UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

July 7, 2011

EPA-SAB-11-008

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: SAB Review of EPA's *Approach for Developing Lead Dust Hazard Standards for Residences (November 2010 Draft)* and *Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings (November 2010 Draft)*

Dear Administrator Jackson:

In 2001, EPA's Office of Pollution Prevention and Toxics (OPPT), under the Toxic Substances Control Act (TSCA), established lead dust hazard standards for residential buildings. The standards are used to identify the presence of lead hazards and are also used as clearance standards for lead abatement and other lead hazard control activities. OPPT is considering possible revision of the residential lead dust hazard standards as well as the development of lead dust hazard standards for public and commercial buildings. OPPT developed two draft documents entitled *Approach for Developing Lead Dust Hazard Standards for Residences (November 2010 Draft)* (hereafter referred to as the "Residential Document") and *Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings (November 2010 Draft)* (hereafter referred to as the "Public and Commercial Document") that describe the technical approach for developing the standards. OPPT sought consultative advice from the SAB Lead Review Panel on early drafts of the documents and requested SAB peer review of the revised documents.

In these two documents, EPA developed candidate lead dust hazard standards (i.e. the amount of lead dust present on floors and window sills) aimed at providing various levels of protection for sensitive populations using blood lead concentration as a marker of adverse health effects. Blood lead concentrations of 1.0, 2.5, and 5.0 micrograms per deciliter were selected to protect children against IQ deficits in both residences and public and commercial buildings. In addition, for public and commercial buildings where children are not expected to visit, the targeted blood lead concentrations were selected to protect against hypertension in adults and against adverse developmental effects on the fetus of a pregnant woman. To develop these candidate standards, EPA used an approach that relied on available data from the National Health and Nutrition

Examination Survey (NHANES) to relate lead dust loading and blood lead concentrations in children in both residences and public and commercial buildings. EPA also utilized biokinetic models that consider all lead exposure pathways (i.e. air, water, diet, soil, dust) to estimate blood lead levels in children and adults.

The SAB was asked to comment on the clarity and transparency of the documents, empirical modeling, biokinetic modeling, analyses of variability and uncertainty, and choice of models for developing the lead dust hazard standards. The charge questions for the two documents are nearly identical. Although the Panel discussed the two documents separately, the Panel's written response to the charge questions are applicable to both documents, except where noted in the report. For both documents, the SAB supports the overall modeling approaches, however, the SAB has a number of recommendations aimed at improving the modeling approaches discussed in the documents. The SAB is not able to provide a specific recommendation about model selection without the benefit of a comparative analysis of the revised empirical and biokinetic modeling approaches. The SAB also recommends inclusion of an incremental risk assessment approach as described in the recommendations below. The SAB responses to the EPA's charge questions are detailed in the report. Major comments and recommendations for both documents are provided below.

- The SAB supports EPA's selection of target blood lead concentrations of 1.0 and 2.5 micrograms per deciliter for children. The SAB does not support the high target blood lead concentration of 5 micrograms per deciliter due to recent studies indicating significant adverse health effects in children with blood lead concentrations well below 10 micrograms per deciliter. In contrast, for the development of an "adult hazard standard", the concentration-response relationship between blood lead and adverse health effects is not as well characterized in adults as in children and the SAB is not making a recommendation on the appropriate target adult blood lead level concentration.

- In modeling the relationship between lead dust and blood lead, EPA considered all routes and pathways of exposure contributing to blood lead levels. Since the focus of EPA's effort is on establishing a lead dust standard, the SAB recommends examining blood lead concentrations as a result of only lead dust exposures by using an incremental risk assessment approach. An incremental risk assessment approach assesses how incremental changes in dust lead result in incremental changes in blood lead concentrations. In the empirical modeling approach, this can be accomplished by varying lead dust and comparing the slopes of the relationship between lead dust and blood lead concentration. In the biokinetic modeling approach, this can be accomplished by either zeroing out all other exposure inputs, or by varying only lead dust while holding all other exposures constant. This will also reduce the considerable uncertainty resulting from estimation of the other exposure parameters.

- In the empirical approach, data from the NHANES was used to develop the relationship between lead dust levels and childhood blood lead levels in residences. Lead dust loading values were first converted to lead dust concentrations and then related to childhood blood lead levels. Since lead dust loading is a better predictor of blood lead concentration than lead dust concentration, and because lead dust standards are expressed as lead dust loading, the SAB recommends assessing the lead dust loading to blood lead concentration relationship directly, without converting lead dust loading to lead dust concentration.

- The SAB is concerned that the lower lead dust loading values from the NHANES data were not evaluated in establishing the candidate lead dust hazard standards. The SAB recommends examining the full range of NHANES data including lead dust loading values less than 5 micrograms per square foot. Furthermore, the SAB is concerned that EPA's reanalysis of the NHANES data does not reflect the importance of window sill contributions to blood lead concentrations and that EPA did not determine whether the NHANES data were representative of high risk exposures and the national housing stock. The SAB recommends comparing the results to other published epidemiologic studies to address these concerns.

- In conducting the biokinetic modeling, the SAB recommends that EPA use the default input parameters indicated in Agency guidance.

- In the absence of data to support an empirical model relating lead dust to childhood blood lead levels for public and commercial buildings, the SAB supports the use of the NHANES residential data for this purpose.

- In developing a hazard standard for adults only, EPA used both the Leggett model and the Adult Lead Methodology. The SAB supports the use of the Adult Lead Methodology for estimating adult blood lead concentrations from lead dust in public and commercial buildings.

The SAB appreciates the opportunity to provide scientific review and advice on this important matter. The SAB looks forward to the Agency's response and would be pleased to provide additional advice on this subject matter.

Sincerely,

/signed/

Dr. Deborah L. Swackhamer
Chair
EPA Science Advisory Board

/signed/

Dr. Timothy J. Buckley
Chair
SAB Lead Review Panel

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ACRONYMS

ALM	Adult Lead Methodology
EPA	United States Environmental Protection Agency
GM	Geometric Mean
GSD	Geometric Standard Deviation
HUD	United States Department of Housing and Urban Development
IEUBK	Integrated Exposure Uptake Biokinetic Model
NHANES	National Health and Nutrition Examination Survey
OPPT	EPA's Office of Pollution Prevention and Toxics
Pb	Lead
PbB	Blood lead
PbD	Lead dust
QL	Quasi-likelihood
SAB	Science Advisory Board

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1. EXECUTIVE SUMMARY

This report was prepared by the Science Advisory Board (SAB) Lead Review Panel (the "Panel") in response to a request by EPA's Office of Pollution Prevention and Toxics (OPPT) to review two documents entitled *Approach for Developing Lead Dust Hazard Standards for Residences (November 2010 Draft)* (hereafter referred to as the "Residential Document") and *Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings (November 2010 Draft)* (hereafter referred to as the "Public and Commercial Buildings Document"). OPPT sought consultative advice from the SAB Lead Review Panel on early drafts of the documents (USEPA SAB Lead Review Panel, 2010) and sought SAB peer review of these documents. The SAB Lead Review Panel held a public meeting on December 6-7, 2010 and deliberated on the charge questions (see Appendix A) and held a follow-up teleconference on February 22, 2011. The Panel's draft report was approved by the Chartered SAB on May 18, 2011. There were 5 charge questions for each document that focused on: the clarity and transparency of the document, empirical modeling, biokinetic modeling, analysis of variability and uncertainty, and choice of model. The two documents utilize a very similar technical approach and the charge questions are nearly identical. Although the Panel discussed the two documents separately, the Panel's written response to the charge questions are applicable to both documents, except where noted in the report. This Executive Summary highlights the Panel's major findings and recommendations.

<u>Charge Question 1 - Overall Technical Approach</u>

EPA's Residential Document describes the methods that EPA proposes to develop candidate lead dust (PbD) hazard standards for floors and windowsills in residences and child-occupied facilities (including daycare facilities). Blood lead (PbB) concentrations resulting from candidate PbD standards are estimated using two different modeling approaches, i.e. empirical and biokinetic. The results are compared against a range of target PbB concentrations (1.0, 2.5, and 5 µg/dL) that offer differing levels of protection against IQ deficits in children.

EPA's Public and Commercial Document describes the methods that EPA proposes to develop candidate PbD hazard standards for floors and windowsills in public and commercial buildings. The approach for estimating the impact of candidate PbD hazard standards on children in public and commercial buildings is identical to the approach used in the Residential Document. In public and commercial buildings where children are not likely to visit, EPA is considering development of an "adult hazard standard" using biokinetic models. The modeling results are compared against a target range of adult PbB concentrations (1.0, 2.5, 5, 10, and 20 µg/dL) that offer differing levels of protection against hypertension in adults and adverse developmental effects on the fetus of a pregnant woman who occupies a public or commercial building.

The SAB supports EPA's selection of target PbB concentrations of 1.0 µg/dL and 2.5 µg/dL for children, but does not support the target PbB concentration of 5 µg/dL due to recent studies indicating significant adverse health effects in children with PbB concentrations well below 10 µg/dL (Canfield et al., 2003; Lanphear et al., 2005). The concentration-response relationship between blood lead and adverse health effects is not as well characterized in adults as in children and the SAB is not making a recommendation on the appropriate target adult blood lead level concentration.

Although the SAB generally supports the overall modeling approaches described in both documents, it recommends a variation on its application. The current application not only considers PbD, but also other sources and pathways of exposure (e.g. diet, drinking water) and their contribution to *absolute* levels of PbB. Since the focus of EPA's effort is on establishing a PbD standard, the SAB recommends that EPA apply its empirical and biokinetic modeling approaches so that the PbD pathway of exposure is more effectively isolated. This can be achieved through an *incremental* modeling approach where the incremental influence of PbD (loading or concentration) on PbB concentration is examined. This approach is advantageous in isolating the PbD contribution and excluding the additional uncertainty associated with other exposure pathways including air, water, soil, and diet. The SAB strongly recommends inclusion of this incremental risk assessment approach which assesses how changes in *incremental* PbD levels result in *incremental* changes in PbB concentrations.

With a few key exceptions, the SAB found both documents to be thoughtfully developed and well written. These documents provide important quantitative insights into the relationships among the variables and the value of different models for estimating PbB concentrations from PbD hazards. The general overall approaches discussed in the documents were clear. However, the overall clarity and transparency of both documents can be improved by including an executive summary, providing an adequate context for how the standards can be used, expanding the discussions on the degree of improvement in PbB concentrations that differing candidate PbD standards will achieve, and providing an analysis of the differences between the different approaches.

<u>Charge Question 2 - Empirical Models</u>

Under the Agency's empirical modeling approach, the PbD to childhood PbB relationship is derived from the National Health and Nutrition Examination Survey (NHANES) data as described in Dixon et al. (2009). However, EPA deviated from the analysis provided by Dixon et al. (2009) due to concerns over their use of log-log regression model approach and other criticisms. The SAB finds many of the criticisms of the Dixon model to be not well-supported, lacking clarity, and in some instances are inaccurate. The SAB expresses confidence in the Dixon model results and recommends that the Agency continue to include these results in comparisons between the various modeling approaches.

EPA also performed a reanalysis of the NHANES data using a quasi-likelihood generalized linear modeling method (hereafter, the "NHANES QL model"). EPA's reanalysis using the NHANES QL model included a conversion from PbD loading to PbD concentration in order to compare the results with the results of the biokinetic modeling. The SAB expresses support for inclusion of the NHANES QL model in the analysis, but strongly recommends that EPA perform a direct analysis of the PbD loading to PbB relationship without converting PbD loading to PbD concentration. For comparison between empirical modeling and biokinetic modeling purposes, the SAB recommends that the PbD loading to PbD concentration conversion be performed within the biokinetic model. The SAB further recommends that EPA include data from other studies describing the relationship of PbD loading to concentration to assess the validity of the modeled loading/concentration relationship.

The SAB is concerned that the lower PbD levels from the NHANES data (<5 µg/ft^2) were not evaluated in establishing the candidate PbD hazard standards. The SAB recommends examining the full range of NHANES data including the lower PbD loading values.

The SAB is concerned that EPA's reanalysis of the NHANES data does not reflect the importance of window sill contributions to PbB and that EPA did not determine whether the NHANES data were representative of high risk exposures and the national housing stock. The SAB recommends comparing the results to other epidemiologic data to address these concerns.

Charge Question 3 - Biokinetic Models

In both documents, EPA used two biokinetic models, the Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK) and the Leggett model, to estimate children's PbB concentrations resulting from the candidate PbD standards. The SAB finds that the results from the IEUBK model used in this approach may not be accurate due to the selection of input parameters differing from the default input parameters recommended in the model guidance. The SAB recommends including IEUBK modeling using the default input parameters. The SAB also recommends providing greater transparency in the rationale for the selection of input parameters differing from the defaults. Since the IEUBK is clearly the preferred model over the Leggett model for estimating children's PbB concentrations, the SAB recommends that the Leggett model results be moved to an appendix.

In the Public and Commercial Document, in the development of the "adult hazard standard", EPA used the Leggett model and the Adult Lead Methodology (ALM) to estimate adult PbB concentrations resulting from the candidate PbD standards. The SAB supports the use of the ALM because it is simple to use, is used extensively in other EPA Programs, and produces more plausible estimates of average population PbB concentrations than the Leggett model.

Charge Question 4 - Analyses of Variability and Uncertainty

EPA expressed the results of the biokinetic modeling as a lognormal distribution using a geometric standard deviation (GSD) as a way of representing variability. The SAB supports expressing variability for the biokinetic modeling in this manner. For the empirical modeling results, the SAB recommends estimating the variability in the predicted PbB distribution directly from the NHANES data.

The SAB acknowledges limited exposure data for relating PbD to childhood PbB in public and commercial buildings. The NHANES data relate PbD to childhood PbB in residential settings and application of this data set in establishing the PbD to childhood PbB relationship in public and commercial buildings introduces uncertainty. Nevertheless, the SAB believes that the NHANES data are the best surrogates given that there are no data available to suggest that the relationship between PbD and PbB differs from public and commercial buildings to residential buildings.

The advantage of the NHANES data and the empirical approach is that the true variability between PbD loading and PbB is captured from a population representative sample. It should be noted that levels of PbD and PbB observed within this study were at relatively low levels. Therefore, the modeled relationship between PbD loading and PbB is largely defined by lower PbD loadings. Accordingly there will be greater uncertainty in the relationship of PbD and PbB levels above the range of data in NHANES. To address this, EPA might consider data from other epidemiologic studies that represent higher ranges, (e.g. Lanphear, 1996; Lanphear 1998). EPA has performed appropriate analyses to adjust for covariates. However, the overall model explains less than 50% of variance and it has a high non-zero intercept term. Clearly, there are many factors that contribute to the variance in PbB. Unmeasured variables effects, which are reflected in the intercept values of the regressions, require further consideration. Uncertainty in the intercept directly affects the baseline PbB concentration and also increases the variance and uncertainty in the predicted values.

The input parameters used in the IEUBK modeling differ from those recommended in the model guidance, particularly for the geometric standard deviation (GSD) term. In the IEUBK model, the GSD term is intended to reflect variability in PbB concentrations between children that are exposed to the same lead media concentrations. In the EPA documents, however, a range of GSD parameters are derived from NHANES survey results, which reflects variability in PbB concentrations from different lead media concentrations and exposures. If EPA considers the GSD from NHANES, it needs to be applied appropriately to reflect variation in PbB for a constant exposure.

Agreement between the mean empirical estimates and the biokinetic modeling estimates would provide considerable comfort in using either, or both, to develop a standard. On the other hand, significant differences in the means or intercept values could suggest that the baseline PbBs are not adequately explained, or there are important input variables missing, or the NHANES database is not representative of the population of concern and the intercept includes significant unmeasured effects. To aid in this comparison between the empirical and biokinetic models, the SAB recommends running the biokinetic models in three ways: (1) using the standard Agency default parameters, (2) adjusting the baseline input parameters to those values that best reflect the NHANES population, and (3) adjusting the baseline parameters to those values that best reflect the population to which the regulation will apply.

Charge Question 5 - Choice of Model for Hazard Standards

For both documents, EPA proposes to use the NHANES QL model to estimate children's PbB concentrations from the candidate PbD standards. The SAB believes it is premature to recommend a specific model for developing PbD hazard standards without additional analysis and justification. As discussed in the empirical modeling section of this report, the SAB supports the inclusion of the NHANES QL model in the analysis; however, the documents do not provide an adequate justification for the Agency's choice of the model. The SAB also would like to see the results of the NHANES Dixon et al. (2009) log-log model considered in EPA's comparison of modeling approaches. Furthermore, the SAB expresses concern about the EPA's selection of input parameters for the IEUBK model and judges it premature to reject the IEUBK approach.

The SAB recommends comparing the results obtained from the revised NHANES QL and IEUBK models to existing results of the Dixon model, using methods comparable to those employed in both documents and also using the incremental approach. Until then, the SAB is unable to recommend a specific model for developing PbD hazard standards.

For the Public and Commercial Document, in the development of an "adult hazard standard", EPA proposes to use the Adult Lead Methodology to estimate adult PbB concentrations from the candidate PbD standards. As discussed in the biokinetic modeling section of the report, the SAB supports EPA's decision to use of the ALM over the Leggett model for this analysis.

2. BACKGROUND

Human exposure to lead may cause a variety of adverse health effects, particularly in children. EPA's Office of Pollution Prevention and Toxics (OPPT) regulates toxic substances, such as lead, through the Toxic Substances Control Act (TSCA). Through TSCA, OPPT established lead dust (PbD) hazard standards for residential buildings in 2001. Under these standards, lead is considered a hazard when equal to or exceeding 40 micrograms (µg) of lead in dust per square foot on floors and 250 micrograms of lead in dust per square foot on interior window sills. The standards are used to identify the presence of lead hazards and are also used as clearance standards for lead abatement activities. OPPT is considering possible revision of the residential PbD hazard standards as well as the development of PbD hazard standards for public and commercial buildings.

EPA previously sought consultative advice from the SAB Lead Review Panel on early drafts of technical approach (August 2010 Consultation Report) and sought SAB peer review of two draft documents entitled *Approach for Developing Lead Dust Hazard Standards for Residences (November 2010 Draft)* (hereafter referred to as the "Residential Document") and *Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings (November 2010 Draft)* (hereafter referred to as the "Public and Commercial Document") which describe the technical approach for developing the standards.

EPA's charge questions on these two documents are presented in Appendix A, and focus on the clarity and transparency of the document, empirical modeling, biokinetic modeling, analysis of variability and uncertainty, and choice of model. The SAB Lead Review Panel held a public meeting on December 6-7, 2010 to deliberate on the charge questions and a follow-up teleconference on February 22, 2011. The Panel's draft report was approved by the chartered SAB on May 18, 2011. The two documents utilize the same technical approach and the charge questions are nearly identical. Although the Panel discussed the two documents separately, the Panel's written response to the charge questions are applicable to both documents, except where noted in the report. Editorial comments are presented in Appendix B.

3. RESPONSE TO EPA CHARGE QUESTIONS

3.1. Charge Question 1 for Both Documents – Approach Document

OPPT has developed an Approach document for developing the hazard standards for floors and windowsills in residences and public and commercial buildings. This includes a description of the empirical and biokinetic approaches, as well as the resultant analyses used to estimate candidate lead dust hazard standards for residences. Please comment on the clarity and transparency of the document.

This general charge question pertains to the overall approach and the clarity and transparency of the documents. EPA's Residential Document describes the approach EPA has taken to examine candidate lead dust (PbD) hazard standards for floors and windowsills in residences and child-occupied facilities (including daycare facilities). Blood lead (PbB) concentrations resulting from candidate PbD standards are estimated using two different modeling approaches, empirical and biokinetic. The results are compared against a range of target PbB concentrations that offer differing levels of protection against IQ deficits in children.

EPA's Public and Commercial Document describes the methods that EPA proposes to examine candidate PbD hazard standards for floors and windowsills in public and commercial buildings. The approach for estimating the impact of candidate PbD hazard standards on children in public and commercial buildings is identical to the approach used in the Residential Document. For public and commercial buildings where children are not likely to visit, EPA is considering development of an "adult hazard standard". Adult PbB concentrations resulting from candidate PbD hazard standards are estimated using the Adult Lead Methodology, which is used extensively in EPA's Superfund Program. The results are compared against a range of target PbB concentrations (1.0, 2.5, 5, 10, 20 µg/dL) that offer differing levels of protection against hypertension in adults and adverse developmental effects on the fetus of a pregnant woman who occupies a public or commercial building.

Target Blood Lead Concentrations

The SAB generally supports the overall modeling approaches described in both documents and supports EPA's selection of target total PbB concentrations of 1.0 and 2.5 µg/dL for children. The SAB does not support a selection of a target PbB concentraion of 5 µg/dL due to recent studies indicating significant adverse health effects in children with PbB concentrations well below 10 µg/dL (Canfield et al., 2003; Lanphear et al., 2005). The concentration-response relationship between blood lead and adverse health effects is not as well characterized in adults as in children and the SAB is not making a recommendation on the appropriate target adult blood lead level concentration.

One advantage of using a target total PbB concentration is that the proposed PbD standard will take into account exposure to lead from other media sources, which can be significant, especially in minority and low-income communities. This provides EPA an opportunity to incorporate environmental justice principles into its decision-making. One disadvantage to using a target total PbB concentration is the uncertainty of estimating the lead exposures from all other media, as detailed below.

Incremental Risk Assessment Approach

Although the SAB supports the selection of target absolute childhood PbB concentrations of 1 and 2.5 µg/dL, the SAB believes the current approach of evaluating a PbD level that *by itself* would achieve a given target PbB concentration is flawed, because lead is a multi-media pollutant. This may simply be a function of how the data are presented. In any case, the SAB concludes that a simpler and more scientifically valid approach is to assess how changes in *incremental* PbD levels result in *incremental* changes in PbB concentrations, holding important covariates and other exposure inputs (i.e. air, water, soil, diet) at either zero and/or at national averages. This dynamic approach has been adopted by the Office of Environmental Health Hazard Assessment of the California Environmental Protection Agency (Carlisle and Dowling, 2007; Carlisle, 2009) and was also used in a pooled analysis of PbD/PbB studies (Lanphear et al., 1998). This approach requires a means of determining the incremental impact on PbB resulting from exposure to both floor and sill PbD. This can be achieved using both the biokinetic and empirical models and helps to alleviate uncertainty about the assumptions made for all other sources of lead exposure and the uncertainty about the absolute PbB concentrations. This method will enable the Agency to focus on likely changes in PbB from a decrement in PbD levels. In the current EPA documents, it is implied that little improvement is likely to occur, regardless of PbD level, because current population PbB concentrations are near the target PbB concentration, driven largely by other sources of lead.

The SAB strongly recommends that EPA consider inclusion of an incremental risk assessment approach in its analysis. Specific advantages of the incremental risk assessment approach include:

1. For the empirical models, incremental PbB can be estimated directly from the partial regression plots and, possibly, from the standardized coefficients of the regression (depending on the magnitude of co-variance with other factors).
2. For the biokinetic models, exposures from non-dust ingestion pathways (diet, air, soil, and water) can either be set to zero or held constant at baseline levels, thereby eliminating many sources of uncertainty from estimating these exposures.
3. The incremental approach facilitates risk management policy decisions regarding a target incremental PbB by providing a simple and clear presentation of the relationship between delta PbD and delta PbB, as well as the key factors that contribute to variability and uncertainty.

The incremental risk assessment approach does require specific decisions and assumptions, including:

1. Percentile of the PbB distribution that is the basis for the target risk level. For example, a delta PbB of 1 or 2 µg/dL at the 90th percentile.
2. Whether or not the PbD standard is intended to reflect the mass contribution of lead to dust from all sources (including non-residential sources) or more specifically lead

sources associated with the residence (i.e., paint). If the standard is intended to control levels from any source, then the "baseline" PbD loading should be set to zero.

The incremental risk assessment approach does not explicitly account for other sources of lead, which may be significant in minority and low-income communities. However, EPA can still apply environmental justice principles in its decision-making by selecting a target risk level (both incremental PbB concentration and percentile) that would be sufficiently protective for all populations, particularly for populations that have greater lead exposure.

Clarity and Transparency of Document

With a few key exceptions, both documents are well written. These analyses provide important quantitative insights into the relationships among the variables and the value of different models for predicting residential PbD hazards for US children. The general overall approaches discussed in the documents were clear. However, there are several critical ways in which the overall clarity and transparency of both documents can be improved. Comments and recommendations on the clarity and transparency of specific assumptions and calculations of the empirical and biokinetic modeling are presented in the responses to those charge questions.

The documents would benefit from the inclusion of an executive summary. The summary should explain the strengths and weaknesses of both the empirical and mechanistic modeling approaches in a way that can be grasped by practitioners. The Executive Summary should conclude with recognition of the generally robust findings across different models and data sets, which serve to strengthen the confidence in the results.

The documents do not currently provide an adequate description of how the standards will be used. The SAB recommends adding a description of the two principal uses for the standards. For example, the first use of the standards is as a means to identify a PbD hazard (as a component of a "lead-based paint hazard"). The second use of the standards is for "clearance," i.e., to determine if PbD levels following repairs or remedial action and cleanup in both market-rate and low-income federally assisted housing and other covered child-occupied facilities and public and commercial buildings has been adequate. For example, if PbD levels remain at levels above the standard, then repeated cleanup and remedial action would be required until compliance is achieved. In addition, levels of PbD greater than the standard would be disclosed to residents or buyers before they are obligated under a sales or lease contract, under existing EPA and HUD regulations.

The documents can be made more transparent by expanding the discussions on the degree of improvement in PbB concentrations that differing candidate PbD standards will achieve. The residential document states, "The results of the analyses…confirm that, under reasonable input assumptions, both the empirical and biokinetic models predict that large proportions (17–99 percent) of young children would have blood-lead levels above all three target levels, even if the standards were set at loading levels far less than the current values (40 µg/ft^2 for floor dust and 250 µg/ft^2 for window-sill dust). This general finding is robust across reasonable ranges of model inputs and exposure factor assumptions" (p.45). This seems to imply that the PbD standard will make little difference in PbB concentrations no matter how low it is set. However, if the residential floor PbD standard were to be reduced from 40 µg/ft^2 (the current standard) to 10 µg/ft^2, the percentage of children with PbB concentrations above 5 µg/dL would improve from 83% to 53% (using the NHANES quasi-likelihood model, holding window sill PbD to 50 µg/ft^2). The Dixon log-log model results showed that the same reduction in PbD levels would result in an improvement from 52% to 24% of children with PbB concentrations greater than 5 µg/dL. These improvements are quite large, yet are not transparent in the EPA documents.

The documents can be made more clear and transparent by providing greater specificity and further technical detail rather than using value-laden terms, such as "reasonable assumptions" or "reasonable ranges".

The documents can also be made more transparent by showing the magnitude of the differences between the approaches. For example, the geometric mean PbB concentrations at a floor PbD loading of 5 µg/ft^2 and window sill PbD loading of 50 µg/ft^2 in the Dixon log-log model and the EPA quasi-likelihood (central tendency) model are very close at 3.8 and 4.1 µg/dL, respectively. Similarly, the percent with PbB concentrations above 5 µg/dL in both models is 33% and 38% respectively, again, very similar.

3.2. Charge Question 2 for Both Documents – Empirical Models

The empirical approach involves the estimation of blood-lead impacts based on analyses of empirical data from the 1999–2004 National Health and Nutrition Examination Survey (NHANES). Two analyses were used. First, the regression relationships among floor and windowsill dust, other covariates, and blood-lead concentrations that Dixon et al. (2009) derived were applied to predict blood-lead levels for the various hazard standards (combinations of floor and windowsill dust loadings). The second was an independent reanalysis of the NHANES data to derive alternate models for predicting blood-lead impacts; the variations from the Dixon et al. (2009) approach included changes to the form of the dust-loading variables and application of models that are inherently linear at low lead exposures, a relationship that is supported by a wide range of biokinetic data, and regression of blood-lead values against estimated dust concentrations, rather than dust loading. Please comment on the EPA reanalysis.

The SAB commends the Agency for consideration of data such as NHANES in developing the PbD hazard standards. The Agency examined the Dixon et al. (2009) analysis of the NHANES data, which used a log-log regression model and also performed a reanalysis of the NHANES data using a quasi-likelihood generalized linear modeling methods (hereafter, the "NHANES QL model").

<u>Dixon et al. (2009) Analysis</u>

The Agency states that the Dixon analysis presents obstacles to its use for evaluating blood-lead impacts of floor and sill PbD hazard standards. The SAB finds many of the criticisms of the Dixon model to be not well-supported, lacking clarity, and in some instances are inaccurate.

One of the Agency's main criticisms of the Dixon log-log regression model is that it "does not appear to be consistent with linear low-dose biokinetics (e.g., linear dependence of PbB on lead dose under steady-state conditions), currently theorized to occur at low levels, that is supported by a large body of experimental and human data (USEPA 2006)" (p. 11 of the Residential Document; p. 22 of the Public and Commercial Document). The SAB does not believe that a linear relationship between low dose lead intake and PbB in certain human biokinetic studies must constrain the development of an empirical model relating *PbD loading* to PbB. The SAB believes that, notwithstanding linear low dose toxicokinetics pertaining to lead ingestion, there can be multiple reasons that might result in a nonlinear relationship between interior PbD and PbB in optimized empirical models of the indoor residential environment. For example, these include differential confounding of PbD by soil lead and nonlinear rates of transfer of dust to the hands and mouth. EPA should carefully consider its rejection of the Dixon log-log regression model.

EPA also seems to believe that the log-log Dixon analysis shows that PbB decreases as floor PbD increases at the upper tail of the data distribution, which is not consistent with the idea that higher exposures should result in higher PbB concentrations. The Dixon analysis used log transformation because that was the best fit to the dataset. The SAB does not believe that it is correct to state that the log-log approach results in a decrease in PbB as PbD increases, because the Dixon model does not in fact show such a relationship. While PbB concentrations do appear to level out or plateau at higher floor PbD levels, none of the published (Lanphear et al., 1998; Lanphear et al., 2002; Dixon et al., 2009), data show the former declining at higher PbD levels.

EPA also states that the Dixon log-log approach introduces co-linearity in the method used to impute missing window sill PbD loadings. Yet it appears EPA used other variables that are also likely to introduce some co-linearity. The documents' clarity can be improved by a more detailed description of the choice of methods used to impute missing window sill PbD loadings. Because floor and window sill PbD levels are so highly correlated, it is not clear why using floor PbD values to impute missing window sill PbD values is less valid than the EPA method of imputing missing values. Different imputation methods might best be explored further in the sensitivity analysis sections of documents. Another approach that could be examined for the imputation of missing PbD loading values, developed specifically for imputing PbD loading values below the detection limit, is that of Succop et al. (2004).

The SAB has confidence in the Dixon model results and recommends that the Agency continue to include these results in comparisons between the various modeling approaches.

<u>NHANES QL Model</u>

The SAB expresses support for inclusion of the NHANES QL model in the analysis, but has several comments and recommendations to improve the modeling approach.

Statistical Software Package

The SAB has concerns regarding the status of the software ("Survey") used to implement the QL modeling. The document references only a faculty web page (http://faculty.washington.edu/tlumley/survey/) as the source for what needs to be a very sophisticated software package to produce valid and efficient analyses. Most readers will not be familiar with the level of maturity and field testing of this particular package (an important activity for all software, commercial or open source), or the specific algorithms utilized for the present analyses, and might have concerns that it has not been vetted sufficiently to qualify for use in guiding important public health policy decisions. It will be important for EPA to document performance in other important settings so that readers have a basis for trusting the validity and efficiency of this package to a degree similar to that of well-known commercial software such as SAS. If this is an experimental package, then it would be necessary to replicate the analyses using other software designed to accomplish the same goals to validate results.

Conversion of Lead Dust Loading to Lead Dust Concentration

The QL model used a conversion from PbD loading to PbD concentration and a second conversion back to dust loading as the output. While it is clearly necessary to convert dust loading to dust concentration for the purposes of comparing the empirical and biokinetic modeling approaches, it is not clear that the PbD loading to concentration conversion is needed for the quasi-likelihood data analysis. If the PbD loading to concentration regression is not used, the "noise" in the empirical models will likely be reduced, increasing the certainty in the results. The SAB strongly recommends that EPA perform the analysis using the QL model without the PbD loading to concentration conversion. The SAB recommends that the PbD loading to concentration conversion should take place in the biokinetic modeling.

Additionally, the EPA documents should include analyses of other data sets to determine if the estimated regression of PbD loading with PbD concentration is consistent. The estimated regression used by EPA uses data from a HUD National Survey from the 1990s, which used a blue nozzle vacuum dust collection method to compare with dust wipe sampling. There are other data sets, such as the Rochester Lead-In-Dust study (Lanphear et al., 1995) that can be used to assess the validity of the loading/concentration relationship. For example, the Lanphear et al. (1995) study evaluated a wipe sampling method, a cyclone vacuum method, and an open-faced filter cassette vacuum method in a side-by-side study design that assessed the relative predictive value of each method compared to children's PbB concentration. It is possible that the different sampling methods capture different particle size distributions, which can in turn affect the PbD level.

Window Sill Lead Dust Assumptions

The SAB believes that EPA should consider the possibility that window sill PbD may exert a stronger influence on PbB than its analysis of the NHANES data using the QL model appears to suggest. Window sill PbD loadings are generally far higher than floor PbD loading (Jacobs et al., 2002). It may be noted that in the analysis of the NHANES data by Dixon et al. (2009), a model for childhood PbB that included both window sill dust and floor PbD yielded an R^2 value of 23.0%, compared to an R^2 value of 19.4% for a model that considered floor PbD alone.

In a recent study (Clark et al., 2011) from the HUD Evaluation, window sill PbD was found to have a significant impact on PbB through two pathways: its contribution to floor PbD which had a direct impact on PbB and through entry PbD which had an impact on floor PbD and then on PbB. In another study, an increase in sill PbD loading from 50 to 700 $\mu g/ft^2$ was associated with a doubling of the proportion of children who have a PbB concentration greater than 10 µg/dL, from 10% to 20% (Lanphear, 2006). The SAB recommends comparing the QL modeling results of their NHANES data analysis with these relevant studies in the literature.

NHANES Data Handling

The SAB has several comments and recommendations on how EPA handled the NHANES data in their reanalysis using the QL model, particularly related to truncation of results, detection limits, and flooring type.

The documents do not display the results of the different models when PbD levels are below 5 $\mu g/ft^2$. This omission unnecessarily truncates the results and reduces the document's transparency. Greater transparency would be achieved if lower PbD levels were also examined. For example, the Dixon et al. model displayed the results down to 0.25 $\mu g/ft^2$ (Dixon, et al. 2009). While there may be important analytical and feasibility constraints at such a level, the SAB strongly believes that the scientific relationship between PbD and PbB should be considered below 5 $\mu g/ft^2$ to fully describe the relationship.

The documents would benefit from a more detailed explanation of how the impact of floor surface type was modeled in the QL model analysis of the NHANES dataset. For example, did the variable encompassing floors that were "smooth and cleanable" include or exclude floors that were carpeted (Table 3-4 in both documents, and Appendix B, Table B-2 in both documents)? The narrative would benefit from a brief discussion of any apparent reasons why floor condition exerted a greater influence on the Dixon log-log empirical model (Dixon et al, 2009) compared to the EPA NHANES QL model (Table 6-1 in the Residential Document and Table 7-1 in the Public and Commercial Document).

<u>Comparison of NHANES Data with Other Studies</u>

The SAB concludes that the results of NHANES data modeling should be compared to other epidemiologic studies, such as the Rochester Lead-In-Dust study (Lanphear et al, 1996) and a pooled analysis of data from 12 childhood PbB investigations (Lanphear et al, 1998). To the extent that there is consistency in the slope of PbD and PbB relationship observed in NHANES and these other epidemiologic studies, (which unlike NHANES accounted for potential confounding by lead in soil and water) there will be enhanced support for relying on the analysis of the NHANES data for PbD hazard standard development.

The SAB believes that the documents would gain greater clarity if they were to examine the influence of higher PbD loadings than those in the NHANES database, because higher loadings are likely to be more representative of higher risk environments. The SAB believes that any PbD standard selected should help to ensure that populations with the highest exposures are adequately protected. Other high exposure data sets that EPA could examine include the

Rochester Lead-In-Dust Study (Lanphear et al., 1995), the Evaluation of the HUD Lead Hazard Control Grant Program (NCHH and UC 2004) and the pooled dust analysis (Lanphear et al., 1998). All of these data sets have higher PbD and PbB values than the NHANES database.

The SAB believes the documents could be improved by examining how well the NHANES data represent the nation's housing stock. This evaluation could easily be accomplished by comparing certain demographic information in the NHANES database with the American Housing Survey and Current Population Survey databases. Such an exercise was completed for the HUD National Survey of Lead and Allergens in Housing (NSLAH), which found that variables such as region, race and ethnicity, housing tenure and type, poverty-to-income ratio, urbanization and others were not significantly different (Jacobs et al., 2002) when comparing the smaller NSLAH data set to the larger data sets. If the NHANES data are representative of both the population and its housing, confidence and transparency will be increased.

3.2. Charge Question 3 – Biokinetic Models

Charge for the Residential document:

Two biokinetic models were used to estimate children's blood lead concentrations including EPA's Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK), and the Leggett model. Information from the exposure scenarios is used to estimate relative contributions of exposures from different sources (soil, dust, air, diet, and water) and in different microenvironments. Please comment on the use of these models and the inputs to these models.

Charge for the Public and Commercial Document:
Two biokinetic models were used to estimate children's blood lead concentrations including EPA's Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK), and the Leggett model. Information from the exposure scenarios is used to estimate relative contributions of exposures from different sources (soil, dust, air, diet, and water) and in different microenvironments. The Leggett model and EPA's Adult Lead Methodology were used to estimate adult blood lead levels resulting from candidate floor and windowsill hazard standards. Please comment on the use of these models and the inputs to these models.

<u>Estimation of Children's Blood Lead Concentrations</u>

The SAB supports the use of the Integrated Exposure Uptake Biokinetic (IEUBK) Model for estimating children's PbB concentrations for both residential and public and commercial settings, but has specific comments and recommendations for improving the model runs. Additionally, the SAB believes that the Leggett model is less scientifically credible for estimating children's PbB concentrations than the IEUBK model, when compared to the empirical results. The SAB therefore recommends moving the results from the Leggett model to an appendix.

The SAB believes that the results from the IEUBK model used in this approach may not be accurate due to the selection of input parameters differing from what is recommended in the model guidance. The clarity and transparency of this modeling approach can be enhanced by providing a more complete description and justification for selection of input parameters. For example, the geometric standard deviation (GSD) is a key parameter in the IEUBK model that requires careful selection, as it exerts considerable influence on the estimated number of children who might have a PbB increment in excess of a targeted value. The GSD term reflects the collective contributions of individual variability in intake, uptake, and biokinetics for a population of children that are exposed to the same lead concentrations in dust and other exposure media. Individuals exposed to the same PbD concentration may experience different intake rates due to variability in soil and dust ingestion rates, for example. By specifying the GSD in this manner, the IEUBK model can be used to estimate the distribution of PbBs associated with a fixed concentration. The GSD of 1.6 recommended in the model guidance is considered to be a broadly applicable value, and was derived from several epidemiologic studies with paired environmental and PbB measurements in children (White et al., 1998). In the EPA documents, however, GSDs of 1.9, 2.1, and 2.3 were used, which were derived from the NHANES data without controlling for lead media concentrations. These GSDs do not reflect the variability of PbB concentrations associated with fixed lead media concentrations, and therefore are different from what the GSD term in the IEUBK model is intended to represent. The SAB recommends using a GSD of 1.6, or providing a justification for deviating from this default value.

The SAB recommends providing greater transparency in how the input values were selected and justified if they differ from EPA guidance. If different input values are used in the IEUBK modeling with sufficient justification, the SAB recommends including modeling with the default input parameters for comparison purposes.

The biokinetic models predict that non PbD exposure sources diet and water together contribute about twice as much to PbB as PbD sources (Table 6-2 in November 5, 2010 Residential document). The SAB recommends that these observations be highlighted and presented in a very transparent manner. To further examine the impact of these non dust sources, the SAB recommends including several model runs using a range of values for diet and water as part of the sensitivity analysis described in the response to Charge Question 4. Because PbD hazard standards are closely tied to predicted PbB concentrations, the SAB strongly suggests that the sensitivity be used to evaluate how PbBs predicted from non-dust pathways compare with alternative PbB thresholds. A threshold may be defined based on the relationship between total exposure and total PbB, or alternatively between the additional (incremental) change in PbB associated with exclusively dust-lead exposure.

Estimation of Adult Blood Lead Concentrations

For the development of an “adult hazard standard”, the Leggett model and EPA’s Adult Lead Methodology were used to estimate adult PbB concentrations resulting from candidate floor and windowsill hazard standards for public and commercial buildings. The SAB supports the use of the Adult Lead Methodology. The ALM is advantageous because it is a relatively simple and easily understood model and because the EPA has considerable experience using the approach. In addition, the ALM produced more plausible estimates of average population PbB concentrations than did the Leggett model. The SAB recommends that the results of the Leggett modeling be moved to an appendix.

Conversion of Lead Dust Loading to Lead Dust Concentration

As noted previously, the SAB believes that converting PbD loading to PbD concentration in the empirical modeling is not appropriate. The SAB appreciates the need to make results consistent between the empirical models and biokinetic models. The SAB suggests that it is more scientifically sound to make this conversion within the biokinetic model for purposes of comparison with the empirical model. Therefore, in running the biokinetic model, EPA should convert PbD loading to PbD concentration to estimate PbB concentration.

Appendix E of both EPA documents presents a mechanistic model used in the PbD loading to PbD concentration conversion. The SAB has two concerns, one conceptual and one computational, about the accuracy of this model for converting loadings to concentrations. First, recent work suggests that the model does not accurately represent the sources and composition of the large majority of particulate mass on indoor surfaces (please see individual comments from Dr. Michael Jayjock from the August 2010 Consultation Report). The second concern is a possible missing unit conversion factor of 10,000,000. This concern is described in further detail in Appendix B of this report.

Limitations of IEUBK and ALM Modeling Approaches

In support of clarity and transparency, it should be recognized that the EPA documents' reliance on the IEUBK and the ALM limits the EPA to considering chronic, steady-state exposures, which is appropriate for setting the PbD hazard standards. This limitation is valid whether the models are used to simulate the contribution of PbD to absolute PbB or an increment change in PbB. While the SAB endorses the use of the IEUBK and ALM models, neither of these modeling approaches is adequate to simulate an acute or intermittent exposure to lead in dust. Recognition and a brief description of this limitation should be part of both the Residential and the Public and Commercial documents.

Similarly, entrainment of PbD to air is not considered in the biokinetic models. That is, in reality, lead in dust may contribute to lead in air, an input not explicitly included in the IEUBK or ALM models. EPA should consider this limitation and evaluate the potential impact of this limitation on PbB predictions, as ignoring the contribution of PbD to airborne lead may under-predict the contribution of dust loading on PbB predictions. Although the SAB is not convinced that entrainment is a significant contributor to PbB, this issue may help explain discrepancies in PbB predictions using the empirical vs. biokinetic models.

Other Biokinetic Modeling Issues

The impact lead in soil has on lead concentrations/loading in indoor dust was not adequately addressed in the assessment. The mechanistic model for indoor dust generation (Figure 3-5, Figure E-1, and elsewhere) designates the tracked in material as "soil". The name of this term needs to be expanded to also include exterior PbD. The material that is tracked in is derived from a number of locations including the surface of the soil, sidewalks, roadways, porch and entryways etc. This material generally comes from the surfaces of these areas. Soil lead measurements are usually determined for cores of soil, most often about one inch in depth. Mielke et al. (2007) have developed a method (PLOPS) to obtain a sample from the surface of soil areas. Data using such a method would more likely represent tracked in particles than soil core concentrations. Terms such as "Outdoor Soil" and "outdoor soil particles" would be more accurately characterized by "outdoor soil and dust particles".

3.3. Charge Question 4 for Both Documents – Analyses of Variability and Uncertainty

Monte Carlo methodology was not used to evaluate the impacts of variability and uncertainty in model parameters on blood-lead estimates as insufficient data exist concerning the potential variability in many key model variables to support informative Monte Carlo modeling. Instead, point estimates of central tendency (geometric mean) blood-lead concentrations in children are derived utilizing statistical models based on empirical data and on biokinetic models of blood lead, coupled with assumptions regarding distributions of highly uncertain variables. The sensitivity of the deterministic relationships between dust lead and blood lead to changes in key variables and covariates is explored through sensitivity analyses. The modeling inputs and assumptions that most strongly affect the predicted blood-lead distributions associated with candidate lead-dust hazard standards have been identified, based on the measures of statistical uncertainty from the empirical analyses and sensitivity analyses of the biokinetic models. Please comment on the characterization of variability and uncertainty.

The SAB has several comments and recommendations regarding EPA's characterization of variability and uncertainty in both the empirical modeling and biokinetic modeling (i.e., both the IEUBK model and the ALM [slope factor] models). In general, the SAB agrees with the decision to move away from the use of Monte Carlo analysis (MCA) as a means of propagating variability and uncertainty in the biokinetic model for purposes of estimating a probability distribution of PbB concentrations. MCA is generally viewed as a very useful tool for exploring questions that require probabilistic expressions for inputs and outputs, as well as for conducting sensitivity analyses. However, insufficient information is available to include biokinetic parameters in a probabilistic evaluation. MCA limited to just the exposure and bioavailability variables would likely underestimate the overall variability and uncertainty in the PbB distribution. Instead, a two-parameter lognormal distribution is used whereby the central tendency parameter is quantified and the variance (represented by the geometric standard deviation [GSD]) is specified. This approach is consistent with historical applications of the IEUBK and ALM models and is a reasonable simplification given the uncertainties in defining input distributions and biokinetic modeling needed to support MCA.

The lognormal model is also applied to the empirical modeling approach as a means of specifying a probability distribution of PbBs so that threshold exceedance probabilities can be estimated. It is intuitively appealing to use the same expressions of variability in the empirical and biokinetic models as this simplifies the model specification and reduces the burden of comparing and contrasting alternative modeling approaches. The GSD parameter becomes the single lumping term for all sources of variability, and the choice of a lognormal model has a long history of use in environmental data analysis and lead risk assessment. However, the SAB concludes that the use of the lognormal model in the empirical approach misses an opportunity to capitalize on a strength of the empirical approach – namely, the fact that a statistical analysis of the NHANES data set presumably allows for a direct measure of the extent to which variance in PbB can be associated with changes in PbD loading (or concentration).

The SAB recommends that EPA adopt a weight of evidence framework that allows for a more direct comparison of estimates of variability and uncertainty in the empirical and biokinetic models. For the empirical models, variability in the predicted PbB distribution can be estimated directly from the data rather than by imposing the lognormal distribution model with an assumed GSD. EPA should explore the use of 100 x (1 – α)% prediction intervals on the regression as well as partial regression plots that relate PbD loading to changes in PbB as a means of estimating the slope (i.e., delta PbB associated with the delta PbD) within the range of the anticipated candidate standard levels. Results from the NHANES data analysis should be presented both graphically and in tables. Intervals for the original Dixon et al. estimates would be interesting, if obtainable, as well. Note that the prediction interval is preferred over the confidence interval because the prediction interval is analogous to percentiles of the PbB distribution at a given PbD, whereas confidence intervals would provide a measure of the uncertainty in the mean PbB at a given PbD. To the extent that the prediction interval from the empirical model overlaps with the distribution obtained by the biokinetic model, this provides greater certainty in using either approach to establish a relationship between a PbD standard and a corresponding reduction in exposure and risk.

Empirical Modeling

The SAB acknowledges that there are very limited exposure data for relating PbD to childhood PbB in public and commercial buildings. The NHANES data relates PbD to childhood PbB in residential settings and application of this data set in establishing the PbD to PbB relationship in public and commercial buildings introduces considerable uncertainty. The SAB agrees with EPA in its use of *residential* NHANES data for establishing the relationship between PbD and childhood PbB within commercial and public buildings. This approach is necessary since there are very limited data available from commercial and public buildings upon which to otherwise estimate this relationship. The SAB believes that the NHANES data are the best surrogates given that there are no data available to suggest that the relationship between PbD and PbB differs from public and commercial buildings to residential buildings.

The advantage of the NHANES data and the empirical approach is that the true variability between PbD loading and PbB is captured from a population representative sample. It should be noted that levels of PbD and PbB observed within this study were below 10 µg/ft^2 (92%) and 10 µg/dL (98%), respectively. Therefore, the relationship between dust Pb loading and blood Pb is largely defined by PbD loadings <10 µg/ft^2. Accordingly, from these data there will be greater uncertainty in the relationship of dust and PbB concentrations above this range. To address this, EPA might consider other epidemiologic studies with data at higher ranges, (e.g. Lanphear, 1996; Lanphear 1998).

EPA has performed appropriate analyses to correct for the measured variables. However, the model has a high non-zero intercept term and the model fit explains less than 50% of variance. Clearly, there are many factors that contribute to the variance in PbB. The effects of unmeasured variables, which are reflected in the intercept values of the regressions, require further consideration. Uncertainty in the intercept directly affects the baseline PbB concentration and also increases the variance and uncertainty in the predicted values. These effects could combine to inflate the estimated percentage of children to exceed target PbB concentrations due to factors unrelated to dust loading.

A key issue addressed in the documents is the conversion of dust concentrations to dust loadings. Biokinetic models require concentration terms and the hazard standards are defined in loading terms, so a conversion is required. EPA used a regression relationship between PbD loading and PbD concentration measurement from HUD data. Uncertainty in the regression equation (p. 16 of the Residential Document and p. 27 of the Public and Commercial Document) should be presented by way of confidence intervals on the regression line to better understand the statistical uncertainty attributed to the model fitting.

NHANES QL model predictions are expected values (arithmetic mean PbB), and yet EPA elected to interpret these as geometric mean (GM) values. The rationale for this interpretation is unclear, and the consequence is to overestimate the true GM values. EPA should consider converting model predictions to true GM values based on (weighted) estimates of variance.

The empirical models use regression techniques to associate PbD loading for floors and sills with PbB. The biokinetic models assume that sill loadings are a minor contribution to the total dose. The apparent insensitivity of PbBs to sill lead raises a question as to the utility of various sill Pb standards as a tool for reducing lead risks. This point is inferred by the summary tables and discussion in the report, but should be more fully developed.

<u>Biokinetic Modeling</u>

The input parameters used in the IEUBK model runs vary significantly from those recommended in other Agency regulatory programs. For example, a range of GSD parameters is evaluated with values based on NHANES survey results. Variability in measured PbBs from NHANES reflects variability from multiple sources of exposure, including differences in PbD loadings (and concentrations). This approach represents a departure from the concept underlying the use of the IEUBK model in which the distribution is intended to reflect variability in the population of children that may be exposed to the same media concentration. The SAB recommends that EPA not use NHANES to derive the GSD for use in the IEUBK model.

The SAB recommends using the default GSD of 1.6 for which the IEUBK model was verified. The GSD should be adjusted upward from the guidance recommendation, only if EPA has justification to assume that the variance in the input exposure parameters is larger than that anticipated in the guidance recommendations. To some extent, this selection can be informed by the variance noted in QL analyses. These adjustments and attendant results should then be discussed in terms of exposure and biological plausibility. A direct comparison of the models can then made in terms of the predicted dust loading values necessary to protect 95% of the childhood population.

As noted previously, it will be instructive to compare the PbB values predicted by the IEUBK model to those derived from the analysis of the NHANES data. Coherence in the outputs between the two modeling approaches may serve to enhance certainty in the findings. To accomplish this comparison, the output of several iterations of the IEUBK model should be examined.

1. The first run should use the default parameters currently recommended in the IEUBK model guidance documents and EPA advisories. The default soil/dust concentration should be varied by substituting the dust concentration from the loading conversion equations into the dust portion of the soil/dust partition, and determining a weighted average for the soil/dust input concentration. The soil portion of the weighted average should remain constant at the default value. The results can be plotted against dust loading to show change in estimated mean PbB concentrations and percent to exceed criteria.

2. A second run should adjust the baseline input parameters to those values, in EPA's judgment, that best reflect the NHANES population that was addressed in the QL and Dixon analyses. The dust concentration should be varied, the soil concentration held constant. The results should be plotted in the same manner. Particular care should be taken in selecting the soil concentration value. The soil value used in the current document, taken from the National Survey of Lead and Allergens in Housing (NSLAH), may not be reflective of the NHANES database, or the population to be regulated. This run should be compared with the Dixon and QL models. Particular attention should be paid to the intercept and slope comparisons. Water and diet input parameters should also be varied.

3. A third run should be examined that sets all of the IEUBK input parameters other than interior dust concentration (i.e. the variables corresponding to diet, air, and water) to zero or held constant at baseline levels (a variety of baseline values can be employed with different input values such as for water and diet to examine whether it would have an impact on the incremental increase of PbB concentrations from the incremental increase in PbD levels). The incremental impact of increasing interior PbD on PbB should be compared to the PbB increments observed in the empirical models from partial regression plots (or the standardized regression coefficients) pertaining to interior PbD.

<u>Comparison of Empirical and Biokinetic Modeling Approaches</u>

The decision to establish a risk metric based upon either an absolute PbB distribution or an incremental PbB concentration may be made after addressing some of the SAB's concerns noted above. Agreement in means between estimates from the empirical and biokinetic models would provide considerable comfort in using either, or both, to develop a standard. On the other hand, significant differences in the means or intercept values could suggest that the baseline

PbBs are not adequately explained, or there are important input variables missing, or the NHANES database is not representative of the population of concern and the intercept includes significant unmeasured effects. If the baseline PbB exceeds the target PbB because of the combined contribution of exposure from other sources, then even the lowest possible PbD standard would be ineffective at reducing exposure sufficiently to achieve a target PbB. Consequently, the SAB would urge EPA to revisit the definition of the risk metric and how the link between changes in PbD exposure to expected changes in PbB is established. Focusing on the delta PbB may prove to be a more viable option.

A decision to use an incremental risk assessment approach may also be informed by comparing the slopes (and confidence intervals on the slopes). Note that estimates of the slopes will be more informative if differences in the intercepts can be reconciled. Differences in the slopes should be explored through sensitivity analyses, and attempt to quantify each of the key sources of uncertainty, including dust loading to concentration conversions, baseline soil concentrations, the soil to dust partition coefficients, and the floor to sill ratios.

3.4. Charge Question 5 – Choice of Model for Hazard Standards

Charge for Residential Document:

The document presents two empirical models and two biokinetics models. OPPT proposes to use the NHANES Quasi-Likelihood, Empirical Model for the estimation of the residential hazard standards. Please comment on this proposed choice.

Charge for Public and Commercial Document:

The document presents empirical and biokinetic models. OPPT proposes to use the NHANES QL, Empirical Model and the ALM model for the estimation of the hazard standards for floors and windowsills for children and adults, respectively. Please comment on these proposed choices.

The SAB did not find that the documents provided adequate justification for the Agency's choice in models to use for the development of the PbD hazard standards. The SAB recommends greater clarity and transparency in the justification of the Agency's choice of models.

<u>Choice of Model for Children</u>

As discussed in further detail in the empirical modeling section of this report, the SAB supports the inclusion of the NHANES QL model in the analysis, but concludes that the documents did not provide adequate justification for EPA's choice. The SAB expresses confidence in the results of the NHANES Dixon et al. (2009) log-log model and is concerned that EPA's presentation and critique of that model lacks clarity and, on certain key points, is likely inaccurate. The SAB would like to see the Dixon et al. (2009) model considered in EPA's comparison of modeling approaches. Furthermore, the SAB expresses concern about the EPA's implementation of the IEUBK model and judges it premature to reject the IEUBK approach.

In this report the SAB has made specific recommendations for revising the NHANES QL and IEUBK models so that their products can be more meaningfully compared to the Dixon et al. (2009) results. Most notably, the SAB recommends (1) that results for all models be presented using an incremental approach that describes how changes in PbD affect changes in children's PbB concentrations, while holding constant all other sources of Pb exposure and relevant covariates; (2) that a more transparent comparison be made between the NHANES QL and the Dixon log-log model by revising the NHANES QL model to use PbD loadings directly, rather than convert loadings to concentrations; (3) that results be presented for the 0.25 $\mu g/ft^2$ – 40 $\mu g/ft^2$ range of PbD loadings, with attention to the need for clarity in describing and displaying results in the range below 5-10 $\mu g/ft^2$; and (4) that the current implementation of the IEUBK model be reviewed to ensure that appropriate default values have been used and that their primary data sources have been fully documented.

The SAB urges EPA to compare the results obtained from the revised NHANES QL and IEUBK models to existing results of the Dixon et al. model, using methods comparable to those employed in the EPA documents and using an incremental approach. Until then, the SAB is unable to recommend a specific model for developing PbD hazard standards.

Choice of Model for Adults

The SAB acknowledges the lack of an empirical data base for estimating the PbB impacts of adult exposure to floor and window sill dust in public and commercial buildings, necessitating the use of a mathematical model. In agreement with EPA, the SAB supports the use of the Adult Lead Methodology (ALM) adapted to accept PbD exposures. The advantages of using the ALM include it being a relatively simple and easily understood model and considerable use and application of the ALM in EPA's Superfund Program. In addition, the adapted ALM produced more plausible estimates of average population PbB concentrations than the Leggett model produced.

Consistent with its recommendations for all other models, the SAB urges the EPA to use an incremental risk assessment approach when implementing and presenting the results of the adapted ALM. In addition, because the model also requires a conversion of PbD concentration to PbD loading it is important to implement any changes made to that conversion algorithm based on the SAB's comments in previous sections of this report.

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APPENDIX A – CHARGE TO THE SAB FROM EPA

EPA Charge Questions for the Approach for Developing Lead Dust Hazard Standards for Residences

Background

TSCA section 403 directs EPA to promulgate regulations that identify, for the purposes of Title X and Title IV of TSCA, dangerous levels of lead in paint, dust, and soil. EPA promulgated regulations pursuant to TSCA section 403 on January 5, 2001, and codified them at 40 CFR part 745, subpart D (USEPA, 2001a). These hazard standards identify dangerous levels of lead in paint, dust, and soil and provide benchmarks on which to base remedial actions taken to safeguard children and the public from the dangers of lead. Lead-based paint hazards in target housing and child-occupied facilities are defined in these standards as paint-lead, dust-lead, and soil-lead hazards. A paint-lead hazard is defined as any damaged or deteriorated lead-based paint, any chewable lead-based painted surface with evidence of teeth marks, or any lead-based paint on a friction surface if lead dust levels underneath the friction surface exceed the dust-lead hazard standards. A dust-lead hazard is surface dust that contains a mass-per-area concentration of lead equal to or exceeding 40 micrograms per square foot ($\mu g/ft^2$) on floors or 250 $\mu g/ft^2$ on interior windowsills based on wipe samples. A soil-lead hazard is bare soil that contains total lead equal to or exceeding 400 parts per million (ppm) in a play area or average of 1,200 ppm of bare soil in the rest of the yard based on soil samples.

On August 10, 2009, EPA received a petition from several environmental and public health advocacy groups requesting that the EPA amend regulations issued under Title IV of TSCA (Sierra Club et al., 2009). Specifically, the petitioners requested that EPA lower the Agency's dust-lead hazard standards issued pursuant to section 403 of TSCA from 40 $\mu g/ft^2$ to 10 $\mu g/ft^2$ or less for floors and from 250 $\mu g/ft^2$ to 100 $\mu g/ft^2$ or less for window sills. On October 22, 2009, EPA granted this petition under section 553(e) of the Administrative Procedures Act, 5 U.S.C. 553(e) (USEPA, 2009a). In granting this petition, EPA agreed to commence the appropriate proceeding, but did not commit to a particular schedule or to a particular outcome.

In June 2010, EPA issued a Proposed Approach for Developing Lead Dust Hazard Standards for Residences and submitted the document to the Science Advisory Board (SAB) Lead Review Panel for a consultation. The SAB Panel met July 6–7, 2010 and provided comments on the Proposed Approach to EPA on August 20, 2010.

The current document entitled "Approach for Developing Lead Dust Hazard Standards for Residences" describes the methods that EPA proposes to examine candidate hazard standards for floors and windowsills in residences. This document takes the SAB comments from the July, 2010 consultation into consideration in developing several candidate standards for residences.

Charge Question 1 - Approach Document

OPPT has developed an Approach document for developing the hazard standards for floors and windowsills in residences. This includes a description of the empirical and biokinetic approaches, as well as the resultant analyses used to estimate candidate lead dust hazard standards for residences.

1. Please comment on the clarity and transparency of the document.

Charge Question 2 - Empirical Models

The empirical approach involves the estimation of blood-lead impacts based on analyses of empirical data from the 1999–2004 National Health and Nutrition Examination Survey (NHANES). Two analyses were used. First, the regression relationships among floor and windowsill dust, other covariates, and blood-lead concentrations that Dixon et al. (2009) derived were applied to predict blood-lead levels for the various hazard standards (combinations of floor and windowsill dust loadings). The second was an independent reanalysis of the NHANES data to derive alternate models for predicting blood-lead impacts; the variations from the Dixon et al. (2009) approach included changes to the form of the dust-loading variables and application of models that are inherently linear at low lead exposures, a relationship that is supported by a wide range of biokinetic data, and regression of blood-lead values against estimated dust concentrations, rather than dust loading.

2. Please comment on the EPA reanalysis.

Charge Question 3 - Biokinetic Models

Two biokinetic models were used to estimate children's blood lead concentrations including EPA's Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK), and the Leggett model. Information from the exposure scenarios is used to estimate relative contributions of exposures from different sources (soil, dust, air, diet, and water) and in different microenvironments.

3. Please comment on the use of the biokinetic models and the inputs to the models.

Charge Question 4 - Analyses of Variability and Uncertainty

Monte Carlo methodology was not used to evaluate the impacts of variability and uncertainty in model parameters on blood-lead estimates as insufficient data exist concerning the potential variability in many key model variables to support informative Monte Carlo modeling. Instead, point estimates of central tendency (geometric mean) blood-lead concentrations in children are derived utilizing statistical models based on empirical data and on biokinetic models of blood lead, coupled with assumptions regarding distributions of highly uncertain variables. The sensitivity of the deterministic relationships between dust lead and blood lead to changes in key variables and covariates is explored through sensitivity analyses. As presented in Section 6, the modeling inputs and assumptions that most strongly affect the predicted blood-lead distributions associated with candidate lead-dust hazard standards have been identified, based on the measures of statistical uncertainty from the empirical analyses and sensitivity analyses of the biokinetic models.

4. Please comment on the characterization of variability and uncertainty.

Charge Question 5 - Choice of Model for Residential Hazard Standards

The document presents two empirical models and two biokinetics models. OPPT proposes to use the NHANES Quasi-Likelihood, Empirical Model for the estimation of the residential hazard standards.

5. Please comment on this proposed choice.

EPA Charge Questions for the Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings

Background

Section 402(c)(3) of TSCA directs EPA to revise the regulations promulgated under TSCA section 402(a), *i.e.*, the Lead-based Paint Activities Regulations, to apply to renovation or remodeling activities in target housing, public buildings constructed before 1978, and commercial buildings that create lead-based paint hazards. In April 2008, EPA issued the final Renovation, Repair and Painting Rule (RRP Rule) under the authority of section 402(c)(3) of TSCA to address lead-based paint hazards created by renovation, repair, and painting activities that disturb lead-based paint in target housing and child-occupied facilities (USEPA, 2008a). The term ''target housing'' is defined in TSCA section 401 as any housing constructed before 1978, except housing for the elderly or persons with disabilities (unless any child under age 6 resides or is expected to reside in such housing) or any 0- bedroom dwelling. Under the RRP Rule, a child-occupied facility is a building, or a portion of a building, constructed prior to 1978, visited regularly by the same child, under 6 years of age, on at least two different days within any week (Sunday through Saturday period), provided that each day's visit lasts at least 3 hours and the combined weekly visits last at least 6 hours, and the combined annual visits last at least 60 hours. The RRP Rule establishes requirements for training renovators, other renovation workers, and dust sampling technicians; for certifying renovators, dust sampling technicians, and renovation firms; for accrediting providers of renovation and dust sampling technician training; for renovation work practices; and for recordkeeping. Interested States, Territories, and Indian Tribes may apply for and receive authorization to administer and enforce all of the elements of the RRP Rule.

Shortly after the RRP Rule was published, several petitions were filed challenging the rule. These petitions were consolidated in the Circuit Court of Appeals for the District of Columbia Circuit. On August 24, 2009, EPA entered into an agreement with the environmental and children's health advocacy groups in settlement of their petitions (USEPA, 2009a). In this agreement, EPA committed to propose several changes to the RRP Rule. EPA also agreed to commence rulemaking to address renovations in public and commercial buildings, other than child-occupied facilities, to the extent those renovations create lead-based paint hazards. For these buildings, EPA agreed, at a minimum, to do the following:

- Issue a proposal to regulate renovations on the exteriors of public and commercial buildings other than child-occupied facilities by December 15, 2011 and to take final action on that proposal by July 15, 2013.
- Consult with EPA's Science Advisory Board by September 30, 2011, on a methodology for evaluating the risk posed by renovations in the interiors of public and commercial buildings other than child-occupied facilities.
- Eighteen months after receipt of the Science Advisory Board's report, either issue a proposal to regulate renovations on the interiors of public and commercial buildings other than child-occupied facilities or conclude that such renovations do not create lead-based paint hazards.

In order to evaluate the potential risks associated with lead exposure due to renovations in public and commercial buildings, and the potential need for regulations on these activities, it is first necessary to develop the hazard standards for lead dust on window sills and floors in public and commercial buildings; these become the standards to help inform the impact of renovation activities. These standards will identify dangerous levels of lead in paint and dust, and provide benchmarks on which to base remedial actions taken to safeguard children and the public from the dangers of lead.

In June 2010, EPA issued a document entitled **"**Proposed Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings" and submitted the document to the Science Advisory Board (SAB) Lead Review Panel for a consultation. The SAB Panel met July 6–7, 2010 and provided comments on the Proposed Approach to EPA on August 20, 2010.

The current document entitled "Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings" describes the methods that EPA proposes to examine candidate hazard standards for floors and windowsills in public and commercial buildings. This document takes the SAB comments from the July, 2010 consultation into consideration in developing several candidate standards for public and commercial buildings.

Charge Question 1 - Approach Document

OPPT has developed an Approach document for developing the hazard standards for floors and windowsills in public and commercial buildings. This includes a description of the empirical and biokinetic approaches, as well as the resultant analyses used to estimate candidate lead dust hazard standards for public and commercial buildings.

1. Please comment on the clarity and transparency of the document.

Charge Question 2 - Empirical Models

The empirical approach involves the estimation of blood-lead impacts based on analyses of empirical data from the 1999–2004 National Health and Nutrition Examination Survey (NHANES). Two analyses were used. First, the regression relationships among floor and windowsill dust, other covariates, and blood-lead concentrations that Dixon et al. (2009) derived were applied to predict blood-lead levels for the various hazard standards (combinations of floor and windowsill dust loadings). The second was an independent reanalysis of the NHANES data to derive alternate models for predicting blood-lead impacts; the variations from the Dixon et al. (2009) approach included changes to the form of the dust-loading variables and application of models that are inherently linear at low lead exposures, a relationship that is supported by a wide range of biokinetic data, and regression of blood-lead values against estimated dust concentrations, rather than dust loading.

2. Please comment on the EPA reanalysis.

Charge Question 3 - Biokinetic Models

Two biokinetic models were used to estimate children's blood lead concentrations including EPA's Integrated Exposure Uptake Biokinetic Model for Lead in Children (IEUBK), and the

Leggett model. Information from the exposure scenarios is used to estimate relative contributions of exposures from different sources (soil, dust, air, diet, and water) and in different microenvironments.

The Leggett model and EPA's Adult Lead Methodology were used to estimate adult blood lead levels resulting from candidate floor and windowsill hazard standards.

3. Please comment on the use of these models and the inputs to these models.

Charge Question 4 - Analyses of Variability and Uncertainty

Monte Carlo methodology was not used to evaluate the impacts of variability and uncertainty in model parameters on blood-lead estimates as insufficient data exist concerning the potential variability in many key model variables to support informative Monte Carlo modeling. Instead, point estimates of central tendency (geometric mean) blood-lead concentrations in children are derived utilizing statistical models based on empirical data and on biokinetic models of blood lead, coupled with assumptions regarding distributions of highly uncertain variables. The sensitivity of the deterministic relationships between dust lead and blood lead to changes in key variables and covariates is explored through sensitivity analyses. The modeling inputs and assumptions that most strongly affect the predicted blood-lead distributions associated with candidate lead-dust hazard standards have been identified, based on the measures of statistical uncertainty from the empirical analyses and sensitivity analyses of the biokinetic models.

4. Please comment on the characterization of variability and uncertainty.

Charge Question 5 - Choice of Model for Public and Commercial Building Hazard Standards

The document presents empirical and biokinetic models. OPPT proposes to use the NHANES QL, Empirical Model and the ALM model for the estimation of the hazard standards for floors and windowsills for children and adults, respectively.

5. Please comment on these proposed choices.

APPENDIX B – EDITORIAL COMMENTS

General Comment Pertaining to Both Documents

A summary table of variables in the NHANES database should be presented to improve clarity. In EPA's documents, the same term “ventilation rate” is used when describing physiological ventilation of the lungs and also used when describing air exchange for rooms or buildings. The use of the same term for two different scenarios can be confusing to the reader and the Panel recommends that EPA use distinct terms when referring to each of these scenarios

Editorial Comments on the Residential Document (also pertains to the corresponding portions in the Public and Commercial Document)

- Pages 21 and 31, Figures 3-8 and 4-2: Both of these scatter plots show the raw data, being the unadjusted raw NHANES data as the dots and the model predictions as the several curves. The figure key of 3-8 says "raw data" which is clear enough, but 4-2 did not. Also, using the word "predicted" in the vertical axis is unclear, since it was also for raw data.

- Page 32, Figure 5-1 - This figure has 9 curves. The clarity of the document would be improved if the figure presented only central tendencies (6 curves), which would make the figure less cluttered. Figure 5-2 shows only those curves, which is clearer. The upper and lower bounds can be presented with error bars about a few points on the central tendency data points.

- Page 6, footnote a, insert “and for blood lead” after “…measurements,”

- Page 23, 2nd paragraph, 3rd line from bottom, change “data that is collected” to “data that are collected”

- Page 27, section 4.1.5, 1st and 2nd lines, “soil” does not appear to be needed in both lines.

- Page 28, Table 4-3 and elsewhere: The units of air concentration and blood lead are typically expressed as “µg”, not “mg”. Please check that the units and values are correct.

- Page 29, second line, change “current proposed hazard standards” to “current hazard standards”

- Page 40, section 6.1, 2nd line, change “dust-lead levels” to “blood lead levels”

- Page 41, 3rd line from bottom, change “flood condition” to “floor condition”

- Page 45, section 7.1, second to last sentence - The meaning of the phrase "support for a key input" is not clear

Specific Comments on the Public and Commercial Document

- Page 44, line 4 : change "76 percent" to "24 percent".
- Page 56, Figure 6-3: in the caption, change "Greater than 5.0" to "Greater than 2.5"
- Page 72, Table 7-2: Many of the units in the first column that are labeled "mg" (milligram) should be changed to "µg" (microgram). Also, the last column should be labeled as applying only to the Leggett model.
- Page 74, Table 7-4: in the second column, third row, change 0.011 to 0.11; in the fifth row, the proportion of time that a child spends at home is listed as 0.76, in contrast to the information on page 35, which indicates a value of 0.83; in the last row of the table, the upper bound and lower bound estimate entries appear to be reversed.
- Page 74, Table 7-5: The narrative indicates this table is intended to apply to adults, but the caption refers to children. The contents and caption should be checked. For example, the dust lead absorption fraction of 0.5 applies to children, but the soil lead absorption fraction applies to adults.

Edits to Appendix E of Both Documents

Page E-7

- Change "$dINAIR_{Pb}/dt$ = change in time of the indoor air lead mass" to "$dINAIR_{Pb}/dt$ = change in time of the indoor airborne lead mass in or as particulate (µg/hr)"
- Change "*Indoor Sources* = generation of mass due to indoor sources such as cooking or smoking" to "*Indoor Sources* = generation of mass to the indoor air due to indoor sources (e.g., cooking or smoking) (g/hr)"
- Change "*Dander Sources* = generation of mass due to human and pet dander" to "*Dander Sources* = generation of mass due to human and pet dander to the indoor air (g/hr)"

Page E-8

- Change "$Resuspension\ Flux_{Pb}$ = resuspension of lead out of the air (µg/h)" to "$Resuspension\ Flux_{Pb}$ = resuspension rate from floor to the air (µg/h)"
- Change "$Resuspension\ Flux_{Part}$ = deposition of particulate out of the air (g/h)" to "$Resuspension\ Flux_{Part}$ = resuspension rate of particulate from floor to the air (g/h)"
- Change "R = deposition rate (h^{-1})" to "R = resuspension rate or proportion of the mass on the floor going to the air per hour (h^{-1})"

Page E-12

Equation 2A seems to be correct conceptually but the unit/conversions appear to be inconsistent. All units of the expressions within the equation should have the units of micrograms/h.

The third expression within this algorithm is reproduced below:

PbPaintConcen x ChipFraction x V x WallLoading x UnitConv

Units for these variables listed on page E-11 are:

$mg/cm^2 \ \ x\ 1/yr\ x\ \ m^3\ x\ m^2/m^3\ x\ 1\ yr/8760\ hr$

In order for this expression to have the units of micrograms/hr one need to convert mg/cm^2 to μg/m^2:

$(1\ mg/cm^2)(1000\ \mu g/mg) = 1000\ \mu g/cm^2 = 1000\ \mu g/cm^2)(10{,}000\ cm^2/m^2) = 10{,}000{,}000\ \mu g/m^2$

As such, a conversion constant of 10,000,000 needs to be included in this algorithm to convert from mg/cm^2 to μg/m^2. Assuming this was done in the computer code would mean that the outputs are correct while this documentation is not. Of course, if it were coded incorrectly then the model output is incorrect.

Page E-12

- In Equation 2B, the variable "PbCoverageDens" does not exist and should be "CoverageDens".
- Change "$INAIPR_{Pb}$ = indoor mass of lead in air (μg)" to "$INAIR_{Pb}$ = indoor mass of lead in air (μg)".
- Change "$INAIPR_{Part}$ = indoor mass of particulate in air (μg)" to "$INAIR_{Part}$ = indoor mass of particulate in air (g)"
- Page E-20 - The title for Table E-9 appears to have been inadvertently used for Table E-10 also.