## 1.0 INTRODUCTION


***CHAPTER 1 SUMMARY***

*This introductory chapter provides the background, objectives, and overview, which includes a description of the organization and general approach of this report. §403 of the Toxic Substances Control Act, as created by Title X, requires EPA to define standards for lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil. This report*

- *documents the scientific basis for regulations called for under §403. Hereinafter, regulations under §403 are referred to by the term §403.*
- *characterizes the health risks to young children from exposures to lead*
- *presents the methodology developed by EPA to estimate the reduction in risk expected to result from promulgation of the §403 standards*
- *applies the methodology to estimate the reductions in childhood health risks and blood-lead concentrations expected to result from example options for the §403 standards*
- *estimates the percentages and numbers of children and housing units affected by example options for the §403 standards.*

*This information is provided to help the risk managers evaluate and compare various regulatory options for §403.*


Title X of the Housing and Community Development Act, known as the Residential Lead-Based Paint Hazard Reduction Act of 1992, contains legislation designed to evaluate and reduce exposures to lead in paint, dust, and soil in the nation's housing. This act provides the framework for developing a national strategy for reducing and preventing lead exposures to children. Consistent implementation of this strategy by federal, state, local and private agencies requires a uniform definition of lead hazards. Title X includes a provision that requires the U.S. Environmental Protection Agency (EPA) to define standards for lead in paint, dust, and soil. More specifically, §403 of the Toxic Substances Control Act (TSCA) is a part of Title IV, "Lead Exposure Reduction," and was added to TSCA by Title X. Section 403 requires EPA to "promulgate regulations which shall identify, for purposes of this title and the Residential Lead-Based Paint Hazard Reduction Act of 1992, lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil."

The §403 regulations will set standards (condition and location of lead-based paint, levels of lead in dust and soil) against which to compare a residential environment when evaluating the presence and magnitude of lead-based paint hazards. Federal, state, and local public health agencies, as well as private property owners and other private sector interests, will use these standards to determine in which homes actions should be taken to reduce or prevent the threat of childhood lead poisoning. Blood-lead concentration is a commonly used indicator of exposure to lead and of childhood lead poisoning. Following the conduct of actions taken in response to the §403 standards, average blood-lead concentrations and collective health risks associated with childhood lead poisoning will be reduced for children currently residing in the residence as well as for those that may later live in the residence. Proper selection of the standards requires both an understanding of the health risks associated with residential exposures to lead, the amount by which these risks can be reduced through intervention strategies, and the numbers of homes and children affected by the standards.

The purpose of this report is to document the scientific basis for the proposed §403 standards. First, the report summarizes EPA's assessment of the health risks to young children from exposures to lead-based paint hazards, lead-contaminated dust, and lead-contaminated soil in the nation's housing. Seven health effect and blood-lead concentration endpoints associated with lead exposures are characterized for children aged 12 to 35 months (cited as aged 1-2 years in this report). While health risks associated with lead exposures are significant for all young children, health risks to children aged 1-2 years are utilized in this risk analysis because it was found (Section 2.4) that the neurotoxicological effects of lead exposure may be best measured for this age group and that the neurotoxicological effects of lead exposure at this age may be irreversible. Second, the report documents the approach developed by EPA to estimate the reductions in these risks following promulgation of the §403 standards, and applies this methodology to evaluate example options for the §403 standards. The benefits of each example option for §403 are expressed in terms of the reduction in health risks attained from actions taken in response to promulgation of the §403 standards. Finally, the report provides estimates of the numbers of homes and children that will be affected by various example standards.

Information presented in this risk analysis will ultimately be used to consider various standards for rulemaking and as input to the Regulatory Impacts Analysis (RIA) for the proposed rule, as well as any interim economic cost-benefit analyses. While the risk analysis provides quantitative estimates of the impact of §403 in terms of health and blood-lead concentration endpoints and documents the scientific basis for these estimates, the RIA and other economic analyses express the impact of the §403 standards in terms of costs: monetary costs of implementing the regulation, monetary benefits associated with reductions in health risks and blood-lead concentrations for various options for the regulation, and the estimated economic impacts of the regulations. The RIA also examines the likelihood of interventions actually taking place. Finally, the RIA summarizes other regulatory actions designed to reduce risks from lead, and presents environmental equity analyses for adults and children.

This report documents the critical decisions on risk-assessment-related tools and data that are being relied upon in the RIA analyses and the actual rulemaking, which relate environmental levels of lead to children's health effect and blood-lead concentration endpoints. This report includes a description of the data used, an assessment of the strengths and weaknesses of that data, and discussions of any additional uncertainties which result from using these particular data sets and tools to create estimates of risk reduction on a national basis. Section 1.1 provides background on the §403 regulations. Statutory/policy constraints of the proposed rule are discussed in Section 1.2. Objectives are presented in Section 1.3 and an overview of the report is given in Section 1.4.

## 1.1 BACKGROUND

On October 29, 1992, the Residential Lead-Based Paint Hazard Reduction Act of 1992 (42 U.S.C. 4851) was signed into law. Subtitle B of Title X amends TSCA, by adding Title IV, "Lead Exposure Reduction." Title IV requires EPA to take certain actions to address lead-based paint concerns, including establishing requirements for training and accreditation of contractors conducting lead paint-related work. Section 403 of TSCA (15 U.S.C. 2683) states:

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

This statute requires EPA to establish criteria for identifying lead-based paint hazards, including lead-contaminated household dust and lead-contaminated residential soil. The statute defines lead-based paint to be dried paint film with a lead content exceeding 1.0 mg of lead per square cm of surface area ($mg/cm^2$) or 0.5 percent (5,000 parts per million (ppm)) by weight[1]. The §403 statute requires EPA to identify the condition and location of lead-based paint that causes exposures to lead in paint, lead-contaminated dust and lead-contaminated soil that would result in unacceptable health risks. The definitions of lead-based paint hazard, lead-contaminated dust and lead-contaminated soil provided in Title X refer to human health effects and human health hazards. A glossary of terms defined in the statute and used in this risk analysis is provided in Appendix A.

Congress concluded in Title X that exposure to deteriorated lead-based paint, lead in dust and lead in soil comprises a serious health problem for American children. Congress further stated that lead exposures to children, even at low levels, may result in intelligence quotient (IQ) deficiencies, reading and learning disabilities, impaired hearing, reduced attention span, hyperactivity, and behavior problems. Actions taken to reduce childhood exposures that are conducted in response to the proposed §403 standards are expected to reduce the incidence of these adverse health effects in young children. Title X states that the adverse health events associated with childhood exposure to lead-based paint hazards can be reduced by abating lead-based paint or by taking interim measures to prevent paint deterioration and limit children's exposure to lead dust and paint chips.

---

[1] The statute defines lead-based paint to be dried paint film with a lead content exceeding 1.0 $mg/cm^2$. However, other EPA and Federal programs (§1018, HUD Guidelines) have defined lead-based paint to be paint with a lead content greater than or equal to 1.0 $mg/cm^2$. To be consistent with other programs, lead-based paint is defined as paint with lead content greater than or equal to 1.0 $mg/cm^2$ in this risk analysis.

## 1.2 STATUTORY/POLICY CONSTRAINTS

During the development of this risk analysis methodology, there were a number of constraints that were imposed for statutory and programmatic reasons. Six of these were especially significant.

First, the §403 statute defines lead-based paint to be any painted surface that contains more than 1.0 mg of lead per $cm^2$ of surface area or 0.5% by weight. Consequently, there are likely to be residences with deteriorated paint that contributes to lead exposure but, according to the above definition, do not contain "lead-based paint." Unless these residences contain dust or soil lead at levels defined as hazardous under the §403 regulations, they would be outside the scope of the Title X program.

Second, by statutory definition, intact lead-based paint is not considered a hazard unless it is present on accessible, friction, or impact surfaces. Intact lead-based paint is lead-based paint that is not deteriorating, chipping, or peeling. The rubbing and scraping of lead-based paint on friction and impact surfaces may cause fine particles of lead to contaminate residential dust. Accessible surfaces are those that are accessible for chewing or mouthing by young children. Under §403 of TSCA, the Agency is required to identify any condition and location of lead-based paint that would result in adverse human health effects. Condition refers to the extent to which the painted surface is deteriorated. For deteriorated lead-based paint, there is an increased potential for both the direct ingestion of paint chips containing lead and for the contamination of the residential dust. This risk analysis uses the amount of deteriorated lead-based paint (in square feet) to estimate the effects of lead-based paint on human health. Data linking lead-based paint on friction or impact surfaces to lead in dust were limited. In addition, the effects of lead on friction, impact, and accessible surfaces on childhood blood-lead concentrations are not well quantified. Therefore, for the purpose of this report only, despite its eligibility, intact lead-based paint is not evaluated as a potential hazard, even on friction, accessible or impact surfaces. The agency has not excluded intact lead-based paint on these surfaces from the options for the proposed §403 rule.

Third, there are two methods for measuring the amount of lead in household dust: loading and concentration. Dust-lead loading measures the mass of lead collected per surface area sampled and is usually expressed in terms of micrograms of lead collected per square foot sampled (µg Pb/$ft^2$). Dust-lead concentration measures the mass of lead collected per mass of dust collected and is usually stated in terms of micrograms of lead collected per gram of dust collected (µg Pb/g dust). Both are commonly used for evaluating exposures to lead in dust. Dust-lead loading measures the amount of lead present on the sampled surface, while dust-lead concentration measures the amount of lead in a given amount of dust. A high dust-lead loading might represent a surface containing a large amount of dust at a low lead concentration or a surface containing a small amount of dust at a high lead concentration. Both measures have been used to predict blood-lead concentrations and there is currently no consensus on which measure may be the better predictor. Ideally, EPA would use both loading and concentration data to characterize hazards and to identify appropriate response actions. The Agency recognizes that setting standards based on both measures might impede implementation of hazard evaluation on a large scale (i.e., in the nation's housing). For policy reasons, it was determined that dust-lead levels would be characterized by a dust-lead loading[2].

There are two limitations to this decision. First, residences with high dust-lead concentrations and low dust-lead loadings will not be identified as exceeding the §403 dust-lead loading standard. The second limitation involves the temporal nature of residential dust. Samples for analysis of both dust-lead loading and dust-lead concentration are routinely collected as grab samples during a scheduled visit to the residence. This means there is no control and no uniformity over the length of time the surface has accumulated dust since the previous thorough cleaning. Dust-lead concentration is assumed to be independent of this period of accumulation, but dust-lead loading is highly dependent, as a long accumulation of dust with a low lead concentration might give the same result as a short accumulation of dust with a high lead concentration. (Although the §403 rulemaking will express the dust standard in terms of a dust-lead loading, dust-lead concentration is employed as an intermediate step in the analysis when using EPA's Integrated Exposure Uptake Biokinetic (IEUBK) model, as this model requires dust-lead concentration.)

<u>Fourth, there are two approaches for collecting samples of dust from a surface: wipe and vacuum sampling. Although dust-lead loading can be measured using both wipe or vacuum sampling, dust-lead concentration can be measured only via vacuum sampling.</u> The interim standards for dust lead in the Interim 403 Guidance Document (USEPA, 1995f) were defined in terms of lead loading. That decision was based, in part, on the wider availability and familiarity of wipe sampling compared to vacuum sampling. Currently, wipe sampling is the method most risk assessors use and few are skilled in vacuum sampling. Therefore, the Agency made a policy decision to define the §403 dust standards in terms of a dust sample collected via wipe sampling.

<u>Fifth, the Agency had to determine for which surfaces it would propose standards for lead in household dust.</u> Dust can accumulate on multiple surfaces in the home: floors, furniture, window sills, and window troughs. Elevated levels of lead in dust accumulated on the window sill may not represent the same degree of health concern as do elevated levels of lead in floor dust. To date, federal, state, and local public health agencies have primarily tested for the presence of lead in dust on three horizontal surfaces: uncarpeted floors, interior window sills, and window troughs. The Interim 403 Guidance Document (USEPA, 1995f) provided standards for lead in dust on floors, window sills, and window troughs.

Technical analysis conducted to support the risk analysis indicated that dust on floors, sills, and troughs are highly correlated. Several studies have observed that the correlation between childhood blood-lead concentration and <u>floor</u> dust-lead loading is stronger than the correlations with either dust-lead loading on sills or on troughs. Such a difference is not always statistically significant nor is it always observed. Three recent studies (Lanphear, 1995; USEPA 1996a; USEPA, 1996b) report comparable correlations between blood-lead concentration and

[2] This applies to interior dust exclusively. The soil standard will be expressed solely as a concentration standard, i.e., µg Pb/g soil.

dust-lead levels (loadings and concentrations) on floors, sills, and troughs. The conventional wisdom, as reflected in the scientific literature, suggests that floor dust-lead levels are the dust lead measure most relevant to childhood lead exposure due to the larger amount of time children spend in contact with floors compared to window sills and troughs. While the same dust can settle on window sills and accumulate in window troughs, the exposure pathway (hand-to-mouth behavior) is thought to primarily occur on the residential floor.

Collecting dust samples from both sills and troughs does not improve a risk assessor's ability to characterize risk sufficiently to justify the sampling and analysis of both surfaces. Because sills are easier to sample than troughs, the Agency has decided to estimate the risk and risk reductions expected to result for various example options for the §403 dust standards for floors and window sills but not for window troughs. However, the Agency recommends that once dust-lead levels are identified to represent a hazard in a home, that appropriate action be taken to reduce dust-lead levels on floors, window sills, window troughs and other surfaces in the home.

<u>Sixth, the regulations on lead levels in soil, as promulgated under §403, apply only to "bare soil." At the time of the development of the risk analysis methodology, "bare soil" had not yet been precisely defined.</u> Currently, the application of the risk analysis methodology presented in this document presumes that the standards for lead in soil apply to all residences that exceed the standard (a soil-lead concentration), without consideration as to whether the soil is "bare." Consequently, the numbers of homes identified in this report as exceeding example options for the §403 soil standard will tend to be overestimated if the standard is defined in terms of bare soil since some of the homes in the analyzed datasets may not contain bare soil. It should also be noted that little or no data are available on the national prevalence of "bare soil," regardless of how that term is ultimately defined in the §403 rulemaking.

## 1.3 OBJECTIVES

Although the standards defined by this rule will not require the conduct of any lead exposure reduction activities, EPA recognizes that they will be used by federal, state, local, and private entities in their efforts to manage the hazards of lead in paint, dust, and soil. Therefore, the objectives of this risk analysis are described below.

### Risk Assessment Objectives

1. Document the scientific basis for the proposed §403 standards.

   This report assesses the risks of childhood exposure to lead in paint, dust and soil. Each component of the risk assessment is documented in this report: hazard identification, exposure assessment, and dose-response assessment. These individual characterizations are integrated to assess the risks of lead exposures to children aged 1-2 years and the reductions in these risks expected to take place as a result of the §403 standards.

2. Characterize the health risks to young children from specific residential exposures to lead.

   This document estimates risks to young children from specific residential sources of lead. These sources are: (1) interior and exterior lead-based paint; (2) lead-contaminated dust, which may contain lead derived from deteriorated interior paint, tracked- or blown-in exterior soil, and other sources and (3) lead-contaminated soil, which may contain lead from deteriorated paint, from past leaded-gasoline vehicle emissions, or from other sources.

   This risk assessment focuses on risks to children aged 1-2 years. Other populations also certainly face risks from lead exposure, including children of other ages, pregnant women, and the general adult population. Characterization of risks and risk reduction for 1-2 year old children was chosen as being representative of total risk and risk reduction. Also, the discussion in Section 2.4 provides evidence that this subgroup of children is among those most appropriate for estimation of the endpoints considered in this risk assessment.

**Risk Management Objectives**

1. Develop methodology to estimate the reduction in risk expected to result from promulgation of the §403 standards.

   This report presents the approach developed by the Agency to characterize the incremental risk reduction expected to result after interventions (actions taken to reduce residential lead exposures) are conducted in response to the §403 standards. Because the §403 rule does not mandate action be taken at any lead levels measured in a residential environment, it was not possible to analyze the risk reductions associated with specific interventions required by the regulation. Instead, the Agency's approach is to characterize the risk reduction consequences that might occur if broadly defined interventions are undertaken to reduce exposures to lead in dust, soil, and paint. Intervention activities considered in this report are: cleaning of house dust, maintenance of interior or exterior paint, encapsulation/abatement of interior or exterior paint, and soil removal.

2. Apply the methodology to characterize the reduction in risk expected to result from implementation of the §403 rule for a broad range of example standards.

   This report implements the risk management methodology to explore the implications of various example options for the §403 standards. The example standards examined in this report are not meant to encompass all possible options for the §403 standards.

3. Estimate the numbers of children and housing units directly impacted by example options for the §403 standards.

> This report estimates numbers of children and numbers of homes in the nation's housing stock that would be affected by the rulemaking for a broad range of example standards. The time frame of the risk analysis is 1997, with the assumption that all actions resulting from the §403 rule occur within that time frame.

Note that the objectives of this report do not include the selection of the §403 standards. Standard selection is a policy decision to be made by the Agency. The purpose of this report is to provide relevant information on the scientific basis for setting the standards and the comparative risk reductions that are expected to result for various example options for the §403 standards.

## 1.4 OVERVIEW OF REPORT

### 1.4.1 Organization of Report

This report serves to answer two questions:

! What are the health risks to young children from exposures to lead in paint, dust, and soil?

! What are the expected reductions in the health risks as a result of actions conducted in response to the proposed §403 standards?

To answer these two questions, the report is divided into two parts: Risk Assessment and Risk Management. The first part, Risk Assessment, contains four chapters, and the second part, Risk Management, includes one chapter. This section provides an overview of the organization of the report.

**Risk Assessment**

Results of the hazard identification are provided in Chapter 2. The information provided in Chapter 2 summarizes the existing knowledge, as documented in the literature, on the health effects of lead exposures. Additional research on the toxicity and hazards of lead was not conducted. For a more comprehensive assessment of lead toxicity, the reader is referred to the evaluations conducted by EPA (USEPA, 1986) and the Agency for Toxic Substances and Disease Registry (ATSDR) (ATSDR, 1993) and to other literature. Children aged 12 to 35 months (cited as aged 1-2 years in this report) are selected as the reference group for assessing risks in Section 2.4. Health effects associated with deficits in IQ scores due to lead exposures and incidence of blood-lead concentration exceeding two thresholds used by the Centers for Disease Control and Prevention (CDC) are selected in Section 2.5 as the endpoints for characterizing the risks associated with lead exposures in this report.

Both environmental levels of lead and childhood blood-lead concentration are used in Chapter 3 to assess lead exposures. Pathways and sources of environmental lead exposure are summarized in Section 3.1. The rather extensive evidence on the relationship between childhood blood-lead concentration and environmental-lead levels is summarized in Section 3.2. The distribution of lead in residential dust, soil, and paint in the nation's housing is estimated in Section 3.3 based on data collected in the Department of Housing and Urban Development's National Survey of Lead-Based Paint in Housing (HUD National Survey) (USEPA, 1995a; USEPA, 1995g; and USEPA, 1995h). The distribution of blood-lead concentration for children aged 1-2 years based on the data reported in Phase 2 of the third National Health and Nutrition Examination Survey (NHANES III) (CDC, 1997) is presented in Section 3.4.

The methods used to characterize the dose-response relationships between environmental lead exposures and the selected health effect and blood-lead concentration endpoints are presented in Chapter 4. Two different types of models are presented in Chapter 4 for predicting blood-lead concentrations from measures of environmental lead: EPA's IEUBK model and an empirical model developed for this study. Because EPA's approach is to define the dust-lead standard in terms of a wipe dust-lead loading and because dust samples in the HUD National Survey were collected via vacuum sampling, Section 4.3 presents equations for converting a dust-lead loading collected via a vacuum sampler to a wipe equivalent dust-lead loading for purposes of this risk analysis. Finally, methods for computing the health effect and blood-lead concentration endpoints evaluated in this report are detailed in Section 4.4.

Chapter 5 integrates the characterizations from the hazard identification, exposure assessment, and the dose-response assessment to characterize health risks to children aged 1-2 years from exposures to lead in paint, dust, and soil. Health risks are predicted for the nation's children aged 1-2 years in 1997 before any actions (pre-§403) are taken in response to the proposed §403 standards (Section 5.1), for children exposed to background levels of lead (Section 5.2), and for individual children exposed to specific levels of environmental lead (Section 5.3). The risk characterization is provided in Section 5.5.

## Risk Management

Implications of example options for the §403 standards are explored in the second part of the report: Risk Management. Chapter 6, Analysis of Example Options for the §403 Standards, presents the methodology developed by the Agency to characterize the incremental risk reductions expected to result from interventions conducted in response to various §403 example standards. The primary purpose of the risk management analyses is to document and illustrate implementation of the approach developed for making relative comparisons among example options for the §403 standards. To predict the distribution of environmental-lead levels that would result from actions conducted in response to the §403 standards, the Agency identified a limited set of intervention activities that are assumed to occur at housing units identified as exceeding one or more of the standards (Section 6.1). The methodology utilized to predict health effect and blood-lead concentration endpoints for children aged 1-2 years associated with distributions of environmental-lead levels expected to take place following implementation of the §403 standards is described in Section 6.2. Results of implementing these methods for example options for the §403 standards are found in Section 6.3.

### 1.4.2 General Approach

Figure 1-1 provides an overview of the risk analysis conducted for the §403 regulation. Hazard identification, exposure assessment, and dose-response assessment provide necessary information to characterize the risks associated with childhood lead exposures. The general approach for these sections are summarized in Section 1.4.2.1. The general approach employed in the Risk Management portion of the report is presented in Section 1.4.2.2.

A scientific assessment of lead exposures on childhood health effects and blood-lead concentrations is a very complex problem. The relationship between lead exposures and health effects possesses both temporal and spatial sources of variation. The Agency is not aware of any modeling tools or data sets that contain all of the information or variables required to estimate the risk associated with lead exposures and the risk reductions expected to result from promulgation of the rule. Therefore, it was necessary to link together multiple models and combine information from multiple data sources in the risk analysis. The Agency acknowledges that there is substantial uncertainty in the estimated risks associated with exposure to lead and in the estimated risk reductions due the uncertainty in the modeling tools, the assumptions underlying linking together various modeling tools, the variability in the measured data, and use of multiple sources of data collected under different conditions using different techniques and procedures.

#### 1.4.2.1 <u>Approach for Risk Assessment</u>

**Hazard Identification**

Figure 2-1 in Chapter 2 presents the approach used for hazard identification. As with most assessments of adverse health effects attributable to environmental exposures to lead, the level of blood-lead concentration is used as the index of exposure. While the health risk associated with lead exposure is significant for all young children, the population of interest selected for this risk analysis was U.S. children aged 1-2 years because, as found in Section 2.4, this subgroup of children is among those most appropriate for estimation of the endpoints considered in this risk assessment. Two types of endpoints are utilized to characterize the adverse health effects in this risk analysis: elevated blood-lead concentration and IQ point deficit. The following seven health effect and blood-lead concentration endpoints are used to characterize the risks associated with lead exposures in children aged 1-2 years:

- The incidence of blood-lead concentration greater than or equal to 10 µg/dL
- The incidence of blood-lead concentration greater than or equal to 20 µg/dL
- The incidence of IQ score less than 70 due to childhood lead exposure
- The likelihood of an IQ score decline greater than 1 point due to childhood lead exposure
- The likelihood of an IQ score decline greater than 2 points due to childhood lead exposure

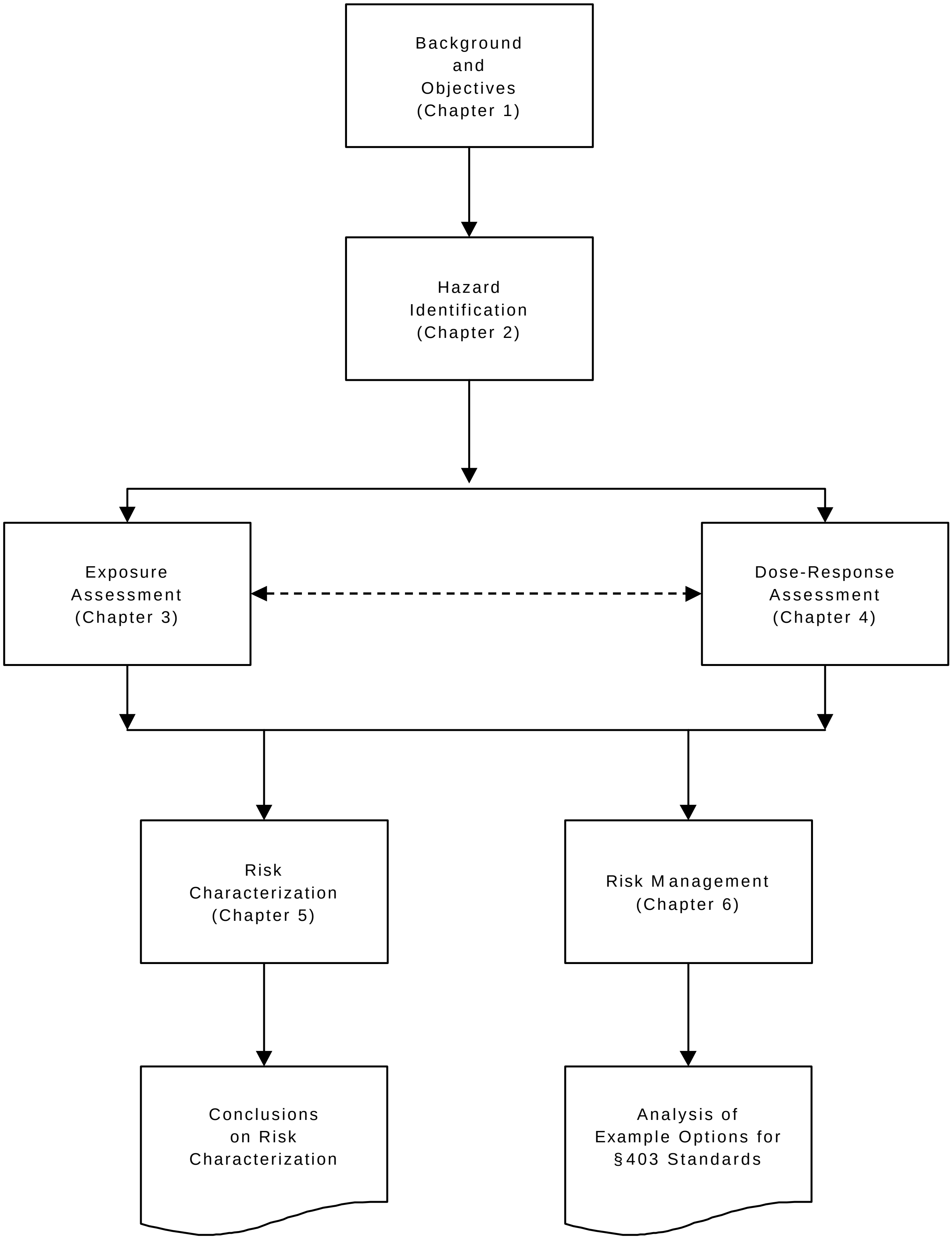


**Figure 1-1. Overview of the Risk Assessment and Risk Management Approach.**

- ! The likelihood of an IQ score decline greater than 3 points due to childhood lead exposure

- ! Average IQ score decline in a child as a result of childhood lead exposure.

### Exposure Assessment

Figure 3-1 in Chapter 3 displays the approach utilized for exposure assessment. Both environmental levels of lead and childhood blood-lead concentrations are employed to characterize exposures to lead. Recognized as the leading source of data on environmental-lead levels in residential environments, the National Survey of Lead-Based Paint in Housing, conducted from 1989-1990 by the U.S. Department of Housing and Urban Development, was the primary source of data on baseline environmental-lead levels in dust and soil in the nation's housing stock. The design and findings of the HUD National Survey have been peer reviewed and published in several government reports. However, there are limitations associated with using the HUD National Survey data in this risk analysis, including limited numbers of environmental samples taken at each housing unit, the sampling of only 284 houses (which were all built prior to 1980), the age of the study, and use of a dust collection device other than the wipe collection method being adopted by the §403 rules. These limitations contribute to overall uncertainty in the analysis results.

The national distribution of baseline blood-lead concentrations in children aged 1-2 years was determined from data collected in phase 2 of the third National Health and Nutrition Examination Survey (NHANES III), conducted from 1991-1994. While the national representation of NHANES III results is widely accepted, some possible limitations in using these data include ignoring any seasonality effects on blood-lead concentrations and any further decline in concentrations that may have occurred since 1994.

Data from the Baltimore Repair and Maintenance Study and the Rochester Lead-in-Dust Study are employed to supplement the national data on environmental-lead levels and childhood blood-lead concentrations with data for inner-city homes and for older homes in an urban setting, respectively.

### Dose-Response Assessment

Figure 4-1 in Chapter 4 describes the approach taken for dose-response assessment. The relationship between environmental-lead levels and the health effect and blood-lead concentration endpoints are estimated in two steps because there is little scientific data for estimating the relationship directly. First, blood-lead concentrations are estimated based on environmental-lead levels, and then health effect and blood-lead concentration endpoints are computed from the predicted blood-lead concentrations. The two-step dose-response relationship was necessary because the majority of the scientific evidence on the relationship between lead exposure and IQ point deficits are stated in terms of blood-lead concentrations.

The Agency used two different tools for linking environmental- and blood-lead levels, because no single tool is considered optimal for the risk analysis. The first tool is the Agency's Integrated Exposure Uptake Biokinetic (IEUBK) model, a "biokinetic"-type model of lead exposure. The IEUBK model employs exposure, uptake, and biokinetic information to predict a distribution of blood-lead concentrations for children corresponding to a specific combination of environmental-lead levels. Actually, the model predicts the center of this distribution, the geometric mean. Because blood-lead concentrations tend to have a skewed distribution, the geometric mean, rather than the arithmetic mean, is used to represent the center of the distribution. A measure of variability and the predicted geometric mean are then used to estimate the distribution of blood-lead concentrations associated with a specific combination of environmental-lead levels. The variability estimate, referred to as the geometric standard deviation (GSD), represents the variability in blood lead concentrations for a given set of environmental exposures due to biological and behavioral variability in the exposed children.

The IEUBK model was initially developed in 1985 by EPA's Office of Air Quality Planning and Standards (OAQPS) as a tool for setting air lead standards. The version used by the Air program was peer reviewed and found acceptable by EPA's Clean Air Science Advisory Committee of the Science Advisory Board (USEPA, 1990b). The IEUBK model, unfortunately, has several limitations for use in the Agency's risk analysis. Specifically, the IEUBK model

1. does not incorporate dust-lead loading on residential surfaces;

2. does not incorporate dust lead exposure from residential window sills;

3. does not directly incorporate a child's tendency to pica behavior (an add-on adjustment for pica, separate from the model's prediction of blood-lead concentration, was necessary).

In addition, the IEUBK model's default parameters are meant to be adjusted for site-specific applications. There are no parameters values available for use in a nationally representative analysis such as this. A second tool, therefore, was developed that addressed each of these limitations.

The second tool is an "empirical" model developed specifically for use in this risk analysis based on data collected in the Rochester Lead-in-Dust Study. The empirical model relates environmental-lead levels observed at a residence to the blood-lead concentration measured for a child living at the residence. For a given set of environmental-lead levels, the model can be used to predict a geometric mean blood-lead concentration for children exposed to the given lead levels. This result, along with a specified value of the GSD, is then applied to estimate the distribution of predicted blood-lead concentrations.

The empirical regression model was developed using data from the Rochester Lead-in-Dust Study, collected in the summer of 1993 to estimate the relationship between blood-lead concentrations in young children and observed levels of lead in environmental media (paint, dust and soil) from their primary residences. The empirical model estimates the average log-transformed childhood blood-lead concentration associated with each studied home. The variables used for prediction are soil-lead concentration, Blue Nozzle vacuum dust-lead loading on floors (carpeted and uncarpeted), Blue Nozzle vacuum dust-lead loading on window sills, and an indicator of paint/pica hazard. (The Blue Nozzle vacuum is the vacuum method employed in the HUD National Survey). It is not intended as a general dose-response model, but rather as a predictive model developed specifically for use in the risk analysis and specifically to predict blood-lead concentrations from estimates of environmental lead as measured in the HUD National Survey.

The choice of the Rochester Lead-in-Dust Study as the data upon which to develop the empirical model was based on three factors:

1. all media, locations, and surfaces that are being considered for the §403 standards were measured for lead in the Rochester study;

2. the Rochester study includes dust-lead loadings from wipe sampling and the §403 dust standard is expected to be based on dust-lead loading from wipe sampling; and,

3. the selection of homes and children in the Rochester study, although targeted, was more random and more representative of a general population than is the case with most recent lead exposure studies in non-smelter communities.

There are also limitations in the use of the empirical model in the Agency's risk analysis. The empirical model is based on only one data set collected at a single city in the northeast. More importantly, perhaps, it has not yet undergone formal peer review or model evaluation. These limitations and those associated with the IEUBK model are why two tools were utilized for linking environmental- and blood-lead levels.

All of the health and blood-lead concentration endpoints are computed using the geometric mean and geometric standard deviation of predicted distributions of children's blood-lead concentrations assuming that the distributions are approximately lognormal (a special statistical distribution). The lognormal assumption is discussed in Sections 5.1.1 and 5.4.4. In addition, computation of the IQ score declines greater than 1, 2, or 3 points and average IQ score decline are based on an average decrease of 0.257 IQ points per increase of one µg/dL in blood-lead concentration (Schwartz, 1994). Estimating the incidence of IQ score less than 70 is based on results in a paper by Wallsten and Whitfield (1986) on the relationship between reduced IQ scores and blood-lead concentration.

## Risk Characterization

Figure 5-1 in Chapter 5 shows the approach taken for risk characterization. Each component of the risk assessment is integrated to characterize the risks to the nation's children aged 1-2 years from exposures to lead in paint, dust, and soil. The hazard identification is used to select the indicators of risk, the health effect and blood-lead concentration endpoints. The exposure assessment is used to characterize the exposure of children, and the dose-response assessment is used to translate exposure into health effect and blood-lead concentration endpoints.

The risk assessment characterizes risks associated with childhood lead exposure by predicting incidence of the selected health effect and elevated blood-lead concentration endpoints among 1-2 year old children for the year 1997. The 1997 baseline distribution of children's blood-lead concentrations was calculated using data from Phase 2 of NHANES III. Risks were projected to 1997 because the rule is expected to be proposed in that year. Although Phase 2 of NHANES III was conducted over the years 1991-1994, the Agency utilized the results of Phase 2 of NHANES III to represent the current blood-lead distribution. The Agency recognizes that children's blood leads may be lower today (levels reported in previous NHANES surveys have shown significant declines over time), but has no information upon which to project additional declines from the 1991-1994 time frame to the present.

Using the IEUBK model and estimates of background soil-lead concentration, the childhood health effect and blood-lead concentration endpoints were estimated at background levels of lead in soil and dust. Selection of the background soil-lead concentration is described in Section 5.2. The predicted health effect and blood-lead concentration endpoints at background lead levels represent the risks that might exist if exposures to lead in paint, dust, and soil, except soil at background concentration, could be eliminated. A comparison of the estimated endpoints at background lead levels to the baseline estimates based on NHANES III provides an estimate of the current risks to children due to exposure to lead in paint, soil, and dust.

The baseline risks based on Phase 2 of NHANES III are population-based risks; they represent the risks posed by childhood lead exposure to our nation as a whole. The risk to children exposed to specific levels of residential environmental lead were also computed using the IEUBK and Rochester multimedia models. The Rochester multimedia model is a regression model relating log-transformed childhood blood-lead concentration to dripline soil-lead concentration, wipe dust-lead loading on floors (carpeted and uncarpeted), wipe dust-lead loading on window sills, and an indicator of paint/pica hazard. The multimedia model was produced as an intermediate step in the development of the empirical model. The empirical model was developed specifically for estimating population-based risks. The multimedia model is a more appropriate tool than the empirical model for estimating risks to children exposed to specific environmental-lead levels. The IEUBK model was employed to predict the probability a child will have a blood-lead concentration greater than or equal to 10 µg/dL for specific sets of soil-lead and dust-lead concentrations. Three dust-lead concentrations were utilized (100, 200, and 500 ppm) and soil-lead concentrations ranged from 25 to 2000 ppm. The Rochester multimedia model was employed to predict the probability a child will have a blood-lead concentration greater than or equal to 10 µg/dL for specific sets of soil-lead concentrations and floor and window sill dust-lead loadings. Two soil-lead concentrations were utilized (100 and 400 ppm) and dust-lead loadings ranged from 1 to 500 µg/ft$^2$.

Sensitivity analyses were performed to gauge the robustness of the risk characterization methodology. Factors evaluated include: 1) age group of interest, 2) relationship between blood-lead concentration and IQ decrements, 3) assumptions on the national blood-lead distribution,

4) adjustment made to correct for HUD National Survey dust sample analysis deficiencies, 5) variability of blood-lead concentrations, 6) daily dietary lead intake, and 7) assumptions on contribution of paint pica tendencies to childhood blood-lead concentration.

#### 1.4.2.2 Approach for Risk Management

The methodology developed for risk management is presented in the second part of the risk analysis document, Risk Management. Figures 6-1 and 6-3 in Chapter 6 illustrate the approach developed for analyzing example options for the §403 standards. The primary purpose of the risk management analysis was to develop and apply methodology for analyzing example options for the §403 standards. Under this methodology, both the IEUBK and empirical models were used to obtain two distributions of blood-lead concentration: one resulting from exposure to pre-§403 environmental-lead levels, and one resulting from exposure to lead levels expected to result after intervention and other activities are conducted in response to the example option for the §403 standards. Both models were applied to characterize the national distribution of blood-lead concentrations of children aged 1-2 years in a pre-§403 environment using environmental lead data collected in the HUD National Survey as inputs. The environmental-lead levels were then adjusted to reflect the impact of interventions conducted in response to the §403 standards, and a new blood-lead concentration distribution was estimated. The difference between these distributions was assumed to be the decline in blood-lead concentrations attributable to performing the interventions. Finally, the baseline distribution of blood-lead concentrations (derived from Phase 2 of NHANES III) and the just-estimated decline in the model-based distribution of blood-lead concentration were used to derive a post-§403 blood-lead concentration distribution.

Environmental-lead levels expected to result after interventions are conducted in response to the §403 standards were determined as follows:

1. Observed levels of lead in paint, dust, and soil for HUD National Survey residential units were compared to the example options for the §403 standards. Dust-lead loadings were converted to wipe dust-lead loadings before comparison to the example standards.

2. For those HUD National Survey residential units that had environmental-lead levels above the example standards, interventions were triggered. If an intervention was triggered, environmental-lead levels at the residential unit were set equal to assumed post-intervention lead levels.

The Agency identified a limited number of intervention activities that were assumed to occur at housing units identified as exceeding one or more of the example options for the §403 standards. These intervention activities include both interim controls and more permanent abatement measures. For each of the intervention activities, post-intervention environmental lead conditions were assumed. Also, the expected duration of the reduction in environmental-lead levels that result from each intervention was specified. In general, these intervention activities are assumed to be medium-specific. For example, if a unit was identified as exceeding the standards for deteriorated exterior paint, the intervention activity would address only the exterior paint. Exceptions are interventions dealing with either interior paint or activities involving soil removal. These two interventions are assumed to be followed by cleaning of interior dust. This is due to the expectation that these activities would create high levels of interior leaded dust that would warrant special cleaning. This risk management analysis also assumes that proper precautions are taken during the conduct of an exterior paint intervention to preclude the requirement of a mandatory soil intervention following an exterior paint intervention.

The risk management methodology is utilized in Section 6.3 to analyze various example options for the §403 standards. The example standards examined are not meant to encompass all possible options for the §403 standards, and the Agency fully anticipates considering other sets of candidate standards.

The major limitation with the approach developed for analyzing example options for the §403 standards is the limited amount of data available for estimating pre- and post-§403 environmental-lead levels. This includes a lack of nationally-representative dust-lead loading data (representing both pre- and post-§403 conditions) where samples were collected by wipe techniques. This data limitation constitutes one of the major data gaps and limitations for the risk management analyses. To help alleviate this limitation, sensitivity analyses were conducted to assess the impact on the estimated endpoints of assumptions on methods for converting dust-lead loadings, post-intervention environmental-lead levels, variability in childhood blood-lead concentrations, daily dietary lead intake, and contribution of paint pica tendencies to childhood blood-lead concentrations. In addition, an alternative approach for estimating the selected endpoints that does not require specifying post-intervention environmental-lead levels was examined in the sensitivity analysis for risk management.

## 1.5 PEER REVIEW

This report was reviewed independently by members of a peer review panel. The panel consisted of a diverse group of six distinguished researchers who, together, had considerable knowledge on all subject areas addressed in this report. The members of this panel and their affiliations were:

Dr. Robert Bornshein, University of Cincinnati
Dr. Ruth Chen, Vanderbilt University Medical School
Mr. Victor Hasselblad, North Carolina State University
Dr. William Richards, Syracuse Research Institute
Dr. Charles Rohde, Johns Hopkins University
Mr. Joseph Schirmer, Wisconsin Division of Health, Bureau of Public Health

The charge given to this panel was to provide comments and responses to six general questions and eight specific questions concerning the contents of this report. The six general questions were as follows:

1. Have we used the best available data?

2. Have we used this data appropriately?

3. Have we fairly characterized the variability, uncertainties, and limitations of the data and our analysis?

4. Are there alternative approaches that would improve our ability to assess the relative impacts of candidate options for paint, dust, and soil hazard standards?

5. The approach employs models that were primarily developed for use in site-specific or localized assessments. Has the use and application of the IEUBK and empirical model in this context been sufficiently explained and justified? Is our use of these tools to estimate nationwide impacts technically sound?

6. Are there any critical differences in environmental lead-blood lead relationships found in local communities that should be considered in interpreting our results at the national level?

The eight specific questions (of which Question #4 had three parts) were as follows:

1. The HUD National Survey, conducted in 1989-90, measured lead levels in paint, dust and soil in 284 privately owned houses. Does our use of this data constitute a reasonable approach to estimating the national distribution of lead in paint, dust and soil? Are any alternatives recommended? (Section 3.3)

2. Is the approach to evaluating the effects of pica for paint reasonable? Are there alternative approaches that would be more appropriate? (Section 4.1.3, Appendix D1)

3. The approach employs conversion factors to combine data from studies that used different sample collection techniques. Is this appropriate? Is the method for developing these conversion factor technically sound? (Section 4.3, Appendix X)

4a. IQ point deficits (Section 4.4) The approach characterizes IQ decrements in the baseline blood-lead distribution, essentially implying that any blood-lead level above zero results in IQ effects. Have we provided a sufficient technical justification for this approach? Is this approach defensible and appropriate? (Section 4.4.1, Appendix D2)

4b. IQ point deficits (Section 4.4) The characterization of IQ point loss in the population includes the summation of fractional IQ points over the entire population of children. Have we provided a sufficient technical justification for this approach? Is this approach defensible and appropriate? (Section 4.4.1)

4c. IQ point deficits (Section 4.4) One of the IQ-related endpoints is incidence of IQ less than 70. Should consideration be given to what the IQ score was, or would have been, prior to the decrement (i.e., should different consideration be given to cases where a small, or even fractional, point decrement causes the <70 occurrence vs. being <70 due to larger decrements)? If so, how might this be done?

5. Are the assumptions regarding duration and effectiveness of intervention activities reasonable? (Section 6.1)

6. Removal and permanent cover (e.g., paving) are the only soil interventions considered. Are there sufficient data on the effectiveness of other soil interventions (e.g., vegetative cover) to quantify their ability to reduce exposure? (Section 6.1)

7. Are the combinations of standards used in Chapter 6 reasonably employed given the potential interrelationships between levels of lead in different media? Are additional data available on the interrelationship between lead levels in paint, dust, and soil prior to and after abatement?

8. The approach for estimating health effect and blood-lead concentration endpoints after interventions is based upon scaling projected declines in the distribution of children's blood-lead concentrations to the distribution reported in Phase 2 of NHANES III. Under this approach, data collected in the HUD National Survey are utilized to generate model-predicted distributions of blood-lead concentrations prior to and after the rule making. The difference between the pre-section 403 and post-section 403 model-predicted distributions is used to estimate the decline in the distribution of children's blood-lead concentration. This decline is then mathematically applied to the distribution reported in NHANES III. Is this adjustment scientifically defensible in general, and in the specific case where the environmental data--from the HUD survey--and the blood lead data--from NHANES III--were collected at different times (1989-90 vs. 1991-1994)? (Section 6.2)

The peer reviewers were also invited to provide general comments and suggestions concerning the report.

In general, the peer reviewers concluded that the approaches and methods used in this report were scientifically sound and that the data to which these methods were applied were the most pertinent data available. However, the peer reviewers did provide useful suggestions for revisions, as well as important issues to consider when interpreting results. The remainder of this section discusses comments from the peer reviewers that were either important for interpreting the study results or resulted in significant modifications to the report.

One reviewer suggested that additional confidence intervals be presented in the report. Based on this comment, confidence intervals associated with the estimates of current risks associated with childhood lead exposures (i.e., risks prior to implementing any proposed §403 rule) were calculated and presented in Sections 3.4, 5.1, and 5.3. These risk estimates are labeled as “baseline” or “pre-§403” risks and are based on results reported in Phase 2 of the NHANES III. However, confidence intervals were not calculated for other estimates within the report, such as estimates of the reduced risks associated with lead exposures expected to exist after implementing the proposed §403 standards. These risk estimates are labeled as “post-§403” risks and are presented in Chapter 6, “Analysis of Example Options for the §403 Standards.” Confidence intervals for post-§403 risk estimates were not computed because it was not possible to quantify important sources of variability required for their calculations, such as variability associated with estimated post-intervention environmental-lead levels, conversions, and intervention durations. Without including information on these sources of variability in the equation calculation, the confidence intervals cannot be meaningfully interpreted.

A reviewer suggested that the Evaluation of the HUD Lead-Based Paint Hazard Control Grant (“HUD Grantees”) Program be included among the lead exposure studies whose data are summarized within this document. This ongoing program provided among the most recent information on lead levels in paint, dust, and soil within U.S. residences, as well as blood-lead concentrations for children within these residences. Data collected prior to any interventions conducted in this program were made available to this risk analysis, and were therefore added to the data summaries in Sections 3.2, 3.3, and 3.4. However, when interpreting these data summaries, one must consider that the housing units included in this program had high potential for containing lead-based paint hazards or contained at least one child with an elevated blood-lead concentration. This issue has also kept the HUD Grantees data from being used to develop the empirical model used in this report to predict blood-lead concentration from environmental-lead levels.

Comments were made to improve characterization of lead-based paint hazards from the data available to the risk analysis. As a result, additional summary tables of lead levels in paint were prepared for the lead-exposure studies whose data were summarized in Chapter 3. These additional summaries included the percentage of surveyed units having lead-based paint on a particular type of building component, the percentage having deteriorated lead-based paint on the given component, and information on the distribution of maximum XRF measurement by component type.

Upon suggestion from the peer reviewers, additional sensitivity analyses were performed to investigate the impact of changes to the assumed values of various non-environmental parameters in the IEUBK model, such as daily dietary lead intake and the geometric standard deviation of children’s blood-lead concentration under a common exposure scenario (Sections 5.4.6, 5.4.7, 6.4.6, 6.4.7). Additional sensitivity analyses were conducted to assess assumptions made when incorporating the effects of paint-chip pica on blood-lead concentration (Sections 5.4.8, 6.4.8). Alternative assumptions on the percentage of children with paint-chip pica tendencies, the percentage living in housing units with deteriorated lead-based paint who recently ingested paint chips, and the blood-lead concentration of children who ingested paint chips either recently or at some earlier time, were evaluated in the sensitivity analysis.

The risk analysis assumes a linear relationship between blood-lead concentration and decline in IQ score. One peer review comment questioned whether there were ranges of blood-lead concentration where the relationship differs from what is assumed, thereby making it nonlinear. Researchers have used both linear and log-linear models to predict decline in IQ score as a function of blood-lead concentration. In his meta-analysis, Schwartz (1994) concluded that the slope of the linear relationship becomes steeper at lower blood-lead concentrations, suggesting a log-linear relationship. However, by assuming a linear relationship (i.e., the same slope for all blood-lead concentrations), this risk analysis is more likely not to overestimate the number of children with low blood-lead concentrations who benefit from intervention (if the findings by Schwartz are true).

One peer reviewer suggested that the baseline risk estimates be adjusted to reflect changes in blood-lead concentration that may have occurred between when data used in this risk analysis were collected and 1998. To address this issue, the sensitivity analysis includes an investigation (Section 5.4.3) of how the baseline risk estimates are affected when blood-lead concentrations are reduced by 10%, 20%, and 30% from values observed in Phase 2 of NHANES III (the survey whose data were used in this report to characterize blood-lead concentrations in U.S. children). However, there was insufficient information to justify a single adjustment for the entire nation. Any such adjustment would, therefore, have considerable variability and would add considerably to the overall level of adjustment being made to the data in this risk analysis. Other data adjustments recommended among the peer reviewers were not made for similar reasons, such as adjusting for type of lead-based paint exposure (paint loading, surface type, paint condition, substrate, and building component) and for regional differences (diet, architecture, climate).

Peer reviewer comments were also useful in determining additional post-intervention settings for dust-lead loadings and soil-lead concentrations for which risk estimates were calculated. However, these additional results were added to Chapter 6 of the report only when they provided additional information from what already existed in this chapter.

EPA has established a public record for the peer review of this report under administrative record AR-188, “Risk Analysis to Support Standards for Lead in Paint, Dust, and Soil: Peer Review.” The record is available in the TSCA Nonconfidential Information Center, which is open from noon to 4 PM Eastern time Monday through Friday, except legal holidays. The TSCA Nonconfidential Information Center is located in Room NE-B607, Northeast Mall, 401 M Street SW, Washington, DC.