Analysis Plan for Human Health and Ecological Risk Assessment For the Review of the Lead National Ambient Air Quality Standards

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This draft scope and methods plan has been prepared by staff from the Ambient Standards Group, Office of Air Quality Planning and Standards, U.S. Environmental Protection Agency, in conjunction with ICF International (through Contract No. 68-D01-052). Any opinions, findings, conclusions, or recommendations are those of the authors and do not necessarily reflect the reviews of the EPA or ICF International. This document is being circulated to obtain review and comment from the Clean Air Scientific Advisory Committee (CASAC) and the general public. Comments on this document should be addressed to Ginger Tennant, U.S. Environmental Protection Agency, Office of Air Quality Planning and Standards, C539-01, Research Triangle Park, North Carolina 27711 (email: tennant.ginger@epa.gov).

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ECOLOGICAL RISK ASSESSMENT

1.0 INTRODUCTION

The U.S. Environmental Protection Agency (EPA) is presently conducting a review of the national ambient air quality standards (NAAQS) for lead (Pb). Sections 108 and 109 of the Clean Air Act (Act) govern the establishment and periodic review of the NAAQS. These standards are established for pollutants that may reasonably be anticipated to endanger public health and welfare, and whose presence in the ambient air results from numerous or diverse mobile or stationary sources. The NAAQS are to be based on air quality criteria, which are to accurately reflect the latest scientific knowledge useful in indicating the kind and extent of identifiable effects on public health or welfare which may be expected from the presence of the pollutant in ambient air. The EPA Administrator is to promulgate and periodically review, at five-year intervals, "primary" (health-based) and "secondary" (welfare-based)[1] NAAQS for such pollutants.[2] Based on periodic reviews of the air quality criteria and standards, the Administrator is to make revisions in the criteria and standards, and promulgate any new standards, as may be appropriate. The Act also requires that an independent scientific review committee advise the Administrator as part of this NAAQS review process, a function now performed by the Clean Air Scientific Advisory Committee (CASAC).

EPA's overall plan and schedule for this Pb NAAQS review is presented in the *Plan for Review of the National Ambient Air Quality Standards for Lead* (EPA, 2006a), which is available at: http://www.epa.gov/ttn/naaqs/standards/pb/data/pbreviewplan_feb2006.pdf . That plan discusses the preparation of two key documents in the NAAQS review process: an Air Quality Criteria Document (AQCD) and a Staff Paper. The AQCD provides a critical assessment of the latest available scientific information upon which the NAAQS are to be based, and the Staff Paper evaluates the policy implications of the information contained in the AQCD and presents staff conclusions and identifies standard-setting options for the Administrator to consider in reaching decisions on the NAAQS.[3] In conjunction with preparation of the Staff Paper, staff in EPA's

[1] Welfare effects, as defined in section 302(h) of the Act include, but are not limited to, "effects on soils, water, crops, vegetation, man-made materials, animals, wildlife, weather, visibility and climate, damage to and deterioration of property, and hazards to transportation, as well as effects on economic values and on personal comfort and well-being."

[2] Section 109(b)(1) [42 U.S.C. 7409] of the Act defines a primary standard as one "the attainment and maintenance of which in the judgment of the Administrator, based on such criteria and allowing an adequate margin of safety, are requisite to protect the public health." Section 109(b)(2) of the Act directs that a secondary standard is to "specify a level of air quality the attainment and maintenance of which, in the judgment of the Administrator, based on such criteria, is requisite to protect the public welfare from any known or anticipated adverse effects associated with the presence of [the] pollutant in the ambient air."

[3] NAAQS decisions involve consideration of the four basic elements of a standard: indicator, averaging time, form, and level. The indicator defines the pollutant to be measured in the ambient air for the purpose of determining compliance with the standard. The averaging time defines the time period over which air quality measurements are to be obtained and averaged, considering evidence of effects associated with various time periods of exposure. The form of a standard defines the air quality statistic that is to be compared to the level of the standard (i.e., an ambient concentration of the indicator pollutant) in determining whether an area attains the standard. The form of the standard specifies the air quality measurements that are to be used for compliance purposes (e.g., the mean average over 90 days), the monitors from which the measurements are to be obtained (e.g., one or more population-oriented monitors in an area), and whether the statistic is to be averaged across multiple years.

Office of Air Quality Planning and Standards (OAQPS) conduct various policy-relevant assessments, including for this Pb NAAQS review, a quantitative human exposure analysis and a human health risk assessment, as well as an ecological exposure and effects analysis.

The purpose of this analysis plan is to outline the scope, approaches, and methods that staff is planning to use for the human health and ecological risk assessments. This plan also highlights key issues in the estimation of human health and ecological exposure and risks posed by Pb under existing air quality levels ("as is" exposures and health risks), upon attainment of the current Pb NAAQS, and upon meeting various alternative standards in selected sample areas.

This analysis plan is intended to facilitate consultation with the CASAC, as well as public review, for the purpose of obtaining advice on the overall scope, approaches, and key issues in advance of the completion of such analyses and presentation of results in the first draft of the Pb Staff Paper. The assessment approaches described in this plan are intended to build upon and extend the exposure and risk assessment approaches employed for the last review,[4] and on Agency experience with Pb exposure and risk assessment since that time, while also drawing from information presented in the December 2005 and May 2006 drafts of the AQCD for the current review (EPA 2005a, 2006b). The final assessments will reflect information in the final AQCD, which will be completed later this year.

1.1 Purpose and Scope of the Assessments

The focus of these assessments is the estimation of risk resulting from exposure to lead released into ambient air. To help inform future policy considerations, this assessment will further attempt to distinguish between Pb exposures associated with currently emitting sources (e.g., primary and secondary Pb smelters) and historical (no longer operative) sources (e.g., emissions associated with leaded gasoline).

This plan recognizes several distinctions with regard to the scope of the risk assessments for Pb. First, because exposure to atmospheric Pb particles occurs not only via direct inhalation, but also via ingestion of deposited particles, the problem being assessed is multimedia in nature, with exposure occurring via both the inhalation and ingestion routes. And, for human health exposure assessment of Pb, in contrast to ozone or particulate matter, the dose metric or biomarker most commonly used and associated with health effects information is internal (i.e., blood Pb). Additionally, the exposure duration of interest (i.e., that influencing internal dose pertinent to health effects of interest) may span months to potentially years, as does the time scale of the environmental processes influencing Pb deposition and fate.

There are a variety of situations involving exposure to Pb in ambient air (and Pb deposited from air to non-air media). These include populations living in the vicinity of a primary Pb smelter,[5] those in areas where multiple significant point sources are concentrated, and those in areas near roadways where anthropogenic Pb contained in roadway dust may become suspended in ambient air and undergo deposition and transport to non-air media. To the extent that the internal biomarker, blood Pb, is used in exposure assessment, the separation of contributions related to

[4] The last Pb NAAQS review was completed in 1991 with no revisions made to the standards at that time.
[5] Currently only one primary Pb smelter (in Herculaneum, MO) is operating in the U.S..

new Pb emissions to ambient air from those reflecting inhalation and ingestion of historically deposited ambient Pb poses a particular challenge.

1.1.1 Air Quality Scenarios

We intend to assess human exposure and health risks, and ecological risks for the following air quality scenarios.

- *Current (baseline) air quality*
- *Attainment of the current NAAQS* (i.e., any reduced ambient air concentrations necessary to meet the current NAAQS)
- *Attainment of alternate NAAQS*

As exposures associated with deposited Pb are of interest to this review, the assessment of each of these air quality scenarios will include estimates of future Pb concentrations in other media (e.g., outdoor soil/dust) associated with deposition.

In modeling scenarios for alternate NAAQSs, the 1990 Staff Paper, with concurrence from CASAC, relied on the assumption that the soil Pb level would remain constant for at least six years after a new standard would be implemented, while they projected changes in indoor air and dust concentrations with the changing air concentration. The plan presented here includes consideration of the use of current methods for estimating the relationship of soil Pb levels to changes in air concentrations (i.e., projection of outdoor soil/dust concentrations for future points in time resulting from changes in ambient air Pb reflecting specific NAAQS scenarios).

As feasible, we are considering utilizing 2005 air quality data as the basis for the baseline scenario. We are investigating the available information on Pb emissions estimates and Pb concentrations in other media to identify that most appropriate for use with 2005 air quality data.

1.1.2 Exposure and Human Health Risk Assessment

The planned Pb exposure analysis and health risk assessment address exposures (of multiple years) to Pb and associated health effects. The risk assessment will characterize health risks associated with Pb exposure pathways that include ambient air (i.e., "NAAQS-relevant") and put those risks into context with other Pb exposure pathways that do not include ambient air, such as indoor paint and drinking water (i.e., “background”).

This assessment will focus on health endpoints associated with the range of exposures expected to most closely reflect current levels and for which there is adequate information to develop quantitative risk assessments. There are some health endpoints, however, for which there currently is insufficient information to develop quantitative risk estimates. We plan to discuss these additional health endpoints qualitatively in the Pb Staff Paper.

The risk assessment is intended as a tool that, together with other information on these health endpoints and other health effects evaluated in the Pb AQCD and Pb Staff Paper, can aid the Administrator in judging whether the current primary standard is adequate to protect public health with an adequate margin of safety, or whether revisions to the standard are appropriate.

The goals of the Pb risk assessment are: (1) to characterize the risks, including estimation of the potential magnitude of risk, associated with current Pb levels and with attaining the current Pb NAAQS (as well as the reduced effects associated with attaining alternative Pb standards), and (2) to develop a better understanding of the influence of various inputs and assumptions on the risk estimates.

1.1.3 Ecological Exposure and Effects Analysis

The planned Pb ecological exposure and risk analyses address the risk to sensitive receptors from exposure to media concentrations resulting from ambient air deposition of Pb over time. In the first tier of this analysis, we will attempt to describe the current media Pb concentrations in the environment and model what those concentrations are likely to be in the future. These future concentrations can then be compared to screening values for effect in soil, water, and sediment to focus the analysis further on those receptors that may be most sensitive to Pb. The second tier of the analysis will focus more detailed modeling on those receptors which seem most likely to be affected to determine intake values or body/tissue concentrations which can then be compared to available concentration effects data.

1.2 Background Regarding the Previous Review

The current primary and secondary standard for Pb is 1.5 micrograms per cubic meter ($\mu g/m^3$) in total suspended particulate matter (TSP), as the maximum arithmetic mean averaged over a calendar quarter.

As part of its last review, EPA's Office of Air Quality Planning and Standards (OAQPS) performed an exposure assessment to estimate blood Pb levels among populations exposed under the current NAAQS, as well as alternate Pb regulations in the future (EPA 1989). For the different regulatory scenarios, the focus of the quantitative risk assessment was primarily on estimating the percentages of children with blood Pb levels above 10 and above 15 µg/dL. The available data at that time indicated impaired neurobehavioral function and development associated with levels of 10-15 ug/d. The available data did not indicate a clear threshold at this range, rather suggesting a continuum of health risks down to the lowest levels measured, although effects below this range were increasingly difficult to detect and their significance more difficult to determine (EPA 1990). The last risk assessment also developed estimates of the percentages of middle-aged men with blood Pb levels above 10 and 12 µg/dL. The dose-response information on blood pressure changes available at the time of the last review was less clear than the information on children, however, the same approximate range of blood Pb levels as for children were also considered for assessing risks among adult men.

The consideration of environmental effects during the last Pb NAAQS review did not include a quantitative risk assessment (EPA 1990). Rather, critical aspects of the evidence regarding Pb

effects on terrestrial and aquatic ecosystems that was presented in the AQCD (EPA 1986) were summarized to provide a basis for staff conclusions and recommendations. Based on this information, EPA concluded that, under ambient Pb exposure conditions existing at the time, the primary standard provided adequate protection to the environment.

1.3 Organization of this Document

The remainder of this document is generally organized into four parts. The first includes a discussion of the case study approach (Section 2), which, like the discussion of air quality scenarios in Section 1.1.1, pertains to both the human health and ecological risk assessments. Next is the plan for the human exposure and health risk assessment (Sections 3 through 7), followed by the plan for the ecological risk assessment (Sections 8 through 9). References for both plans are provided in Section 10. While separate plans are described for the ecological and human health risk assessments, the assessments will draw, to a large extent, from common environmental characterizations (e.g., air quality scenarios with associated media concentrations, and some case studies).

2.0 CASE STUDY APPROACH

A case study approach will be used for both the human exposure and risk assessment (described in Sections 3 through 7) and the ecological risk assessment (described in Sections 8 and 9). Some case studies will be "shared" by the two assessments (e.g., with one characterization of environmental conditions serving the purposes of both assessments), while we plan to also have some cases studies that are used only by either the human health or ecological risk assessment. A description of such a case study that is particular to ecological risk assessment is discussed in Chapter 9. The discussion provided here is intended to address case studies common to both types of assessment as well as those that may serve only the purposes of the human health assessment.

The general strategy for assessment of each case study will consider characteristics of the source(s) of interest, as well as the availability of measurement and source characterization data. Selection of case study locations will reflect the following factors:

- *Variety of ambient air sources of Pb emissions*: Pb emissions sources ranging from the primary Pb smelter, to other significant stationary sources (e.g., metal refinishing and ceramics manufacturing) and emitters of historically deposited Pb (e.g., urban roadways) will be considered. In addition to the magnitude of Pb emissions, other attributes related to emissions that influence exposure (e.g., effective stack height, particle size profiles, etc.) will be considered.

- *Available monitoring data for ambient air:* As discussed below, characterization of ambient air concentrations and soil deposition will rely on (a) monitoring data (if a case study location has sufficient monitor coverage) and/or (b) dispersion modeling, supported by monitoring data, particularly those that are appropriate for source-apportionment. Consequently, selection of case studies may favor locations which have local Pb monitoring data that can be source-apportioned. In addition to national Pb monitoring networks (see Chapter 3 of the AQCD), state and local sources will be considered.

- *Available soil monitoring data and, for purposes of the human health assessment, biomonitoring (blood Pb) data*: When available, measurements of Pb soil concentrations for a study area together with blood Pb levels for the residential population can considerably increase confidence levels associated with characterizing human health risk associated with baseline conditions. Therefore, locations where relevant biomonitoring and/or collection of Pb soil concentrations has been conducted will be favored in the selection of case study locations. Note, that such data heavily influenced by sources unrelated to air (e.g., Pb paint) will be less useful for our purposes.

- *For purposes of the human health assessment, socioeconomic status (SES) and other demographic attributes related to Pb exposure and risk:* If specific demographic and/or SES factors are linked quantitatively to increased exposure or concentration-response for Pb effects being modeled, then those factors may also be considered in selecting case study locations. Potential factors currently under consideration include: (a) general

population density (would favor locations with higher population densities since will have larger modeled population and more fully characterized population risk distributions), (b) housing age (for background exposure levels to Pb paint), and (c) SES (race and income) to inform estimation of risk characteristics (e.g., baseline blood pressure levels, which could result in greater blood pressure impacts following Pb exposure).

- *Available water quality and sediment monitoring data, for purposes of ecological risk assessment:* Locations which include the presence of a surface water body for which measurements of Pb are available for water and sediment will be favored in selection of case study locations.

We also plan to select case studies that reflect particular types of ambient Pb emissions and exposure situations, such as the following:

- *Primary lead smelter*: This case study would be expected to reflect Pb contamination of the surrounding study area which is dominated by emissions from this facility, with other sources being of relatively lesser importance.

- *Other significant stationary sources*: This category of case study would reflect a location impacted by Pb emissions from multiple point and area sources, with emissions from any particular source being significantly lower than those for the primary Pb smelter, but where combined impacts from these multiple sources (including re-entrainment of historically deposited near-roadway Pb) may be significant.

- *Near roadway re-entrainment*: This category of case study reflects environmental Pb contamination dominated by re-emission of historically deposited Pb near roadways (i.e., re-entrainment of near-roadway Pb). This may include consideration of a general urban scenario with heavy road traffic, historic dust (e.g., reflecting old housing sources) and proximal residential areas, but without large local sources of industrial Pb emissions.

It is anticipated that one or more locations will be modeled for each of the above categories of case studies described in the following section, the final number for each category will reflect consideration of a number of factors including a desire to characterize population risk variability associated with these situations within the US. The following subsection focuses on distinctions among these categories with regard to the approaches we intend to employ to characterize exposure and risk.

2.1 Primary Lead Smelter

There is presently only one primary Pb smelter operating in the U.S. Source characterization information is available from past regulatory analyses, EPA Regional Office permit files, and state/local offices. The Staff anticipates that there will be more available site-specific ambient air, soil, and blood Pb level measurement data for areas near this facility than for any other facility in the U.S. As a result, it is expected that measurement data (e.g., ambient air monitoring

data and soil sampling data) will play a major role in characterizing exposures and risks associated with this facility.

The primary Pb smelter case study is anticipated to have the most comprehensive site-specific blood Pb monitoring data among the three categories of case studies, a feature relevant to the human health assessment. This may support the site-specific characterization of blood Pb levels for key target populations. These data will also be useful in evaluating performance of the blood Pb modeling approach applied to this case study location. For example, we may be able to compare model predicted blood Pb distributions for the study area to site-specific blood Pb data in order to (a) evaluate the overall representativeness of the blood Pb modeling approach and (b) guide refinement of that modeling approach as appropriate.

2.2 Other Significant Stationary Sources

As described in the Pb AQCD (EPA 2006b), there are numerous stationary sources of Pb to air, including secondary Pb smelters, metal finishing facilities, and ceramic manufacturers. Assessments for this category of case study will rely on locations and emissions characterization information for these facilities from EPA's National Emissions Inventory (NEI), supplemented by available data from Regional Office permit files, emissions standards (MACT and residual risk) files, and state/local offices. This case study category will address co-location of these types of facilities to the extent feasible. We anticipate that air, soil and blood Pb measurements in locations for this category of case studies may be limited relative to site-specific data available for the primary Pb smelter, necessitating a greater reliance on modeling to estimate environmental concentrations (as described in sections 4.1.2 and 4.1.3).

Because this case study category is expected to have limited (or no) site-specific blood Pb monitoring data, the degree to which blood Pb modeling performance can be evaluated will be limited. Therefore, more general regional or national-scale blood Pb data obtained form NHANES (possibly differentiated by relevant SES factors) may be used for performance evaluation. Note, however, that locations for which local blood Pb data are available will be given preference in selection.

2.3 Near-Roadway re-entrainment

The use of leaded gasoline in the U.S. resulted in accumulation of Pb in soils near roadways and the resuspension of this Pb may have the potential to contribute significantly to concentrations of airborne Pb (Harris et al. 2005). Besides historic combustion, there are other auto-related releases of Pb near roadways (see EPA 2006b). Measurements of concentrations near some roadways have been reported (Filippelli et al. 2005; Teichman et al. 1993). This case study category is intended to provide some characterization of associated exposures and risks for this type of air emissions source. Consequently, selection of locations will favor areas that are not significantly influenced by other types of air sources.

To develop estimates of associated media concentrations for this case study category, we intend to consider the available literature, as well as potential use of modeling tools, ambient measurements and source apportionment methods (discussed in Section 4.1.1 and 4.1.2). The

use of multiple methods may inform characterization of uncertainty in estimated concentrations. As with the last case study category discussed, locations for which blood Pb measurements are available will be favored. As available such data will be used, in preference to NHANES data, and in conjunction with socioeconomic and demographics data, to evaluate blood Pb model performance.

HUMAN EXPOSURE AND HEALTH RISK ASSESSMENT

3.0 OVERVIEW OF ANALYSIS PLAN

This risk assessment is designed to estimate various health effects associated with current, and some alternate, exposures to Pb emitted into ambient air in the U.S. This includes new emissions of Pb into ambient air as well as emissions of historically deposited Pb. As recognized in Section 1.1, the exposure assessment will not only include inhalation but also the ingestion route (e.g., incidental ingestion of ambient Pb deposited to residential soils and that transported indoors). In addition to ambient air associated Pb, exposure to Pb from other (i.e., "background") sources will be assessed. "Background" for the purposes of this assessment refers to sources, pathways and exposures that do not involve ambient air (e.g., Pb in drinking water and Pb paint-related dust). As described in Section 2.0, we will use a case study approach wherein a small set of locations intended to illustrate the variety of exposure conditions associated with ambient air associated Pb that occur in the U.S. This assessment will focus on health endpoints, associated with the range of exposures expected to most closely reflect current levels, and for which there is adequate information to develop quantitative risk assessments. For example, we intend to assess neurological effects in young children, and we are also considering other endpoints for adults. In the risk characterization, we will characterize the magnitude and distribution of Pb-related risk within the case study populations.

The risk assessment will be completed in two stages. The first stage, referred to as the Pilot, will be completed by the end of this year and will be described in the first draft of the exposure/risk report and summarized in the first draft of the Staff Paper, both of which will undergo CASAC review. We anticipate including 3-4 case studies for the Pilot, with a primary focus being on testing and refining the assessment approaches. The methodology for the Full-Scale assessment will build on our experience with and CASAC comments on the Pilot assessment. The Full-Scale risk assessment will be described in the second draft exposure/risk report, which we intend to complete in mid-2007. We anticipate expanding the number of case studies for the Full-Scale analysis (e.g., 5-10).

The following subsections provide an overview of the analysis plan. Section 3.1 presents the conceptual model for Pb human health risk assessment, describing both the elements generally pertinent to the assessment of health risk associated with Pb, and identifying those elements to be included and a focus of this assessment. Section 3.2 expands on the elements of this assessment, although with a grouping of conceptual model elements that reflects basic steps of the general approach for this assessment. Section 3.3 describes issues related to spatial scale and the definition of the GIS-based spatial template used as the basis for modeling in the analysis. Lastly, Section 3.4 generally describes how we will characterize uncertainty and variability associated with those steps.

3.1 Conceptual Model for Pb Human Health Risk Assessment

This section presents the conceptual model (Figure 3-1) intended to illustrate the elements pertinent to assessment of public health risks associated with environmental Pb exposures.

For purposes of this risk assessment, "background" is intended to refer to sources of, exposures to, etc, Pb associated with pathways that do not involve ambient air. Included among these would be pathways associated with indoor Pb paint, Pb in drinking water, Pb in food, etc. Background elements are shown in Figure 3-1 in non-bold (regular) type. As shown in Figure 3-1, the assessment will include contributions from all sources. We intend, however, to characterize risks associated with ambient air associated sources separately from background sources.

Sources: The focus of this review is on sources to ambient air (e.g., current sources of new Pb emissions and re-emission of historically deposited Pb). Other ("background") sources of environmental Pb that are significant contributors to population Pb exposures (e.g., indoor Pb paint) will also be considered in estimating blood Pb levels associated with all sources.

Pathways: Figure 3-1 is intended to generally illustrate the many pathways by which Pb emitted into the environment becomes available for human exposure. Those not passing through ambient air are considered "background" for the purposes of this assessment. For those case studies in which modeling is employed for exposure assessment (in lieu of adequate measurements), those pathways shown with white background in Figure 3-1 will not be explicitly modeled.

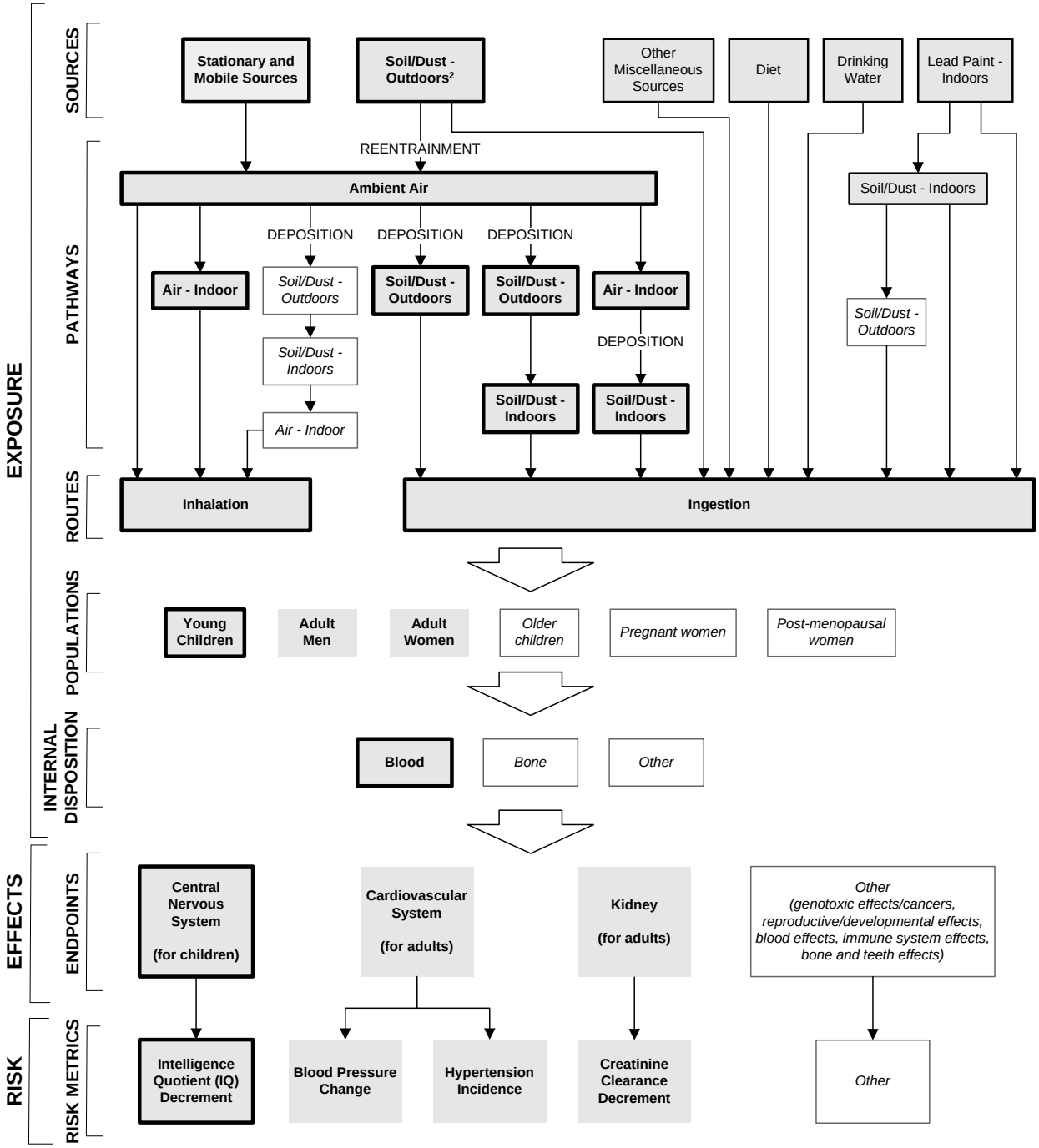
Routes: The ingestion and inhalation routes are considered the primary routes of human exposures to environmental Pb, and the ingestion route (e.g., inclusion of incidental ingestion) is expected to be the more significant. Both routes will be included in this assessment.

Exposed Populations: The Pb exposed populations can be characterized and subset based on a variety of characteristics. Figure 3-1 identifies groups based primarily on age or lifestage, which has an influence on behaviors that can influence exposure or susceptibility. It is recognized that more specific factors (e.g., calcium deficiency, to name one) also influence susceptibility. Such characteristics will be addressed as feasible in the assessment, given limitations of the currently available information (e.g., differing exposure/dose – response functions). Where quantitative assessment of particular subgroups (e.g., children with calcium deficiencies) may not be feasible, qualitative characterization will be important. In this assessment, we intend to quantify risks to young children, and are considering also quantifying risks for adult populations.

Internal Disposition: While Pb is distributed throughout the body, bone is an established site of internal accumulation of Pb, while blood is an established internal dose metric for purposes of both exposure and risk assessment. This risk assessment will rely primarily on blood Pb with corresponding dose-response functions. The tools employed will recognize the role of bone as a reservoir with the potential to act as source and storage site.

Endpoints: Figure 3-1 generally identifies the wide variety of health endpoints recognized in the draft AQCD (EPA, 2006b) as associated with Pb exposures. As mentioned previously, the endpoints of interest for this assessment are those associated with the range of exposures expected to most closely reflect current levels, and for which there is adequate information to develop quantitative risk assessments. Recognizing that, the primary endpoint we currently intend to include in the assessment (indicated in Figure 3-1 via bold outlined box) is neurological effects in children, while we are considering the additional endpoints of cardiovascular and renal effects in adults.

Figure 3-1. Conceptual Model for Pb Human Health Risk Assessment



NOTES

[1] Components with gray background and solid borders will be included in this assessment. Components depicted in gray but without borders are being considered for inclusion in the assessment. Further, a distinction is made between components linked to exposure pathways involving ambient air (shown in bold) and components involving other pathways (i.e., background).

[2] Includes contributions of historical sources, including (but not limited to) emissions from the use of leaded gasoline, historical emissions from stationary sources, and exterior leaded paints.

Metrics: Figure 3-1 generally recognizes that there are many metrics that might be considered for risk assessment. Recognizing the need for the metrics used in this assessment to have sufficient support for use in quantifying population health risk, we currently intend to use IQ decrement in children, and are considering the inclusion of blood pressure and kidney effects in adults. We will use these metrics to characterize the magnitude and distribution of Pb-related risk within the exposed populations.

3.2 General Approach

This section presents the general approach for the exposure and risk assessment methodology for generation of population-level risk estimates.

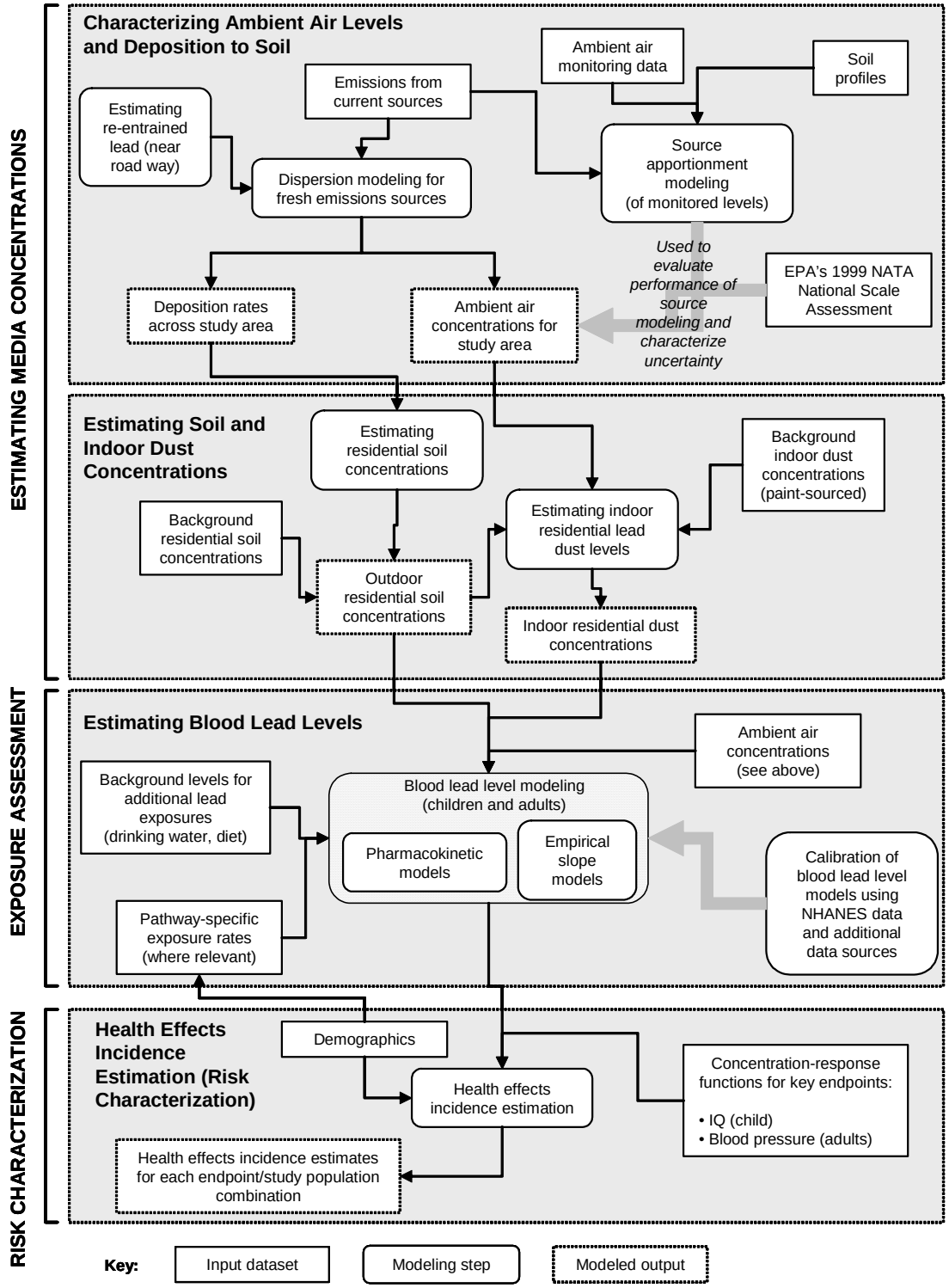
The specific approach used to estimate exposure and risk for individual case studies is expected to differ depending on the amount of site-specific monitoring data available for characterizing Pb concentrations in ambient air and outdoor soil/dust. For example, where there is adequate monitoring coverage, we will rely primarily on measurements to establish baseline conditions for both ambient air and soil Pb concentrations. By contrast, for those case study sites lacking in ambient monitoring data, we will depend primarily on modeling to characterize baseline soil and ambient air Pb conditions. In all cases, future projections of soil Pb concentrations (and related media concentrations such as indoor dust), designed to reflect conditions under various NAAQS scenarios, will rely on modeling.

The general approach for a case study location at which modeling is used to characterize baseline ambient air Pb concentrations or soil Pb concentrations is illustrated in Figure 3-2. This approach is divided into four components, the first three of which comprise steps in the exposure assessment (intended to cover the components indicated in bold in the conceptual model, Figure 3-1) and the last of which represents the effects and risk assessment. The four components are: (a) estimating ambient air concentrations and deposition to soil, (b) estimating soil and indoor dust concentrations, (c) estimating blood Pb levels and (d) health effects incidence estimation (risk characterization). Each of these components is discussed below. This discussion also highlights ways in which the fully-modeled approach presented in Figure 3-2 would be modified for those case studies where there are sufficient ambient air and/or soil measurements to support characterization of baseline conditions without or with lesser use of modeling. The approach for characterizing uncertainty and variability associated with the steps in this approach, while not illustrated in Figure 3-2, is described in section 3.4.

Estimating Ambient Air Concentrations and Deposition to Soil

We intend to rely on air monitoring data, where available, in preference to modeling, to characterize baseline conditions across the study area. For those case studies lacking sufficient ambient air monitoring data to characterize baseline conditions across the study area, we intend to model the dispersion of air emissions in order to characterize the spatial and temporal distribution of ambient air concentrations across the study area, and also to estimate Pb deposition to soil. If a case study area has some ambient monitors (but not enough to fully characterize baseline conditions), then we will consider source-apportioning those monitoring data and using the results to performance-evaluate the ambient air concentration surface

Exhibit 3-2. Overview of Analysis Approach relying on Modeling. Where measurement data are available and sufficient, they will be used in preference to, or in combination with, modeling steps shown here to characterize baseline conditions. The lower two boxes are to be implemented for each population and endpoint assessed.



projected by modeling. If the modeled ambient air surface differs significantly from the source-apportioned monitor values (in the vicinity of the monitor) then key elements of the dispersion modeling, including emissions profiles for modeled sources, would be reevaluated in order to reduce uncertainty and improve model performance.

For those case studies with sufficient monitor coverage for the study area, we are considering using those monitor data to characterize the spatial and temporal distribution of ambient air Pb concentrations across the study area without relying on dispersion modeling. We are additionally considering the use of source-apportionment to determine which fraction of each monitored concentration is associated with a particular source grouping in order to obtain separate estimates of ambient air concentration for different source groupings of interest. In these case study locations, modeling will still be required to project deposition to soil for characterization of future conditions.

Estimating Soil and Indoor Dust Concentrations

We intend to rely on soil measurements, where available, in preference to modeling, to characterize baseline conditions across the study area. For those case study locations in areas impacted by both emissions of new Pb as well as historically deposited Pb arising from combustion of leaded fuels, but lacking sufficient soil concentration data to characterize baseline conditions, a hybrid modeling approach which uses background soil Pb data together with multi-media fate and transport modeling is being considered to characterize baseline soil Pb concentrations. This hybrid approach has two steps:

- *Estimation of soil concentrations associated with historically deposited Pb associated with historical leaded automobile emissions:* Soil Pb monitoring data from locations similar to the case study area but not impacted by significant ongoing Pb emissions will be used to represent Pb concentrations from older (primarily auto emissions) deposition.

- *Deposition modeling and application of a soil reservoir model to estimate soil Pb for current/ongoing emissions sources:* The contribution of ongoing local point source and mobile emissions to soil concentrations will be modeled by using the deposition rates from ongoing (current) air emissions, to predict loading to soil and translating those to soil concentrations with a simple reservoir model.

The combination of these two estimates is intended to produce an estimate of baseline soil Pb concentrations that reflects both older (e.g., primarily automobile-related deposition) and more current loading related to local sources of interest (e.g., secondary smelters). As with ambient air, future soil concentrations will be projected using modeling to reflect any changes in soil Pb concentrations resulting from deposition of Pb under alternate NAAQS scenarios.

We are considering estimating indoor dust concentrations attributable to outdoor air and soil/dust based on empirical relationships of Pb concentrations in outdoor soil and ambient air to indoor dust concentrations. For residences impacted by Pb paint, this approach would estimate total indoor dust concentrations by combining these modeled concentrations with existing estimates of

Pb concentrations in indoor dust impacted by Pb-based paint, taking into account the variability in indoor dust concentrations based on the presence of Pb paint.

Characterization of baseline conditions for locations with sufficient soil monitoring data will be simpler than the modeled approach described above, since these monitor data reflect the aggregate impact of older and ongoing (current) deposition, and can be used directly. For projection of future soil concentrations for these locations, however, we will still rely on modeling to project changes in soil concentrations associated with reductions in ambient air concentrations and deposition of Pb.

Estimating Blood Pb Levels

Exposures to media containing Pb for the populations of interest will be quantified using blood Pb concentration as the exposure metric. For example, we plan to use the IEUBK model to estimate blood levels for children less than 7 years of age. Other models being considered are described in Section 4.3. Exposure to air, outdoor soil, and indoor dust will be estimated from the concentrations described above. These exposures, along with estimates of exposures from other pathways (e.g., drinking water, diet), will be provided as inputs to the blood Pb models. Any and all models used will be subjected to performance evaluation to ensure that: (1) they are being applied appropriately; (2) assumptions related to Pb intake and uptake (where they are calculated) are consistent across models; and (3) the models, as applied, produce estimated blood Pb levels that are reasonably consistent with their underlying basis and previous evaluations, and with available data sets (e.g., NHANES).

In modeling exposure for children, we are planning to use IEUBK as typically applied in the regulatory context, including the use of a GSD to provide coverage for inter-individual variability in both exposure and biokinetics. However, we are also considering an alternative approach of using probabilistic simulation to model inter-individual variability in exposure outside of IEUBK and then running those simulated individuals through IEUBK in batch-mode. Inter-individual variability in biokinetics might then be addressed using a purpose-defined GSD. A similar approach is being considered for the adult age group, should risk for that group be modeled.

Estimating Health Effects Incidence (Risk Characterization)

From the estimated blood Pb levels, we will estimate distributions of health effects for the populations of interest using concentration-response functions for the chosen endpoints. Risk estimates will be generated by applying the blood-Pb adverse effect relationships to the blood Pb distributions derived as described above. For the Pilot analysis, we are planning to model IQ loss for children and are considering the option of modeling of blood pressure changes and renal effects for adults. In the case of children (IQ loss), we are planning to use concentration-response functions derived from the Lanphear et al. (2005) study, including nonlinear models that predict higher slopes at lower blood Pb levels. While Lanphear (2005) represents our preferred study, we are also considering including a range of studies to provide coverage for uncertainty in the modeling of this endpoint. For adults, we are considering the use of the Nawrot et al. (2002) meta-analysis as the basis for a concentration-response function for blood-

pressure effects, while for renal effects we have not identified a single preferred study and instead, are considering a range of studies.

The focus of this analysis is on characterizing population-level risk for modeled study populations (i.e., characterization the distribution of risk levels across a particular study population). Once these distributions have been developed, we then plan to generate several types of population-level risk metrics from these distributions including: (a) the degree of risk (e.g., IQ loss) experienced by individuals at various percentiles on the risk distribution and (b) the number of simulated individuals falling within specific risk ranges (e.g., number of children predicted to have 1-2 IQ point loss). We are planning to generate risk metrics that will specify the degree of risk attributable to NAAQS-relevant emissions sources at a particular case study location, relative to risk associated with background exposures. As noted earlier, for the Pilot analysis, we are also planning to generate risk metrics for both current conditions and any reductions in air concentrations associated with attainment of the current NAAQS standard. Estimation of risk reductions associated with attaining alternative standards would be reserved for the Full Scale risk analysis.

3.3 Spatial Scale of Analysis

To capture the spatial variability in exposure media concentrations, a "GIS-based spatial template" will be created for each case study location that defines the outer boundary of the study area and determines the level of refinement to be incorporated in subdividing the area into discrete spatial units.

Defining the Study Area Boundary

The overall size of the area to be modeled will depend on the specific attributes of each case study (see Section 2.0). For case studies where transport of Pb through the air beyond the immediate area surrounding the facility of interest, the study area size may extend out to 50 km from the primary source. For a case study that includes multiple contributing sources, the study area size may extend up to 50 km from the source with the highest emissions. A maximum radius of 50 km is being considered because application of Gaussian plume dispersion models (e.g., AERMOD, ISC) are not recommended beyond this distance. This radius is expected to capture the area over which the impact of the source is distinguishable from background concentrations. A smaller radius may be selected for case studies with lower emissions levels where estimated media concentrations are close to background.

Refinement within the Study Area

The level of spatial refinement within the modeling region will depend on the available data and modeling methods that are employed. As appropriate for the case study type (see Section 2.0), media concentrations will be estimated for spatial units that adequately represent the observed or expected variability in media concentrations. Consequently, the level of spatial refinement may vary by media.

For case studies employing air dispersion modeling, modeled air concentration and deposition estimates will be generated at grid points designed to capture variability in media concentrations across the study area (taking into account the locations of any monitoring stations present in the case study area). The resolution of the grid may vary depending on the case study and within a case study (e.g., dense near the source and less dense with greater distance from the source). The grid for each case study will also be designed taking into account locations of measured air concentrations and soil concentrations in order to optimize comparisons with and utilization of monitoring data. At a minimum, the grid will be designed to allow for the calculation of media concentrations at the resolution of the demographic data being used.

To select the appropriate resolution for demographic data, the staff considered the expected spatial variability in media concentrations and the availability of demographic data at different resolutions from the U.S. Census. Based on these considerations, U.S. Census block groups are being considered as the demographic spatial units because they provide the required demographic information and sufficient resolution to capture spatial variability in media concentrations (including "hot spots"). In many locations, Census tracts would be too coarse to capture spatial variability, and Census blocks, while providing even more resolution than block groups, offer only limited demographic data and would require increased computational resources (see Section 4.2 for additional detail on study populations).

3.4 Uncertainty and Variability Characterization

For the Pilot analysis, we are considering the use of an integrated approach for addressing both uncertainty and variability, which will combine probabilistic simulation (for addressing exposure-related variability) with sensitivity analysis techniques (for addressing parameter and model uncertainty). At this stage, it is not possible to address uncertainty using probabilistic simulation due to data limitations, necessitating the need for a sensitivity-based approach that characterizes the range of risk results reflecting specific sources of model and parameter uncertainty.

The integrated approach will use a modeling options "tree" to represent model uncertainty, with each branch on the tree representing a distinct combination of modeling options for the analysis (a number of the modeling steps in the analysis are subject to model uncertainty, leading to multiple modeling options at those nodes). For the Pilot analysis, we are considering the option of identifying the high-bound (Max), low-bound (Min) and central tendency modeling branches, these reflecting, respectively, the combination of model options that produce the highest risk, lowest risk and central-tendency risk for a given age-group/endpoint combination. We would then examine those three modeling branches (Max, Min and central tendency) in greater detail, by considering (a) parameter uncertainty through the application of various sensitivity analysis techniques and (b) exposure parameter-related variability using probabilistic simulation.

This integrated approach, will generate risk metrics that reflect the distribution of risk across modeled age group/endpoint combinations resulting from exposure-related variability. With regard to uncertainty, this approach will show the range of potential risk results resulting from uncertainty in key model steps and input parameters. However, as noted above, we will not be

producing confidence intervals for population risk distributions since uncertainty is being addressed with sensitivity analysis techniques and not through probabilistic simulation.

An expanded discussion of methods used in the Pilot Analysis to address both variability and uncertainty is included in Section 7.0.

4.0 EXPOSURE ASSESSMENT

4.1 Estimating Media Concentrations

This section describes the approaches we intend to use and others we are considering for estimating Pb concentrations in the exposure media of interest for this analysis. In order to model the exposure pathways outlined in Figure 3-1, we need to estimate Pb concentrations in the following media:

- Ambient air;
- Indoor air;
- Soil/dust – outdoors; and
- Soil/dust – indoors.

Our needs for characterizing media concentrations for this analysis can be divided broadly into (a) estimating baseline conditions (for all relevant media) and (b) estimating future conditions (for all media) reflecting a particular NAAQS scenario. The extent to which empirical data will be used relative to modeling in establishing baseline conditions for a particular case study location will depend on the degree of coverage provided by available monitoring data. In some instances, it may be possible to establish baseline conditions largely using measured data for ambient air, soil and even indoor dust, while other case study locations may require modeling to characterize baseline conditions, with measured data being used largely for performance assessment of those modeled concentrations. And there may be locations for which a combination is employed. By contrast, future conditions for ambient air will be estimated either by (a) adjusting air concentration surfaces to reduce air concentrations in areas exceeding a particular NAAQS standard or (b) conducting modeling with reduced emissions estimates in order to achieve a modeled surface without exceedances of a particular standard. Future conditions for other media besides ambient air (e.g., outdoor soil, indoor dust) will be estimated through modeling.

The remainder of this section begins with a brief discussion of the general approach for characterizing spatial variability in demographics and media concentrations using a GIS-based spatial template, followed by descriptions of the approaches being considered for estimating media concentrations in each medium of interest.

4.1.1 Ambient Air

As described in Section 3.2, the approach used to characterize ambient air Pb concentrations for a particular case study will depend on the sufficiency of the monitoring data available. For current conditions, we will rely upon air monitoring data, as feasible, to estimate ambient air concentrations. As described in the draft AQCD (EPA, 2006b) there are a number of monitoring networks that may be useful for this purpose, and we will also investigate the availability of additional data in particular locations (e.g., near sources of interest). We will augment this approach with modeling as needed for current and for future conditions.

We have identified a number of modeling tools which may be combined with ambient monitoring data in order to characterize air concentrations resulting from different emissions sources (i.e., current direct releases and reentrainment). These tools include:

- *Air quality modeling*: We intend to rely on air quality models (e.g., AERMOD, ISC, and CALPUFF)[6] for modeling ambient air concentrations associated with sources of new Pb emissions (e.g., ongoing stationary and mobile sources), as well as re-emission of historically deposited Pb (i.e., re-entrainment of Pb associated with soil/dust).

- *Source apportionment modeling*: We are considering the use of source apportionment models for two purposes: 1) to identify contributions of different source types to measured air concentrations (e.g., to apportion ambient monitor Pb concentrations between specific industrial point sources and reentrainment), and 2) to evaluate model performance and guide refinement of air quality modeling (i.e., compare modeled surfaces in the vicinity of a monitor to the relevant source-apportioned component of that monitor to determine whether modeling seems representative and if not, then reexamine elements of modeling including emissions profiles). Specific source apportionment methods being considered include: (a) Chemical Mass Balance (CMB) and (b) Positive Matrix Factorization (PMF). In addition, we will consider using source-apportioned results conducted for PM (from the literature) and then applying soil/dust Pb concentration values to convert those PM-related sourced-apportioned data into Pb-specific estimates.

- *Reentrainment modeling:* To estimate re-emissions of historically deposited Pb (for use in the air quality modeling), we are considering the following tools: (a) particulate emission factors (PEFs) as described in the Superfund Soil Screening Guidance (EPA, 1996a) and EPA's AP-42 emission factor documentation and (b) Wind Erosion Prediction System (WEPS) which is a dust resuspension model developed by the USDA Agricultural Research Service.

- *Use of National Air Toxics Assessment-national scale assessment (NATA-nsa):* Another approach for developing estimates of re-emissions of historically deposited Pb that we are considering involves comparison of the ambient concentrations predicted in the most recent NATA-nsa[7] to ambient monitoring data. As the NATA-nsa estimates are developed from dispersion modeling of emissions from the National Emissions Inventory (NEI), which does not include reentrainment of road and soil dust, the delta, which may result form several factors including reentrainment, may provide a perspective on the contribution of that source type to ambient air concentrations.

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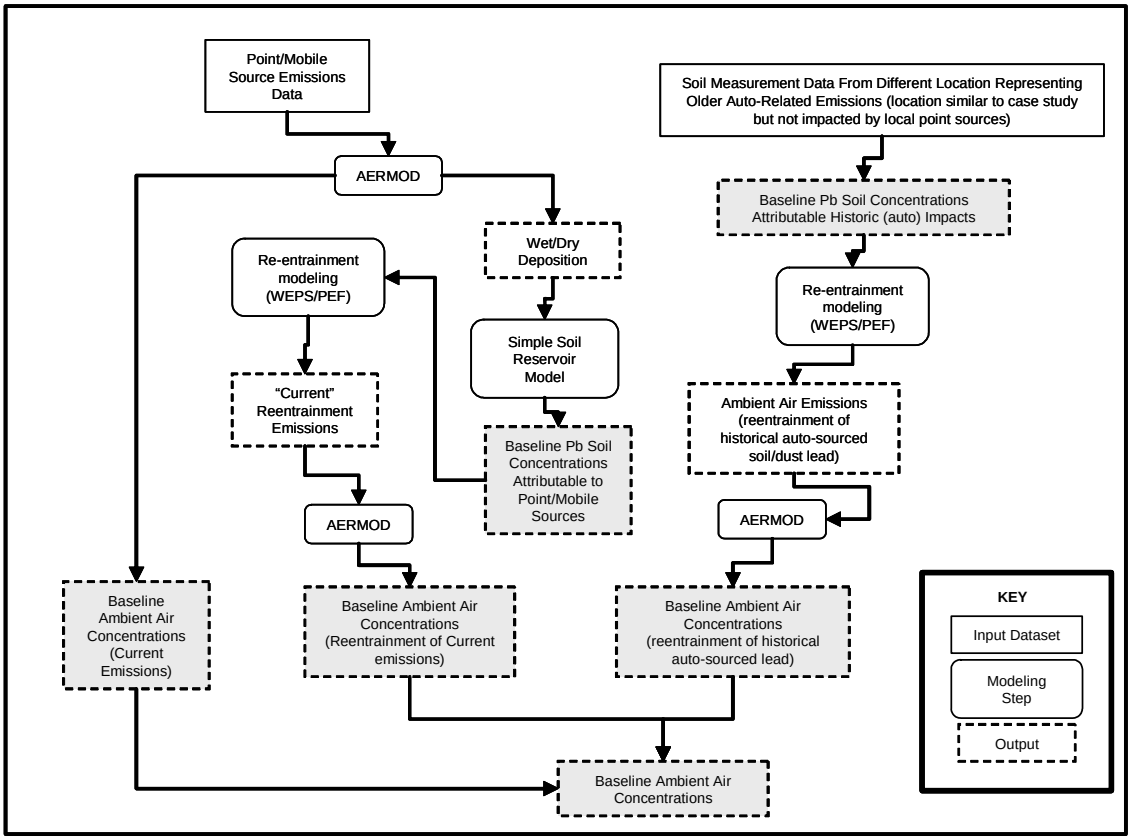
[6] AERMOD and ISC (Industrial Source Complex) are Gaussian plume dispersion models, with AERMOD being the more current model. CalPuff, another refined model, is a puff dispersion model. http://www.epa.gov/scram001/dispersion_prefrec.htm#aermod

[7] EPA's NATA-nsa is a national scale assessment of air toxics emissions, ambient concentrations, inhalation exposures, and human health risk performed on a triennial basis. http://www.epa.gov/ttn/atw/nata1999/ The most recently available assessment is based on the 1999 NEI.

- *Literature-based re-entrainment estimates:* We intend to consider, as appropriate, information in the literature in developing estimates of emissions of historically deposited Pb , e.g., that described and cited in the draft AQCD (EPA 2006b).

Figure 3-3 illustrates an application of tools described above to characterize baseline ambient air concentrations (e.g., a "fully modeled approach"). In this example, both point/mobile source emissions and re-entrainment of historically deposited Pb are modeled explicitly. As feasible, performance evaluation of this type of approach could involve source-apportioned monitor data. Specifically, modeled air concentrations resulting from point and mobile sources, as well as reentrainment could be compared with the relevant source-apportioned signal from ambient monitors within the study area.

Figure 3-3 Overview of Modeling Approach for Ambient Air (where measurement data are available and sufficient, they will be used in preference to, or in combination with modeling steps shown here to characterize baseline conditions)



4.1.2. Indoor Air

To estimate indoor inhalation exposures indoors associated with ambient (outdoor) air concentrations, we intend to use either ambient-to-exposure concentration ratios or inhalation exposure modeling. The inhalation exposure modeling approach, described in Section 4.1.5,

takes into account differences in indoor and ambient air concentrations, time spent indoors vs. outdoors and other activity patterns, and variability in concentrations across a variety of different microenvironments (e.g., cars, offices, outside).

4.1.3 Outdoor Soil/Dust

The approach used to characterize outdoor soil/dust concentrations for a particular study area will depend on the amount of site-specific soil measurement data available. However, it is anticipated that for all case study locations, potential future changes in soil Pb concentrations under different NAAQS scenarios will need to be modeled to reflect the potential impact of decreases in deposition of Pb across the study area, reflecting decreases in ambient air-related Pb.

To predict future soil Pb concentrations (or baseline conditions for those case studies lacking sufficient monitoring data), we are considering using deposition predicted from the air quality modeling combined with a simple soil reservoir model, such as EPA's Multipathway Exposure (MPE) methodology (EPA, 1998a). MPE is a set of algorithms developed to estimate cumulative soil concentration as a function of dry and wet particle deposition, soil mixing depth and bulk density, and a soil loss constants for processes of interest that impact concentrations in surface soil. As an alternative to MPE, we are considering the option of using EPA's Total Risk Integrated Methodology Fate, Transport and Ecological Exposure model (TRIM.FaTE) which employs a fully coupled mass balanced approach to simulating distribution of pollutants of interest among media of the simulated ecosystem (http://www.epa.gov/ttn/fera/trim_fate.html). TRIM.FaTE includes the capability for dynamic as well as steady-state modeling and has sensitivity analysis and MonteCarlo features.

4.1.4 Indoor Soil/Dust

The approach used to characterize indoor dust concentrations for a particular study area will depend on the amount of site-specific measurement data available. For example at the primary smelter case study location, some site-specific residential dust data are available. For other case study locations, we may consider the use of literature-based concentrations for comparable residences or a modeling approach (e.g., below). Additionally, for all locations under future air quality scenarios, we intend to use a modeling approach.

We are considering the modeling approach employed by the IEUBK model (EPA 2005a, EPA 2006b, EPA 1994) which presumes a linear regression relationship between air Pb (PbA), outdoor soil Pb (PbS) and indoor dust Pb (PbD), and accommodates user-specified inputs.

$$PbD = \beta_{(other\ sources)} + \beta_S\ PbS + \beta_A\ PbA$$

The IEUBK recommended default values for β_S and β_A, respectively, are 0.70 and 100 ug/g per ug/m^3, with the former being based on site-specific data where soil was a major contribution to household dust. Prior to adoption, we intend to evaluate the application of this equation and these defaults in light of alternates currently available in the literature, including information discussed in the draft AQCD (EPA, 2006b). Note, that $\beta_{(other\ sources)}$ covers background exposure

sources, including Pb paint in older houses (the characterization of background exposures including Pb paint levels in indoor dust is discussed in Section 4.1.6). We also plan to evaluate the performance of the modeling approach in light of the current literature.

4.1.5 Estimating Inhalation Exposure Concentrations

Estimates of inhalation exposure concentrations for the population subgroups of interest will be derived in the Pilot assessment using ambient air concentration estimates (see Section 4.1.1). A potentially important factor to consider in assessing inhalation exposure is an individual's daily activity patterns including their commuting activity (e.g., home to work, home to school). In order to incorporate consideration for daily mobility into our modeling of inhalation exposure, we are considering the use of data generated as part of the recent NATA-nsa. Specifically, we are considering also using ratios of *modeled exposure Pb concentrations* to *ambient air Pb concentrations* (the former reflecting daily mobility and generated at the US Census tract-level) to adjust our ambient air concentration values to reflect consideration for daily mobility. For the NATA-nsa, annual average ambient air concentrations were estimated for all U.S. census tracts and 30 replicates of annual average exposure concentrations were estimated for five different population subgroups (i.e., five age groups) in each census tract reflecting daily activity patterns including commuting trips. We may use these data to develop 30 replicate exposure-to-ambient concentration ratios per census tract and population group in a study area and these ratios in turn, used to derive 30 replicate estimates of annual average inhalation exposure concentrations for each population subgroup in each geographic unit (block group) in the study area. The 30 replicate estimates of annual average inhalation could then be used to establish central tendency inhalation estimates at the US Census block group-level and the full distribution could be used in Monte Carlo simulation of exposure-related variability (see Section 4.3.4).

If the Pilot analysis suggests that inhalation exposure to Pb is a significant contributor to overall Pb exposure, then we may consider a further refinement in our consideration of daily mobility by running HAPEM or APEX for each study area and population subgroup of interest rather than relying on the ratios generated from the NATA-nsa.

4.1.6 Background (Non-Air-Related) Exposure

In addition to estimating media concentrations for air-related exposure pathways, we will also estimate Pb exposures for media pathways that are not directly linked to air concentrations (i.e., background exposure levels). Consideration of these background exposures allows us to model total Pb exposure for our study populations. Potential sources of data and a brief overview of how media concentrations will be estimated are presented here by medium:

- *Indoor and Outdoor Soil/Dust Associated with Lead Paint.* EPA, HUD, FDA, and other Agencies have developed extensive monitoring programs to address non-air related Pb exposure concentrations. For children living in older housing or in urban areas, Pb levels in outdoor soils and house dust are likely to contribute the bulk of total Pb intake. For the portion of these exposures not due to re-entrainment, we are considering a number of surveys of urban soil and house dust Pb levels (Lanphear et al. 1998; EPA 1998b, 2000, Jacobson et al., 2002) as potential sources of exposure concentration values spanning the

range of housing stock and urban settings. The National Research Council (2005) has also reviewed a number of soil Pb data sets for communities near Pb mining and smelting operations.

- *Dietary Exposures***.** Similar to air Pb levels, Pb concentrations in food have also been decreasing over the last two decades. In a recent project for the Office of Water (OW), Agency contractors reviewed available data sources related to dietary Pb concentrations (ICF 2005) and evaluated the trends in Pb concentrations in major food groups reported in FDA's Total Diet Survey data from 1992-2002 (FDA 2004). These and similar data are being considered, along with information related to food intake patterns, to estimate Pb intake from foods. We do not expect to identify any site-specific food consumption data for the case study sites.

- *Drinking Water***.** We plan to gather data on the distribution of Pb concentrations in drinking water to monitor compliance with the "Lead and Copper Rule" (EPA 2004b). These data document decreases in water concentrations since the promulgation of that rule in 1991. However, the summarized data provided in this data set are not suitable for detailed exposure estimation because (1) the sampling program is targeted rather than random and (2) data are reported as 90^{th} percentile values rather than means, percentiles, or individual values. As part of ongoing work for OW, we will pursue additional data, either individual sample data from EPA's SDWIS system and/or data from a small number of individual systems in an effort to characterize exposure concentrations related to drinking water.

4.2 Study Population(s) and Potential Stratification Based on Socioeconomic Factors

The selection of subpopulations to be included in this assessment focused on those for which there are endpoints associated with the range of exposures expected to most closely reflect current levels and for which there is adequate information to support quantitative risk estimates. We are currently planning on modeling risk metrics related to IQ loss for children under seven years of age and are considering various options for modeling blood pressure and renal endpoints for adults. Each of these demographic groups is discussed below, including the degree to which they can be differentiated in modeling based on gender and race. In addition, several additional subpopulations of potential interest are discussed (e.g., pregnant women, post-menopausal women), although we do not expect to quantitatively assess risks to them.

- *Children from birth through age 6:* We will consider the option of differentiating blood Pb level modeling for different socioeconomic subpopulations to the extent that there are data that (a) specify different behavior translating into differential exposure levels for key media (e.g., dietary ingestion rates), or (b) specify different Pb concentration levels (e.g., paint-related dust contamination based on age of housing). Consideration of socioeconomic-related differences in exposure may be treated as part of sensitivity analyses rather than explicitly in population-level exposure modeling.

- *Adults:* We are considering modeling both working-age (18-64 year olds) and retired (65 to 80 year olds) adult populations. In addition, we may consider modeling adult subpopulations known to have high occupational exposures to Pb, or subpopulations expected to experience high Pb exposure due to a confluence of Pb exposure-related factors (e.g., housing age, dietary exposure, proximity to ambient air sources). As with the child study population, we are considering the option of differentiating blood Pb modeling for adults based on socioeconomic status (e.g., differences in behavior that translates into increased exposure levels, differences in Pb concentrations in key media such as indoor dust related to housing age).

- *Pregnant women*: While this subgroup will not be quantitatively assessed here (see EPA 2006b for summary of currently available studies), fetal exposure from the mother will be include in estimating blood Pb levels for children.

- *African Americans (and blood pressure modeling):* Racial and ethnic differences in blood Pb concentrations are well-demonstrated and age-specific average blood pressure is known to be substantially higher in African Americans than in other groups (Pirkle et al. 1998, Vupputuri et al. 2003). However, we are not aware of an approach to differentiate exposure-response relationships for the African American sub-population in particular. However, should we undertake an assessment of the potential shift in population-level blood pressure distributions for the case studies as part of the Pilot, we may consider African Americans separately through the use of socioeconomically-differentiated blood pressure distributions and the impact that Pb-related exposure has on those distributions.

4.3 Estimating Blood Lead

Once exposure levels in the form of either modeled intake rates (e.g., for dietary items and indoor dust) or exposure concentrations (e.g., for ambient air) have been generated for study populations of concern, the next step, as outlined in Figure 3-2, is to model blood Pb levels for those populations. The concentration of Pb in whole blood is the most commonly used measure, or "biomarker," primarily because it is most convenient and easily measured, but also because blood Pb tends to be a good indicator of recent exposures. Pb in long-term body stores (primarily bone) may also contribute to blood Pb concentrations and to the risk of adverse effects. Thus, most approaches for estimating adverse effects take into account the "biokinetics" (i.e., uptake, deposition, mobilization, and excretion) of Pb in the body. Simplified forms of biokinetic models (e.g. "slope factor models") involve a linear projection of blood Pb from either intake or uptake estimates developed outside the model. "Empirical" approaches bypass the explicit modeling of biokinetics and predict blood Pb levels directly based on concentrations in exposure media. This section discusses the approaches we are considering for modeling blood Pb levels in children and adults, which include all three types of models.

Although the various models involve different ways of accepting "inputs" (e.g., media concentration with ingestion rate vs intake rate), we intend to ensure that we provide the models used with the same inputs. For example, the Model B input for intake rate will match the combination of Model A's inputs for media concentration and ingestion rate. This will ensure that differences in model outputs will be reflective of differences in the models themselves.

The section begins by discussing the models selected for children, followed by options identified for modeling adults. We note that in our use of any model, all inputs will be considered, with values chosen based on the best available information as replacement for defaults as supported. The section then discusses blood Pb metrics under consideration for both children and adults (e.g., concurrent or lifetime-averaged values). The section then discusses a probabilistic Monte Carlo-based approach being considered for exposure variables, with subsequent "batch mode" modeling of blood Pb levels through the various models (Note, this probabilistic simulation of exposure is an option that applies both to children and adults and consequently is discussed in its own subsection). The section concludes with a discussion of model preparation and evaluation.

4.3.1 Children

We intend to use the IEUBK model (EPA, 1994, 2002a, 2002b) for modeling blood Pb levels in children. We are also considering employing an additional biokinetic model (Leggett et al., 1993) and an empirical model (Lanphear et al., 1998) in order to consider model uncertainty in this key step in the risk assessment. As discussed below, the Leggett model is being considered for predicting both children's and adult (if included) blood Pb levels. Chapter 4 of the draft AQCD (2006b) discusses these models.

We are also considering the pharmacokinetic model of O'Flaherty et al. (1993) as another option for use in this analysis. While its approach to blood Pb modeling is also quite sophisticated, the O'Flaherty model has been subject to considerably less independent validation against human population data and other models than the Leggett model. Also, the precise model structure and parameter values are less well-documented than those of the other models.

As noted earlier, we are also considering an "empirical" model (the Lanphear model) for estimating blood Pb levels in children, however, its use poses some challenges. The model includes no component for inhalation exposures, so it is necessary to assume that the main blood Pb impact of changes in ambient air levels occurs through changes in soil and indoor dust Pb levels. In addition, the full Lanphear et al. model includes parameter values for many variables for which data may not be available for some or all of the study populations. In addition, the study identifier variable (specifying the different populations combined in the analysis) is highly significant and has a substantial impact on estimated blood Pb levels. This variable presumably captures unidentified site-specific covariates that strongly effect blood Pb levels, that may or may not apply to a specific case study location.

One way to apply the model that is being considered involves adapting the Lanphear et al. (1998) output tables as "response surfaces" for evaluating changes in exposure concentrations. The tables give predicted geometric mean blood Pb levels for various combinations of soil Pb concentration and house dust Pb loading, with all other covariates held at mean or median values. Changes in ambient and indoor air concentrations associated with the different case studies/exposure scenarios would enter into the model through their effect on soil concentrations and indoor dust Pb loading, estimated through deposition modeling. We recognize, however, that this approach would ignore the significant role of covariates in predicting blood Pb levels.

4.3.2 Adults

For adults, we are considering the use of both a biokinetic model (Leggett 1993) and a "slope factor" model (the Adult Lead Methodology, ALM, EPA, 1996b, Maddaloni 2005 or Bowers et al 1994). The Leggett model was discussed in the previous section and will not be covered further here. However, it is important to note that if employed, the Leggett model will provide a "bridge" between the children's and adult's blood estimates. The remainder of this section will focus on the ALM, derived from the Bowers et al (1994) model.

The ALM was originally developed by EPA (1996b) for the purpose of estimating changes in long-term (months or years) adult blood Pb levels arising from non-occupational (i.e., residential) exposures to contaminated soil near "Superfund sites." The model has two parts. The first, which is implicit, is the calculation of a long-term average Pb uptake from soil Pb concentration data. The parameters in the uptake calculation are the soil Pb concentration, a combined ingestion rate of soil, including both outdoor soil and indoor soil-derived dust, an absolute gastrointestinal absorption fraction (for soil and dust from soil), and exposure frequency and averaging times.

The estimated Pb uptake is multiplied by a "biokinetic slope factor", derived from data from human exposures (Pocock et al 1983, Sherlock et al 1982, 1984), which is intended to capture the relationship between long-term Pb intake and the estimated increment in blood Pb levels. The increment is added to a population-specific "background" central tendency blood Pb level to generate an estimate of the central tendency blood Pb concentration associated with soil exposures at the specified concentration. In hazardous waste site applications, this background blood level has been derived from a national databases such as the NHANES.

The output of the ALM is a central estimate of the "quasi-steady state blood Pb concentration for the population exposed to the specified Pb concentration in soil. Maddaloni et al (2005) presented an approach to estimating the distribution of estimated blood Pb levels based on the assumption of lognormality, again using data from NHANES. The ALM model can be expressed as a set of simple equations, facilitating adapting of the model for Monte Carlo analysis, should that be undertaken.

4.3.3 Blood Lead Metrics

The "raw" outputs from the blood Pb models will be time profiles of blood Pb levels across the ages of interest, which will be converted to metrics that can serve as inputs to the adverse effects models discussed in the following section. Metrics under consideration for children and adults include:

- *Child blood lead metrics:* The metrics will be those particular to the adverse effects models chosen to quantify IQ risk, such as "concurrent" (i.e., blood level at a particular age typically associated with testing for the endpoint of interest such as IQ) or lifetime average blood Pb levels (birth through particular age). The models being considered are presented in Table 5-1.

- *Adult blood lead metrics*: If adults are included, estimated adult blood Pb concentrations will be used with the adverse effects models chosen to quantify blood pressure or renal effects. Blood Pb metrics for adults will focus on the average over the adult-aged exposure period (e.g., the average modeled blood Pb levels for ages 18-64 for the "working aged" adult population).

4.3.4 Probabilistic Analysis of Exposure Parameters

As described in Section 3.2, the IEUBK model is typically applied with the use of a GSD to estimate the distribution of blood Pb concentrations reflecting inter-individual variability in both exposure and biokinetics. In their recent evaluation of a risk assessment conducted for soil Pb contamination at large Superfund Sites, the NRC (2005) suggested that future use of the IEUBK and similar blood Pb models, in that context, should employ probabilistic simulation of exposure-related variables. We are considering employing such an approach[8] in this assessment for all of the selected models. This approach would involve implementation of external Monte Carlo-based modeling of population exposure, followed by "batch-mode" blood Pb modeling for the set of Monte Carlo generated exposure simulations.

If this is pursued, the probabilistic simulation of exposure will be conducted using a one-dimensional Monte Carlo model which uses probability distributions for exposure concentrations and intake/uptake factors in the case of IEUBK, Leggett and ALM models. The probabilistic exposure model used to feed the Lanphear model would include distributions of estimated changes in soil Pb and house dust concentrations, since that model does not include any exposure factor values.

While the focus here is on sources of variability (with sources of uncertainty reserved for the sensitivity analysis - see Section 7.0), as is often the case with stochasticity in exposure, some sources mix variability and uncertainty. For example, distributions of exposure concentrations estimated for specific portions of a study area using a particular modeling approach can reflect both spatial variability in Pb levels across that area, as well as uncertainty in capturing that variability. In this case, it is difficult to separate these two sources of variability in Pb levels and it is likely that Monte Carlo simulation of exposure variation will reflect both variability and uncertainty in the case of this factor.

Exposure factor distributions used in probabilistic modeling (reflecting variations in receptor behavior) will be developed based on available literature data. For some variables (drinking water and food consumption), substantial data are available from surveys and other studies to support the derivation of probability distributions reflecting the expected wide range of variability across the exposed populations (EPA 1997, 2002a, 2002b) Similarly, the databases used in the inhalation exposure models include probabilistic representations of time activity patterns. Children's soil and house dust ingestion have been subject to extensive study, while for other exposure factors (adult soil ingestion, for example) there are far fewer data to support estimation of probability distributions (Maddaloni et al. 2005). Probabilistic representations of

gastrointestinal absorption fraction will be chosen to reflect the literature related to GI absorption from various Pb species (EPA 2005b, Maddaloni et al. 2005).

An initial assumption used in developing the probabilistic simulation would be that the input distributions of the exposure concentrations and exposure factors are independent (not correlated) except to the extent that they co-vary in space and are age-specific. This assumption could be examined more closely in an effort to evaluate uncertainty related to correlation for the Full Scale analysis, should probabilistic simulation be undertaken.

Evaluation of this modeling analysis will include comparison of the resultant modeled distributions of blood Pb levels with empirical measures of variability in blood Pb levels obtained either from site-specific data or NHANES. Such a comparison may also inform our understanding of the contribution to population blood Pb variability (e.g., as characterized by GSD) from biokinetic variability for modeled populations.

If this option is pursued, the blood Pb distributions generated will be carried through the assessment of adverse health effects in order to generate distributions of IQ loss estimates and blood pressure effects for modeled populations.

4.3.5 Preparation of Models and Inputs, and Evaluation of Performance

Briefly, the preparation of models for application and their evaluation will involve the following steps.

- Develop and document consistent sets of intake/uptake assumptions (exposure factor values, absorption fractions, etc.) for the three biokinetic models[9] derived from the outputs of the case study exposure concentration models.
- Run the IEUBK, and Leggett, and Lanphear et al. models (assuming these other models are employed) for a small number of children's exposure scenarios covering a credible range of exposure conditions and parameter values. If adults are included, run Leggett and the ALM for a small number of adult exposure scenarios.
- Compare results of models to age-specific population blood Pb data from the most recent NHANES, and data from Superfund sites and/or HUD housing studies.
- Compare model results to each other within age ranges.
- Conduct sensitivity analysis to identify parameters/assumptions contributing the most to differences/uncertainties in results. The first step in this analysis will be the comparison of model performance in the selected test scenarios; additional model runs will be conducted if necessary.
- Fully document the process.
- Evaluate overall performance of the models for each age group.

In these steps, we will draw extensively on the previous published modeling comparisons and studies, and may confer with the model authors and other experts during the process. The

[9] A preliminary review of the available literature suggests that previous comparisons did not always involve consistent exposure, intake, and uptake models and parameter values across the models being compared. Once consistent intake/uptake assumptions have been defined, the results from the various models can be compared.

sensitivity of the models to changes in specific parameters will be evaluated. Systematic differences among the model predictions will also be noted; that is, where one or more model predictions differ consistently relative to another under specified sets of exposure conditions. Analysis of the patterns of differences will inform consideration of specific model intake/uptake parameters. In evaluating the reasonableness of model predictions, greater weight would be given to deviations from observational data (when available) than to differences among models.

5.0 EFFECTS ASSESSMENT

Lead exposure has been shown to affect a wide range of organ systems and physiological processes at differing doses in adults and children. The most recent epidemiological studies have been reviewed by EPA in the latest draft AQCD (EPA 2006b). Because extensive *de novo* biostatistical analyses are beyond the scope of the assessment, we intend to draw from the evaluation and identification of adverse effects models contained in the draft AQCD (EPA, 2006b). The staff's basic approach will be to (1) identify a small number of the most appropriate studies and associated models and (2) apply them to each endpoint of concern to derive a range of model-dependent risk estimates.

5.1 Endpoints to be Evaluated

For the Pilot analysis, we are planning to model IQ effects in children and will consider options for modeling blood pressure and renal effects using creatinine clearance (a commonly used measure of glomerular filtration rate (GFR), an index of kidney function) in adults. As feasible, the full assessment may include all three endpoints. As described in the current draft of the draft AQCD (EPA 2006b), there are a number of high-quality studies reporting these effects that are available and a consensus that these effects are "adverse" and occur in the range of exposure anticipated to be relevant to this analysis and the case studies included. The draft AQCD (EPA, 2006b) presents findings regarding susceptible subpopulations (e.g., renal effects in hypertensive subpopulations) that will be considered in characterizing risk associated with the endpoints included in the assessment.

5.2 Models for Estimating Adverse Effects

5.2.1 IQ Reduction in Children

We intend to focus on the Lanphear et al (2005) study as our primary source of exposure-response functions for use in quantifying the relationship between children's blood Pb and IQ decrements. In our use of Lanphear et al (2005) in this assessment, we intend to rely on a nonlinear model, such as the log-linear or piece-wise linear fits depicted in Figures 3 and 4, respectively, of that study, to estimate IQ decrement associated with estimated blood Pb concentrations, and to capture the higher slope indicated by this analysis at lower blood Pb levels (note, the current approach does not call for conducting adjustments for covariates for individual case study populations).

We are also considering the other studies identified in the draft AQCD (Table 6-2.2 of EPA 2006b) reporting quantitative relationships of IQ and blood Pb for populations with blood Pb levels less than 10 µg/dL. [10] These studies are listed in Table 5-1. Although included in this set are several studies on non-U.S. populations, the responses of these populations do not appear to differ substantially from the responses in the U.S. populations. For example, the estimated slopes for blood Pb under 10 µg/dL provided in Table 6-2.2 of the draft AQCD (EPA 2006b) for the two U.S. studies range from -0.8 to -1.6 IQ points per µg/dL blood Pb, while the other

[10] We have not included Al-Saleh et al (2001) which studied children of notably older ages (6-12 years) than the other studies being considered.

studies, which include non-US populations, range from -0.8 to -1.1 IQ points per µg/dL blood Pb. In selecting a set of studies for use in characterizing the range of uncertainty associated with modeling the IQ endpoint, preference will be given to studies conducted in the US reflecting concerns over study population and exposure condition relevance.

Table 5-1. Studies with Quantitative Relationships of IQ and Blood Lead for Blood Lead Levels Less than 10 µg/dL (drawn from draft AQCD Table 6-2.2, EPA, 2006b).

Reference	Study Location	Exposure/Dose Metric having strongest association with IQ
Tellez-Rojo et al. (2006)	Mexico City, Mexico	Pb-B @ 24 months
Bellinger et al. (1992)	Boston, Massachusetts	Pb-B @ 24 months
Kordas et al. (2006)	Torreón, Mexico	Concurrent Pb-B , 6-8 yr
Canfield et al. (2003)	Rochester, New York	Concurrent @ 5yrs
Lanphear et al. (2005)	**International Pooled Analysis**	**Concurrent Pb-B 4.8 – 10 yrs**

5.2.2 Blood Pressure Effects in Adults

For quantifying blood pressure changes associated with blood Pb levels in this assessment, if included, we are focusing on the Nawrot et al (2002) meta-analysis and its log-linear slope estimate as our primary blood Pb-blood pressure model for adult populations. The study also provides confidence limits that can be considered for use as an index of the uncertainty in the assessment associated with sample sizes considerations, and for sensitivity analyses.

We are also considering the other studies identified in the draft AQCD (Table 6-5.1 of EPA 2006b) reports quantitative relationships between systolic blood pressure and blood Pb for mean blood Pb levels below 10 µg/dl. These studies (listed in Table 5-2) analyzed blood pressure effects in particular populations differentiated by gender and race. If this endpoint is included, these studies may be relied on in the full assessment to provide risk estimates based on gender and race specific response functions. Additionally, the current draft of the AQCD includes a meta analysis inclusive of studies published since the Nawrot et al (2002) analysis (EPA 2006b). This analysis also is being considered for use in quantifying this effect.

Table 5-2. Studies under Consideration for Quantification of Blood Pressure Change Associated with Blood Lead Levels (drawn from draft AQCD Table 6-5.1, EPA, 2006b).

Reference	Study Location – and gender
Vupputuri et al. (2003)	NHANES III* - White Males
	NHANES III - White females
	NHANES III - Black Males
	NHANES III - Black females
Den Hond et al. (2002)	NHANES III 1988-94 - White males
	NHANES III 1988-94 - White females
	NHANES III 1988-94 - Black males
	NHANES III 1988-94 - Black females
Nash et al. (2003)	NHANES II - Females
Cheng et al. (2001)	Boston normative aging- Males (about 97% white)
Procter et al. (1996)	US Boston Normative aging study -Males
Nawrot et al. (2002)	31 US and European Studies (includes occupationally exposed)

* NHANES – United States population sample.

5.2.3 Renal Effects in Adults

For quantifying renal effects associated with blood Pb levels in this assessment, if included, we intend to use changes in urinary creatinine clearance as the specific endpoint. Creatinine clearance is a commonly used measure of glomerular filtration rate (GFR), an index of kidney function. The draft AQCD describes multiple studies in which a relationship of this effect with blood Pb (and bone Pb) has been observed for both the general population and specific subgroups such as hypertensives (EPA 2006b). To quantify this endpoint in the risk assessment, we are considering the studies for which estimates of slope for creatinine clearance[11] per blood Pb are presented in Figure 6-4.1 of the draft AQCD (EPA 2006b). These studies, which were for general populations and generally had mean blood Pb levels less than 10 µg/dL, are listed in Table 5-3.

[11] For studies where creatinine clearance was not measured, it was estimated using the relationship based on creatinine levels, age and weight from Cockcroft and Gault (1976).

Table 5-3. Studies under Consideration for Quantification of Creatinine Clearance Change Associated with Blood Lead Levels (drawn from draft AQCD Figure 6-4.1 and Table 6-4.1, EPA, 2006b).

Reference	Study location - Study population
Payton et al. (1994)	Boston, MA - Normative Aging Study, 1988-1991
Kim et al. (1996)	Boston, MA - Normative Aging Study, 1979-1994
Tsaih et al. (2004)	Boston, MA- Normative Aging Study- 1991-~2001
Staessen et al. (1992)	Belgium - Cadmibel Study
Akesson et al. (2005)	Women's Health in the Lund Area Study, Sweden - 1999-2000

We are also considering potential use of Muntner et al (2003), which included a focused analysis on creatinine clearance changes in hypertensives.

6.0 RISK ASSESSMENT

Once blood Pb metrics have been generated for the study populations of interest (for each case study location), the next step, as outlined in Figure 3-2, is to combine these exposure estimates with concentration responses functions developed as part of Effects Assessment to generate risk estimates. This analysis is primarily focused on generating population risk metrics (i.e., distributions of risk levels across modeled populations). Note, however, that we may consider generating more hypothetical individual or small-group risk estimates in order to cover higher-level exposures which may not have been captured in the population-level risk estimates generated for the analysis. We are planning currently, to generate risk estimates for IQ loss for children and are considering the option of generating risk estimates covering blood pressure and renal function effects for adults. This section begins by describing options for defining modeled populations from the stand point of risk characterization, including options for assigning exposure concentrations (e.g., modeling a cohort as beginning exposure all at the same age, or modeling a cohort with distributed ages that experiences varying exposure windows). The section then describes risk metrics being considered for both the child and adult age groups. Note, that risk metrics generated as part of the integrated strategy for addressing uncertainty and variability described in Section 7.0 are discussed separately in Section 7.2.

6.1 Defining Modeled Populations in (Assigning Exposure Concentrations)

A key issue in generating population risk estimates is whether study populations are defined as cohorts which begin exposure all at the same age and then are tracked forward in terms of exposure and risk, or as cohorts with a distribution of ages experiencing a range of exposure windows across the simulation period. An additional factor to consider in modeling population-level risk, is how to treat the period before the exposure of interest begins (e.g., assign all modeled individuals baseline exposure levels prior to implementation of the alternate NAAQS standard). There are several options under consideration for defining study populations for purposes of this analysis. As this issue has policy-related aspects, we do not expect to be selecting a specific approach, and instead, may run multiple options in order to characterize the sensitivity of risk results to this factor. Specific options available for defining the modeled populations in terms of assigning exposure concentrations include:

- *Uniform age cohort*: This option defines the population as a group of individuals at the age defining the lower end of the age range being modeled (e.g., for children, beginning all modeled individuals at age 0 yrs). Therefore, exposure to the levels of interest (e.g., those associated with a particular alternate NAAQS standard), would begin when they are at the lower-bound age. In the case of adults (and the mothers of children for purposes of predicting prenatal Pb contributions where appropriate), we would assume that exposures prior to the start age is at background levels.

- *Distributed (demographically representative) cohort*: This option defines the population as distributed across the age range of interest, as reflected in available demographic data (e.g., 10% of children at 0-1 yrs, 15% at 1-2 yrs and so on). With this option, modeled individuals begin the exposure of interest (e.g., an alternative NAAQS level) at different

ages across the age range. As with the uniform age cohort option, the assumption would be made that exposures at ages before initiation of the NAAQS level of interest, would occur at background levels.

In modeling adult blood Pb levels, depending on the approach used, it may be necessary to track blood Pb levels across consecutive age ranges. For the childhood period, biokinetic and/or empirical models could be used to estimate central tendency blood Pb profiles as a function of age for the adult population. For adults of working age, it is likely adult average blood Pb levels would be used across the ages of 18 to 64 to estimate health impacts. For retired adults, the working age exposure scenarios would be run, followed by the exposures scenarios for retirement, and time-average blood levels for ages 65 to 80 would be used to estimate health impacts.

6.2 Risk Metrics for Children

In previous analyses of Pb risks, EPA has adopted a number of metrics for expressing population risks from Pb exposure in children. These have included average changes in blood Pb levels, changes in the numbers of children with blood Pb levels above 10 µg/dL, and population average and aggregate changes in children's IQ.

For the Pilot, we are planning to generate risk metrics characterizing IQ changes in children, including degrees of IQ reductions for specific percentiles of the population as well as population-level estimates of the number of kids experiencing specific ranges of IQ reductions. In addition to population-level risk metrics, we may consider changes in population-level blood Pb distributions.

We are also planning to differentiate all risk metrics as to background versus NAAQS-relevant exposures (e.g., Pb exposure-related IQ loss for a particular percentile of the children at a case study location would be further differentiated as to magnitude of IQ loss from exposures to "NAAQS-relevant exposures" versus exposures to "background".

It is important to note that the degree to which we can generate refined population-level risk metrics that capture risks at the tails of the distribution (i.e., for more highly exposed individuals), or identify the number of individuals with blood Pb levels exceeding science-policy thresholds of interest, will depend critically on the degree of uncertainty associated with our characterization of population variability in blood Pb levels. This, in turn, will depend on the overall degree of uncertainty associated with the two methods described above for modeling population variability in blood Pb levels (i.e., application of the GSD approach and use of probabilistic simulation to cover exposure-related variability).

It is also important to make clear that the population-level risk metric planned for the Pilot assessment is the distribution of IQ loss across the case study population, not the change in absolute IQ levels in the exposed populations. The process of modeling shifts in absolute IQ for a population requires that (a) the underlying IQ distribution for that population be established and (b) that a reasonable understanding of the correlation between absolute IQ and the level of Pb-related IQ loss exist (e.g., is greater IQ loss correlated with lower IQ for a particular

population or are they uncorrelated?). The process of establishing the absolute IQ distributions for specific populations associated with a given case study location would be challenging and subject to considerable uncertainty, which in turn, would mean that an analysis of a shift in absolute IQ resulting from Pb-related exposure would be subject to as much, if not more uncertainty (since the potential correlation between Pb-related IQ loss and absolute IQ could have an significant impact on this risk metric). Because of the significant uncertainty associated with projecting reductions in absolute IQ distributions for specific populations (uncertainty that can not be reduced without significant research to identify representative data for a particular population), we are not planning to project shifts in absolute IQ as part of the Pilot analysis.

6.3 Risk Metrics for Adults

As was the case for children, if undertaken, risk calculations for adults will be based on estimates of blood Pb changes for central tendency adults derived from the Leggett or ALM models. Corresponding log-normal distributions of blood Pb levels will be derived using GSD estimates derived from large population data (NHANES) for groups with similar demographic and socioeconomic characteristics as the exposed populations or for the general population where population-specific data are not available. Average increases in central tendency blood Pb levels will serve as simple summary values for comparing the general magnitude of effects of different exposure scenarios. Percentile values and proportions of the exposed populations with estimated blood Pb levels in specified ranges will also be provided.

As with children, the staff will also consider using a Monte Carlo-based simulation of blood Pb levels for adults, reflecting exposure factor variability. This probabilistic analysis will generate population-level blood Pb results paralleling those generated using the GSD approach described above, with the exception that they will not provide coverage for biokinetic variability (we will look into options for developing a GSD just to cover this specific factor). The primary outputs from the adult risk assessment will be tabular summaries of the changes in the distribution of blood pressure in the exposed populations.

In the Pilot assessment, we will explore the estimation of incidence of clinical hypertension by adding the estimated increase in blood pressure to national gender- and age-specific absolute blood pressure distributions relevant to the case study locations.

As noted earlier, there will be no attempt to predict the changes in incidence of cardiovascular disease resulting from Pb exposure in the risk assessment.

7.0 UNCERTAINTY AND VARIABILITY ASSESSMENT

Modeling of Pb-related exposure and risk is subject to a variety of sources of variability (e.g., residential location, daily activity patterns, dietary ingestion rates, Pb uptake rates) as well as sources of uncertainty (e.g., different blood Pb models, different health endpoint concentration-response functions). A comprehensive analysis of uncertainty and variability typically involves two-dimensional probabilistic simulation with one dimension designed to represent variability and the other uncertainty. Probabilistic simulation of uncertainty requires development of confidence distributions for uncertain input variables (parameter uncertainty) and the establishing of degrees of confidence for multiple competing models identified for the same modeling step (model uncertainty). Because of data limitations and constraints, it is not feasible to develop confidence distributions for many of the sources of parameter and model uncertainty identified for this risk analysis. Therefore, for the Pilot analysis, the staff will use sensitivity analysis techniques to examine the impact of sources of uncertainty on exposure and risk results. These techniques involve establishing plausible ranges for input parameters and identifying multiple modeling options reflecting model uncertainty for specific modeling steps. Then each uncertainty parameter (or possibly pairings of parameters expected to exhibit correlation) is varied across its plausible range as the remaining parameters are held at their central tendency (or expected) values. The impact of each input parameter on model outputs can then be ascertained. The impact of individual parameters can then be compared to identify those having the greatest impact on model results and the general degree of that impact can be evaluated to gain perspectives on the magnitude of potential uncertainties. Similarly with model uncertainty, alternate models can be substituted one at a time into the analytical framework to determine the consequent impact on model results. As with sensitivity analysis results for parameter uncertainty, these results can be evaluated to compare the impact from different sources of model uncertainty and the overall degree of the impact from model uncertainty on model results can be determined.

Regarding variability, as noted earlier in Section 7.2, we are considering the use of probabilistic (Monte Carlo-based) simulation to characterize the impact of exposure variability on blood Pb levels and ultimately, risk metrics. It is also important to note that the modeling framework developed for this analysis reflects coverage for a range of other sources of variability besides the exposure related factors covered in the probabilistic analysis. For example, the GIS-based spatial modeling framework explicitly reflects variability resulting from the demographic spatial profiles associated with modeled populations within a given study area, as well as the intersection of those populations with the Pb media concentration fields of interest (e.g., ambient air, outdoor soil/dust, indoor dust). Spatial and temporal variability in media concentration fields will also be reflected in both the air monitor data and dispersion modeling used to establish those fields.

Table 7-1 presents examples of: (a) competing models for specific steps in the modeling framework (representing model uncertainty), (b) sources of input parameter uncertainty and (c) specific sources of exposure-related variability associated with the risk modeling framework. It is these sources of model and parameter uncertainty as well as exposure-related variability that are addressed in the integrated approach discussed below.

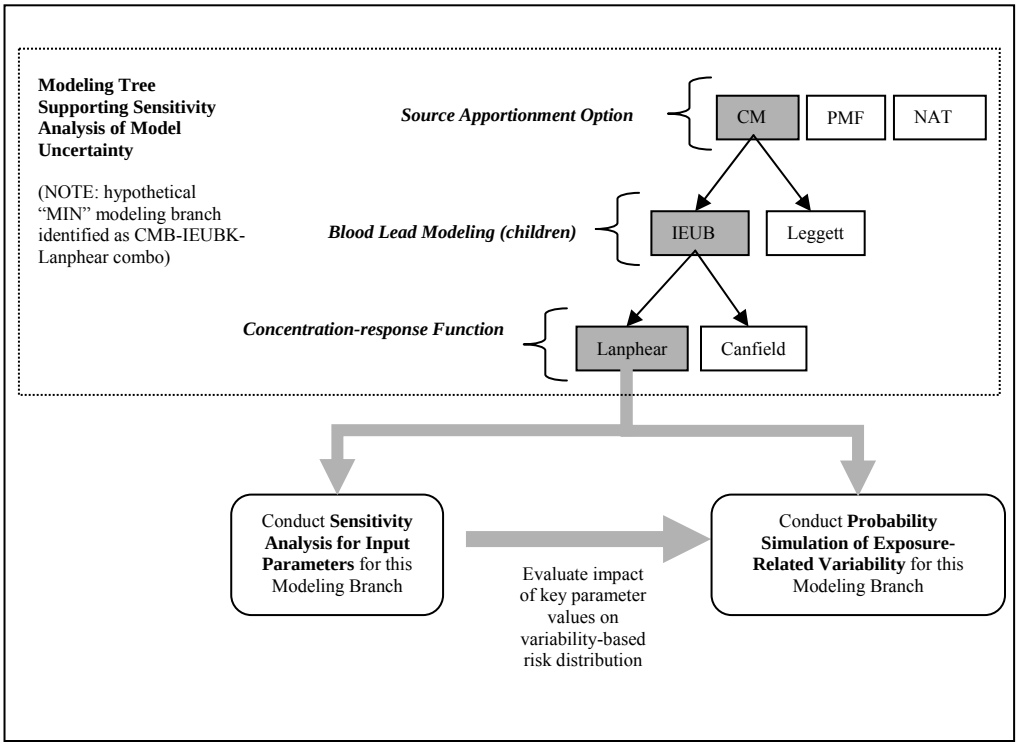
Table 7-1 Sources of Model/Parameter Uncertainty and Exposure-Related Variability Potentially Impacting the Risk Assessment

Model Uncertainty	Parameter Uncertainty	Exposure-Related Variability
• Source apportionment models (PMF, CMB, NATA-based) • Blood Pb modeling (IEUBK, Leggett, ALM, Lanphear) • Health effects (concentration-response model) for IQ (Canfield, Lanphear) • OTHERS	• Pb Emissions Estimation • Blood Pb Metrics • Pb Uptake Factors • Soil/House Dust Pb • Blood Pb GSD • Background blood Pb levels • OTHERS	• Exposure/Intake Factors • Background Exposure Levels (e.g., diet, paint) • NAAQS-Relevant Exposure Levels

7.1 Integrated Approach for Considering Uncertainty and Variability

We are considering the use of an integrated approach that combines probabilistic modeling of variability with sensitivity analysis techniques intended to examine both parameter and model uncertainty. This approach, which is depicted in Figure 7-1, involves development of a

Figure 7-1 Integrated Approach for Considering Model Uncertainty, Parameter Uncertainty and Exposure-Related Variability



modeling options tree where each branch represents a unique combination of models identified for the analysis (i.e., a selection of specific models for each modeling step subject to model uncertainty). This means that the risk estimates generated by a specific combination of modeling options would be represented as a distinct set of risk results located at the end of a particular branch of the modeling options tree. Therefore, looking across the range of risk results generated at the ends of the branches, provides perspective on the overall impact of model uncertainty on risk results. Note, however, that because confidence levels have not been assigned to any of the modeling options, it is not possible to develop a confidence distribution across the branches. All that can be said is that the spread in risk estimates across the branches reflects the range of model uncertainty impact on risk estimates.

We may then integrate consideration of parameter uncertainty into the modeling options tree by taking a particular modeling branch and conducting parameter sensitivity analysis on that model combination. Specifically, a given input parameter that is subject to uncertainty can be varied from its central tendency (or expected) value across its plausible range and the impact on risk estimates at the end of that modeling branch recorded. This process can be repeated for other uncertain parameters (and for pairings of input likely to exhibit correlation) to determine the potential impact of each uncertain parameter on risk estimates. This procedure when completed provides a parameter sensitivity analysis for that particular branch. This procedure could then be repeated for each modeling branch in the tree, providing a set of parameter sensitivity results for each modeling option. This then would reflect a combination of sensitivity analysis techniques considering both model uncertainty and parameter uncertainty.

To facilitate comparison of sensitivity analysis results both within a given modeling branch and across branches, the parameter sensitivity analysis results for each modeling branch can be standardized by dividing the results derived using the high-end values by the all-central tendency estimate. This will provide a rough estimate of the degree of uncertainty (roughly equivalent to the proportion of variance) contributed to the risk estimate by each step in the analysis.

Finally, we may integrate consideration of exposure-related variability into this integrated modeling options tree by conducting Monte Carlo simulation of exposure parameter variability (as described in Section 4.3.4) for each modeling branch. This would produce a distribution of risk estimates at the end of each modeling branch which represent inter-individual variability in key exposure-related factors. In addition, we may use the parameter uncertainty sensitivity analysis approach described above to derive multiple variability distributions for each branch, each reflecting the impact of a specific uncertain input parameter. By looking across the risk distributions at the end of the modeling branches, the impact of model uncertainty on the distribution of population risk can be considered. For example, comparison of the 95th% risk estimates at the end of the modeling branches may reflect the impact of model uncertainty on this risk metric. Furthermore, the set of 95th% risk estimates at the end of a particular modeling branch can be compared to provide an indication of the impact of specific uncertain input parameters on that particular risk metric (for that particular modeling combination).

Rather than generating full probabilistic risk metrics for the full spread of modeling branches (i.e., running the probabilistic variability simulation for each combination of modeling options), we would likely focus the analysis on those key branches of greatest utility to decision makers.

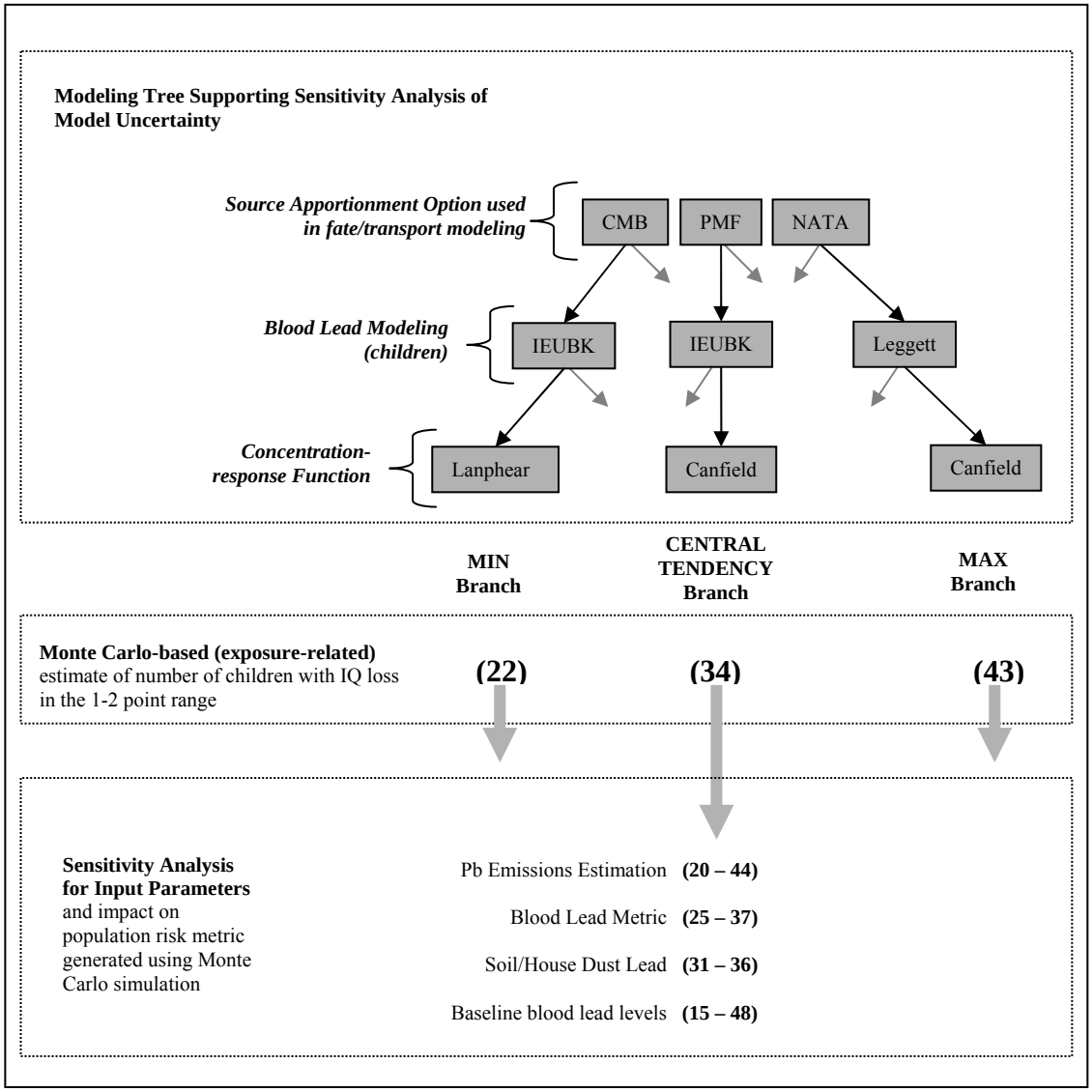
These include (a) the central tendency modeling branch (i.e., the combination of model options generating risk estimates falling in the middle of the full range of estimates generated) and (b) the upper- and lower-bound modeling branches (i.e., the modeling options producing the highest and lowest risk distributions of all the branches). Central tendency and upper- and lower-bound modeling branches could be identified by first running each modeling branch without consideration for either probabilistic variability analysis or parameter uncertainty. The point estimate risk results generated for each modeling branch will then be compared to identify branches with the lowest (MIN), the highest (MAX) and the central tendency risk estimates.

The staff could then conduct full comprehensive application of the integrated approach to these three key modeling branches. This approach will allow identification of a clear central tendency modeling approach (which can be presented as the best estimate, in the absence of additional confidence information allowing a more explicit and quantitative treatment of model uncertainty). Risk results for the max and min modeling branches can then be evaluated to provide perspective on the range or spread of model uncertainty impact on modeled results.

7.2 Risk and Exposure Metrics Generated with the Integrated Approach

As mentioned above, we are considering implementing the integrated approach for model uncertainty, parameter uncertainty and exposure-related variability for the max, min and central tendency modeling branches. This approach will generate three sets of risk and exposure metrics, each reflecting a particular combination of modeling options. In addition, each of these three sets of results will involve consideration for input parameter uncertainty as described above. Therefore, it would be possible, for example, to estimate at the number of children with IQ loss from air pathway-related Pb sources in the range of 1-2 IQ points for the max, min and central tendency modeling options. It would also be possible to see how this population risk-bin metric varies given parameter uncertainty for each modeling option (and to compare the impact of that parameter uncertainty across the three modeling branches). This hypothetical example is presented in Figure 7-2.

Figure 7-2 Example Risk Metrics Generated Using the Integrated Approach



ECOLOGICAL RISK ASSESSMENT

8.0 OVERVIEW OF ANALYSIS PLAN

8.1 Conceptual Model for Lead Ecological Risk Assessment

Figure 8-1 represents a conceptual model of the elements pertinent to assessing ecological risks associated with environmental Pb exposures. The freshwater and soil pathways are the primary pathways of interest to this analysis and will be addressed quantitatively in this assessment.

Sources: The focus of the NAAQS review is on sources of Pb to ambient air (e.g., stationary and mobile emissions sources and resuspension of anthropogenic Pb). Other non-air sources of environmental Pb (including mining activities, contaminated landfills, etc.) may contribute to Pb concentrations in environmental media. This analysis deals primarily with present and past emissions to air and the resulting deposition.

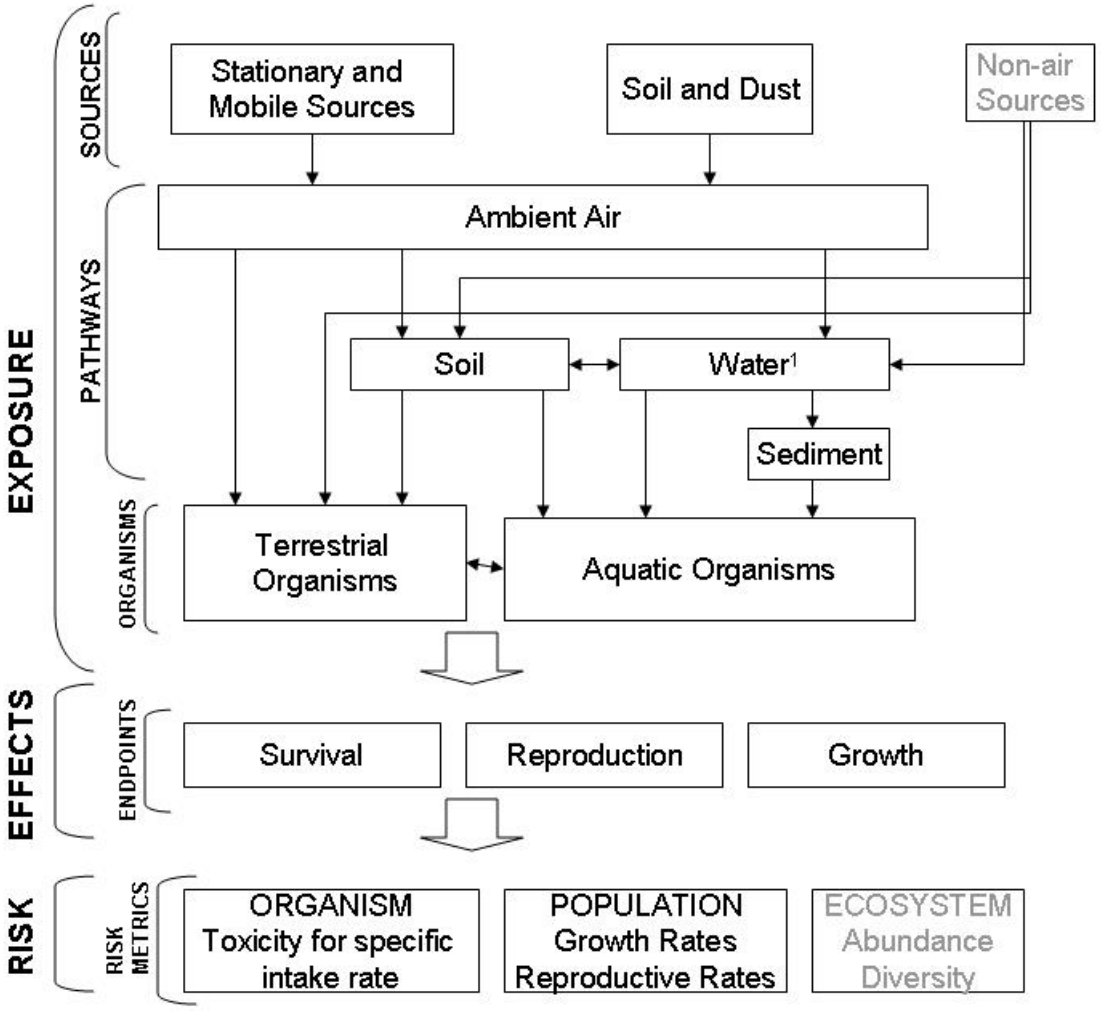
Pathways: The ecologically significant pathways of exposure are through ambient air and the accumulation of Pb in media (soil, water, sediment). Direct inhalation of Pb, while a source of exposure, is probably the less significant one. This analysis will deal primarily with deposition and resulting concentrations in environmental media.

Organisms: Those organisms in direct contact with Pb contaminated media whether directly or by prey selection are most likely to be the most highly exposed organisms in the environment. There is limited evidence for biomagnification of Pb in food chains, but sensitivities to lead do vary widely within and among groups of organisms with similar exposures.

Endpoints: Exposure to Pb at significantly high levels can cause effects to individuals and populations thereby altering processes and interdependencies of ecosystems. Known effects of high Pb exposure include stunted growth, decreased fecundity, and increased mortality rates among some organisms.

Risk Metrics: Metrics could be developed to look at individual, population, and ecosystem effects from led exposures. Individual-level toxicity data that are likely to represent thresholds for population level effects in sensitive species were used to develop the screening methods that are be considered for this analysis.

Figure 8-1. Conceptual Model of Lead in Ecosystems



NOTES

Many of the processes and pathways above are circular in nature. For the clarity of the schematic they are shown as unidirectional.

Components with gray text will not be addressed in the quantitative assessment due to uncertainty regarding available data and modeling tools.

[1] Water in this schematic represents all surface water bodies but only freshwater is addressed in the analysis plan.

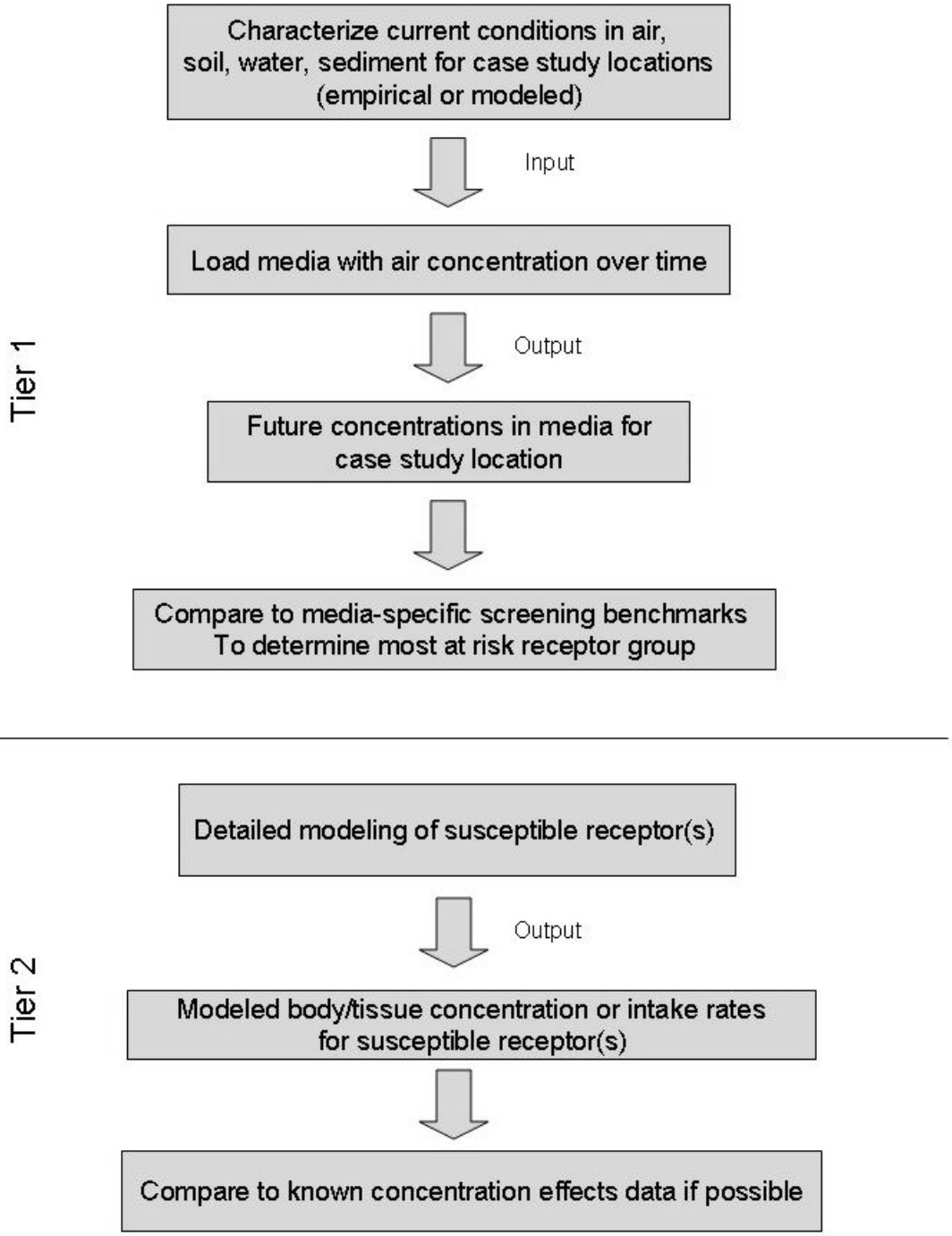
8.2 General Overview of Analysis

The primary route of exposure to Pb for ecological receptors is very different than the typical inhalation exposure path of most other criteria air pollutants. In general, exposure to Pb comes through contact with or ingestion of media that contains Pb by way of air deposition, runoff, dispersion of man made materials containing Pb, and exposed mining waste. In addition, Pb accumulates in the environment over time and does not dissipate readily. These two facts make a multimedia approach to Pb analysis necessary to assess the long term effects of deposition from ambient air.

This assessment will be performed in two steps or tiers. The first tier will use case study locations developed in conjunction with the primary standard assessment to determine predicted concentrations of Pb in soils and will consider water and sediment based on availability of data. These media concentrations will then be compared to environmental screening levels developed for ecological receptors to focus the analysis on those receptors most likely to be affected by ambient Pb concentrations. The second tier of the analysis will then use available modeling to determine what the intake rate is likely to be for sensitive receptors and compare these rates with available data on concentration effects.

The sections that follow describe in more detail what is envisioned for analyzing each component as illustrated in Figure 8-1. Section 9.1 describes how estimates of current and future media concentrations will be generated using empirical data and modeling to provide a comparison with several screening tools available for predicting the likelihood of adverse effect to organisms from specific concentrations of Pb in soil, freshwater, and sediment. These screening risk results can be used to focus further analysis on those receptors thought to be most at risk based on the outcome of the screening step. Section 9.2 is a discussion of the proposed detailed analysis of those receptors found to be at risk in the tier 1 analysis. A discussion of the model and method for determining intake rates or body/tissue concentrations for the susceptible receptor(s) is also found in this section of the plan. Figure 8-2 gives an overview of the proposed analysis.

Figure 8-2. Overview of Planned Analysis



8.3 Uncertainty and Variability

Modeling of Pb related exposure and risk to ecological receptors is subject to a wide array of sources of both variability and uncertainty. Variability is associated with geographic location, habitat types, physical and chemical characteristics of soils and water that influence Pb bioavailability, terrestrial and aquatic community composition, Pb uptake rates by invertebrates, fish, and plants by species and season. For wildlife, variability also is associated with food ingestion rates by species and season, prey selection, and locations of home ranges for foraging relative to the Pb contamination levels. Sources of uncertainty include modeling choices for future media concentrations and assumptions used to derive the ecotoxicity screening benchmarks. Uncertainty and variability will be discussed to the extent possible for each step of the analysis, and where feasible, comparisons will be made between model outputs and empirical data.

As discussed in Section 7 for the pilot human health risk analysis, we are considering the use of an integrated approach for addressing both uncertainty and variability, which will combine probabilistic simulation (for addressing exposure-related variability) with sensitivity analysis techniques (for addressing both parameter and model uncertainty). The integrated approach would include a "modeling tree" to represent model uncertainty with three branches representing the high-bound (Max), low-bound (Min), and central tendency modeling risks for a given receptor/medium combination. Because of data limitations and constraints, it is not feasible to develop confidence distributions for many of the sources of parameter and model uncertainty identified for this risk analysis. Thus, the staff will use sensitivity analysis techniques to examine the impact of sources of uncertainty on exposure and risk results.

The sensitivity analysis techniques involve establishing plausible ranges for input parameters and identifying multiple modeling options reflecting model uncertainty for specific modeling steps, as described in Section 7.1. For the screening-level ecological risk assessment, the key sources of modeling uncertainty should be those related to future predictions of concentrations of Pb in environmental media and the assumptions or models used to develop media-specific ecotoxicity benchmarks (e.g., EPA's sediment criteria based on the equilibrium partitioning approach). Exposure parameters for which uncertainty is likely to be key include the emissions input parameters and various exposure parameter values that are built into the ecotoxicity benchmarks (e.g., for Eco-SSLs for birds and mammals, food ingestion rates, diet selection; for EPA equilibrium-based sediment benchmarks, values for SAV, FOC, and TOC) and the applicability of the species represented in the ecotoxicity benchmarks to a given case study site location. Values for these parameters are both variable (if they were known with accuracy) and uncertain (given that we don't know the true distribution of values or even have good estimates of mean values for a parameter for given species and locations). Data from a variety of sources can be used to bound the possible parameter values in general or for a specific case study location.

At a screening level, the impact of using more stringent compared to less stringent toxicity reference values could be evaluated to develop both minimum and maximum estimates of risk. For soils, these could be based on NOAEL to LOAEL-based toxicity reference values; for sediments these could be based on TECs to PECs; and for surface waters, these could be based on AWQC calculated for a water hardness of 50 to 200 mg/L $CaCO_3$. Also, for soils, the impact

of different parameters used to calculate the Eco-SSL (e.g., for birds and mammals, soil ingestion rate, food ingestion rate, and composition of diet) on the risk results could be examined. Possible variability in Pb concentrations for each environmental medium could be assessed on the basis of available data (e.g., are there enough soil or surface water/sediment sampling sites for the case study location to characterize spatial and/or temporal variability in Pb concentrations in these media) or discussed qualitatively.

Additional sources of uncertainty that would require qualitative discussion include uncertainty about the presence or absence of most susceptible or sensitive species that are the basis of the ecotoxicity benchmarks at a particular site, proportion of a population of plants or animals that might be exposed at or above different Pb concentrations, and whether local pH levels and organic content are much different than those associated with the experiments on which the ecotoxicity benchmarks are based.

9.0 ECOLOGICAL RISK ANALYSIS PLAN

9.1 Tier 1: Screening Level Analysis

9.1.1 Overview

To establish to potential for adverse effects to ecosystems from ambient Pb, it is necessary to first characterize current levels of Pb in environmental media (air, soil, freshwater, and sediment). A broader analysis would include terrestrial systems, aquatic systems, marine systems, and estuarine/wetland systems. Given the available data and the potential for effects from Pb, this analysis focuses on current and future concentrations of Pb in terrestrial soils as well as concentrations in ambient air. We are currently evaluating the availability of data and the feasibility of models to characterize aquatic exposures using freshwater and sediment. Evidence presented in the CD suggests that, in highly impacted areas at least, soil concentrations do not change over small time intervals even if sources of Pb are removed or emissions decreased. Given advances in modeling and larger data sets, this analysis attempts to test and expand this assumption by applying more recent data, existing screening tools, and current models to look at areas with high media concentrations of Pb as well as more typical areas in which Pb emissions may be very low.

Current media concentrations for specific case study locations can then be compared to established ecotoxicity screening benchmarks for soils (e.g., Ecological Soil Screening Levels or Eco-SSLs), freshwater (e.g., ambient water quality criteria for the protection of aquatic life, or AWQC), and sediments (e.g., sediment quality criteria for the protection of aquatic life) to select locations for analysis in which there appears to be the potential for adverse effects from Pb and to identify which media and receptor combinations, if any, are likely to be adversely impacted by current and future Pb concentrations given current ambient air conditions. Once current Pb concentrations are known for a specific location, future concentrations may be predicted based on various air quality scenarios to determine what happens to Pb concentrations in media over time given changes to Pb concentrations in ambient air.

9.1.2 Data Sources for Determining Media Concentrations

Empirical data sources for current ambient levels of Pb in air, soil, freshwater, and sediment will be needed to establish current media conditions. Modeling will be used to estimate future media concentrations given various NAAQS-relevant scenarios. The CASAC review of the 1989 exposure and risk assessment recommended that a constant soil concentration should be used in predicting future scenarios. The plan detailed here considers using current methods for estimating the relationship between soil Pb and air concentrations for future scenarios.

Air:
Sources of data for air emissions and monitoring data for selected locations will be used to establish current air conditions as discussed in Section 4.1.1. As described in the AQCD, there are a number of monitoring networks that may be useful for this purpose, and we will also investigate the availability of additional data in particular locations (e.g., near sources of interest).

Soils:
Relevant literature will be scanned to determine the most reasonable source of data on current soil concentrations for a given study location. Depending on the study location there are several options for soil data (e.g., regional and local entities, soil monitoring protocols for primary and secondary sources, and urban areas monitoring programs). Data sources might be needed for "background" Pb concentrations in areas removed from historical and current anthropogenic Pb sources as well.

In developing the Eco-SSLs, EPA compiled data on metals concentrations in soils across the United States (EPA 2005a; Appendix A of Attachment 1-4) in areas that might be considered "background". The data sources for Pb in Appendix A include a variety of county- and state-wide assessments conducted using a variety of different analytic techniques and sampling strategies. National-level assessments have been conducted by the US Geological Survey (USGS).

The USGS data primarily were collected in the 1970's and therefore were taken before the removal of Pb in gasoline; however, collection sites were far from urban areas and other point sources of Pb and also were at least 100 m from any road. Preliminary review of this data set indicates that the higher soil Pb concentrations in the US (i.e., 25 to 30 ppm) tend to be localized in certain areas, including the western mineral mining areas, but high Pb concentrations also are present in areas of the northeast. Given that Pb is very stable in soil, these data are probably still the best available for large areas of the country.

For screening-level ecological risk assessments for areas in the vicinity of selected case study sites, the county- and state-wide soil assessments presented in the Eco-SSL documentation (Appendix A of Attachment 4-1) may provide additional information, depending on the location.

Staff currently is assessing the degree to which the USGS soil sampling data, from the 1970s, may or may not be representative of current concentrations. For this data set, only 14 percent of samples fell below the detection limit of 10 ppm, which is very close to the Eco-SSL for birds of 11 ppm based on the woodcock (see Section 9.1.5.1). More than 99 percent of these background soil concentrations for Pb are less than the next highest Eco-SSL for birds of 46 ppm for the dove (see Section 9.1.5.1).

Freshwater Surface Waters
Ambient water concentrations of Pb may be found in several national datasets which are currently being evaluated for this analysis, including both EPA and USGS datasets.

The EPA STORET database from the EPA Office of Water includes the water quality sampling data developed by states to determine compliance with water quality standards and reported to EPA annually, sampling data from Superfund sites, and data from other sources (e.g., U.S. Army Corps of Engineers). EPA's EnviroMapper can be used to focus on localized geographic areas to identify sampling locations and to download requested water quality data for those locations. Limitations of STORET data include differences in sampling density and detection limits across states. For Pb, a limitation is that many states do not attempt to measure dissolved Pb

concentrations, only total Pb concentrations, because most of the Pb in most surface waters is sorbed to particulate matter in the water column or is in the sediments. (The AWQC for Pb is based on dissolved (bioavailable) Pb, not total Pb). For the states that do sample for dissolved Pb, the analytic techniques used do not detect any dissolved Pb in most samples (exceptions near urban areas and mining sites). Moreover, the detection limit for dissolved Pb varies by state and some states use analysis methods with detection limits at or above the chronic AWQC for Pb in freshwater (2.5 ug/L at a water hardness of 100 mg/L as $CaCO_3$). Preliminary review of data in STORET indicate exceedances of the AWQC for aquatic life at only a few locations, principally in the midwest near mining sites and at some urban or industrial locations.

The USGS maintains water quality data in two separate data sets: the National Water Information System (NWIS) Network and the National Water Quality Assessment (NAWQA) Data Warehouse. The NWIS system was originally developed for water flow data, and includes data from 1.5 million sites across all 50 states, the District of Columbia, and Puerto Rico. Chemical quality data have been added to it in recent years. The data have been compiled from a variety of projects ranging from national level studies to small watershed projects up through 2004; therefore, the sampling methods, density of sampling sites, and detection limits are variable across the data set. Lead has been an analyte at some of the sites; however, how well different geographic areas are represented for Pb is not known at this time and might be difficult to determine.

The NAWQA Data Warehouse includes the sampling data from the NAWQA program that started systematically collecting chemical, biological, and physical water quality data from 42 study unit basins across the nation in 1991 (data compiled through 9/30/2004 at this time). Basins from all regions of the United States are included; however, only approximately 50 percent of the land base is covered by these basins. Lead is one of the analytes in the program, and measurements of dissolved and total Pb are available from most locations. An analysis of the data in NAWQ by EPA, the current draft AWQCD found a total of 3,445 measurements of dissolved Pb in surface waters, for which 86 percent were non-detects. When looking at a subset of those data determined to be "natural" or background areas, of 430 samples for dissolved Pb in surface waters, 88 percent were nondetects. The mean and upper 95^{th} percentile concentrations of dissolved Pb in the total sample were 0.66 and 1.10 ug/L, respectively, both of which are less than the most stringent chronic AWQC of 1.2 ug/L (at a water hardness of 50 mg/L $CaCO_3$). The mean and upper 95^{th} percentile concentrations of dissolved Pb in the natural samples were slightly lower, 0.52 and 0.50 ug/L, respectively, indicating a skewed distribution of Pb concentrations, as is expected. Thus, risks for aquatic biota in the water column, as assessed by exceedance of the AWQC for Pb (see Section 9.1.5.2), are expected at less than 5 percent of the NAWQA sampling stations nationwide. Maximum dissolved Pb concentrations for all sites and for the subset of natural sites were 29.8 and 8.4 ug/L, both of which exceed the AWQC. With the latitude and longitude of sampling locations known for both databases, it is possible to use existing GIS data layers to identify the local land uses and other relevant river basin/watershed data in the vicinity of the sampling locations that show exceedances of AWQC.

Of the three available surface water quality databases, STORET and NWIS include samples from more locations in the US than does the NAWQA data set, but the sampling techniques and sampling methods represented in STORET and NWIS are inconsistent from site to site. The

NAWQA data set provides representative, although not complete, coverage of the US and a consistent approach to sampling and analysis of the elements assessed. Thus, the NAWQA data set may be more appropriate for a national-level ecological risk screening assessment than the other two data sets. For the assessment of ecological risks at selected case study locations, the availability of data from NAWQA, STORET, and NWIS could be assessed, in that order.

Sediments:
Sediment data are available from the USGS NAWQA program as well as from the EPA STORET database. The USGS program database includes Pb concentrations in sediments measured using consistent sampling techniques from 42 river basin areas across the conterminous United States. The STORET sediment Pb data, while providing more complete coverage of the United States, again vary from state to state with respect to density of sampling locations, sampling methods, and detection limits. With the latitude and longitude of sampling locations known for both databases, it is possible to use existing GIS data layers to identify the local land uses and other relevant river basin/watershed data.

An analysis of the data in the NAWQA Data Warehouse by EPA, the AWQCD found a total of 1,466 measurements of Pb in bulk sediments with a grain size less than 63 um. Of the total, only 0.48 percent of all samples were non-detect. Looking at a subset of 258 of those data determined to be from "natural" areas, 1.2 percent were nondetects. The mean and upper 95th percentile concentrations of Pb in bulk sediments for all samples were 120 and 162 ug/g dry wt, respectively. The mean and upper 95th percentile concentrations of Pb in the natural samples were slightly lower, 109 and 162 ug/L, respectively. Using the "Consensus-based" sediment quality guidelines for Pb of 36 mg/kg dry weight as a concentration that is unlikely to cause adverse effects in benthic organisms (threshold-effect concentrations or TECs) and 130 mg/kg dry weight as a concentration that *is* likely to cause adverse effects on sediment-dwelling organisms (probable-effect concentrations or PECs) (MacDonald et al. 2003) (see Section 9.1.5.3), it is apparent that a much higher proportion of the samples of Pb concentrations in sediments in the NAWQA data set exceed one or both of the sediment quality guidelines for the protection of benthic life than do the surface water concentrations exceed AWQC. The consensus-based guidelines were developed by the USGS in cooperation with EPA and other federal, state, and local agencies, as discussed in Section 9.1.5.3.

9.1.3 Case Study Selection

The challenge in selecting locations for analysis are that the ideal location would be 1) ecologically relevant (contain significant ecological resources such as forests, water bodies, and known populations of specific receptors used in the screening levels); 2) contain complete empirical data sets from air monitoring, media sampling, and land use data; and 3) contain a known air source with good data on emissions. It is also important to analyze a location that is highly impacted by Pb emissions (exceeds ecotoxicity screening values) to be certain that the long term effects at this atypically high level of deposition be captured as well as a site(s) that are more typical. However, it is possible that at such sites, existing Pb concentrations in soils and sediments are sufficiently high as to be relatively insensitive to alternative NAAQS scenarios. Therefore, locations in areas where current Pb contamination is close to levels that might reflect

a threshold for adverse ecological effects might be more informative in analyzing alternative NAAQS. To conserve time and resources, locations with higher exposures to Pb, as described in section 2.0, will be parameterized as much as possible to include ecologically relevant criteria and thereby used in the welfare assessment. In addition, 1-2 locations that are more typical of low level exposures or alternate ecological scenarios might be modeled in tier 2 as well.

9.1.4 TRIM.FaTE Model

In addition to the MPE model discussed in section 4.1.3, TRIM-FaTE is being considered to model both future media concentrations and intake rates for susceptible receptors. TRIM is a time series modeling system with multimedia capabilities for assessing human health and ecological risks from hazardous and criteria air pollutants developed by the US EPA. The Environmental Fate, Transport, and Ecological Exposure module, TRIM.FaTE, accounts for movement of a chemical through a comprehensive system of discrete compartments (e.g., media and biota) that represent possible locations of the chemical in the physical and biological environments of the modeled ecosystem and provides an inventory, over time, of a chemical throughout the entire system. TRIM.FaTE is a mass-balanced based multimedia model, with broad flexibility in spatial, temporal and simulation design complexity.

In the tier 1 analysis, this model (or MPE) may be used to load various media over time under current ambient air conditions to estimate concentrations of Pb in soil, freshwater, and sediment for case study locations. The model will need to be parameterized for Pb and it requires inputs for current media concentrations and air emissions/deposition rates for each location. Data for emissions and deposition rates will be similar to those discussed in earlier sections of this plan. The contents of the biota compartments may be simplified to provide only media concentrations not biotic concentrations for this tier of the analysis.

9.1.5 Determination of Potential Adverse Effects

9.1.5.1 Ecological Soil Screening Levels

Ecological Soil Screening Levels (Eco-SSLs) were developed by the EPA (2005a,b) as concentrations of contaminants in soil that are protective of ecological receptors that commonly come into contact with soil or ingest biota that live in or on soil (Table 9-1). They are derived separately for four groups of ecological receptors: plants, soil invertebrates, birds and mammals and as such, are presumed to provide protection of terrestrial ecosystems. Several species in each receptor category were assessed to develop the Eco-SSL for that category. In general, the same toxicity reference value (TRV) applies (e.g., the reference dose for the most sensitive of the adverse ecological effects on birds) to all species in each receptor category; however, differences in chemical intake associated with foraging techniques and diet generally result in different Eco-SSL values, expressed as a soil concentration, for the different receptors (e.g., bird species) in each receptor category. Scenarios were developed for each of the representative species, and the most sensitive organism for which the Eco-SSL was lowest was chosen in each category to establish the Eco-SSL. They are conservative values and are intended to be applied at the screening stage of an ecological risk assessment.

Table 9-1. Ecological Soil Screening Levels for Lead for Various Receptors (EPA 2005b)	
Receptor	Soil Concentration (mg Pb/kg soil dry weight)
Plants	120
Soil Invertebrates	1,700
Birds	11
Mammals	56

In this analysis, Eco-SSLs are intended to be used as screening values to focus further analyses on receptors that are likely to be exposed to soils that exceed the relative Eco-SSL for that receptor, thereby indicating the potential for adverse effects to that receptor. It should be noted that the value given for birds (11 mg/kg dry weight in soil) is likely to be exceeded currently by most soils in the United States. Therefore, this value is not useful in focusing the analysis or looking at the impact of current ambient air on this receptor. As the avian value is too conservative to reflect conditions in the real world, there are three options for the purpose of this analysis: 1) ignore birds in the analysis and use other receptors as necessary, 2) use another bird value from the original Eco-SSLs for Pb to develop the Eco-SSL for birds (e.g., the next highest avian Eco-SSL of 46 mg/kg soil dry weight for a dove), or 3) recalculate value for the current bird species, the woodcock, based on more realistic diet composition (not 100 percent earthworms), food intake rates and incidental soil intake rates for woodcock (both are somewhat higher in the calculation of the Eco-SSL for woodcock than provided in EPA's 1993 Wildlife Exposure Factors Handbook; EPA 1993a,b), and a best estimate of earthworm absorption of Pb, rather than an upper 95th percentile estimate of earthworm absorption of Pb.. The second option may be most useful for this analysis as it would rely on peer-reviewed Eco-SSLs and woodcock are found only in the eastern half of the United States and are not found in all habitat types there. Recalculation of the woodcock Eco-SSL using more realistic exposure assumptions for the woodcock would also be considered for an ecological risk assessment for areas in the eastern half of the United States for which the conservative Eco-SSL value for woodcock is exceeded.

9.1.5.2 Ambient Water Quality Criteria

Ambient Water Quality Criteria (AWQC) were developed by the EPA to provide guidance to states and tribes to use in adopting water quality standards. AWQC values for Pb are given for chronic and acute exposures as well as for freshwater and marine environments (EPA 1985). The freshwater criteria depend on water hardness. The values provided in Table 9-2 for freshwater are based on a water hardness of 100 mg/L as CaCO3; while the values for saltwater are not dependent on any water characteristics. The current equations/values may be reissued based on pH at the conclusion of the current revision scheduled to be completed in 2007. These are values based on toxicity testing in aquatic organisms.

Table 9-2. Recommended Ambient Water Quality Criteria			
Freshwater (µg Pb/L)		Saltwater (µg Pb/L)	
Acute	Chronic	Acute	Chronic
65	2.5	210	8.1

In this analysis AWQC will be used to evaluate the potential for adverse effect to freshwater organisms (exposed via the water column) over time under the current ambient air levels.

9.1.5.3 Sediment Criteria

Sediment screening-level (and other) criteria or benchmarks have been established by EPA regions and at the state level for Pb. Some work also has been done at the national level (EPA 2005c). For the EPA national sediment quality benchmarks, equations based on an equilibrium partitioning approach have been established to relate the Pb concentration benchmark to pH (acid volatile sulfide or AVS), fraction organic carbon (FOC), and total organic carbon (TOC). These benchmarks also assess three levels of effect on benthic invertebrates: no-effect, threshold-effect, and probable-effect concentrations. The dependence of these benchmarks on values for AVS, FOC, and TOC mean that appropriate data for their calculation might or might not be available for a given site. That dependence also means that the values are not readily useful for screening national-level data to identify locations where sediment concentrations might exceed the threshold- or probable-effect levels.

Another source of national-level sediment quality benchmarks is from the cooperative *Freshwater Sediment Quality Assessment Initiative* that began in 2000 and that included the Florida Department of Environmental Protection (FDEP), the EPA, and the USGS, with participants from the US Fish and Wildlife Service (USFWS), National Oceanic and Atmospheric Administration (NOAA), consultants, academics, county governments, and water management districts (MacDonald et al. 2003). The Initiative recommended use of a "Consensus approach" to developing threshold- and probable-effects concentrations (TEC and PEC values, respectively) of metals in sediments. The approach basically consisted of calculating a geometric mean sediment concentration from, in the case of Pb, sediment values from five different approaches to estimating both the TEC and PEC. These values can be used in the absence of data on AVS, FOC, and TOC; however, it is likely that they will be less "accurate" for sediments for which the AVS, FOC, and TOC values are far from typical values.

Note that the screening-level sediment quality benchmarks representing a threshold for effects (not a probable-effect level) for EPA Regions 4, 5, and 6, Environment Canada, and EPA's Assessment and Remediation of Contaminated Sediments (ARCS) Program are all between 30 and 36 mg Pb/kg dry weight.[12] Given that mean sediment concentrations measured in the NAWQA program are well above these levels, at probable-effect level may be more appropriate for the screening ecological risk assessment. As an initial screen for a large number of sites, the Consensus-based benchmarks may be easier to use because additional data on AVS, FOC, and TOC are not needed. For specific case study locations, once selected, EPA's equilibrium partitioning approach-based values, based on site-specific values for AVS, FOC, and TOC, may be more appropriate for comparison with current and future predicted concentrations of Pb in sediments.

[12] Available from the Risk Assessment Information System (RAIS) (see http://risk.lsd.ornl.gov/homepage/benchmark.shtml).

9.2 Tier 2: Analysis of Sensitive Receptors

9.2.1 Overview

The second tier analysis consists of more detailed modeling of intake rates or body/tissue concentrations for receptor(s) identified for potential adverse effects in the tier 1 analysis and may include additional case study locations based on empirical data. This step will provide less conservative estimates of the potential for effect based on published concentration effects for specific receptors, if such data is available, and based on more realistic exposure factors (e.g., dietary composition, food ingestion rates) and possibly a less conservative threshold for effects. For example, the current Eco-SSL toxicity reference values (TRVs) for birds and mammals are based on a geometric mean of no-observed-adverse-effect levels (NOAELs) for the most sensitive of the effects on reproduction or growth. It may be that use of a lowest-observed-adverse-effect level (LOAEL) for such effects may be more representative of a threshold for population-level effects in the most susceptible bird or mammal populations.

9.2.2 Estimation of Exposure for Sensitive Receptor(s)

9.2.2.1Detailed Modeling of Intake or Body/Tissue Concentration

TRIM.FaTE may be used to provide a more detailed picture of actual intake rates or body tissue concentrations expected in sensitive receptor(s) given a specific soil (or surface water or sediment) concentration. This step may be undertaken for those locations in the tier one screening analysis where there is the potential for adverse effect to a specific receptor (screening values are exceeded either currently or in the future). The model will be more fully developed to include more biotic compartments and tailored to produce either intake rates or body/tissue concentrations depending on the metric used by published concentrations effects studies for that receptor.

9.2.2.2 Comparison to Known Concentration Effects

Reference toxicity values expressed as a daily dose (daily intake via ingestion) have been developed for the Eco-SSLs for birds and mammals. Those values are based on NOAELs, rather than LOAELs, for reproduction and growth. The corresponding LOAEL data are provided, however, and could be analyzed for use in this context.

If other receptor groups turn out to be more at risk than birds and mammals, in support of a Tier 2 analysis, we will identify appropriate toxicity benchmarks from other sources or perform a review of scientific literature to identify concentration effects studies relevant to these other sensitive receptor(s) chosen in the tier one analysis. Specific known physiological effects, if any, will be discussed based on likely intake rates or body/tissue concentrations resulting from the future media concentrations. This step is dependent on the availability of data on specific effects to specific receptors (or classes of receptors).

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