5.0 RISK CHARACTERIZATION

CHAPTER 5 SUMMARY

This chapter characterizes risks associated with current residential lead exposures (pre-§403) for children aged 1-2 years. Risks are quantified by predicting incidences of selected health effect and blood-lead concentration endpoints. Baseline risk is computed using NHANES III, Phase 2 survey data. Alternative risk estimates are computed as a function of environmental-lead levels using HUD National Survey data. The tools developed and presented in Chapter 4 are used to produce, from the observational data, the risk estimates presented in this chapter.

Estimates of risk to 1-2 year olds due to background lead exposure levels are also presented in this chapter. These estimates help to quantify the maximum possible reduction in adverse health effects which could be achieved by any type of §403 rule. These are useful for comparison with the other risk estimates of this chapter and Chapter 6.

Because individual children are exposed to specific residential environments having specific (possibly known) levels of environmental lead, risk to children exposed to specific environmental-lead levels are presented. These estimates are based on the IEUBK model and the Rochester multimedia model presented in Chapter 4.

Sensitivity and uncertainty analyses are performed in this chapter to gauge the robustness of the risk characterization methodology to minor changes in assumptions. The risk characterization is sensitive to the assumed relationship between blood-lead concentration and IQ score decrements. Risk estimates based on the HUD National Survey data are also sensitive to this relationship, to the adjustment made to tap weights in the HUD National Survey dust samples, and to assumptions on the geometric standard deviation associated with blood-lead concentrations under specific exposure scenarios.

Figure 5-1 outlines the approach for the risk characterization. Risk characterization conclusions, which include conclusions from hazard identification, exposure assessment, and dose response assessment, are presented in Section 5.5.

This chapter answers four questions:

1. How can the material presented in the Hazard Identification, Exposure Assessment, and Dose-Response Assessment chapters be integrated to characterize health risks to young children due to residential exposures to lead in paint, dust, and soil?

2. What are the health risks to children exposed to specific levels of environmental lead?

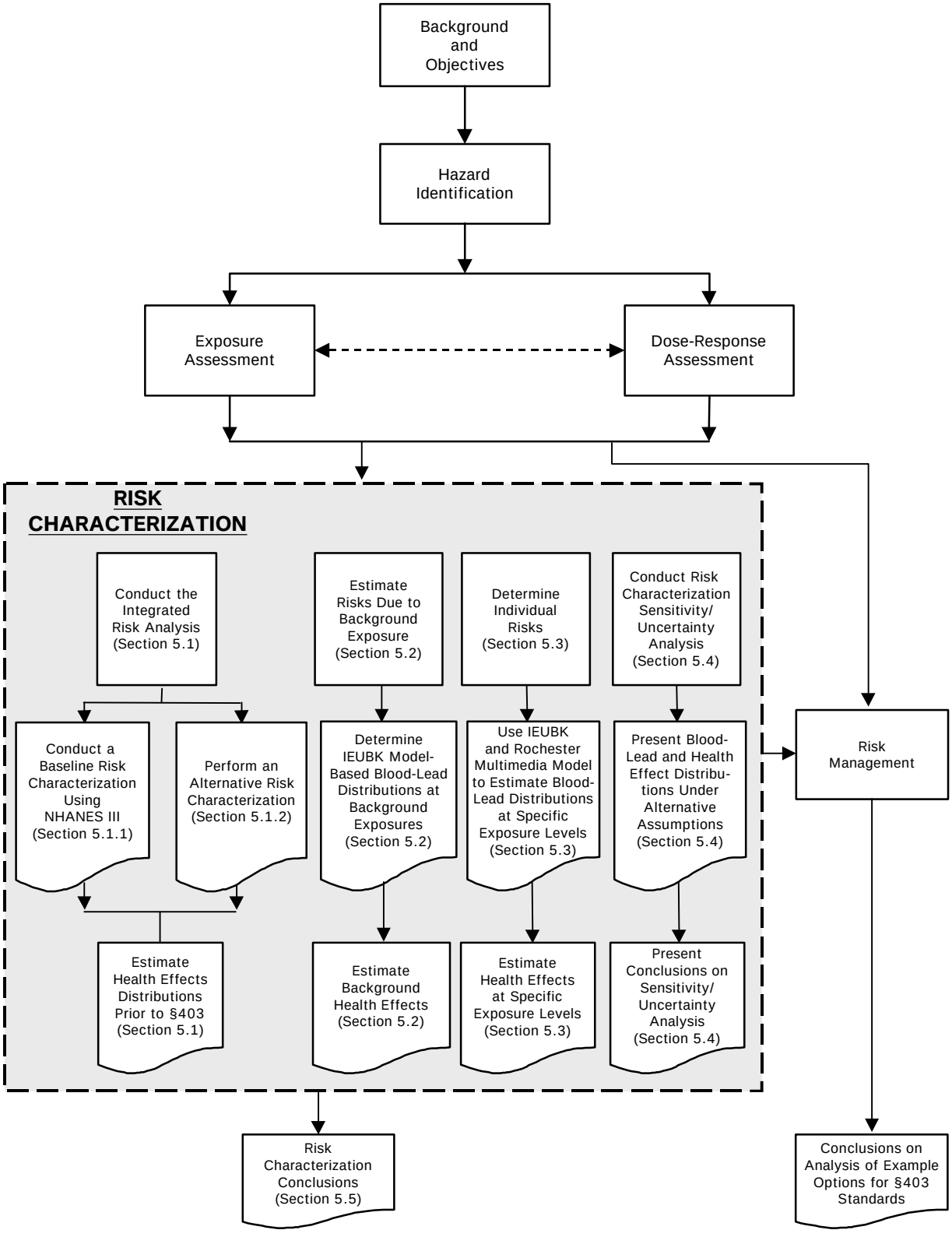


Figure 5-1. Risk Characterization Overview.

3. How does uncertainty in each step of the risk characterization affect estimates of health risks to young children?

4. What are the overall conclusions of the risk assessment?

To answer the first question, Section 5.1 presents estimated prevalences of selected adverse health effect and blood-lead concentration endpoints among the nation's 1-2 year olds, projected to the year 1997. Where possible, 95% confidence intervals are presented to characterize the uncertainty associated with the estimates. Each component of the risk assessment is integrated to produce this characterization. The Hazard Identification component is used to select the indicators of risk, the health effect and blood-lead concentration endpoints. The Exposure Assessment component is used to characterize the exposure of children, and the Dose-Response Assessment component is used to translate exposure into health effect and blood-lead concentration endpoints.

To provide the reader a basis of comparison for current risk estimates presented in Section 5.1, risks due to childhood lead exposure at background lead levels are estimated in Section 5.2. Risks are estimated as the percentage of the nation's 1-2 year olds expected to experience selected health effect and blood-lead concentration endpoints. In this context, background levels of environmental lead are defined as levels which might have existed if humans had not introduced lead into the environment through leaded gasoline consumption, lead-based paint usage, and various other activities.

Section 5.3 presents a risk characterization for children exposed to specific levels of residential environmental lead. The tools used to construct the individual risk estimates are the appropriate blood-lead concentration/environmental-lead exposure relationships presented in Chapter 4. Because the empirical model was developed specifically to characterize population risk based on HUD National Survey data, the Rochester multimedia model and the IEUBK model were used to characterize individual risks rather than the empirical model. Where possible, 95% confidence intervals are presented to characterize the uncertainty associated with the estimates. This information serves to answer question 2 above.

Sensitivity analyses in Section 5.4 are performed to gauge the uncertainty associated with the estimated adverse health effect and blood-lead concentration endpoints due to methodological assumptions. These analyses focus on potential weaknesses identified in the risk characterization process. The sensitivity analyses were designed to produce a range of estimates for an unknown parameter within which the true value of the parameter may reasonably be expected to fall.

Figure 5-1 provides an overview and roadmap to this chapter. The overall risk assessment conclusions are discussed in Section 5.5.

5.1 INTEGRATED RISK ANALYSIS

This risk analysis characterizes risks associated with childhood lead exposure by predicting the incidence (both number and percentage) of selected health effect and blood-lead concentration

endpoints among 1-2 year old children. In this section, risks are projected for 1997, prior to EPA proposing §403 standards, using pre-1997 data adjusted, when possible, to reflect current conditions. Risks due to childhood lead exposure characterized in this section are population-based risks. The particular risk endpoints chosen for characterization of risk were first presented in Section 2.4. These endpoints are

- Incidence of blood-lead concentration (PbB) greater than or equal to 20 µg/dL
- Incidence of blood-lead concentration greater than or equal to 10 µg/dL
- Incidence of IQ score less than 70 resulting from lead exposure
- Incidence of IQ score decrement greater than or equal to 1 resulting from lead exposure
- Incidence of IQ score decrement greater than or equal to 2 resulting from lead exposure
- Incidence of IQ score decrement greater than or equal to 3 resulting from lead exposure
- Average IQ decrement in a child, resulting from lead exposure.

As discussed in Section 2.4, blood-lead concentration endpoints are not health effects, but serve as surrogates for a number of lead-associated health effects.

Because this risk analysis attempts to estimate population-based risks for the U.S. population of 1-2 year olds, nationally representative data are required. However, nationally representative data for which the selected endpoints can be estimated directly are not available. There are, however, two studies measuring different aspects of lead exposure whose results are nationally representative. These studies, the HUD National Survey and NHANES III, are discussed in Sections 3.3 and 3.4, respectively, of the Exposure Assessment chapter. The former study measures environmental lead exposure from residential dust, soil, and paint. The latter study provides information on children's blood-lead concentrations. While the HUD National Survey was conducted in 1989-1990, and Phase 2 of NHANES III was conducted from 1991 to 1994, data from both studies are being used in this risk analysis to characterize children’s lead exposure in 1997, adjusted, when possible, to reflect current conditions. For example, this risk analysis has updated the sampling weights associated with the HUD National Survey units to make the model-predicted risk estimates more representative of conditions in 1997. (See Section 3.3 for an overview and Appendix C1 for details.) It would be ideal to use data collected in 1997 to characterize 1997 health risks to young children, but no such data were available.

When blood-lead concentration data are directly available (i.e., NHANES III), incidences of the health effect and blood-lead concentration endpoints are calculated from the distribution of blood-lead concentrations characterized by these data, using the methods in Section 4.4.

However, this risk analysis also uses statistical models to characterize the blood-lead concentration distribution as a function of environmental-lead levels from the HUD National Survey. Once blood-lead concentration is predicted from environmental exposure using either the IEUBK model (Section 4.1) or the empirical model (Section 4.2), incidences of the selected endpoints are calculated from the blood-lead concentration distribution, using methods in Section 4.4.

The risk estimates computed directly from blood-lead concentration data collected in NHANES III, Phase 2, are preferred to those based on model predicted blood-lead concentrations using environmental-lead exposures in the HUD National Survey. In this section, risk estimates are calculated under both approaches. The model-predicted estimates of risk are of interest because:

- The §403 standards for lead in paint, dust, and soil will directly impact levels of lead in dust, soil, and paint. An assessment of options for standards requires quantifying the reduction in adverse health effect and blood-lead concentration endpoints associated with reduced environmental-lead exposures expected to result from the proposed rule. The approach used in Chapter 6 is based on the two-step process for computing health effect and blood-lead concentration endpoints presented in Chapter 4.

- Presenting an approach for characterizing current risks due to childhood lead exposure, which uses both steps of the two-step process, illustrates how each component of the risk assessment feeds into the risk characterization. Sensitivity analyses on the integrated risk analysis produced by this approach reflect how the uncertainty associated with each component of the risk assessment affects the overall risk characterization.

Subsection 5.1.1 presents the *baseline* risk characterization, obtained using NHANES III, Phase 2 data. The *alternative* characterization of current risks, based on the IEUBK or empirical model applied to the HUD National Survey data, is presented in subsection 5.1.2. Figure 5-2 summarizes both approaches. Approximate 95% confidence intervals, which reflect sampling variability from NHANES III and uncertainty in the blood-lead concentration to IQ score decrement relationship, are presented for most of the health effect and blood-lead concentration endpoints in the baseline risk characterization. Because of the many steps to the alternative risk characterization (e.g., blood-lead concentration had to predicted for each HUD National Survey unit), confidence intervals are not presented for the alternative risk characterization.

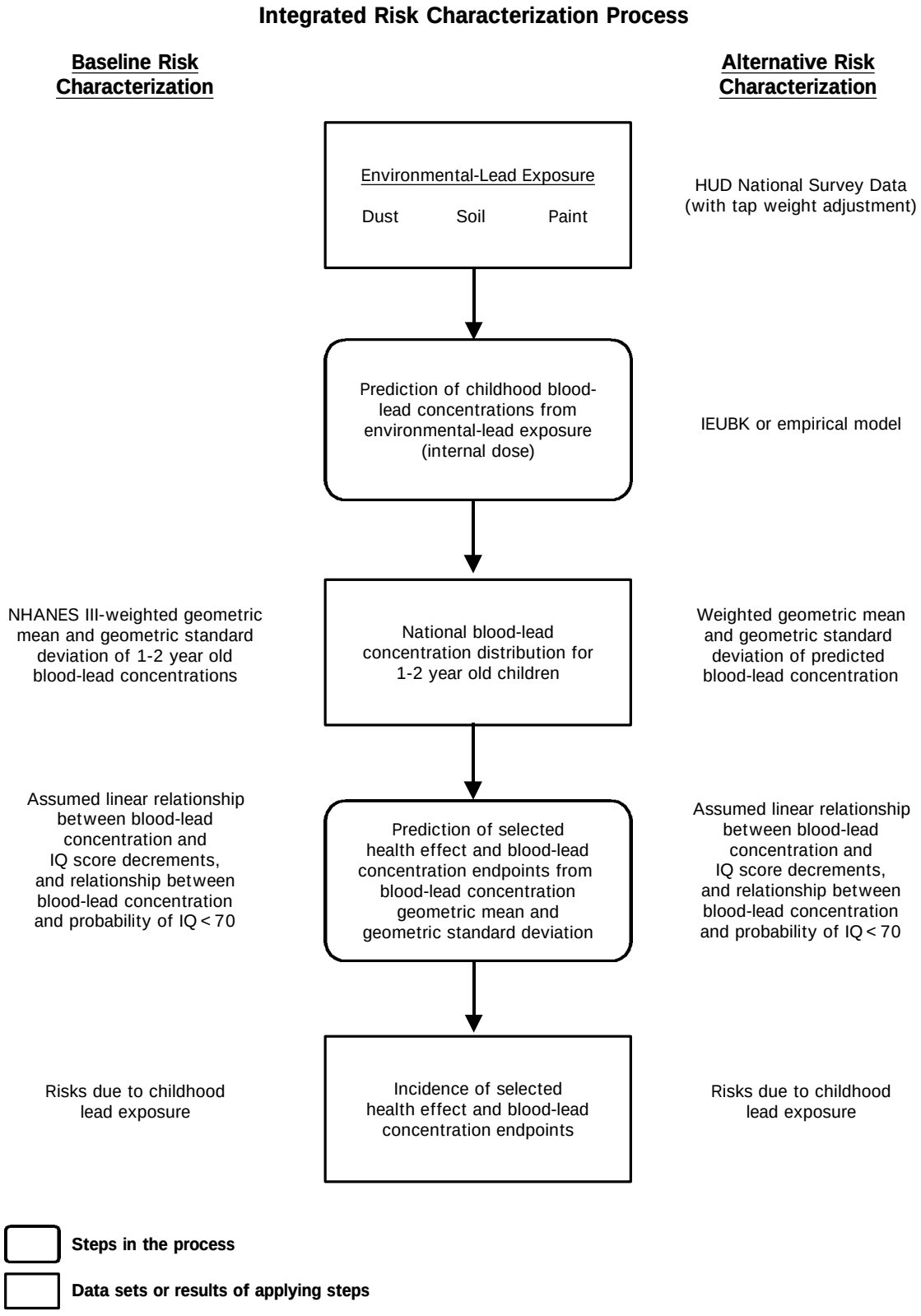


Figure 5-2. Summary of Risk Characterization Process.

5.1.1 Baseline Risk Characterization

The baseline risk characterization is based on the distribution of blood-lead concentrations for children aged 1-2 years determined in Phase 2 of NHANES III. This survey provides a national distribution of blood-lead concentration for the period 1991-1994.

In NHANES III, each surveyed participant was assigned a sampling weight, where the sum of the sampling weights equaled the total U.S. population. For children aged 1-2 years, the sum of these weights (6,789,000) was less than the total number predicted in 1997 by this risk analysis (7,961,000; see Table 3-35 of Chapter 3). Thus, numbers of children experiencing particular health effect and blood-lead concentration endpoints are estimated by multiplying the estimated percentage of children experiencing the given endpoint by the predicted number of children in the age group (i.e., 7,961,000 1-2 year olds).

The bar graph in the top part of Figure 5-3 summarizes blood-lead concentrations for children aged 1-2 years as measured in NHANES III, Phase 2. Each bar indicates the percentage of children having a given blood-lead concentration, where the concentration for each surveyed child is weighted by his/her sampling weight. Using information portrayed in this bar graph, the estimated geometric mean blood-lead concentration for children aged 1-2 years was 3.14 µg/dL, and the estimated geometric standard deviation was 2.1.

The distribution of blood-lead concentrations used in the baseline risk characterization was assumed to be lognormal with the same geometric mean and geometric standard deviation as that observed in NHANES III, Phase 2. This distribution is plotted as the smooth curve in the top graph of Figure 5-3; the lognormal distribution closely resembles the bar graph for the NHANES III data. The close agreement between the lognormal distribution and the bar graph was used to validate the lognormal assumption for blood-lead concentrations.

The bottom graph in Figure 5-3 presents the cumulative distribution function (cdf) of the blood-lead concentration distribution, which is used to determine the estimated percentage of children having a blood-lead concentration below a specified value. Two curves are presented: the cdf of the observed NHANES III data (jagged curve) and the cdf of the lognormal distribution used in the baseline risk characterization (smooth curve). The close agreement between the two curves indicates that the lognormal assumption is appropriate. Using the procedures documented in Appendix E1, the smooth curve is used to determine the baseline estimates of the two blood-lead concentration endpoints: the percentage of children with a blood-lead concentration at or above 10 µg/dL, and the percentage at or above 20 µg/dL. These estimated percentages, along with the associated numbers of children and approximate 95% confidence intervals for these percentages, are provided in Table 5-1. These confidence intervals were computed based on the lognormality assumption, using standard error estimates calculated to account for the complex survey design employed in NHANES III. This methodology is presented in Appendix C2, Section 2.0. These estimates and confidence intervals are slightly different than those presented in CDC, 1997, and Section 3.4 because they are based on the lognormality assumption.

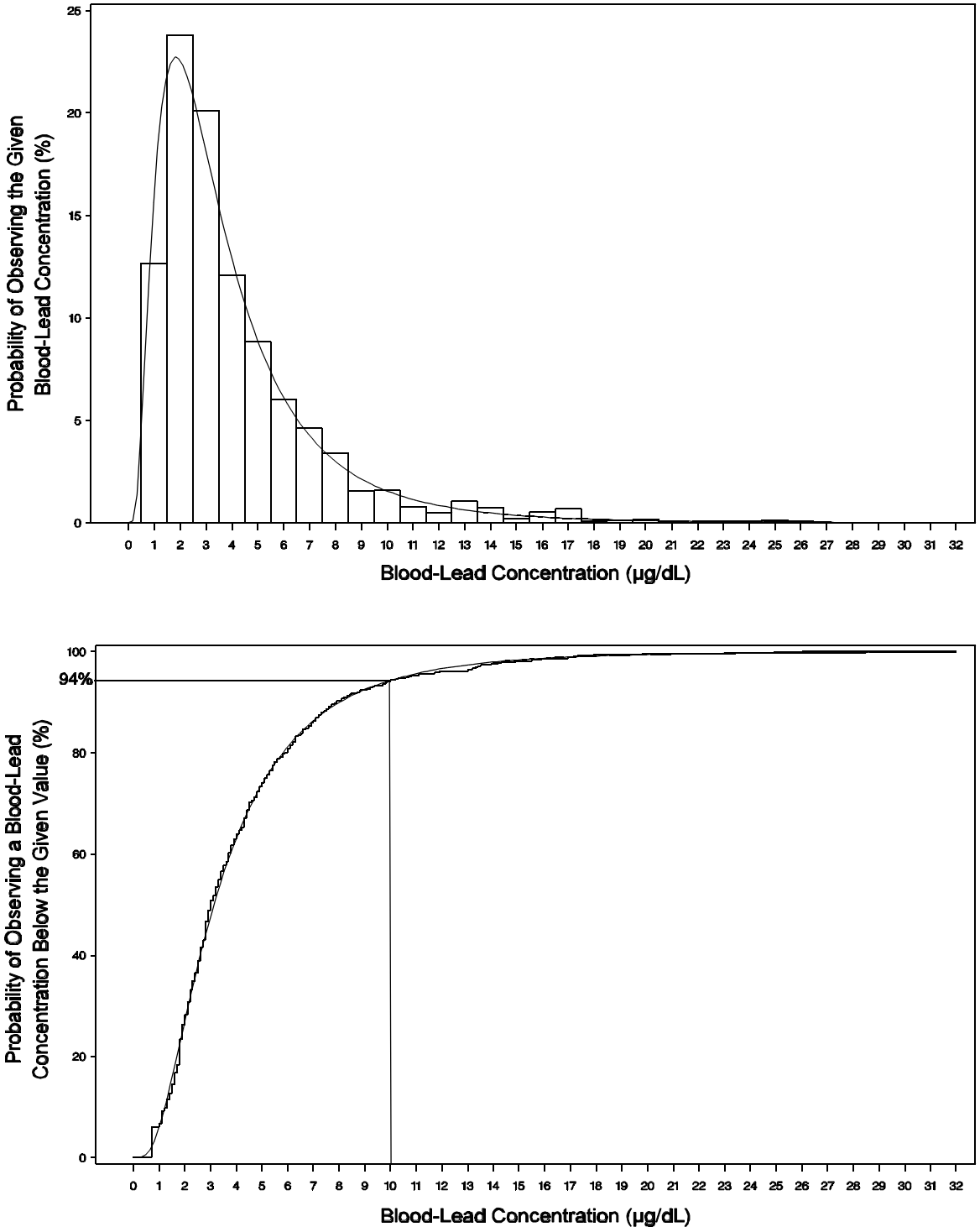


Figure 5-3. Baseline Distribution of Blood-Lead Concentrations Based on NHANES III, Phase 2 (0.07 Percent of Children Had Blood-Lead Concentration Greater than 32 µg/dL).

Table 5-1. Estimated Baseline Number and Percentage of Children Aged 1-2 Years Having Specific Health Effect and Blood-Lead Concentration Endpoints.

Health Effect and Blood-Lead Concentration Endpoints	Estimated Baseline Number of Children	Baseline Percentage of Children	
		Estimate	95% Confidence Interval
PbB ≥ 20 µg/dL[1]	46,800	0.588%	(0.256, 1.35)
PbB ≥ 10 µg/dL[1]	458,000	5.75%	(3.73, 8.84)
IQ score less than 70[2]	9,130	0.115%	--[4]
IQ score decrement ≥ 1[3]	3,060,000	38.5%	(24.6, 60.2)
IQ score decrement ≥ 2[3]	863,000	10.8%	(4.86, 24.1)
IQ score decrement ≥ 3[3]	294,000	3.70%	(1.28, 10.7)
	Estimate		95% Confidence Interval
Average IQ decrement	1.06 points		(0.703, 1.41)

[1] Determined from Figure 5-3.
[2] Determined from methods in Section 4.4.2
[3] Determined from Figure 5-4.
[4] A confidence interval could not be estimated for this endpoint.

Given the lognormal distribution of blood-lead concentration portrayed in Figure 5-3 and using the procedures documented in Section 4.4 and Appendix E1, a baseline distribution of children's IQ point decrements due to residential lead exposure was calculated. This distribution is plotted in the top graph of Figure 5-4; the cdf of the distribution appears in the bottom graph. From this distribution, baseline estimates of the numbers and percentages of children experiencing a specified IQ point decrement resulting from lead exposure were calculated and are presented in Table 5-1, along with approximate 95% confidence intervals for these percentages. The confidence intervals reflect sampling variability from NHANES III and uncertainty in the relationship between blood-lead concentration and IQ decrement, and are calculated using methods described in Appendix C2, Section 3.0. Table 5-1 also contains baseline estimates for numbers and percentages of children having IQ score less than 70, as well as average IQ decrement per child, that are expected to result from lead exposure.

Since Phase 2 of NHANES III was conducted, there have been many ongoing local, state, and federal initiatives to reduce childhood blood-lead concentrations. These actions contribute to differences between the actual distribution of childhood blood-lead concentrations in 1997 and that estimated above. Specifically, if the government strategies already in place are effective, the estimated distribution may assign higher probabilities to elevated blood-lead concentrations than does the actual distribution for 1997.

The sensitivity analysis (Section 5.4) addresses the impact on the baseline risk characterization of various assumptions on adjusting the NHANES data to reflect 1997 conditions. Such adjustments were not made in the baseline risk characterization presented in

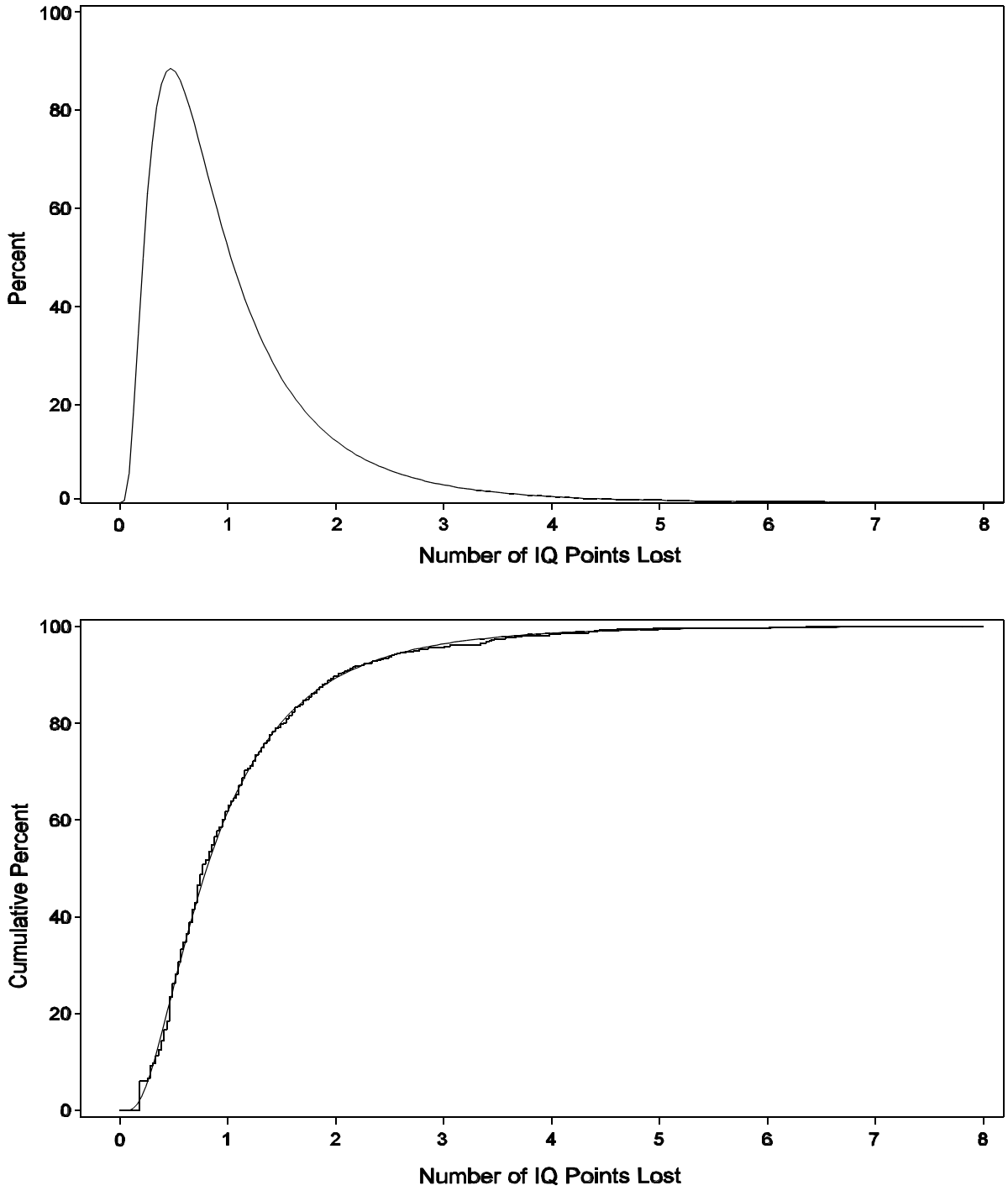


Figure 5-4. Baseline Distribution of IQ Decrements Due to Elevated Blood-Lead Concentration Based on NHANES III, Phase 2 (0.07 Percent of Children Had in Excess of 8 IQ Points Lost).

this section, primarily due to the lack of available information to support making one type of adjustment over another, and due to questions on whether a single adjustment can be made at the national level. Nevertheless, data from Phase 2 of NHANES III are considered the best available data for estimating the distribution of blood-lead concentrations in 1997.

5.1.2 Alternative Risk Characterization

Using the environmental-lead data from the HUD National Survey (Section 3.3.1) as input, the IEUBK model (Section 4.1) and empirical model (Section 4.2) were each used to predict an alternative national distribution of blood-lead concentrations for 1-2 year old children in 1997 (pre-§403). Using methods presented in Appendix E1, these blood-lead concentration distributions were then used to estimate health effect and blood-lead concentration endpoints. This section details this alternative risk characterization and presents comparisons among the three approaches to risk characterization: NHANES III (Section 5.1.1); HUD National Survey/IEUBK model; and HUD National Survey/empirical model. The empirical model was developed with the property that the geometric mean blood-lead concentration predicted by this model (based on the HUD National Survey data) would match that obtained from NHANES III.

As detailed in Sections 4.1 and 4.2, respectively, the alternative risk characterization applies the IEUBK and empirical models to environmental-lead levels associated with each housing unit in the HUD National Survey. Specifically, a geometric mean blood-lead concentration for children aged 1-2 years is predicted for each unit in the National Survey, and a geometric standard deviation (GSD) of 1.6 is assumed for each unit. Data from various studies indicate that the inherent variability in blood-lead concentration among children exposed to similar environmental-lead levels corresponds to a GSD of 1.6, the default GSD recommended in the IEUBK guidance manual (USEPA, 1994a). The predicted geometric mean associated with the national distribution of children's blood-lead concentrations is calculated by taking a weighted geometric mean of the IEUBK or empirical model-predicted blood-lead concentrations associated with each HUD National Survey unit, with each unit weighted by its sampling weight adjusted for 1997 population totals. The predicted national GSD is calculated as a function of variability in blood-lead concentration at a given exposure level and variability associated with different exposure levels. (Details are in Appendix E2.) The alternative national distribution of children's blood-lead concentration is assumed to have a lognormal distribution with this geometric mean and geometric standard deviation.

The predicted 1997 distributions of 1-2 year old children's blood-lead concentrations obtained by applying the IEUBK and the empirical models to environmental-lead data from the HUD National Survey are graphically displayed in Figure 5-5 along with the distribution reported in Section 5.1.1 based on NHANES III data. The bottom graph in Figure 5-5 presents the national distribution of children's blood-lead concentration as a cdf. The empirical model-predicted blood-lead distribution has a geometric mean value that is identical to NHANES III (by design), but has much shorter tails than the distribution based on NHANES III, due to lower variability associated with the distribution based on the empirical model.

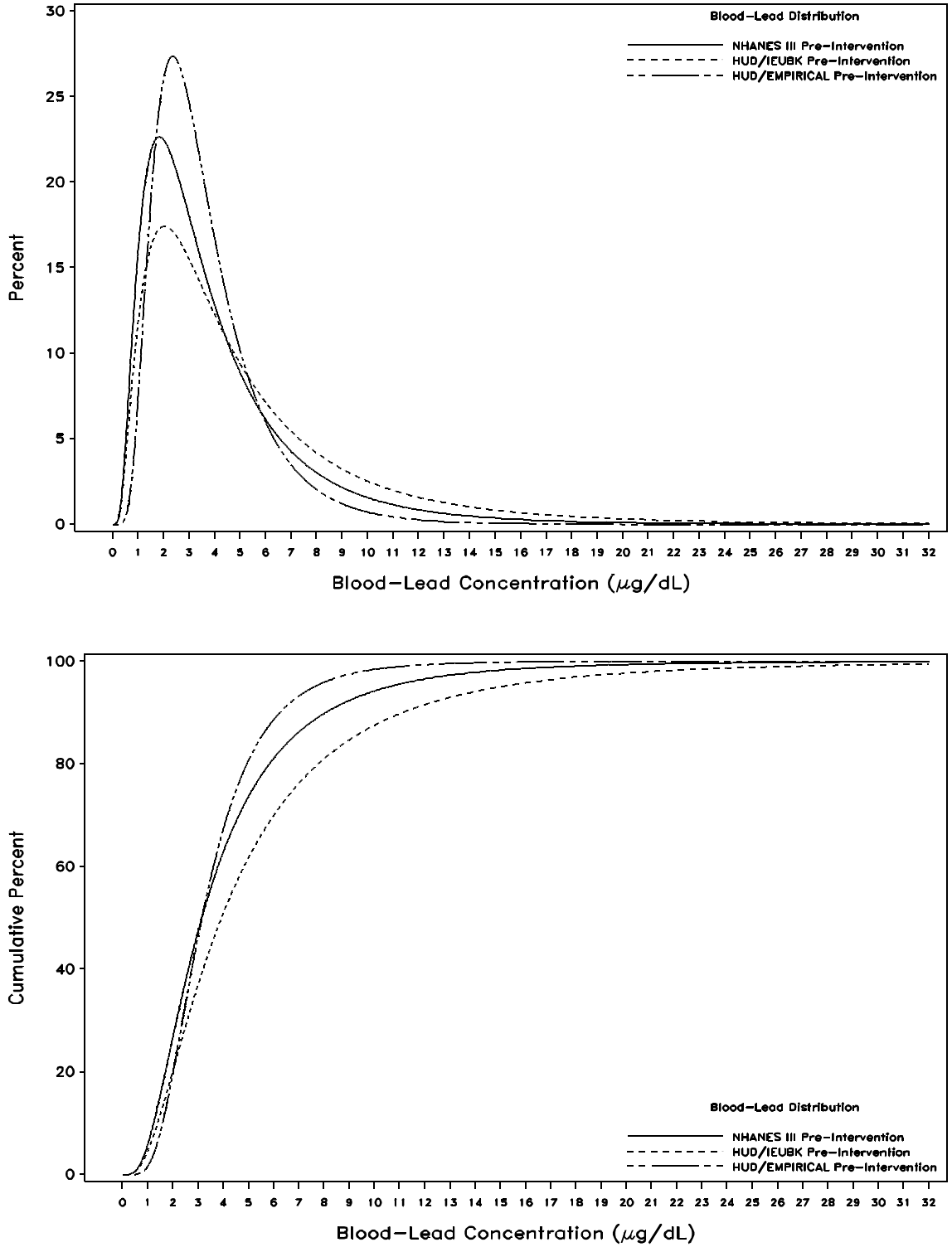


Figure 5-5. Distribution of Blood-Lead Concentrations (µg/dL) for Children Aged 1-2 Years Based on NHANES III, and IEUBK and Empirical Model Predictions.

The geometric mean blood-lead concentration based on NHANES III data is 3.14 µg/dL (GSD=2.1), while the predicted geometric means of 3.9 µg/dL (GSD=2.3) and 3.14 µg/dL (GSD=1.7) are obtained from the IEUBK model and the empirical model, respectively. The IEUBK-predicted geometric mean and GSD are close to those reported in Phase 1 of NHANES III for 1-2 year olds (4.1 µg/dL, with GSD = 2.1). The time periods of data collection in the HUD National Survey (1989-1990) and NHANES III, Phase 1 (1988-1991) overlap more closely than do the HUD National Survey and NHANES III, Phase 2 (1991-1994).

The IEUBK and empirical model-predicted national blood-lead concentration distributions were calculated to estimate the incidence of health effect and blood-lead concentration endpoints using the methods presented in Appendix E1. Table 5-2 presents the estimated health effect and blood-lead concentration endpoints. The estimated percentages of children 1-2 years old having blood-lead concentration at or above 10 µg/dL are 5.75% as estimated by the baseline risk characterization, 12.4% as predicted by the IEUBK model, and 1.5% as predicted by the empirical model. The empirical model predicts a lower estimate of the percentage of children affected by health effect and blood-lead concentration endpoints than the baseline risk characterization due to the smaller estimated geometric standard deviation (1.7 vs. 2.1). Conversely, the IEUBK model predicts larger estimates of the percentage of children affected compared to the baseline estimate because it predicts a higher geometric mean and geometric standard deviation than does the baseline risk characterization. These findings reflect differences in the use and development of these models.

Table 5-2. IEUBK and Empirical Model Predicted Health Effect and Blood-Lead Concentration Endpoints for Children Aged 1-2 Years.

Blood-Lead Concentration and Health Effect Endpoints	Percentage of Children Aged 1-2 Years		
	Empirical Model Prediction	IEUBK Model Prediction	Baseline Risk Characterization
PbB ≥ 20 µg/dL	0.0278%	2.24%	0.588%
PbB ≥ 10 µg/dL	1.54%	12.4%	5.75%
IQ score less than 70 resulting from lead exposure	0.0997%	0.146%	0.115%
IQ decrement ≥ 1 resulting from lead exposure	34.5%	50.4%	38.5%
IQ decrement ≥ 2 resulting from lead exposure	4.53%	19.9%	10.8%
IQ decrement ≥ 3 resulting from lead exposure	0.718%	8.95%	3.70%
Average IQ decrement resulting from lead exposure	0.932 points	1.40 points	1.06 points

While comparisons can be made between health effect and blood-lead concentration endpoints estimated from the NHANES data and HUD National Survey data using the IEUBK and empirical models, such comparisons should not be used to evaluate the quality of either model. Too many other factors (e.g., survey times are not the same, HUD National Survey may not represent actual lead levels in U.S. housing, no post-1979 housing was actually sampled in the HUD National Survey) vary between the two methods of estimating health effect and blood-lead

concentration endpoints. This makes it impossible to affirm that observed differences are due to model deficiencies.

The IEUBK model was developed and calibrated for children at certain large area lead sites identified in the Superfund program. In general, these are children in housing for which lead in soil contributes significantly to lead in house dust, and this lead is accessible and bioavailable. It is not clear that the default parameters, which were selected as appropriate for Superfund sites (USEPA, 1994a; Section 4.1), are applicable to all U.S. children. Conditions at general residential sites have not been investigated to the same level of detail.

The empirical model was derived from a single urban lead exposure study (the Rochester Lead-in-Dust Study) with parameters adjusted for measurement error and "calibrated" for use with HUD National Survey data (see Section 4.2). The relationship between blood-lead concentration and lead in soil and dust is not as strong based on the Rochester data as that predicted by the IEUBK model. This contributes to the smaller geometric standard deviation observed when applying the empirical model to the HUD National Survey data, compared to applying the IEUBK model. Empirical studies rarely find relationships as song as that predicted by the IEUBK model. This is due in part to underlying assumptions of the IEUBK model and in part to factors in the real world which attenuate the observed relationships between blood-lead concentrations and environmental-lead levels. Factors that contribute to the attenuation include variations in children's biokinetics of lead, behavioral activities, hand washing practices and nonresidential lead exposures, house cleaning practices, and extent of groundcover.

Comparing estimates of health effect and blood-lead concentration endpoints between the IEUBK and empirical models is also restricted because the two models require different inputs from the HUD National Survey data. Specifically, the IEUBK model requires only the floor dust-lead concentration, while the empirical model uses the floor and window sill dust-lead loadings. The dust-lead concentrations measured in the HUD National Survey required a tap weight adjustment before use in the risk analysis (USEPA, 1996c).

5.2 ESTIMATION OF RISKS DUE TO BACKGROUND EXPOSURE

This risk analysis addresses adverse health effects due to exposure to lead-based paint hazards (i.e., the condition, location, and amount of lead-based paint that causes exposure to lead in paint, lead-contaminated dust and lead-contaminated soil that would result in adverse health risks). Therefore, it is desirable to quantify the potential reduction in health effect and blood-lead concentration endpoints that would occur by completely eliminating lead exposures associated with lead-based paint hazards. However, it is difficult to quantify the contribution of sources other than lead-based paint (for example, smelters or battery plants) to lead in dust and soil. Therefore, to quantify the portion of adverse health effects which could be prevented by reducing childhood lead exposure from all sources, this section estimates health effect and blood-lead concentration endpoints at background levels of lead in dust and soil. Because complete elimination of lead-based paint hazards will not necessarily reduce levels of lead in dust and soil to background levels, this analysis puts an upper bound on the potential reductions in adverse health effects resulting from promulgation of the §403 rule.

The approach is based on using the IEUBK model to predict the average blood-lead concentration for children aged 1-2 years that are exposed to background levels of lead. The specified levels are based upon the best available scientific evidence, but actual levels representative of an environment free of lead hazards are unknown. No contribution due to pica for paint is considered in this analysis as it is assumed there is no lead-based paint. Figure 5-6 presents an overview of the process for estimating background risks.

To address the uncertainty regarding soil-lead and dust-lead concentrations corresponding to lead levels representative of an environment free of lead hazards, four possible soil-lead concentrations and two different dust-lead concentrations were considered. The various soil-lead concentrations used corresponded to no soil lead (0 µg/g), background soil-lead concentration (16 µg/g rounded up to 20 µg/g) in non-urban environments without lead-based paint, and two larger soil-lead concentrations for comparative purposes (50 and 100 µg/g). The background soil-lead concentration was obtained from Shacklette et al. (1984).

The two dust-lead concentrations considered corresponded to no dust lead (0 µg/g) and the default dust-lead concentration assumed by the IEUBK Multiple Source Analysis (USEPA 1994a). The default value for dust-lead concentration in the Multiple Source Analysis assumes that both soil and air contribute to dust-lead concentrations. The default dust-lead concentration is computed as

$$dust\text{-}lead\ \ concentration\ =\ 0.70*(soil\text{-}lead\ \ concentration)\ +\ 100\ \ \mu g/g/\mu g/m^3*(air\text{-}lead\ \ concentration)$$

where the air-lead concentration is set equal to 0.10 µg/m³ (the approximate average 1990 urban air-lead concentration (USEPA, 1991)). All other default values defined by the IEUBK model were used in these analyses (Section 4.1). The IEUBK Guidance Manual (USEPA, 1994a) contains a complete discussion of the Multiple Source Analysis and other default values used for this analysis.

The results of this analysis are presented in Table 5-3. The second and third columns of the table show the predicted geometric mean blood-lead concentration for both definitions of background dust-lead concentration. The geometric mean blood-lead concentration estimated at a soil- and dust-lead concentration of 0 µg/g (i.e., blood-lead concentration resulting from other sources, such as food and water) suggests an upper bound on adverse health effect reductions due to promulgation of the §403 rule (i.e., complete elimination of lead-based paint hazards, including lead-based paint in soil and dust, and removing soil as a source of exposure, is not anticipated to reduce the national geometric mean blood-lead concentration below this point). Estimating the geometric mean blood-lead concentration at soil-lead concentrations of 50 and 100 µg/g and dust-lead concentrations set according to the IEUBK Multiple Source Analysis provides additional understanding of the impact of sources of lead other than lead-based paint on potential benefits of the §403 rule.

Background Exposure Risk

Characterization Process

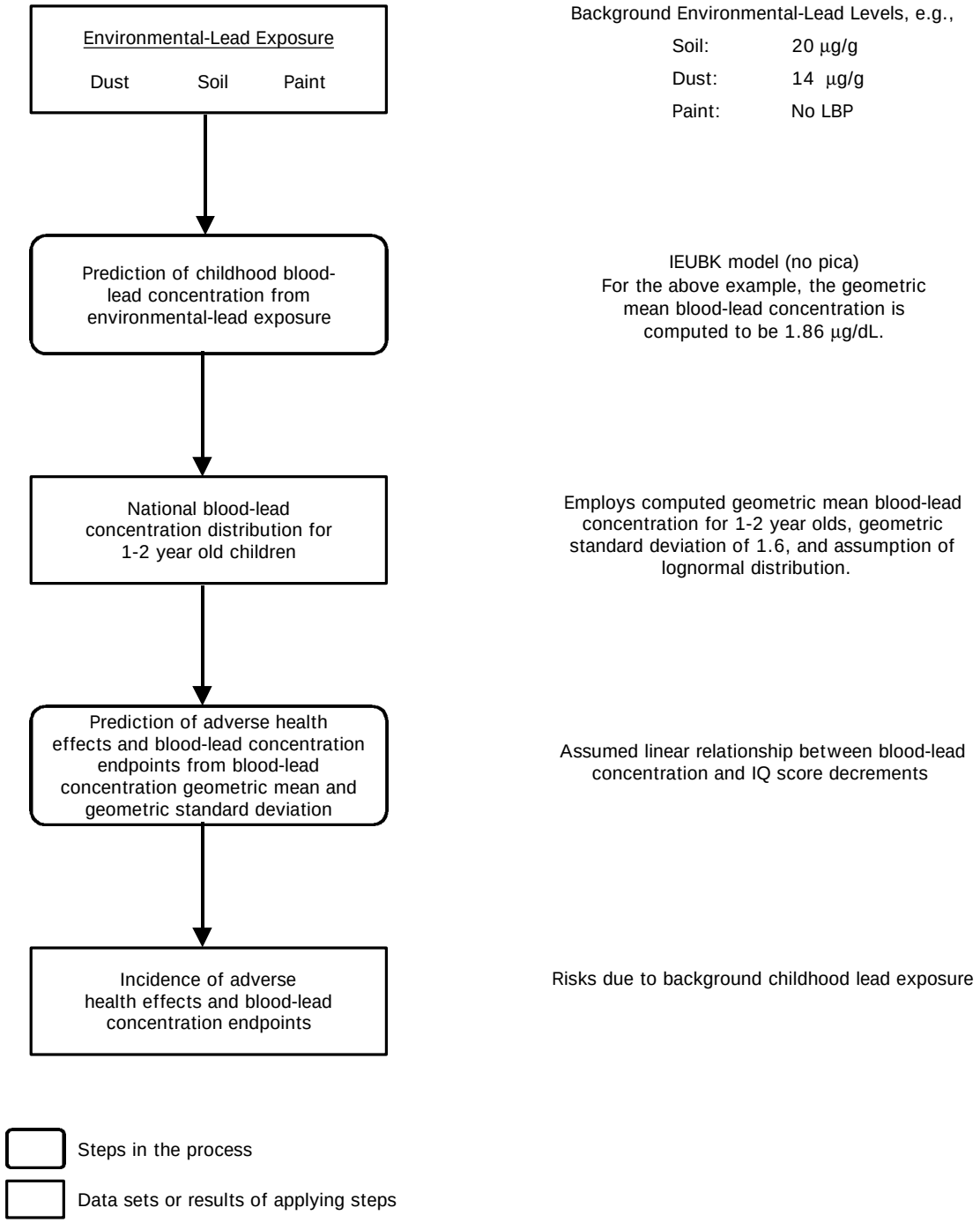


Figure 5-6. Overview of Process for Estimating Risks Due to Background Lead Exposure.

Table 5-3. IEUBK Model-Predicted Blood-Lead Concentrations for Children Aged 1-2 Years Under Different Soil-Lead Concentrations and at Dust-Lead Concentrations Equal to Either 0 µg/g or IEUBK Multiple Source Analysis Default Values.

Background Soil-Lead Concentration (µg/g)	IEUBK Geometric Mean Predicted Blood-Lead Concentration (µg/dL)		Weighted Geometric Mean from NHANES III Study (µg/dL)
	Dust Lead Concentration = Multiple Source Analysis Default[1]	Dust Lead Concentration = 0 µg/g	
0	1.61	1.52	3.14
20	**1.86 (41%)[2]**	**1.66 (47%)[3]**	
50	2.23	1.86	
100	2.83	2.20	

[1] Dust-lead concentration = 0.7 * (soil-lead concentration) + 10 µg/g.
[2] Total potential for reduction in geometric mean blood-lead concentration for 1-2 year olds is 41%.
[3] Total potential for reduction in geometric mean blood-lead concentration for 1-2 year olds is 47%.

The weighted geometric mean from Phase 2 of NHANES III, 3.14 µg/dL, is shown in the last column of Table 5-3. **The difference between 3.14 µg/dL and that estimated at background lead exposures may be used to estimate the total potential for reduction in adverse health effects due to childhood lead exposure.**

Using a soil-lead concentration of 20 µg/g as an example, when dust-lead concentration is assumed to be 0 µg/g, the geometric mean blood-lead concentration could be reduced up to 47% (47% = 100 x (3.14 - 1.66 / 3.14)). Under conditions reflected by the Multiple Source Analysis results, it could be reduced up to 41%.

Results in Table 5-3 for the soil-lead concentration of 20 µg/g were used to estimate health effect and blood-lead concentration endpoints due to background lead exposure. Health effect and blood-lead concentration endpoints were computed using methodologies detailed in Chapter 4 and Appendix E1 and consistent with Section 5.1, assuming that

1. Blood-lead concentrations are lognormally distributed,

2. The geometric standard deviation of blood-lead concentrations for children with comparable lead exposures is 1.6,

3. The geometric mean blood-lead concentration is either 1.86 µg/dL (Multiple Source Analysis dust-lead concentration of 24 µg/g) or 1.66 µg/dL (dust-lead concentration of 0 µg/g).

Table 5-4 presents health effect and blood-lead concentration endpoints calculated based on these assumptions and using data from Phase 2 of NHANES III.

Table 5-4. Percentage of Children Aged 1-2 Years Having Specific Health Effect and Blood-Lead Concentration Endpoints, Based on IEUBK-Predicted Blood-Lead Concentrations Under Background Soil- and Dust-Lead Concentrations, Compared with Estimates from the Baseline Risk Characterization.

Health Effect and Blood-Lead Concentration Endpoints	Percentage of Children Aged 1-2 Years		
	Soil-Lead Conc. = 20 µg/g Dust Lead Conc. = 24 µg/g[1]	Soil-Lead Conc. = 20 µg/g Dust Lead Conc. = 0 µg/g	Baseline Risk Characterization (Section 5.1.1)
PbB ≥ 20 µg/dL	2.17×10^{-5}%	5.93×10^{-6}%	0.588%
PbB ≥ 10 µg/dL	0.0173%	0.00665%	5.75%
IQ score less than 70	0.0877%	0.0868%	0.115%
IQ score decrement ≥ 1	5.82%	3.50%	38.5%
IQ score decrement ≥ 2	0.116%	0.0506%	10.8%
IQ score decrement ≥ 3	0.00466%	0.00166%	3.70%
Average IQ decrement	0.534 points	0.476 points	1.06 points

[1] Multiple Source Analysis default.

5.3 INDIVIDUAL RISKS

Risk estimates in Section 5.1 represent risk to the nation's population of 1-2 year old children (12-35 months) exposed to residential environmental-lead levels existing within the 1997 housing stock. These *population-based risks* characterize hazards posed by childhood lead exposure to the nation as a whole. The risk to children exposed to specific levels of residential environmental lead are better characterized by estimating the impact of the specific environmental exposure levels if those levels are known or can be estimated. The exposure levels of a child may be estimated, for example, based on the results of a risk assessment conducted in that child's residence.

The *individual risks* presented in this chapter refer to the risks estimated for (a population of) children exposed to specified levels of environmental lead. These risks are different from the population-based risks of Section 5.1 in that those risks are estimated based on the distribution of environmental-lead levels occurring in the U.S. housing stock. Individual risks do not represent the risks of a specific child, as such risks are best determined by medical professionals who have access to specific information on the characteristics of the child as well as his/her environment. The estimates of individual risks take the form of, for example, the percentage of children exposed to an average floor dust-lead loading of 200 µg/ft², window sill dust-lead loading of 700 µg/ft², and soil-lead concentration of 2,000 ppm who experience a blood-lead concentration greater than or equal to 10 µg/dL.

There are two tools available for estimating individual risks based on residential environmental-lead levels: the IEUBK model (Section 4.1) and the Rochester multimedia model (Section 4.2). The Rochester multimedia model differs from the empirical model in three ways: it has not been adjusted for HUD National Survey specific measurement error, it was not calibrated to produce a geometric mean blood-lead concentration of 3.14 µg/dL (the geometric mean in Phase 2 of NHANES III) when applied to the HUD National Survey data, and it predicts blood-lead concentrations based on wipe dust-lead loadings rather than Blue Nozzle vacuum dust-lead loadings. These differences make the Rochester multimedia model more appropriate than the empirical model for use in the individual risk analysis.

The IEUBK model is used to estimate the risks of childhood blood-lead concentration greater than or equal to 10 µg/dL for various soil-lead concentrations. The Rochester multimedia model takes as input dripline soil-lead concentration, and therefore, was not considered appropriate for evaluating the risks at specified yard average soil-lead concentrations. The Rochester multimedia model is employed to estimate the risks of childhood blood-lead concentration greater than or equal to 10 µg/dL for various combinations of floor and window sill dust-lead loading. The IEUBK model employs dust-lead concentration as its input measure of dust lead, and therefore, was not considered appropriate for evaluating the risks at specified dust-lead loadings.

Figure 5-7 presents estimates of the percentage of children's blood-lead concentrations that will exceed (or equal) 10 µg/dL as a function of soil-lead concentration, as predicted by the IEUBK model, assuming dust-lead concentrations of 100, 200, and 500 µg/g. These dust-lead concentrations were chosen as representative of typical dust-lead concentrations in homes built in the period 1960-1979, 1940-1959, and pre-1940, respectively (see Table 3-7).

Figure 5-7 suggests that the percentage of children aged 1-2 years having blood-lead concentrations greater than or equal to 10 µg/dL is larger than 5% for any soil-lead concentration, if the children are exposed to a dust-lead concentration of 500 µg/g (top-most curve). For children exposed to a dust-lead concentration between 100 and 200 µg/g, a soil-lead concentration between 250 and 350 µg/g would provide an approximately 5% chance of having a blood-lead concentration greater than or equal to 10 µg/dL. Table 5-5 presents the soil-lead concentrations predicted to maintain the percentage of children having blood-lead concentrations above (or equal to) 10 µg/dL at 1%, 5%, and 10% for the dust-lead concentrations considered in Figure 5-7.

As shown in Table 5-5, for all dust-lead concentrations considered, the soil-lead concentrations estimated to maintain risks at 1% and 5% are less than 500 ppm; even a soil-lead concentration of 0 ppm would not achieve these levels of protection if children are exposed to dust-lead concentrations of 500 µg/g. Based on Table 5-5, if dust-lead concentrations are equal to 100 µg/g, a soil-lead concentration of approximately 400 µg/g maintains the percentage of blood-lead concentrations greater than or equal to 10 µg/dL at 5%.

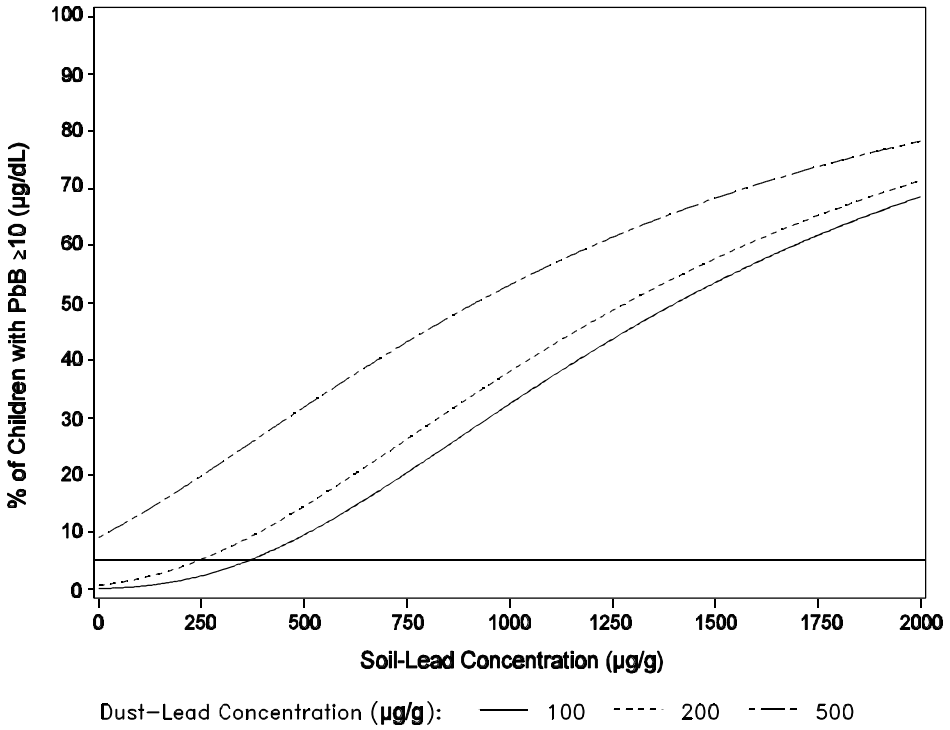


Figure 5-7. Percentage of Children's Blood-Lead Concentrations, as Predicted by the IEUBK Model, That Will Exceed or Equal 10 µg/dL as a Function of Soil-Lead Concentration for Three Dust-Lead Concentrations.

Table 5-5. Soil-Lead Concentrations at Which the Percentage of Children Aged 1-2 Years Having a Blood-Lead Concentration Above or Equal to 10 µg/dL is Estimated by the IEUBK Model at 1, 5, or 10%, Under Three Assumed Dust-Lead Concentrations.

Floor Dust-Lead Concentration (µg/g)	Soil-Lead Concentration (µg/g)		
	1%	5%	10%
100	155	365	515
200	35	245	395
500	Not achievable	Not achievable	25

Figure 5-8 graphs the estimated percentage of children having blood-lead concentrations above or equal to 10 µg/dL as a function of floor dust-lead loadings. The percentages are plotted for soil-lead concentrations of 100 and 400 µg/g and window sill dust-lead loadings of 200 and 500 µg/ft², with separate plots for the two specified window sill dust-lead loadings. Soil-lead concentrations of 100 and 400 µg/g were chosen based on the previous analysis of soil-lead concentrations. Window sill dust-lead loadings were chosen because they are representative of homes built in the period pre-1940 (see Table 3-8) and interim guidance levels (USEPA, 1995h).

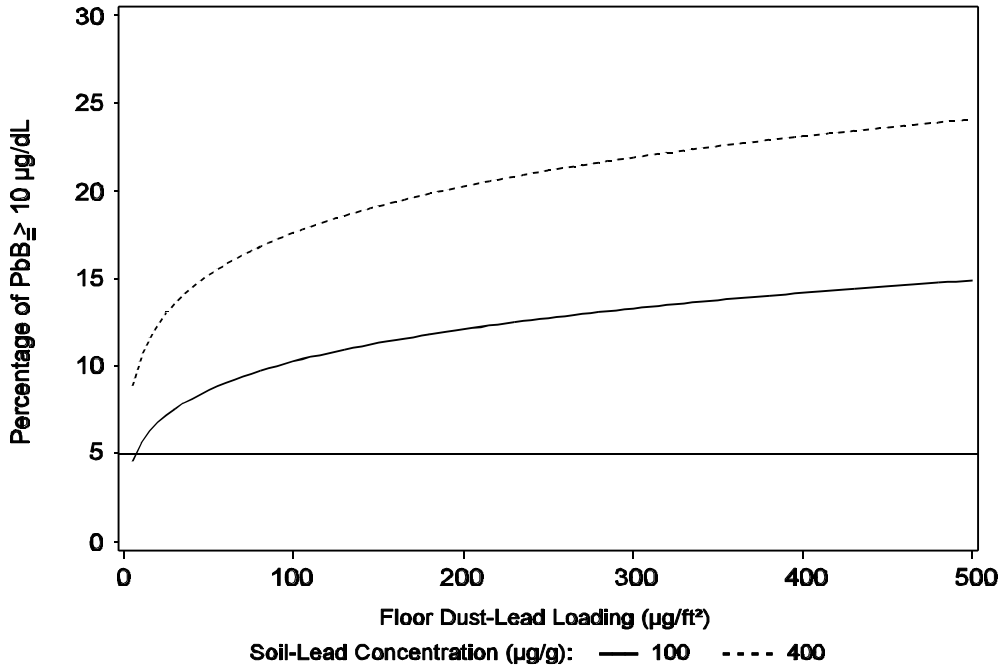
Figure 5-8 indicates that at the specified soil-lead concentrations and window sill dust-lead loadings, floor dust-lead loading must be less than 10 µg/ft² to control the percentage of children predicted to have blood-lead concentrations greater than or equal to 10 µg/dL at 5%. When soil-lead concentration is 100 µg/g and window sill dust-lead loadings is 200 µg/ft², a risk of 10% can be achieved by floor dust-lead loadings around 90 µg/ft².

Tables 5-6 and 5-7 present the floor and window sill dust-lead loadings, respectively, that are predicted to maintain the percentage of children having blood-lead concentrations above or equal to 10 µg/dL at 1%, 5%, and 10% for specified levels of soil-lead concentration and dust-lead loading on window sills or floors, respectively. Approximate 95% upper confidence bounds, which account for the variability of parameter estimates from the Rochester multimedia model, are also provided in Tables 5-6 and 5-7. Confidence bounds are included in Tables 5-6 and 5-7 but not Table 5-5 because of fundamental differences in the IEUBK and Rochester multimedia models. Specifically, the Rochester model was estimated empirically, and thus, uncertainty in the model can be quantified. (This captures variability in the relationship between environmental lead and blood-lead concentration in the Rochester study and assumes that this relationship is representative of the entire nation). The IEUBK model, however, is mechanistic, and no measure of uncertainty in prediction of mean blood-lead concentration associated with input environmental-lead levels is available. The methodology used to compute the upper confidence bounds is provided in Appendix C2, Section 5.0.

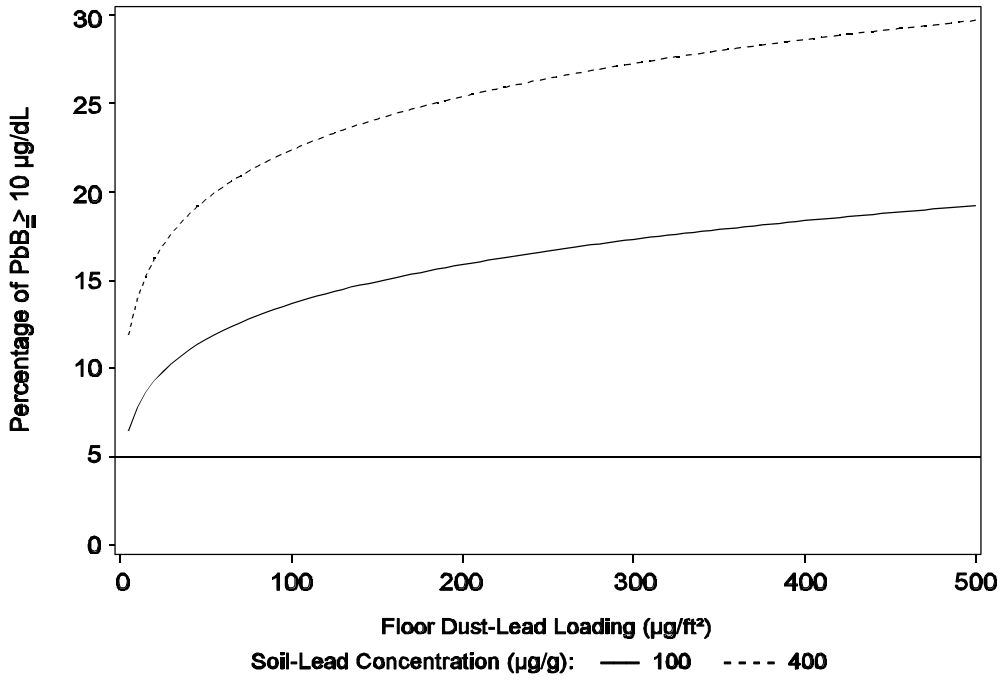
Floor dust-lead loadings that control the percentage (risk) of children having blood-lead concentrations above (or equal to) 10 µg/dL at 1% are less than 1 µg/ft² for all soil-lead concentrations and window sill dust-lead loadings considered. Floor dust-lead loadings that maintain risk at the 10% level are less than 100 µg/ft². Similar results are observed for window sill dust-lead loadings in Table 5-7. Window sill and floor dust-lead loadings that control risk at 5% range from 4.2 to 74 µg/ft² and from 0.2 to 6.7 µg/ft², respectively.

Table 5-6. Floor Dust-Lead Loadings at Which the Percentage of Children Aged 1-2 Years Having a Blood-Lead Concentration Above or Equal to 10 µg/dL is Estimated by the Rochester Multimedia Model at 1, 5, or 10% Under Two Assumed Soil-Lead Concentrations and Two Assumed Window Sill Dust-Lead Loadings.

Soil-Lead Concentration (µg/g)	Window Sill Dust-Lead Loading (µg/ft²)	Floor Dust-Lead Loading (µg/ft²)					
		1%		5%		10%	
		Estimate	95% Upper Confidence Bound	Estimate	95% Upper Confidence Bound	Estimate	95% Upper Confidence Bound
100	200	0.05	1.32	6.7	170	89	2200
	500	0.02	0.42	2.0	54	27	710
400	200	Not achievable	0.13	0.61	17	8.1	220
	500		0.04	0.18	5.3	2.4	71



a) Window Sill Dust-Lead Loading = 200 µg/ft²



b) Window Sill Dust-Lead Loading = 500 µg/ft²

Figure 5-8. Percentage of Children's Blood-Lead Concentrations, As Predicted By the Rochester Multimedia Model, That Will Exceed or Equal 10 µg/dL as a Function of Floor Dust-Lead Loading for Two Soil-Lead Concentrations and Two Window Sill Dust-Lead Loadings.

Table 5-7. Window Sill Dust-Lead Loadings at Which the Percentage of Children Aged 1-2 Years Having a Blood-Lead Concentration Above or Equal to 10 µg/dL is Estimated by the Rochester Multimedia Model at 1, 5, or 10% Under Two Assumed Soil-Lead Concentrations and Two Assumed Floor Dust-Lead Loadings.

Soil-Lead Concentration (µg/g)	Floor Dust-Lead Loading (µg/ft²)	Window Sill Dust-Lead Loading (µg/ft²)					
		1%		5%		10%	
		Estimate	95% Upper Confidence Bound	Estimate	95% Upper Confidence Bound	Estimate	95% Upper Confidence Bound
100	25	1.9	25	74	990	520	7000
	100	0.65	9.5	26	380	180	2700
400	25	0.30	4.5	12	180	85	1300
	100	0.11	1.7	4.2	67	30	480

5.4 RISK CHARACTERIZATION SENSITIVITY AND UNCERTAINTY ANALYSIS

Results presented in this risk characterization are dependent on a number of factors, including the assumptions and data analysis approaches taken, the outcomes of supporting data analyses, and the availability of sufficient data. Sensitivity analyses address the extent to which variations in key assumptions and approaches affect the outcome. These variations are associated with overall uncertainty. Thus, sensitivity analysis within the risk characterization evaluates how sensitive the results and conclusions of the characterization are to the uncertainty present in the analysis.

Table 5-8 summarizes the components of the risk characterization that were addressed by the sensitivity analysis and the alternative approach considered for each component. This section presents the findings of the sensitivity analysis. Justification for each alternative approach considered in the analysis is provided, and reasons for not including certain factors of the risk assessment in the sensitivity analysis are discussed.

Note that the sensitivity analysis does not consider other options for obtaining estimated numbers of housing units in the 1997 housing stock or numbers of children residing in the housing stock (presented in Chapter 3). In preliminary analyses, it was observed that regardless of the method used to obtain an estimated number of units (or children) within the four categories determined by housing age, the percentage of the total housing stock (or the total population of children) within each group remained relatively constant. Therefore, it was not deemed necessary to consider alternative methods for determining numbers of housing units or children.

Table 5-8. Components of the Risk Characterization Addressed By the Sensitivity Analysis.

Risk Characterization Component	Approach Taken in the Risk Analysis	Alternative(s) Considered in the Sensitivity Analysis
Determine an appropriate age group of children	Age group = 1-2 years (i.e., 12 to 35 months) for both population and individual risk characterization	Baseline (Population) Risk Characterization: Age group = 1-5 years (i.e., 12 to 71 months) Individual Risk Characterization (IEUBK Model): Age group = 0-5 years (i.e., 0 to 71 months) Section 5.4.1
Determine an average IQ point loss associated with every 1 µg/dL increase in blood-lead concentration in children	Average IQ point loss = 0.257.	Alt. #1: Average IQ point loss = 0.185 Alt. #2: Average IQ point loss = 0.323 Section 5.4.2
Determine the baseline (pre-§403) blood-lead concentration in children aged 1-2 years in U.S. housing	Use data collected in Phase 2 of NHANES III, with no adjustments to the reported blood-lead concentrations	Consider across-the-board declines of 10%, 20%, and 30% in blood-lead concentration from those concentrations reported in Phase 2 of NHANES III Section 5.4.3
	Assume a lognormal distribution (See Section 5.1.1)	Use the observed distribution data reported in the NHANES III without any assumption of lognormality. Section 5.4.4
When using modeling techniques to predict pre-intervention values of the health effect and blood-lead concentration endpoints, determine an appropriate value for the geometric standard deviation (GSD) of the blood-lead concentrations associated with a given environmental-lead exposure scenario	Assume a GSD of 1.6	Alt. #1: Assume a GSD of 1.4 Alt. #2: Assume a GSD of 1.9 Alt. #3: Assume a GSD of 2.1 Section 5.4.6
When using the IEUBK model to predict pre-intervention values of the health effect and blood-lead concentration endpoints, determine an appropriate value for daily dietary lead intake for a child aged 1-2 years (an input parameter to the IEUBK model)	Assume daily dietary lead intake is 5.78 µg (the model's default value for children aged 1-2 years)	Alt. #1: Daily dietary lead intake = 1.29 µg Alt. #2: Daily dietary lead intake = 3.53 µg Section 5.4.7
When using modeling techniques to predict pre-intervention values of the health effect and blood-lead concentration endpoints, adjust model-based results to reflect the effects of paint pica tendencies on blood-lead concentration	Make assumptions on the prevalence of paint pica and the effects of paint pica on blood-lead concentration that are documented in Section 4.1.3 and Appendix D1	Alt. #1: Make no adjustment for paint pica effects Alt. #2: Assume a lower prevalence of paint pica and lower effects of paint pica on blood-lead concentration than that used in the risk analysis Alt. #3: Assume a higher prevalence of paint pica and higher effects of paint pica on blood-lead concentration than that used in the risk analysis Section 5.4.8

Table 5-8. Components of the Risk Characterization That Were Addressed By the Sensitivity Analysis (Continued)

Risk Characterization Component	Approach Taken in the Risk Analysis	Alternative(s) Considered in the Sensitivity Analysis
When using the IEUBK model to predict a pre-intervention geometric mean blood-lead concentration, adjust dust-lead concentrations in the HUD National Survey to reflect the dust sample's total weight, not just the tap weight	For a given dust sample, use a regression model (USEPA, 1996c) to predict the ratio of the sample's total weight to its tap weight, then divide the sample's reported lead concentration by this ratio.	Alt. #1 (low estimate): Divide the reported dust-lead concentration by the upper 90% confidence bound on the sample's expected ratio. Alt. #2 (high estimate): Divide the reported dust-lead concentration by the lower 90% confidence bound on the sample's expected ratio. Alt. #3 (high estimate): Make no adjustment to the sample's reported concentration. Section 5.4.5

5.4.1 Alternative Age Range of Children

As discussed in Section 2.4, this risk analysis characterized lead exposures and health effects for children aged 1-2 years. However, as the interventions that result from §403 rules are expected to benefit young children of other ages as well, this sensitivity analysis calculated health effect and blood-lead concentration endpoints associated with children in broader age ranges: children aged 1-5 years (12-71 months) when characterizing population-based risks based on NHANES III, and children aged 0-5 years when characterizing individual risks. These alternative age ranges are considered as Title X has defined target housing as housing built prior to 1978 in which children less than six years of age may reside. Broadening the age range to include older children will likely result in an emphasis on lower blood-lead concentrations in the overall distribution, as older children tend to have lower blood-lead concentrations than children 1-2 years of age.

Characterizing Population-Based Risks

Using the approach to baseline risk characterization presented in Section 5.1.1, Tables 5-9a and 5-9b present baseline estimates (pre-§403) of numbers and percentages of children in the U.S. aged 1-5 years in 1997 experiencing the various health effect and blood-lead concentration endpoints. Results for the 1-2 year age group, duplicated from Table 5-1 of Section 5.1.1, are included for comparison purposes. Table 5-9a presents estimated percentages of children with blood-lead concentrations greater than or equal to 10 and 20, IQ less than 70, due to lead exposure, and specified decrements in IQ score due to lead exposure. Approximate 95% confidence intervals associated with these percentage estimates are also included in this table; the methods for calculating these confidence intervals are documented in Appendix C2. A 95% confidence interval could not be calculated for the percentage with IQ < 70 resulting from lead exposure, due to its method of calculation.

Table 5-9a. Sensitivity Analysis for Estimated Baseline Number and Percentage of Children Having Specific Health Effects and Blood-Lead Concentration Endpoints for Two Age Groups of Children and Under Three Assumptions on Average Decline in IQ Score per Unit Increase in Blood-Lead Concentration.

Health Effect and Blood-Lead Concentration Endpoints[1]		Children Aged 1-2 Years Having the Given Health Effect		Children Aged 1-5 Years Having the Given Health Effect	
		Number (millions)	Percentage (%) (95% CI)	Number (millions)	Percentage (%) (95% CI)
PbB ≥ 20 µg/dL		0.0468	0.588 (0.256, 1.35)	0.0673	0.330 (0.153, 0.714)
PbB ≥ 10 µg/dL		0.458	5.75 (3.73, 8.84)	0.785	3.85 (2.55, 5.79)
IQ score less than 70		0.00913	0.115	0.0216	0.106
IQ score decrement ≥ 1	0.185 decline/ 1µg/dL increase	1.83	23.0 (10.2, 51.7)	3.61	17.7 (7.21, 43.3)
	0.257 decline/ 1µg/dL increase	3.06	38.5 (24.6, 60.2)	6.45	31.6 (19.1, 52.2)
	0.323 decline/ 1µg/dL increase	4.04	50.7 (38.0, 67.8)	8.85	43.4 (31.3, 60.2)
IQ score decrement ≥ 2	0.185 decline/ 1µg/dL increase	0.368	4.62 (1.23, 17.4)	6.20	3.04 (0.737, 12.5)
	0.257 decline/ 1µg/dL increase	0.863	10.8 (4.86, 24.1)	1.57	7.69 (3.25, 18.2)
	0.323 decline/ 1µg/dL increase	1.41	17.8 (10.2, 31.0)	2.71	13.3 (7.27, 24.2)
IQ score decrement ≥ 3	0.185 decline/ 1µg/dL increase	0.101	1.27 (0.238, 6.81)	0.154	0.756 (0.130, 4.40)
	0.257 decline/ 1µg/dL increase	0.294	3.70 (1.28, 10.7)	0.485	2.38 (0.781, 7.27)
	0.323 decline/ 1µg/dL increase	0.557	7.00 (3.27, 15.0)	0.973	4.77 (2.13, 10.7)

[1] For IQ score decrement, this column also includes the assumption on average IQ score decline per 1 µg/dL increase in blood-lead concentration.

Shaded cells correspond to results that were presented in Table 5-1.

Table 5-9b. Sensitivity Analysis for Estimated Baseline Average IQ Decrement for Two Age Groups of Children and Under Three Assumptions on Average Decline in IQ Score per Unit Increase in Blood-Lead Concentration.

Assumption on Average IQ Score Decline per 1.0 µg/dL Increase in Blood-Lead Concentration	Average IQ Decrement (95% Confidence Interval)	
	Children Aged 1-2 Years	Children Aged 1-5 Years
0.185	0.761 (0.418, 1.10)	0.663 (0.368, 0.958)
0.257	1.06 (0.703, 1.41)	0.921 (0.619, 1.22)
0.323	1.33 (0.961, 1.70)	1.16 (0.848, 1.47)

Shaded cell corresponds to results that were presented in Table 5-1.

Effect on risk analysis: The percentages for the 1-5 year age group are approximately 15%-35% lower than those for the 1-2 year age group. For example, Table 5-9a indicates that the expected percentage of children aged 1-2 years having blood-lead concentration of at least 10 µg/dL is approximately 6%, compared to approximately 4% for children aged 1-5 years. However, these differences are generally not statistically significant at a 5% error rate. Table 5-9b presented estimated average IQ score loss; similar declines are observed here. Observed declines are likely the result of lower blood-lead concentrations introduced to the distribution by increasing the representation of older children.

Characterizing Individual-Based Risks

Individual risks were also calculated for the age group 0-5 years. However, there are restrictions associated with applying a broader age range in characterizing individual risks. In particular, the Rochester multimedia model (Section 4.2), used to estimate individual risks as a function of dust-lead loadings on floors and window sills, was developed from data in the Rochester Lead-in-Dust Study, which included only children aged 12-31 months. Therefore, the Rochester multimedia model could not be used to obtain risk estimates for children aged 0-5 years.

The IEUBK model (Section 4.1) was used to estimate individual risks as a function of soil-lead concentration, at specified values of dust-lead concentration. As the IEUBK model produces longitudinal blood-lead concentration estimates for children aged 0-7 years under specific exposure scenarios, it was possible to consider the broader age range of 0-5 years in this sensitivity analysis.

As described in Section 4.1.4, when using the IEUBK model to characterize risks to children in a specified age range, a representative age within this range (in months) was selected to estimate blood-lead concentration. The IEUBK model was used to obtain predicted blood-lead concentrations for each month in the range 0-71 months. The predicted blood-lead concentration at 49 months was approximately equal to the geometric mean of blood-lead concentrations over the entire age range for a number of lead exposure scenarios. Therefore, in this sensitivity analysis, IEUBK model predictions at age 49 months were used to characterize blood-lead concentrations of children aged 0-5 years.

Table 5-10 presents soil-lead concentrations predicted by the IEUBK model to control the percentage of 0-5 year old children estimated to have blood-lead concentration greater than or equal to 10 µg/dL at 1%, 5%, and 10% under three dust-lead concentrations: 100, 200, and 500 µg/g. Comparable results first presented in Table 5-5 for children aged 1-2 years are also provided in Table 5-10.

Effect on risk analysis: As expected, when considering the broader age range of 0-5 years, the maximum soil-lead concentration necessary to control the percentage of children with elevated blood-lead concentration at 1 or 5% is somewhat higher than that associated with the 1-2

year olds (under a fixed floor dust-lead concentration). However, the increased soil-lead concentration is still within the same working range observed for 1-2 year olds.

Table 5-10. Soil-Lead Concentration at Which the Percentage of Children Having a Blood-Lead Concentration Above or Equal to 10 µg/dL is Estimated by the IEUBK Model at 1, 5, or 10% Under Three Assumed Dust-Lead Concentrations and Two Age Groups of Children.

Floor Dust-Lead Concentration (µg/g)	Soil-Lead Concentration (µg/g)					
	Children Aged 1-2 Years			Children Aged 0-5 Years		
	1%	5%	10%	1%	5%	10%
100	155	365	515	230	480	655
200	35	245	395	110	360	535
500	Not achievable		25	Not achievable		165

Shaded cells correspond to results that were presented in Table 5-5.

5.4.2 Alternative Assumptions on Average IQ Score Decline Per Unit Increase in Blood-Lead Concentration

As discussed in Chapter 4, results of the meta-analysis documented in Schwartz (1994) indicate that an average IQ point loss of 0.257 is predicted for every 1.0 µg/dL increase in blood-lead concentration. This relationship was used in the risk characterization to characterize health effects associated with elevated blood-lead concentration. In the sensitivity analysis, two alternative average IQ point loss estimates were considered: 0.185 and 0.323. The lower value of 0.185 was selected based on a meta-analysis that combined the findings of prospective studies that relate blood-lead concentration for children approximately two years of age to IQ scores at age 5 to 10 years, as reported in Pocock et al. (1994). The higher value of 0.323 corresponds to an examination in Schwartz (1994) on the existence of a threshold in the relationship between IQ score and blood-lead concentration. For four studies where the mean blood-lead concentration was 15 µg/dL or lower, the estimated average IQ point loss was reported to be 0.323. The estimates of 0.185 and 0.323 result in a lower and higher estimate, respectively, of the adverse health effect endpoints. The sensitivity analysis did not consider alternative methods for estimating the probability of observing IQ scores less than 70.

In Tables 5-9a and 5-9b of the previous subsection, the estimated percentages of children with IQ score decrements greater than 1, 2, or 3 under assumptions of an IQ score decline of 0.185, 0.257, and 0.323 points for every 1.0 µg/dL increase in blood-lead concentration are presented, along with approximate 95% confidence intervals associated with these percentages. These percentages reflect baseline (pre-§403) conditions and are presented for children aged 1-2 years and 1-5 years.

Effect on risk analysis: The magnitude of the decline in IQ score associated with a 1 µg/dL increase in blood-lead concentration has a considerable impact on the likelihood that a child will experience an IQ score decrement greater than 1, 2, or 3, with its effect increasing as the decrement of interest increases. As seen in Table 5-9a, the estimated percentage of children aged 1-2 years with an IQ score decrement of at least one, as calculated using the low estimate of IQ point loss (0.185), more than doubles when the high estimate (0.323) is used instead (from 23% to 51%). A more than fivefold increase in the percentage of children aged 1-2 years with an IQ score decrement of at least three is observed between the low and high estimates of IQ point loss (from 1.3% to 7.0%). In Table 5-9b, average IQ decrement increases from 0.76 to 1.33 for children aged 1-2 years, with a similar increase observed for children aged 1-5 years. However, as the 95% confidence intervals overlap across the three assumptions on IQ score decline, the observed differences in the estimates across these assumptions are not statistically significant at a 5% error rate.

5.4.3 Considering Potential Declines in Blood-Lead Concentration from NHANES III Phase 2 Measures

Blood-lead concentrations in the U.S. population have consistently declined in recent years. Therefore, it is likely that blood-lead concentrations have continued to decline since 1994, the last year of Phase 2 of NHANES III for which blood-lead concentration data were utilized in this risk analysis. This portion of the sensitivity analysis investigated how baseline estimates of the blood-lead concentration and health effect endpoints for children aged 1-2 years (Section 5.1.1) may change under different assumptions on the decline in geometric mean blood-lead concentration since 1994.

Between the two phases of NHANES III, the measured geometric mean blood-lead concentration for children aged 1-2 years declined 22.5%, from 4.05 µg/dL in Phase 1 (1988-1991) to 3.14 µg/dL in Phase 2 (1991-1994). Therefore, this sensitivity analysis calculated baseline estimates of the blood-lead concentration and health effect endpoints for children aged 1-2 years, where each blood-lead concentration measurement in Phase 2 of NHANES III was reduced by the same amount: 10%, 20%, or 30%. Table 5-11 presents these estimates, along with the estimates reported in the risk analysis (where no reduction was assumed).

Effect on risk analysis: According to Table 5-11, a 10% across-the-board decline in blood-lead concentration reduced the estimated number of children whose blood-lead concentration was at or above 20 µg/dL from 46,800 to 30,900, a decline of 34%, while the estimated number at or above 10 µg/dL was reduced by 26%. Similar percentage declines were also observed for numbers of children with IQ score decrements of 2 or 3 as a result of lead exposure. A 30% across-the-board decline reduced the estimated number of children at or above 10 µg/dL by 66%, and the estimated number of children at or above 20 µg/dL by 77%.

The results in Table 5-11 are based on the assumption that the blood-lead concentrations for each child in the population are reduced by the same percentage. In reality, some subgroups achieve less of a decline, with others achieving a greater decline. However, considering different percentage declines for different subgroups would be very difficult, and the resulting estimates of

the health effect and blood-lead concentration endpoints would likely differ only slightly from that observed in Table 5-11.

Table 5-11. Sensitivity Analysis for the Estimated Baseline Number and Percentage of Children Aged 1-2 Years Having Specific Health Effect and Blood-Lead Concentration Endpoints, Assuming Various Percentage Declines in Blood-Lead Concentration Since NHANES III Phase 2.

Health Effect and Blood-Lead Concentration Endpoints	Numbers (%) of Children Aged 1-2 Years			
	Risk analysis estimate (Table 5-1)	Percentage Decline in Blood-Lead Concentration Since NHANES III Phase 2		
		10%	20%	30%
PbB ≥ 20 µg/dL	46,800 (0.588%)	30,900 (0.388%)	18,900 (0.238%)	10,600 (0.133%)
PbB ≥ 10 µg/dL	458,000 (5.75%)	340,000 (4.27%)	239,000 (3.00%)	156,000 (1.96%)
IQ score less than 70	9,130 (0.115%)	8,610 (0.108%)	8,160 (0.102%)	7,760 (0.098%)
IQ score decrement ≥ 1	3,060,000 (38.5%)	2,640,000 (33.2%)	2,190,000 (27.6%)	1,740,000 (21.8%)
IQ score decrement ≥ 2	863,000 (10.8%)	669,000 (8.40%)	493,000 (6.19%)	340,000 (4.27%)
IQ score decrement ≥ 3	294,000 (3.70%)	213,000 (2.68%)	146,000 (1.83%)	91,900 (1.15%)
Average IQ score decrement	1.06	0.951	0.845	0.740
Geometric Mean (µg/dL)	3.14	2.82	2.51	2.20

5.4.4 Alternative Approach to Characterizing a Baseline Blood-Lead Distribution from NHANES III Data

As discussed in Section 5.1.1, the baseline distribution of blood-lead concentration in children aged 1-2 years was assumed to be lognormal, with geometric mean (3.14 µg/dL) and geometric standard deviation (2.1 µg/dL) calculated from NHANES III Phase 2 data. Health effect and blood-lead concentration endpoints were then calculated from this distribution. Although a plot of the fitted lognormal distribution is in close agreement with the NHANES III data (see Figure 5-3), some deviation from the lognormal distribution was evident, especially in the upper tail. Therefore, an alternative approach to characterizing the baseline distribution using the NHANES III data considered an empirical distribution (i.e., the distribution of the observed data, represented by the bar chart in Figure 5-3), with no lognormal assumption. This alternative approach was applied in the sensitivity analysis to evaluate the effect of the lognormal assumption on the results of the baseline risk characterization.

The NHANES III, Phase 2 database included blood-lead concentrations for 987 children aged 1-2 years at the time of their survey interview. At the time of the physical examinations, each child in the survey was assigned a sampling weight corresponding to the number of children

in the country being represented by the child. In this risk assessment, these weights were scaled to represent the 1997 population (see Section 5.1.1). This combination of blood-lead concentration and sample weight for each surveyed child provided an empirical distribution of blood-lead concentration for children aged 1-2 years. The percentage of children with a blood-lead concentration greater than or equal to 10 µg/dL was estimated from this distribution by summing the sample weights for children with blood-lead concentrations greater than or equal to 10 µg/dL, then dividing by the total of all sampling weights. This same approach as used to summarize the NHANES III data in Section 3.4.1. The percentage of children experiencing certain IQ decrements as a result of lead exposure was obtained by transforming the IQ decrement to a specific blood-lead concentration threshold, assuming a 0.257 IQ score decrement for every 1.0 µg/dL of blood-lead concentration, then estimating the percentage of children at or above this threshold. The percentage of children with an IQ score less than 70 due to lead exposure was calculated by determining the probability of this occurrence for each surveyed child based on his/her blood-lead concentration (using the methods in Section 4.4.2), then multiplying by the child's sample weight, summing the results across children, and dividing by the total of all sampling weights.

Effect on risk analysis: The values of the health effect and blood-lead concentration endpoints under the empirical distribution of blood lead concentration, as well as under the baseline distribution used in the risk assessment, are provided in Table 5-12. The estimated health effect and blood-lead concentration endpoints are very similar for the two distributions. The empirical distribution method estimates a higher percentage of children with blood-lead concentration greater than or equal to 10 µg/dL (5.88% versus 5.75% for the risk assessment baseline distribution), but a smaller percentage exceeding 20 µg/dL (0.43% versus 0.59%). Estimated average IQ score loss is virtually identical for the two distributions, with a larger difference observed for an IQ decrement of 3 or higher. The empirical distribution yields higher estimates for the endpoints associated with the most severe effects compared to the lognormal distribution due to its greater emphasis of data in the upper tail of the distribution.

5.4.5 Uncertainty in Adjusting Dust-Lead Concentrations to Reflect the Sample's Total Weight

Section 5.1.2 presented a model-based approach to characterizing a pre-intervention distribution of blood-lead concentrations. Under this method, environmental-lead levels measured in the HUD National Survey are used as input to a model to predict the geometric mean blood-lead concentration in a particular population exposed to such levels. Model inputs for the IEUBK model (Section 4.1) include dust-lead concentrations from the HUD National Survey (Section 3.3.1). As the HUD National Survey reported lead concentration within a dust sample as the amount of lead in the entire sample divided by the weight of only that portion of the sample that could be tapped out of the vacuum collection cassette (i.e., the "tap weight"), it was necessary to adjust these reported concentrations to reflect the sample's total weight prior to using the dust-lead concentrations in the risk assessment. Otherwise, the reported lead concentration might overestimate the true concentration in the sample. The methods developed in this risk assessment for making the adjustments to dust-lead concentration are documented in USEPA, 1996c. In this component of the sensitivity analysis, geometric mean blood-lead concentrations (as determined

by fitting the IEUBK model to the dust-lead concentrations) and the resulting health effects were recalculated using three alternative sets of adjusted dust-lead concentrations that were either lower or higher than those used in the risk assessment.

Table 5-12. Sensitivity Analysis for Estimated Baseline Health Effect and Blood-Lead Concentration Endpoints, for Children Aged 1-2 Years, as Calculated Under Two Approaches to Calculating the Baseline Distribution of Blood-Lead Concentration Using NHANES III Data.

Health Effect and Blood-Lead Concentration Endpoints	Children Aged 1-2 Years	
	Risk Analysis Estimates (Table 5-1) (%)	Estimates Based on Alternative (Empirical) Approach (%)
PbB ≥ 20 µg/dL	0.588	0.431
PbB ≥ 10 µg/dL	5.75	5.88
IQ score less than 70	0.115	0.115
IQ score decrement ≥ 1	38.5	38.3
IQ score decrement ≥ 2	10.8	10.5
IQ score decrement ≥ 3	3.70	4.47
Average IQ decrement	1.06 points	1.06 points

The adjustment of dust-lead concentrations in National Survey units to correct for tap weight bias involved dividing each dust sample's reported concentration by the predicted ratio of the total weight of the sample to its tap weight (USEPA, 1996c). A sample's predicted ratio was a function of its tap weight (mg) and was obtained from the following formula:

$$\text{Predicted Ratio} = 30.71 - 19.54*X + 3.36*X^2 - 0.061*W$$

where X equals the minimum of 2.903 and the sample's tap weight, and W equals the maximum of (tap weight - 2.903) and zero. If the tap weight was greater than or equal to 23.44 mg, the predicted ratio was taken to be one. Dust-lead concentrations were omitted from the risk analysis for samples having a tap weight of less than 0.7 mg.

The above formula was determined from a nonlinear regression analysis performed as part of a laboratory study (USEPA, 1996c). Thus, the coefficients 30.71, -19.54, 3.36, and -0.061 in the formula were estimates based on the data collected in the laboratory study. Therefore, assuming normality, lower and upper one-sided 90% confidence bounds on the predicted ratio were determined in the following manner:

$$\text{Lower 90\% confidence bound on ratio} = \text{Predicted Ratio} - (1.3*SE_{\text{Predicted Ratio}})$$
$$\text{Upper 90\% confidence bound on ratio} = \text{Predicted Ratio} + (1.3*SE_{\text{Predicted Ratio}})$$

where $SE_{\text{Predicted Ratio}}$ is the standard error of the predicted ratio, which was a function of the standard errors of the estimated coefficients and the covariances between pairs of coefficients that

were obtained in the regression analysis. The lower and upper confidence bounds on the predicted ratio presented are for the mean predicted ratio, and, as such, do not account for house to house variability. Accounting for house to house variability would result in a smaller, lower bound and a larger upper bound. The above estimates of the upper and lower bounds are useful, however, to portray the impact of the assumptions for tap weight adjustments on the risk estimates.

The upper and lower confidence bounds were used to obtain low and high estimates, respectively, for the adjusted dust-lead concentrations in the HUD National Survey:

$$\text{Low estimate of adjusted dust-lead conc.} = \frac{\text{unadjusted dust-lead conc.}}{\text{upper 90\% conf. bound on ratio}}$$

$$\text{High estimate of adjusted dust-lead conc.} = \frac{\text{unadjusted dust-lead conc.}}{\text{lower 90\% conf. bound on ratio}}$$

Therefore, the low and high estimates represent two alternative sets of adjusted dust-lead concentrations for the HUD National Survey dust samples. In addition, as the predicted ratios are never less than one, the adjusted concentrations can never be larger than their respective unadjusted values. Thus, the unadjusted concentrations serve as upper limits on the adjusted concentrations. This sensitivity analysis considered three alternative sets of dust-lead concentrations when predicting geometric mean blood-lead concentrations under the IEUBK model: the set of low adjusted estimates (Alternative set #1), the set of high adjusted estimates (Alternative set #2), and the set of unadjusted concentrations (Alternative set #3)[1].

For each alternative set of dust-lead concentrations, the mass-weighted arithmetic mean dust-lead concentrations for both floors and window sills were calculated for each National Survey unit (i.e., each sample concentration was weighted by the sample's tap weight). The IEUBK model was then applied to these data for each unit to obtain a predicted baseline geometric mean blood-lead concentration for the nation.

From this geometric mean, health effect and blood-lead concentration endpoints were calculated. The findings were compared across the three alternative sets of concentrations to evaluate the impact of the adjustment method. Table 5-13 presents estimated pre-intervention health effect and blood-lead concentration endpoints (obtained using the IEUBK model on the HUD National Survey data) as reported in the risk characterization (and presented in Table 5-2) and under the three alternative sets of adjusted dust-lead concentrations.

[1] Dust-lead concentrations with tap weights less than 0.7 mg were omitted from all alternative sets.

Table 5-13. Sensitivity Analysis for Estimated Health Effect and Blood-Lead Concentration Endpoints for Children Aged 1-2 Years, as Calculated Using the IEUBK Model and Under Four Approaches to Adjusting Dust-Lead Concentrations for Low Tap Weight.

Blood-Lead Concentration and Health Effect Endpoints	Risk Analysis Estimates (Table 5-2)	Estimates Under Alternative #1[1]	Estimates Under Alternative #2[2]	Estimates Under Alternative #3 (no adjustment)
Geometric mean blood-lead concentration (µg/dL) (geometric standard deviation in parentheses)	3.92 (2.26)	3.85 (2.25)	3.96 (2.22)	4.45 (2.32)
PbB ≥ 20 µg/dL (%)	2.24	2.13	2.10	3.74
PbB ≥ 10 µg/dL (%)	12.4	12.0	12.2	16.9
IQ score less than 70 (%)	0.146	0.144	0.144	0.169
IQ decrement ≥ 1 (%)	50.4	49.5	50.9	56.3
IQ decrement ≥ 2 (%)	19.9	19.3	19.8	25.4
IQ decrement ≥ 3 (%)	8.95	8.62	8.73	12.7
Average IQ decrement (# points)	1.40	1.38	1.40	1.63

[1] Low estimates for the tap-weight adjusted dust-lead concentration (unadjusted concentration divided by the upper 90% confidence bound for the ratio of total dust weight to tap weight).
[2] High estimates for the tap-weight adjusted dust-lead concentration (unadjusted concentration divided by the lower 90% confidence bound for the ratio of total dust weight to tap weight).

Effect on risk analysis: Table 5-13 indicates that using the upper or lower 90% confidence bound on the ratio of the tap weight to the entire sample's weight to adjust HUD National Survey dust-lead concentration values (i.e., Alternatives #1 and #2) has little impact on risk estimates. Therefore, risk estimates are probably not sensitive to the exact method chosen to do the tap weight adjustment. However, health effect and blood-lead concentration endpoints for the no-adjustment alternative (#3) suggest estimates of health risks due to childhood lead exposure are more severe if no tap weight adjustment is done. Based on the dust sample collection and analysis protocol used in the HUD National Survey, it is clear that some adjustment needs to be made to the dust-lead concentration values to remove potential bias associated with these values.

5.4.6 Alternative Estimates for the Geometric Standard Deviation of Blood-Lead Concentrations

In using the IEUBK and empirical models to characterize the distribution of blood-lead concentrations in children aged 1-2 years exposed to a specified set of environmental-lead levels, this risk analysis assumes that the geometric standard deviation (GSD) of this distribution is 1.6. This component of the sensitivity analysis considers alternatives to this GSD value.

Three alternative GSD values were considered: 1.4, 1.9, and 2.1. The value 1.4 was the GSD for the distribution of blood-lead concentrations for the national population of children aged 1-2 years in 1979 and 1980, as estimated by NHANES II. The value 2.1 was the GSD as estimated in both phases of NHANES III. The value 1.9 falls approximately halfway between the NHANES III estimate of 2.1 and the value of 1.6 used in the risk analysis.

In the risk analysis, a GSD of 1.6 is assumed to reflect only "inter-individual" variability, or variability among children exposed to the same environmental-lead levels. Sources of "inter-individual" variability include behavioral differences, the extent of accessibility to and contact with available lead, measurement variability, biological diversity, and differences in food consumption. In contrast, GSD values calculated from blood-lead concentrations measured in the NHANES (e.g., the lowest and highest values specified in the previous paragraph) reflect variability due to these sources, as well as "inter-neighborhood" variability, or variability associated with exposure to different environmental-lead levels. Therefore, the range of alternative values is highly likely to contain the "true" value for the GSD which reflects only variability among children exposed to the same environmental-lead levels.

As the results in Table 5-2 and Tables 5-4 through 5-7 are dependent on the value of the "inter-individual" GSD, the numbers in these tables were recalculated under the three alternative GSD values. Section 6.4.6 presents results of applying these alternative values to estimate endpoint values following promulgation of the proposed §403 rules, under a specific set of example options for the §403 standards.

Effect on risk analysis: Under the three alternative GSD assumptions, Table 5-14 presents model-predicted, pre-§403 health effect and blood-lead concentration endpoints, while Table 5-15 presents these estimates under dust-lead and soil-lead concentrations that represent background conditions. According to these tables, the choice of GSD value impacts results under the empirical model more than the IEUBK model. For example, the pre-§403 probability of a child having a blood-lead concentration at or above 10 µg/dL, as estimated by the empirical model, ranges from 0.316% to 7.02% as the GSD varies from 1.4 to 2.1, respectively (Table 5-14). In contrast, this probability ranges from 10.4% to 17.3% under the IEUBK model. When considering the IQ parameters, those representing the greatest health effects were most sensitive to the GSD value.

The effect of alternative GSD values on estimates of individual risks (Section 5.3) is investigated in Tables 5-16 through 5-18. These tables have the same formats as Tables 5-5 through 5-7 and provide estimates of the maximum environmental-lead level in a specific medium that would keep the percentage of children with blood-lead concentrations at or above 10 µg/dL to within a specified threshold, assuming fixed lead levels in other media. These maximum lead levels decline as the GSD increases; levels are generally very low and/or unachievable for GSDs of 1.9 and 2.1. The estimates differ substantially between GSD values of 1.6 and 1.4, indicating that the assumed value of the GSD has a large impact on the individual risk estimates.

Table 5-14. Sensitivity Analysis on the Model-Predicted, Pre-§403 Health Effect and Blood-Lead Concentration Endpoints for Children Aged 1-2 Years, Under Three Alternative Values (1.4, 1.9, 2.1) for the Geometric Standard Deviation (GSD) of the Blood-Lead Concentration Distribution and Under the Value Used in the Risk Analysis (1.6).

Health Effect and Blood-Lead Concentration Endpoints	Pre-§403 Predictions: IEUBK Model				Pre-§403 Predictions: Empirical Model			
	GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1	GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1
PbB ≥ 20 µg/dL (%)	1.41	2.24	3.86	5.06	0.0006	0.0278	0.372	0.922
PbB ≥ 10 µg/dL (%)	10.4	12.4	15.5	17.3	0.316	1.54	4.70	7.02
IQ < 70 (%)	0.135	0.146	0.167	0.184	0.0950	0.0997	0.111	0.120
IQ decrement ≥ 1 (%)	50.4	50.4	50.3	50.3	30.6	34.5	37.8	39.2
IQ decrement ≥ 2 (%)	17.8	19.9	22.9	24.5	1.62	4.53	9.48	12.4
IQ decrement ≥ 3 (%)	7.09	8.95	11.8	13.6	0.0984	0.718	2.89	4.73
Average IQ decrement (# points)	1.33	1.40	1.54	1.65	0.883	0.932	1.03	1.10

Note: Results in shaded cells were presented in Table 5-2.

Table 5-15. Sensitivity Analysis on IEUBK Model-Predicted Health Effect and Blood-Lead Concentration Endpoints for Children Aged 1-2 Years, Under Three Alternative Values (1.4, 1.9, 2.1) for the Geometric Standard Deviation (GSD), Assuming a Background Soil-Lead Concentration of 20 µg/g and One of Two Estimates of Background Dust-Lead Concentration.

Health Effect and Blood-Lead Concentration Endpoints	Dust-Lead Concentration = Multiple Source Analysis Default				Dust-Lead Concentration = 0 µg/g			
	GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1	GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1
PbB ≥ 20 µg/dL (%)	8.39×10^{-13}	2.17×10^{-5}	0.0108	0.0684	6.96×10^{-14}	5.93×10^{-6}	0.0053	0.0397
PbB ≥ 10 µg/dL (%)	2.88×10^{-5}	0.0173	0.439	1.17	4.72×10^{-6}	0.0067	0.257	0.775
IQ < 70 (%)	0.0871	0.0877	0.0902	0.0932	0.0863	0.0868	0.0886	0.0909
IQ decrement ≥ 1 (%)	1.41	5.82	12.5	16.0	0.568	3.50	9.22	12.5
IQ decrement ≥ 2 (%)	0.0011	0.116	1.29	2.69	0.0002	0.0506	0.804	1.87
IQ decrement ≥ 3 (%)	2.40×10^{-6}	0.0047	0.211	0.665	3.38×10^{-7}	0.0017	0.119	0.428
Average IQ decrement (# points)	0.506	0.534	0.587	0.629	0.451	0.476	0.524	0.562

Note: Results in shaded cells were presented in Table 5-4. When background dust-lead concentration is taken to be the multiple source analysis default, the endpoints are estimated assuming a geometric mean of 1.86 µg/dL, and when background dust-lead concentration is taken to be zero, the endpoints are estimated assuming a geometric mean of 1.66 µg/dL (see Table 5-3).

Table 5-16. Sensitivity Analysis on the Soil-Lead Concentrations at Which the Percentage of Children Aged 1-2 Years Having Blood-Lead Concentration at Least 10 µg/dL is Estimated by the IEUBK Model at 1, 5, or 10%, Under Three Assumed Dust-Lead Concentrations and for Alternative Assumptions on the Geometric Standard Deviation (GSD) for the Blood-Lead Distribution.

Floor Dust-Lead Conc. (µg/g)	Soil-Lead Concentration (µg/g)											
	%children with blood-lead conc. ≥ 10 µg/dL = 1%				%children with blood-lead conc. ≥ 10 µg/dL = 5%				%children with blood-lead conc. ≥ 10 µg/dL = 10%			
	GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1	GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1	GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1
100	360	155	na	na	565	365	180	95	700	515	325	240
200	235	35	na	na	440	245	55	na	575	395	205	115
500	na	na	na	na	75	na	na	na	210	25	na	na

Note: Results in shaded cells were presented in Table 5-5. "na" = not achievable.

Table 5-17. Sensitivity Analysis on the Floor Dust-Lead Loadings at Which the Percentage of Children Aged 1-2 Years Having Blood-Lead Concentration at Least 10 µg/dL is Estimated by the Rochester Multimedia Model at 1, 5, or 10%, for Two Assumed Soil-Lead Concentrations and Two assumed Window Sill Dust-Lead Loadings, and for Alternative Assumptions on the Geometric Standard Deviation (GSD) for the Blood-Lead Distribution.

Soil-Lead Conc. (µg/g)	Window Sill Dust-Lead Loading (µg/ft^2)	Floor Dust-Lead Loading (µg/ft^2)											
		%children with blood-lead conc. ≥ 10 µg/dL = 1%				%children with blood-lead conc. ≥ 10 µg/dL = 5%				%children with blood-lead conc. ≥ 10 µg/dL = 10%			
		GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1	GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1	GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1
100	200	5.8	0.05	na	na	190	6.7	0.09	0.01	1200	89	3.2	0.45
	500	1.7	0.02	na	na	56	2.0	0.03	na	360	27	0.95	0.14
400	200	0.53	na	na	na	17	0.61	0.01	na	110	8.1	0.29	0.04
	500	0.16	na	na	na	5.1	0.18	na	na	32	2.4	0.09	0.01

Note: Results in shaded cells were presented in Table 5-6. "na" = not achievable.

Table 5-18. Sensitivity Analysis on the Window Sill Dust-Lead Loadings at Which the Percentage of Children Aged 1-2 Years Having Blood-Lead Concentration at Least 10 µg/dL is Estimated by the Rochester Multimedia Model at 1, 5, or 10%, for Two Assumed Soil-Lead Concentrations and Two Assumed Floor Dust-Lead Loadings, and for Alternative Assumptions on the Geometric Standard Deviation (GSD) for the Blood-Lead Distribution.

Soil-Lead Conc. (µg/g)	Floor Dust-Lead Loading (µg/ft²)	Window Sill Dust-Lead Loading (µg/ft²)											
		%children with blood-lead conc. ≥ 10 µg/dL = 1%				%children with blood-lead conc. ≥ 10 µg/dL = 5%				%children with blood-lead conc. ≥ 10 µg/dL = 10%			
		GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1	GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1	GSD = 1.4	GSD = 1.6	GSD = 1.9	GSD = 2.1
100	25	66	1.9	0.02	na	920	74	2.9	0.43	3700	520	42	9.5
	100	23	0.65	0.01	na	320	26	1.0	0.15	1300	180	15	3.3
400	25	11	0.30	na	na	150	12	0.46	0.07	610	85	6.8	1.6
	100	3.7	0.11	na	na	52	4.2	0.16	0.02	210	30	2.4	0.54

Note: Results in shaded cells were presented in Table 5-7. "na" = not achievable.

5.4.7 Alternative Estimates for Daily Dietary Lead Intake Assumed in Fitting the IEUBK Model

When the IEUBK model was applied in this risk analysis to obtain a geometric mean blood-lead concentration as a function of soil-lead concentration and floor dust-lead concentration, default values were used for parameters that represent lead exposures associated with sources other than soil and dust. In this component of the sensitivity analysis, alternative values for one of these parameters, daily dietary lead intake, are considered. Insufficient information was available to consider alternative values for the other parameters.

The IEUBK model's default value for daily dietary lead intake in children aged 1-2 years is 5.78 µg (Table 4-1). This value was estimated from data collected in the Food and Drug Administration's Market Basket Survey from 1986 (fourth quarter) to 1988 (third quarter), as well as from other sources. This value was used when fitting the IEUBK model to data within the risk analysis. In this sensitivity analysis, two alternative values were considered: 1.29 µg and 3.53 µg. The former value was reported for children aged two years in a more recent Market Basket Survey, and the latter is the average of the former value and the value of 5.78 µg used in the risk analysis. As lead concentrations in food are assumed to decline over time, no alternative value larger than 5.78 µg was considered.

As the results in Tables 5-2 through 5-5 are dependent on the value of the daily diet intake parameter in the IEUBK model, these tables were recalculated under the two alternative values for this parameter.

Effect on risk analysis: Under the two alternative values for the daily diet intake parameter (as well as the default value of 5.78 µg used in the risk analysis), Table 5-19 presents IEUBK model-predicted, pre-§403 health effect and blood-lead concentration endpoints, as well as at dust-lead and soil-lead concentrations representing background conditions. When the daily

Table 5-19. Sensitivity Analysis on the IEUBK Model-Predicted, Pre-§403 Health Effect and Blood-Lead Concentration Endpoints for Children Aged 1-2 Years, Under Two Alternative Values (1.29 µg, 3.53 µg) for the Daily Lead Dietary Intake Parameter and Under the Value Used in the Risk Analysis (5.78 µg).

Health Effect and Blood-Lead Concentration Endpoints	Pre-§403 Predictions			Background Predictions at Soil-Lead Concentration = 20 µg/g					
				Dust-Lead Concentration = Multiple Source Analysis Default			Dust-Lead Concentration = 0 µg/g		
	1.29 µg	3.53 µg	5.78 µg	1.29 µg	3.53 µg	5.78 µg	1.29 µg	3.53 µg	5.78 µg
% with PbB ≥ 20 µg/dL	2.12	2.13	2.24	1.21×10^{-8}	1.08×10^{-6}	2.17×10^{-5}	4.48×10^{-10}	1.65×10^{-7}	5.93×10^{-6}
% with PbB ≥ 10 µg/dL	9.78	11.0	12.4	5.96×10^{-5}	1.87×10^{-3}	0.0173	4.46×10^{-6}	4.47×10^{-4}	0.0067
% with IQ < 70	0.136	0.140	0.146	0.0841	0.0858	0.0877	0.0833	0.0850	0.0868
% with IQ decrement ≥ 1	38.5	44.5	50.4	0.220	1.72	5.82	0.0420	0.749	3.50
% with IQ decrement ≥ 2	15.2	17.4	19.9	7.68×10^{-4}	0.0166	0.116	7.40×10^{-5}	0.0047	0.0506
% with IQ decrement ≥ 3	7.24	7.98	8.95	1.07×10^{-5}	4.25×10^{-4}	0.0047	6.87×10^{-7}	9.19×10^{-5}	0.0017
Average IQ decrement (# points)	1.18	1.29	1.40	0.293	0.413	0.534	0.232	0.356	0.476
Geometric mean blood-lead conc. (µg/dL)	2.95	3.45	3.92	1.02	1.44	1.86	0.81	1.24	1.66

Note: Results in shaded cells were presented in Tables 5-2 through 5-4.

dietary lead intake is equal to 3.53 µg, the geometric mean blood-lead concentrations are from 12 to 25 percent lower than those presented in the risk analysis. The decline is even greater, from 25 to 51 percent, when the daily dietary lead intake is equal to 1.29 µg. Only slight differences are observed in the IEUBK model-predicted pre-§403 endpoints for the three values of daily dietary lead intake. However, the assumed value of the daily dietary lead intake has a larger impact on the estimated endpoints for background environmental-lead exposures. Estimated endpoints at background lead exposures are more sensitive to the assumed value of daily dietary lead intake because dietary lead comprises a larger portion of the total lead exposure at background environmental-lead levels.

The effect of alternative values for daily dietary lead intake on IEUBK model-predicted individual risks (Section 5.3) is investigated in Table 5-20. This table, a companion of Table 5-5, provides estimates of the maximum soil-lead concentration necessary to keep the percentage of children with blood-lead concentrations at or above 10 µg/dL to within specified percentages, assuming a fixed value for floor dust-lead concentration. According to this table, the maximum soil-lead concentration does not differ appreciably when daily dietary lead intake is varied.

Therefore, results of this sensitivity analysis conclude that when soil-lead and dust-lead concentrations are above background levels, the value of daily dietary lead intake has a small effect on the IEUBK model-predicted health effect and blood-lead concentration endpoints.

Table 5-20. Sensitivity Analysis on the Soil-Lead Concentrations at Which the Percentage of Children Aged 1-2 Years Having Blood-Lead Concentration at Least 10 µg/dL is Estimated by the IEUBK Model at 1, 5, or 10%, for Three Assumed Dust-Lead Concentrations and for Alternative Assumptions on Daily Dietary Lead Intake.

Floor Dust-Lead Concentration (µg/g)	Soil-Lead Concentration (µg/g)								
	% children with blood-lead concentration ≥ 10 µg/dL = 1%			% children with blood-lead concentration ≥ 10 µg/dL = 5%			% children with blood-lead concentration ≥ 10 µg/dL = 10%		
	1.29 µg	3.53 µg	5.78 µg	1.29 µg	3.53 µg	5.78 µg	1.29 µg	3.53 µg	5.78 µg
100	280	220	155	490	425	365	635	575	515
200	155	95	35	365	305	245	515	455	395
500	na	na	na	na	na	na	150	85	25

Note: Results in shaded cells were presented in Table 5-5. "na" = not achievable.

5.4.8 Alternative Assumptions on Paint Pica Tendencies in Children and the Effect of Paint Pica on Blood-Lead Concentration

Section 4.1.3 and Appendix D1 present the method used in this risk analysis for obtaining a model-predicted geometric mean blood-lead concentration for those children who have ingested paint chips. The set of assumptions used by this method differs according to which model is being used to predict the geometric mean blood-lead concentration:

Assumptions under the empirical model:

- 9% of children aged 1-2 years have paint pica tendencies
- a value of 1.5 is used for the model's paint pica parameter when predicting the geometric mean blood-lead concentration for children having paint pica tendencies and living in a housing unit with damaged lead-based paint, and a value of zero is used for all other situations

Assumptions under the IEUBK model:

- 9% of children aged 1-2 years have paint pica tendencies
- 0.03% of children aged 1-2 years living in housing units containing damaged lead-based paint have recently ingested paint chips.
- children aged 1-2 years who recently ingested paint chips have a blood-lead concentration of 63 µg/dL.
- children aged 1-2 years who ingested paint chips at some time, but not recently, have a 3 µg/dL increase in their geometric mean blood-lead concentration from children who do not ingest paint chips.

This component of the sensitivity analysis considers how alternatives to these assumptions impact model-predicted, pre-§403 health effect and blood-lead concentration endpoints. As the estimates of individual risks presented in Section 5.3 assume no deteriorated lead-based paint is present, there is no effect of paint pica on these estimates.

As the sets of assumptions for handling paint pica differ between the empirical and IEUBK models, each model is addressed separately within the following two subsections.

5.4.8.1 Empirical Model

When addressing the approach to handling paint pica under the empirical model, the sensitivity analysis considers three alternatives to the assumed percentage of children aged 1-2 years that have paint pica tendencies: 0%, 6%, and 14%. The assumption of 0% is equivalent to making no adjustment for paint pica, while the assumptions of 6% and 14% correspond to the lower and upper limits of an approximate 95% confidence interval on the percentage of children with paint pica tendencies in the Rochester Lead-in-Dust study.

Effect on risk analysis: Table 5-21 presents the empirical model-predicted, pre-§403 health effect and blood-lead concentration endpoints, under the three alternative assumptions on the percentage of children with paint pica tendencies, as well as under the 9% assumption used in the risk analysis. As seen in this table, the differences among the pica percentage assumptions are relatively minor. The largest observed difference was a 14% difference in the probability of observing a child with blood-lead concentration of at least 20 µg/dL between the risk analysis estimate (0.0278%) and the percentage that is estimated when no paint pica tendencies are assumed (0.0239%). All other differences from the risk analysis estimates in Table 5-21 were less than 10%.

Table 5-21. Sensitivity Analysis on the Empirical Model-Predicted, Pre-§403 Health Effect and Blood-Lead Concentration Endpoints for Children Aged 1-2 Years, Under Three Alternative Values (0%, 6%, 14%) for the Percentage of Children with Paint Pica Tendencies, and Under the Value Used in the Risk Analysis (9%).

Health Effect and Blood-Lead Concentration Endpoints	0% of children w/paint pica	6% of children w/paint pica	9% of children w/paint pica	14% of children w/paint pica
PbB ≥ 20 µg/dL (%)	0.0239	0.0265	0.0278	0.0302
PbB ≥ 10 µg/dL (%)	1.43	1.50	1.54	1.60
IQ < 70 (%)	0.0993	0.0996	0.0997	0.100
IQ decrement ≥ 1 (%)	34.0	34.3	34.5	34.7
IQ decrement ≥ 2 (%)	4.30	4.45	4.53	4.66
IQ decrement ≥ 3 (%)	0.657	0.697	0.718	0.752
Average IQ decrement (# points)	0.924	0.929	0.932	0.936

Note: Results in shaded cells were presented in Table 5-2.

5.4.8.2 IEUBK Model

The approach to handling effects of paint pica on geometric mean blood-lead concentrations estimated from the IEUBK model is more complex than that for the empirical model, due to the greater number of assumptions going into the approach. In the sensitivity analysis, three sets of alternative assumptions were considered:

Alternative set #1: Assumes 0% of children have paint pica tendencies. (This is equivalent to making no adjustment for paint pica, so no alternatives need be specified for the other assumptions.)

Alternative set #2: Assumes that paint pica tendencies have less of an impact than that assumed in the risk analysis:

- 6% of children aged 1-2 years have paint pica tendencies (the lower bound of a 95% confidence interval on the percentage as estimated from the Rochester Lead-in-Dust study)
- 0.01% of children aged 1-2 years living in housing units containing damaged lead-based paint have recently ingested paint chips.
- children aged 1-2 years who recently ingested paint chips have a blood-lead concentration of 55 µg/dL (a low estimate based on information from McElvaine et al., 1992).
- children aged 1-2 years who ingested paint chips at some time, but not recently, have a 15% increase in their geometric mean blood-lead concentration from children who do not ingest paint chips (the lower bound of a 95% confidence interval on the percentage in the Rochester Lead-in-Dust study).

Alternative set #3: Assumes that paint pica tendencies have more of an impact than that assumed in the risk analysis:

- 14% of children aged 1-2 years have paint pica tendencies (the upper bound of a 95% confidence interval on the percentage as estimated from the Rochester Lead-in-Dust study)
- 0.10% of children aged 1-2 years living in housing units containing damaged lead-based paint have recently ingested paint chips.
- children aged 1-2 years who recently ingested paint chips have a blood-lead concentration of 63 µg/dL.
- children aged 1-2 years who ingested paint chips at some time, but not recently, have a 100% increase in their geometric mean blood-lead concentration from children who do not ingest paint chips (the upper bound of a 95% confidence interval on the percentage in the Rochester Lead-in-Dust study).

Effect on risk analysis: Table 5-22 presents the IEUBK model-predicted, pre-§403 health effect and blood-lead concentration endpoints, under the three alternative sets of assumptions, as well as under the set of assumptions used in the risk analysis. Results differed only slightly between the approach used in the risk analysis to adjust for paint pica and when no adjustment is made (alternative set #1). The differences in results were larger between the approach used in the risk analysis and when a larger impact of paint pica is assumed (alternative set #3), but remained relatively minor.

Table 5-22. Sensitivity Analysis on the IEUBK Model-Predicted, Pre-§403 Health Effect and Blood-Lead Concentration Endpoints for Children Aged 1-2 Years, Under Three Alternative Sets of Assumptions on Paint Pica Effects, and Under the Set of Assumptions Used in the Risk Analysis.

Health Effect and Blood-Lead Concentration Endpoints	Pica Assumptions in the Risk Analysis	Pica Alternative Set #1 (no adjustment)	Pica Alternative Set #2 (low adjustment)	Pica Alternative Set #3 (high adjustment)
PbB ≥ 20 µg/dL (%)	2.24	2.16	2.18	2.60
PbB ≥ 10 µg/dL (%)	12.4	12.2	12.3	13.3
IQ < 70 (%)	0.146	0.144	0.145	0.151
IQ decrement ≥ 1 (%)	50.4	50.1	50.2	50.9
IQ decrement ≥ 2 (%)	19.9	19.6	19.7	20.9
IQ decrement ≥ 3 (%)	8.95	8.75	8.81	9.73
Average IQ decrement (# points)	1.40	1.39	1.39	1.44

Note: Results in shaded cells were presented in Table 5-2.

5.4.9 Conclusions from Sensitivity Analysis

Several analyses were conducted to assess the sensitivity of the characterization of current risks to the uncertainty in the underlying assumptions and methods utilized in the risk assessment.

- Estimating baseline health effect and blood-lead concentration endpoints for a broader age group.
- Estimating baseline health effect and blood-lead concentration endpoints using three different assumptions on the decline in IQ score associated with a unit increase in blood-lead concentration.
- Estimating baseline health effect and blood-lead concentration endpoints when blood-lead concentrations are assumed to have declined since 1994.

- Estimating baseline health effect and blood-lead concentration endpoints using an empirical approach to characterizing the distribution of blood-lead concentrations from NHANES III data.

- Estimating baseline health effect and blood-lead concentration endpoints using the IEUBK model, under three different approaches to adjusting HUD National Survey dust-lead concentrations to reflect the sample's total weight, under alternative estimates for the geometric standard deviation of the blood-lead concentration distribution, under alternative estimates for a child's daily dietary lead intake, and under different assumptions on the prevalence of paint pica tendencies and their effect on blood-lead concentration.

- Estimating baseline health effect and blood-lead concentration endpoints using the empirical model, under alternative estimates for the geometric standard deviation of the blood-lead concentration distribution and under different assumptions on the prevalence of paint pica tendencies.

It may be concluded from this sensitivity analysis that the risk characterization is sensitive to uncertainty in the relationship between declines in IQ score and increases in blood-lead concentration (Section 5.4.2). The alternative risk characterization (Section 5.1.2) is also sensitive to whether or not the HUD National Survey dust-lead concentration measurements are adjusted to account for tap weights and on assumptions on the geometric standard deviation associated with blood-lead concentration at a given lead exposure level. Failing to make some tap weight adjustment leads to significantly increased risk estimates. Risk estimates were also increased when the geometric standard deviation is increased, or if any decline in blood-lead concentrations since 1994, when NHANES III Phase 2 was completed, was ignored.

The assumption of an 0.257 decrease in IQ score for an increase of one µg/dL in blood-lead concentration has considerable impact on the estimates of numbers of children with specified IQ decrements and average decline in IQ due to lead exposures. However, even if the decline is less severe (0.185 vs. 0.257), approximately 1.45 million children 1-2 years old, and 2.95 million children 1-5 years old suffer IQ decrements greater or equal to than 2 points due to exposures to lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil.

5.5 RISK CHARACTERIZATION CONCLUSIONS

There is essentially no question in the scientific community as to whether or not lead is a hazard. Lead is a neurotoxin causing reductions in IQ scores as well as other neurological problems, including, in extreme cases, illness and death.

One to two year old children are particularly sensitive to lead for two reasons. Their rapidly developing central nervous systems are more readily damaged than the central nervous systems of older age groups. Also, the frequent hand-mouth activity exhibited by 1-2 year olds increases the quantity of environmental lead ingested. Thus, the most sensitive age group is also the most exposed.

In this risk assessment, estimates of internal lead dose are a necessary intermediary step between environmental exposure to and adverse health effects of lead. Blood-lead concentration is the most commonly used measure of internal lead dose or lead body burden and the measure for which the most data are available to make the connection between environmental lead exposure and adverse health effects. In fact, many general adverse health effects resulting from exposure to lead are quantified in this risk assessment by the incidences of children with blood-lead concentrations above certain values.

Quantification of the health hazard due to childhood lead exposure is a difficult problem. There are many diverse adverse health effects that have been associated with lead exposure. In this risk assessment, risks are quantified by estimating incidences of seven health effect and blood-lead concentration endpoints among 1-2 year old children in 1997. The selected health effect and blood-lead concentration endpoints are

- Incidence of blood-lead concentration greater than or equal to 10 µg/dL
- Incidence of blood-lead concentration greater than or equal to 20 µg/dL
- Incidence of IQ decrement greater than or equal to 1 resulting from lead exposure
- Incidence of IQ decrement greater than or equal to 2 resulting from lead exposure
- Incidence of IQ decrement greater than or equal to 3 resulting from lead exposure
- Average IQ decrement resulting from lead exposure
- Incidence of IQ less than 70 resulting from lead exposure.

The blood-lead concentration endpoints, while not health effects, serve as surrogates for a number of other adverse health effects.

There are several sources of lead in the environment, including lead-based paint, lead plumbing, lead solder, lead glazes, industrial emissions, and auto emissions (before lead was banned as a gasoline additive). These sources have resulted in exposure to lead in multiple media (e.g., dust, soil, paint, food, water) to which children are exposed.

The HUD National Survey provides the most comprehensive, nationally representative data on lead in residential dust, soil, and paint. According to this survey,

- 8.9% of the nation's housing contain floor dust-lead loadings greater than 100 µg/ft^2,
- 12.8% have soil-lead concentrations greater than 400 µg/g, and
- 13.6% contain more than 5 ft^2 of damaged lead-based paint.

Data from Phase 2 of NHANES III (conducted from 1991-1994) provide the most comprehensive and current nationally representative data on children's blood-lead concentrations. These data indicate that many children continue to have elevated blood-lead concentrations. Specifically, 5.75% of the nation's 1-2 year old children are estimated to have blood-lead concentrations greater than or equal to 10 µg/dL. Estimates for certain subgroups (e.g., low-income and inner-city children) are more alarming. NHANES III and HUD National Survey data are consistent in suggesting that some subgroups are disproportionately exposed to lead, i.e., both

environmental- and blood-lead measurements are above average for some subpopulations, including low-income and inner-city children.

Nationally representative data are not available for relating the health effect and blood-lead concentration endpoints directly to environmental lead levels. Therefore, an alternative risk characterization was performed to predict blood lead distribution as a function of environmental exposure measures collected in the HUD National Survey, using both the IEUBK and empirical models. The alternative risk characterization based on the IEUBK model and the HUD National Survey data produced higher risk estimates than did the baseline risk characterization, while the alternative risk characterization based on the empirical model produced lower risk estimates. All methods of characterizing risks indicate substantial numbers of children suffer adverse health effects. For example, the baseline risk characterization indicates that 39% of children aged 1-2 years (3,060,000) will experience at least a 1 point IQ decrement as a result of lead exposure, while 3.7% (294,000) will experience a 3 point decrement.

Using NHANES III data, the IEUBK model, and estimated national background soil-lead concentration, estimates of the maximum possible reduction in childhood blood-lead concentrations and adverse health effects were produced. These estimates suggest that if the contributions of lead-based paint and all other anthropogenic sources contributing to lead in dust and soil could be removed from total lead exposure, the geometric mean 1-2 year old blood-lead concentration would be reduced by approximately 40-45%. This reduction is considered an estimate of the maximum reduction that promulgation of the §403 rule could achieve. It is expected that this maximum cannot be achieved, as levels of lead in all dust and soil will not be reduced to background levels.

In Section 5.3, risks to children exposed to specific levels of environmental lead were characterized, with particular attention paid to determining levels of lead in dust and soil which would independently be protective of children. The IEUBK and Rochester multimedia models were both used for this characterization. If floor dust-lead concentration is equal to 100 µg/g, the IEUBK model predicts that a soil-lead concentration of 370 µg/g will control the probability of a 1-2 year old child having a blood-lead concentration greater than or equal to 10 µg/dL (risk) to be 5%.

Using the Rochester multimedia model, floor (window sill) dust-lead loadings which control the percentage of children having blood-lead concentration at or above 10 µg/dL to 5% can be predicted when soil-lead concentration and window sill (floor) dust-lead loading are equal to 400 µg/g and 200 µg/ft² (25 µg/ft²), respectively. This analysis resulted in a dust-lead loading of 0.6 µg/ft² for floors (12 µg/ft² for window sills).

Sensitivity analyses were performed to gauge the robustness of the methodology employed for characterizing population-based risk. These included

- Estimating baseline health effect and blood-lead concentration endpoints for a broader age group.

- Estimating baseline health effect and blood-lead concentration endpoints using three different assumptions on the decline in IQ score associated with a unit increase in blood-lead concentration.

- Estimating baseline health effect and blood-lead concentration endpoints when blood-lead concentrations are assumed to have declined since 1994.

- Estimating baseline health effect and blood-lead concentration endpoints using an empirical approach to characterizing the distribution of blood-lead concentrations from NHANES III data.

- Estimating baseline health effect and blood-lead concentration endpoints using the IEUBK model, under three different approaches to adjusting HUD National Survey dust-lead concentrations to reflect the sample's total weight, under alternative estimates for the geometric standard deviation of the blood-lead concentration distribution, under alternative estimates for a child's daily dietary lead intake, and under different assumptions on the prevalence of paint pica tendencies and their effect on blood-lead concentration.

- Estimating baseline health effect and blood-lead concentration endpoints using the empirical model, under alternative estimates for the geometric standard deviation of the blood-lead concentration distribution and under different assumptions on the prevalence of paint pica tendencies.

The risk characterization is most sensitive to assumptions about the relationship between blood-lead concentration and IQ score decrements. The alternative risk characterization (Section 5.1.2) was significantly impacted by the decision to perform a tap weight adjustment to the HUD National Survey dust samples, but much less impacted by the particular adjustment made when a range of reasonable adjustments were considered. The alternative risk characterization was also significantly impacted by assumptions on the geometric standard deviation associated with blood-lead concentrations for a given lead exposure scenario, i.e., by the GSD used to represent inter-individual variability in blood-lead concentrations.

Sensitivity analyses were also performed to gauge the robustness of the individual risk methodology and the methodology to predict risks at background exposure levels. In particular, the impact on individual risks of considering children 0-5 rather than 1-2 years of age was examined and determined not to significantly impact conclusions. The impact of varying the GSD assumed to characterize inter-individual variability on both individual risks and risks predicted at background exposure levels was also considered and determined to be very significant. A sensitivity analysis varying the dietary lead intake parameter of the IEUBK model confirmed that while individual risk conclusions were not sensitive to this parameter, estimates of risk at background levels of lead exposure were. This conclusion is highly intuitive as dietary lead plays a much larger role at background environmental-lead exposures.

In summary all methods employed in this risk assessment indicate significant risk to children from exposure to lead and significant evidence that those risks are related to levels of lead in paint, dust and soil in the residential environment.