areas where additional site-specific study is required. The conservatism introduced into the models is likely a combination of the deterministic approach of the model itself, as well as the individual parameters used to represent the exposed population. Compared to the deterministic models, the *ISE* model (based on preliminary work conducted by Dr. Susan Griffin in EPA Region 8) is a much more accurate predictive lead model. Although to date model verification of the *ISE* remains incomplete (due to the small sample size) the PbB levels predicted with the *ISE* model are very close to the measured PbB levels. The *ISE* model is based on the most recent USEPA policy and guidance on probabilistic risk assessment that is advancing the science of all risk assessment. In this regard, the *ISE* model shows tremendous promise.

Several examples were provided in this report to show that risk assessment models can result in costly overestimates of risk. The degree to which these models will over-predict risks depends on the amount and quality of site-specific information used in the lead risk assessment. Unfortunately, even when a great deal of site-specific information is gathered and appropriately used with the various risk assessment models, the models will almost always over estimate PbB levels. However, the Navy has rarely (if ever) had biomonitoring data available to gauge the accuracy of model-predicted PbB levels. At many sites, this inherent problem of conservatism with the deterministic lead models poses a costly dilemma for the Navy. The dilemma is whether it will be more cost effective to simply remediate lead sites based on the results of over predictive PbB levels or collect biomonitoring data. At some sites, the latter option may not be possible because no receptors are currently exposed.

One of the limitations of this analysis was that an actual Navy dataset with lead data and measured PbB levels were not available to test each risk assessment model to verify each model

and to determine under what conditions the models best perform. Since this study was generally limited to an evaluation of the fundamental technical underpinnings of the of the models.

It should be noted that the problem of over predicted risks inherent with each model are can be compounded during the risk management phase. This is because the same models that are used to estimate PbB levels and lead risks are also used to determine final cleanup levels. Moreover, the same input parameters that are used to (over) estimate risk are used to determine acceptable levels.

One unequivocal conclusion that can be drawn from this report is that the *IEUBK*, *AL*, and Ca*LS* model results based on default input parameters should *only* be used for *screening* purposes. Information yielded by these models should be used solely to identify sites that require further and more detailed risk assessment evaluations. Frequently, remediation goals are derived from default assumptions that do not represent site-specific conditions but rather conservative conditions based on statistical analysis of the general U.S. population. The descriptive statistics from such a large population are influenced by the extreme diversity and wide variability within the U.S. population from which USEPA and DTSC select a conservative *single value* to represent the entire population that will be protective of any U.S. population at any site. At individual sites there is much less variability within the exposed population. Although the current risk assessment models require single value input values they should reflect the actual site under investigation and not the U.S. population at large. Cleanup or remediation levels should be developed based on site-specific conditions and represent plausible current and future exposures. It cannot be over emphasized how important it is to correctly identify the most reasonable current and future land use for lead contaminated sites. As presented in this report, the model PbB levels predicted vary greatly depending on the assumed receptor. At a particular site the predicted PbB levels can result in a definitive "no further action" conclusion for industrial land use assumption to costly and protracted remediation for an assumed future residential land use. Ultimately, the assumption of future land use may be one of the most important determinations in the Navy's environmental restoration program.

The last general conclusion that can be made in this evaluation is that the *ISE* model is superior to all other models by virtue of the scientific principals upon which the model is based. Rather than attempting to predict lead risks for a single individual (50th, 95th, or 99th percentile) based on a "best guess" that each single variable accurately represents actual conditions, the *ISE* model iteratively simulates risk for each individual in a population. Any individual risk level from that

population can then be easily identified. In addition to the sound scientific principals used to develop the *ISE* model, from preliminary studies it appears to accomplish the goal of more accurately predicting the physical world, which should be the goal of all models. It is strongly recommended that the Navy take steps to ensure the *ISE* model is further developed and field tested to provide support for a risk assessment model that will likely yield more accurate PbB level estimates, which will result in more cost-effective health-protective risk management decisions.

8.2 Recommendations

The following recommendations can be made on the basis of the analysis in this report:

Screening levels (or PRGs based on default assumptions) for lead should be revised based on recent scientific information as presented this report.

1. The Navy should begin to use the *ISE* model as the primary tool to accurately estimate PbB levels and lead risks at all Navy sites and to determine appropriate health-protective cleanup levels.

2. A thorough evaluation of future land use should be conducted to a.) identify appropriate risk-based screening levels.

3. Site-specific information should always be collected and used with all lead models (rather than default parameters).

4. *Average* values for each exposure parameter should be used with all lead risk assessment models (rather than upper-bound values which are used in conventional risk assessments) to predict PbB levels.

5. The *average* soil lead concentration should be used in the risk assessment based on *random* sampling within the exposure area (not the 95UCL concentration which is used in conventional risk assessments).

It is highly recommended that the *IEUBK*, *AL*, and Ca*LS* models be used as risk- screening tools and only when little site-specific data is available. Additionally, the PRGs calculated with previous input parameters should be revised. Predicted PbB levels with these models should be

considered upper-bound estimates particularly when little site-specific information is available and default parameters (representing the general U.S. population) must be used.

The Navy should take steps to further develop and verify the *ISE* model (perhaps in a collaborative relationship with Dr. Susan Griffin) by either using it together with other lead models (for comparison purposes) at all Navy sites (the model is currently used only in EPA Region 8). As with any new technical approach there is always an initial reluctance for change and the *ISE* model will be no exception. It is more complex than the existing deterministic lead models and will only gain acceptance with wider use at more and diverse lead sites. The Navy could accelerate acceptance of the model the regulatory community by consistently using the model at all lead sites. Once accepted, the Navy would realize significant cost savings because the *ISE* model is a more accurate predictive tool that will not greatly exaggerate lead risks (as other models tend to do).

To gain wider acceptance, the Navy should consider initially designing and implementing a stand-alone study (perhaps in collaboration with Dr. Griffin, EPA Region 8) to verify the technical approach with a much larger biomonitoring data set. Although final risk management decisions regarding cleanup levels are dependent on myriad factors unrelated to the lead risk assessment, it is in best interest of the Navy, regulatory agencies, and all stakeholders to use the lead model that best predicts PbB levels so that meaningful risk management decision are made.

Regardless of the lead model used to evaluate risks it is highly recommended that current and future land use be correctly defined. In fact, this evaluation must be conducted before initiating the lead risk assessment because the correct model can only be selected on the basis of the exposed population under study. It will also be necessary to develop a detailed site conceptual model to identify potential exposure routes. For example, assuming all receptors will ingest home-grown produce at the assumed default levels in the Ca*LS* model may lead to overly conservative remediation if site conditions will not permit a garden. Furthermore, it is necessary to evaluate some groups of receptors in based on a more refined site-conceptual model. Obviously, outdoor workers with significant exposure to soil lead would have greater lead intake than an office worker (see Table 6.12).

Table 8.1 presents revised default risk-based screening levels (PRGs) that should be used to screen sites together with current regulatory-derived values. These recommended values should be considered very conservative and also should not be used as final remediation goals.

TABLE 8.1

RECOMMENDED DEFAULT RISK-BASED SOIL LEAD CONCENTRATIONS FOR SCREENING SITES

	PRELIMINARY REMEDIATION GOALS		
	RESIDENTIAL EXPOSURE	OCCUPATIONAL EXPOSURE	
		OUTDOOR WORKER	INDOOR WORKER
RECOMMENDED CONCENTRATION -REVISED INPUT PARAMETERS	550 ppm (1)	6,473 ppm (2)	9,247 ppm (3)
USEPA-CURRENT VALUES	400 ppm (4)	888 ppm (5)	NA
CALIFORNIA DTSC-CURRENT VALUES	94(6) – 146 (7)	3,468 ppm (8)	NA
EPA Region 8	~1,300 ppm (9)		

(1) Value was calculated with *IEUBK* model using recent data.

(2) Value was calculated with *AL* model using recent data.

(3) Value was calculated with *AL* model using recent data and adjusted for outdoor soil contribution to indoor dust.

(4) Based on *IEUBK* model and current default parameters.

(5) Based on *AL* model and current default parameters.

(6) Based on Ca*LS* model (V.7) and current default parameters.

(7) Based on Ca*LS* model (V.7) for pica behavior and current default parameters.

(8) Based on Ca*LS* model (V.7) and current default parameters.

(9) Based on the EPA Region 8 *ISE* model.

The final recommendation is that USEPA *IEUBK* model be used for all residential sites in California rather than the Ca*LS* model because the Ca*LS* has not undergone verification and it appears to be ultraconservative under almost all site conditions.