UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

August *xx*, 2007

EPA-CASAC-07-00*x*

Honorable Stephen L. Johnson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, DC 20460

Subject: Clean Air Scientific Advisory Committee's (CASAC) Review of EPA-OPPT's Draft Approach for Estimating IQ Change from Lead Renovation, Repair, and Painting (LRRP) Activities and the OPPT Dust Study

Dear Administrator Johnson:

The Clean Air Scientific Advisory Committee (CASAC or Committee) Panel for Review of EPA's Lead Renovation, Repair, and Painting (LRRP) Activities (CASAC Panel) met on July 9–10, 2007 in Durham, NC to conduct a peer review of the Agency's *Draft Approach for Estimating Changes in Children's IQ from Lead Dust Generated During Renovation, Repair, and Painting in Residences and Child-Occupied Facilities* (Draft LRRP Activity IQ-Change Methodology, June 2007), and the *Draft Final Report on Characterization of Dust Lead Levels After Renovation, Repair, and Painting Activities* (OPPT Dust Study, January 2007). The roster of CASAC members is attached as Appendix A of this letter, and the Panel roster is found in Appendix B. EPA's charge to the Panel is contained in Appendix C to this letter, and Panel members' individual written comments are provided in Appendix D. These individual review comments provide Panelists' more detailed critiques, which include direct responses to the charge questions.

EPA's Office of Pollution Prevention and Toxics (OPPT) had requested that the CASAC conduct a peer review of these two Agency documents — and an earlier consultation on OPPT's *Draft Assessment to Support the LRRP Rule* (1^{st} Draft LRRP Assessment, January 2007) — in support of the EPA's LRRP rule-making activity. In a notice published in the **Federal Register** on January 10, 2006 (71 FR 1587–1636), the Agency proposed new requirements to reduce exposure to lead hazards created by renovation, repair, and painting activities that disturb lead-based paint. This action supports the attainment of the Federal government's goal of eliminating childhood lead poisoning by 2010. The rule is intended to address EPA's concern that RRP work conducted by untrained and uncertified contractors may create new lead hazards, thus increasing the risk of lead exposure to the residents of homes containing lead-based paint.

The peer review of the Agency's Draft LRRP Activity IQ-Change Methodology, June 2007), and the OPPT Dust Study was a follow-up to the CASAC's consultation on 1st Draft LRRP Assessment, January 2007) conducted on February 5, 2007, as documented in our letter to you dated April 3, 2007 (EPA-CASAC-07-004). Some of the key points that the CASAC Panel suggested to the Agency have yet to be addressed; for example, a separate consideration of uncertainty and variability; use of the most-recent epidemiology studies indicating that children are more sensitive to lead poisoning than previously thought; and, in particular, greater emphasis on the use of empirical data rather than on model estimates alone.

The CASAC Panel is pleased to review and provide advice on the approaches under consideration by the Agency. This letter provides a summary of the major findings with respect to the CASAC's peer review of the OPPT Dust Study and the Draft Approach for Estimating IQ Change from LRRP Activities. The Panel agrees that there is ample evidence that exposure of children to lead dust poses a major health risk. The data are sufficiently compelling as to require both prevention of new dust lead exposures and control of existing dust lead exposures. Home and child-occupied facility (COF) repair and renovation where lead-based paint surfaces are present require practices that minimize dust lead exposures of children. The Panel recommends that young children be removed from such premises where feasible. If this is not feasible, it is important for the Agency to provide guidance to reduce such exposures to children.

Having completed its peer-review of these OPPT documents, *the Panel's overall conclusion was that the available data are insufficient and the procedures and analyses are inadequate to support the proposed approach for estimating the IQ changes in children exposed during renovation procedures. Therefore, the approach would not adequately support a rigorous cost/benefit analysis. Accordingly, the Panel cannot endorse the Agency's methodology as presented.* Specifically, the Panel's principal concerns are:

- OPPT's draft methodology is likely to underestimate IQ loss because it is based on the current lead national ambient air quality standards (NAAQS), which are presently under Agency review. These standards are likely to be strengthened on the basis of recent epidemiological data indicating that children are more susceptible to effects from lead exposure than was previously thought.

- Outdated residual surface contamination standards (*i.e.*, dust lead cleanup levels of 40 $\mu g/ft^2$ for floors and 250 $\mu g/ft^2$ for window sills) are being used that are insufficiently protective of children's health, as indicated by recent epidemiological studies.

- The cleaning procedures employed are inadequate, such that post-cleaning lead levels do not even meet these existing EPA standards. Moreover, the qualitative and simplistic method used to verify the effectiveness of these cleaning procedures does not yield consistently-reliable results, leading to an inaccurate assessment of cleaning efficiency after repair and renovation activities.

- The limited data from residential housing units and COFs included in the Dust Study do not represent a valid sample of housing at the *national* level, and provide a limited and insufficient experimental data set for use as input into the biokinetic models.

- There is no indication of the variability of the findings (*e.g.*, standard deviation, range, *etc.*), which limits the usefulness of the data.

- High uncertainties are associated with the use of the biokinetic lead models, especially for episodic exposures. *The CASAC Panel strongly favored greater use of empirical data for estimating blood lead levels following exposure to lead dust during renovation activities.*

- There is a lack of consideration for the activity patterns of children as a sensitive subpopulation.

The Panel's specific comments and recommendations on these two Agency documents are as follows:

OPPT Dust Study

The Dust Study, which was conducted by an outside contractor (Battelle), was designed to compare environmental lead levels at appropriate stages after various types of RRP activities were conducted on the interior and exterior of residential housing units and COFs. All jobs disturbed more than two square feet (2 ft^2) of lead-based paint, which is the *de minimus* amount of disturbed area to which the proposed rule applies. Of particular interest was the impact of using specific work practices that repair and renovation contractors would be required to follow under the proposed rule. The RRP procedures undertaken represented the range of activities that are permitted under the proposed rule. Importantly, the Dust Study also provided input for the type of exposure data needed for the draft LRRP document.

The Panel found that the OPPT Dust Study was reasonably well-designed, considering the complexity of the problem, and that the report provided information not available from any other source. The study indicated that the rule cleaning procedures reduced the residual lead (Pb) remaining after a renovation more than did the baseline cleaning procedures. Another positive aspect of the Dust Study was that it described deviations from the protocol when they occurred.

Despite these positive aspects of the OPPT Dust Study, the CASAC Panel had several areas of significant concern:

1. The lead dust loading values of 40 $\mu g/ft^2$ for floors and 250 $\mu g/ft^2$ for window sills are *presented as adequately protective of children against lead poisoning, i.e., to guard against blood lead levels of greater than ten (>10) µg/dL. However, the Panel notes that these residual surface contamination standards are obsolete on the basis of recent epidemiology findings that indicate that adverse health effects are found in children with blood lead levels less than five (<5) µg/dL* (Lanphear *et al.*, 2005; Lanphear *et al.*, 2002, Lanphear *et al.*, 1998, Lanphear *et al.*, 1996, and Malcoe *et al.*, 2002). Unless EPA's new LRRP regulation reflects the data reported in the forthcoming Lead NAAQS that is presently undergoing Agency review, public health will not be adequately protected.

2. Also problematic is that the Dust Study appears to ignore measured lead values indicating that post-cleaning Pb levels do not meet even the *current* EPA standards. *Such non-compliant measurement data strongly suggest that a modification of the cleaning*

procedures is required. As an example of an effective cleaning method, there are data available from the ongoing Cincinnati Children's Hospital Medical Center HOME (Health Outcomes and Measures of the Environment) Study, funded in part by EPA, demonstrating that over 99% of housing units can achieve dust lead loading values of 10 $\mu g/ft^2$ and 50 $\mu g/ft^2$ on floors and windows sills, respectively, after the implementation of interim lead hazard controls (which are similar to repair and renovation activities).

3. The method used to assess the effectiveness of the cleaning procedures does not yield results that are consistently-reliable. The use of white cloth (wet or dry) swipes to verify the degree of cleanup was employed as an alternative to lead measurements because the white cloth test was "quick, inexpensive, reliable and easy to perform." However, quality assurance tests of the method showed that the results were *not* reliable. As an example, the report states, "Overall, only three window sills failed the first wet cloth verification despite the fact that nineteen window sills had post-cleaning levels >250 $\mu g/ft^2$." The study also points out that the simple coloration test had several problems associated with it as well, including the fact that some forms of lead are white and the cleanup solution (*Simple Green*®) sometimes darkened the white cloths. One member of the CASAC Panel suggested that the white cloth test might be used as a screening method, but that a measured value should be obtained for final verification of the effectiveness of the clean-up. *Indeed, for as important a responsibility as protecting children against lead poisoning, the Panel strongly feels that it is imprudent to substitute a simplistic and qualitative white cloth test for highly-specific, analytical measures of lead in house dust.*

4. The limited data from residential housing units and COFs used in the Dust Study did not represent a valid sample of housing at the national level. Moreover, there is no indication of the variability of the data (*e.g.*, standard deviation, range, *etc.*), which limits the usefulness of the data.

In addition to these major concerns, several additional minor or editorial changes are recommended:

- The conclusions of the report should be linked to the Dust Study's objectives.
- Dust loadings, as well as dust *lead* loading, should be reported, if possible.
- The tables and figures are not complete, and some figures do not have properly labeled axes. In some tables, only the p-values are given; the magnitude of changes should also be stated.
- The Panel thought that the Dust Study should have documented blood lead levels in the workers before and after their work activities. This important information could have been reported in a form that could not be linked to the individual workers.

Additional remarks on the OPPT Dust Study are found in Panel members' individual written comments provided in Appendix D.

Draft Approach for Estimating IQ Change from Lead RRP Activities (Draft LRRP Activity IQ-Change Methodology)

Pursuant to Executive Order 12866, *Regulatory Planning and Review* (1993), the Agency is required to conduct an economic analysis of the costs and benefits associated with "significant regulatory action[s]" such as the LRRP rule-making. OPPT developed the Draft LRRP Activity IQ-Change Methodology to support the benefits assessment in this economic analysis. As stated in the introduction to the draft Approach document, "The quantified benefits analysis will be based primarily on changes in neurocognitive function in children (as measured by IQ) due to lead exposure from specific renovation, repair and painting (RRP) activities. OPPT is using data from a variety of sources … to determine the specific types and frequencies of RRP activities that occur in residences and child-occupied facilities.... In support of the economic analysis, it is necessary to have a scientifically sound approach for estimating changes in children's IQ from lead exposure due to a variety of RRP activities in residences and child-occupied facilities." Therefore, the Draft LRRP Activity IQ-Change Methodology document describes an approach for estimating lead exposures and resulting changes in IQ for children under age six that could result from various RRP activities conducted in all of the residential houses and child-occupied facilities required for the economic analysis. As noted above, OPPT's Lead Dust Study provided the input exposure data for use in the estimation of IQ changes in children exposed to lead during renovation activities.

The Agency authors are to be commended for the large effort that went into the document to define and describe the conceptual elements linking Rule and non-Rule LRRP protocols to established biomarkers of lead exposure and established toxic endpoints from these exposures. In addition, the general, three-step approach described in this draft methodology document — (1) estimating the dust lead generated from specific renovation activities and converting the dust lead loadings to dust lead concentrations, (2) estimating blood lead levels from exposure to the dust lead concentrations, and (3) from those values, estimating IQ changes in exposed children — is both logical and reasonable.

However, the CASAC Panel's major concerns are that the methodology, in its current form, is not adequate for the main objective of the approach, i.e., cost/benefit analyses. These concerns are delineated as follows, both as an overarching concern and then by the three steps of the approach:

- <u>Overall Concern</u>: Since lead is a multimedia pollutant, the Panel questions whether it is appropriate to conduct economic analyses on each increment of exposure (such as during restoration) without considering the degree to which that increment builds on other pathways of exposure. Evaluating each source of lead as an increment to all other sources could (in the extreme) lead to the conclusion that no individual source is significant while it is clear that the combined, accumulated effects of multimedia lead exposure is harmful.

- <u>Step 1</u>: Significantly, for the first step in this approach, *there are insufficient data to determine if the results of the limited dust studies and measurements conducted by Battelle are representative of a* national *sampling of renovations of either homes or child-occupied facilities.* As mentioned previously, the data on the effectiveness of lead cleanup in the Dust Study is also limited, and yet this information is essential for determining lead exposures associated with the renovation procedures. Furthermore, while the document does a good job of noting its limitations, there are no suggestions of how to improve on or eliminate those limitations.

- Step 2: For the step in the approach that converts exposure to dust lead to blood lead concentrations, two biokinetic models were proposed. The panel discussed at length the advantages and limitations of the Integrated Exposure Uptake Biokinetic (IEUBK) model for lead in children and the Leggett model for use in predicting the blood levels of children exposed during renovation activities (see, in particular, the individual written comments of Panel member Mr. Sean Hays found on page D-*x*). The IEUBK model was considered inadequate because it is based on steady-state conditions for exposure to lead — not episodic, peak exposures as would be encountered in renovation activities. The Leggett model, which predicts higher blood lead levels than the IEUBK model, allows for input of data from such acute, peak exposures. The fact that the IEUBK model produces values closer to the Centers for Disease Control and Prevention (CDC) National Health and Nutrition Examination Survey (NHANES) data is probably because both the NHANES data set and the data input for the IEUBK model include homes (and children living in homes) with no lead paint. It is likely that the upper tail of the NHANES data would be a better basis for comparison. Neither model was thought to be accurate, although it was suggested that the two models might be used to bound the actual values (IEUBK for the lower bound, and Leggett for the upper bound). Some members of the Panel suggested using the O'Flaherty model as another option.

  As mentioned in the earlier consultation, *the CASAC Panel strongly favored greater use of empirical data for estimating blood lead levels following exposure to lead dust.* At least four sets of published data were suggested for this: Pirkle *et al.*, *EHP*, 1998; Galke *et al.*, *Environ. Res.*, 2001; Ettinger *et al.*, *EHP*, 2002; Rabinowitz *et al.*, *Amer. J. Public Hlth*, 1985. (In addition, see the individual written comments of Panel member Dr. Paul Mushak found on page D-*x*).

  Furthermore, one member of the Panel outlined how such an empirical approach might be undertaken: (1) Begin with population blood lead levels for a cohort of one- to two-year-old children from NHANES using the upper tail of the distribution; (2) estimate the increase in blood lead concentration due to renovation and repair activities using empirical published values in the range of 12.5% to 30% increase (Rabinowitz *et al.*, *Amer. J. Public Hlth*, 1985; Lanphear *et al*., unpublished data); (3) estimate the reduction in IQ associated with a increase in population mean blood lead concentration in this range using the -2.94 IQ decrement per 1 μg/dL from the piecewise linear analysis for children with blood lead concentration <7.5 μg/dL; (4) determine the range of estimated IQ benefits of the proposed rule; and (5) use these empirical estimates to calculate the cost-benefit of the proposed rule for a U.S. birth cohort of one- to two-year-old children. (For additional detail, see the individual written comments of Panel member Dr. Bruce Lanphear found on page D-*x*).

- Step 3: The next step described in the draft Approach document was to estimate IQ loss in children based on their estimated blood levels. The approach was, understandably, based on the current standards for lead toxicity, but these standards are out-of-date due to recent epidemiological data showing that children are more sensitive to lead toxicity than previously thought. If the EPA goal of eliminating lead poisoning in children by the year 2010 is to be achieved, the toxicity estimates must be based on the latest data.

The Panel discussed the log-linear model with a cutpoint of 1 µg/dL versus the piecewise linear model for estimating IQ change based on blood lead. Arguments can be made for each of the models (see the response to Charge Question #4 found on pages D-*x*). Both models fit the existing data well, with a slight edge to the log-linear model for the entire range of blood Pb levels. However, compared to the piecewise linear model, the log-linear model underestimates the magnitude of effects on IQ for those children currently having low blood Pb values (*i.e.*, <7.5 µg Pb/dL) because the slope of the log-linear model is not as steep as that of the piecewise linear model in this lower range. Also, the piecewise analysis may be more appropriate because the majority of children have maximal baseline blood levels below 7.5 µg/dL, and the mean increase in blood lead concentration, on a population level, would generally be up to, but not exceeding, a blood lead concentration of 7.5 µg/dL. Thus, the majority of the Panel recommends using the piecewise linear model for estimating potential effects on IQ of household lead arising from renovation activities. The newly-recognized steep slope for the exposure response curve below 7.5 µg/dL (*i.e.*, -2.94 IQ decrements per 1 µg/dL blood lead) should be used to estimate the effect of the exposures. The approach should also take into consideration sensitive subpopulations of children such as those with aminolevulinate dehydratase (ALAD) polymorphisms or children with either particularly-low initial blood lead levels or children of low socio-economic status (SES).

Finally, the following significant technical concerns were also noted:

- The sparseness of data is illustrated in the Monte Carlo simulations for uncertainty in indoor dust lead concentrations. In Appendix D of the draft LRRP Activity IQ-Change Methodology document, the authors state, with no defense, that low and high values were assumed to represent two standard deviations above and below the mean. With no scientific basis for such assumptions, the Monte Carlo simulations are suspect. Another assumption — that children occupy the entire house or yard equally during a renovation project — is not realistic. *Activity patterns for children as a sensitive subpopulation should have been included in the analyses.* There is also a need to consider newer data for deposition of airborne lead dust both in the respiratory tract and in the head.

- As discussed in the earlier consultation, variability needs to be considered separately from uncertainty. In the judgment of the Panel, the sensitivity analyses were performed using too small an alteration in input variables (*i.e.*, 10%); larger alterations should therefore be probed. Additionally, there is no indication given as to how the 10% alteration relates to variability in the data (that is, it is not clear what fraction of a standard deviation is represented by a 10% change in the input variables).

As with the OPPT Dust Study, additional remarks on the Draft LRRP Activity IQ-Change Methodology are provided in Panelist' individual written comments (Appendix D).

The CASAC Panel was pleased to be of service to EPA in its review of these two documents related to the avoidance of lead poisoning during restoration of residential properties and COFs contaminated with lead. If the Agency wishes additional advice or recommendations from the CASAC on EPA documents related to the forthcoming LRRP rule, the Panel would be happy to assist you again in the future. As always, we wish the Agency well in this important task.

Sincerely,

/Signed/

Dr. Rogene Henderson, Chair
Clean Air Scientific Advisory Committee

Appendix A – Roster of the Clean Air Scientific Advisory Committee

Appendix B – Roster of the CASAC Panel for Review of EPA's LRRP Activities

Appendix C – Agency Charge to the CASAC Panel

Appendix D – Review Comments from Individual CASAC Panel Members

NOTICE

This report has been written as part of the activities of the U.S. Environmental Protection Agency's (EPA) Clean Air Scientific Advisory Committee (CASAC), a Federal advisory committee administratively located under the EPA Science Advisory Board (SAB) Staff Office that is chartered to provide extramural scientific information and advice to the Administrator and other officials of the EPA. The CASAC is structured to provide balanced, expert assessment of scientific matters related to issue and problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the EPA, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names or commercial products constitute a recommendation for use. CASAC reports are posted on the SAB Web site at: http://www.epa.gov/sab.

Appendix A – Roster of the Clean Air Scientific Advisory Committee

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U.S. Environmental Protection Agency
Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)

CHAIR

Dr. Rogene Henderson, Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

MEMBERS

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Dr. James D. Crapo, Professor, Department of Medicine, National Jewish Medical and Research Center, Denver, CO

Dr. Douglas Crawford-Brown, Director, Carolina Environmental Program; Professor, Environmental Sciences and Engineering; and Professor, Public Policy, Department of Environmental Sciences and Engineering, University of North Carolina at Chapel Hill, Chapel Hill, NC

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Dr. Armistead (Ted) Russell, Georgia Power Distinguished Professor of Environmental Engineering, Environmental Engineering Group, School of Civil and Environmental Engineering, Georgia Institute of Technology, Atlanta, GA

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Appendix B – Roster of the CASAC Panel for Review of EPA's LRRP Activities

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U.S. Environmental Protection Agency
Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)
CASAC Panel for Review of EPA's
Lead Renovation, Repair, and Painting (LRRP) Activities

CHAIR

Dr. Rogene Henderson*, Scientist Emeritus, Lovelace Respiratory Research Institute, Albuquerque, NM

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Dr. Bruce Fowler**, Assistant Director for Science, Division of Toxicology and Environmental Medicine, Office of the Director, Agency for Toxic Substances and Disease Registry, U.S. Centers for Disease Control and Prevention (ATSDR/CDC), Chamblee, GA

Dr. Philip Goodrum†, Senior Scientist I/Manager, ARCADIS BBL, ARCADIS of New York, Inc., Syracuse, NY

Dr. Robert Goyer [M.D.]**, Emeritus Professor of Pathology, Faculty of Medicine, University of Western Ontario (Canada), Chapel Hill, NC

Mr. Sean Hays**, President, Summit Toxicology, Allenspark, CO

Dr. Bruce Lanphear [M.D.]**, Sloan Professor of Children's Environmental Health, and the Director of the Cincinnati Children's Environmental Health Center at Cincinnati Children's Hospital Medical Center and the University of Cincinnati, Cincinnati, OH

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** Members of the CASAC Lead Review Panel

† Members of the Science Advisory Board (SAB) or SAB panel

Appendix C – Agency Charge to the CASAC Panel

Charge to the CASAC Panel for the Review of EPA-OPPT's *Draft Approach for Estimating Changes in Children's IQ from Lead Dust Generated During Renovation, Repair, and Painting in Residences and Child-Occupied Facilities* (Draft LRRP Activity IQ-Change Methodology, June 2007)

1. Overall Approach.

Please comment overall on the Approach and its utility for "building" all of the houses and child-occupied facilities (COFs) required for the economic analysis. Please comment on the clarity and transparency of the document.

2. Sensitivity and Monte Carlo Analyses

The approach of this document assumes that variable reduction (reduction of the number of potentially influential factors carried through the analysis) is carried out following a sensitivity analysis and that Monte Carlo analyses permit the estimates to account for magnitude of uncertainty as well as variability.

a. The document describes a sensitivity analysis for each of the two examples. They suggest which factors are important to describe the features of lead (Pb) exposure. The examples, however, provide only a sense of the impact on that particular example and not necessarily for the whole. Please comment on the strengths and weaknesses of the sensitivity analyses. Please comment on whether the sensitivity analysis using the two examples is sufficient to characterize the factors that are most important for determining Pb exposure or should a separate sensitivity analysis be conducted for each of the houses and COFs that will be "built" for the economic analysis.

b. The document describes Monte Carlo analyses for each of the two examples. Please comment on the strengths and weaknesses of the Monte Carlo analyses. Please comment on whether the Monte Carlo analyses using the two examples is sufficient to characterize the variability in Pb exposures or should a separate Monte Carlo analysis be conducted for each of the houses and COFs that will be "built" for the economic analysis.

c. Dust study results that are observed to be non-monotonic across increasing Control Options will likely translate into similar patterns following application of the approach to estimate IQ changes. IQ change models only use geometric means from the Dust Study. Please comment on the usefulness of an additional Monte Carlo step as the way to account for the variances in the Dust Study.

d. The blood Pb models assume that variability in the population around any mean blood Pb is approximately that displayed in the general population. The assumption that the estimated mean blood lead values are accompanied by geometric standard deviations of 1.2 is made explicit in the IEUBK model documentation and is extended implicitly in these analyses for the Leggett model. Nonetheless, the assumption currently is not discussed in the description of the Approach given to the CASAC nor would it be displayed numerically in any results from its application; the approach shown carries out all simulations during one phase of analysis. A Monte Carlo step between the application of the blood lead model and a model for estimating changes in IQ would expand the characterization of differences between similarly aged children experiencing the same renovation, repair and painting (RRP) activities. Please comment on the usefulness of an additional Monte Carlo step between the application of the blood lead model and the IQ change model as the way to display differences.

e. In addition to the aspects addressed by 2b-2d, the document mentions several ways in which assumptions have been incorporated into the approach in a deterministic fashion. Please comment on the strengths, weaknesses, and necessity of introducing additional Monte Carlo analyses or markedly changing these assumptions, and whether these would be applied to each of the houses and COFs that will be "built" for the economic analysis.

3. Blood Lead Modeling

The document describes use of the Leggett and IEUBK models for each of the two examples. Both models are used because exposures to Pb from RRP activities are anticipated to be of short duration, and fluctuate frequently. In this context, applying the IEUBK to estimate the impacts of short-term fluctuations in Pb exposure (weekly in this approach) may stretch the IEUBK to the limits of its temporal resolution. Both models are used in this document to display the impact of model uncertainty. The two examples presented in this document show that predictions by the Leggett model are about three times those predicted by the IEUBK. This is consistent with the findings of Pounds and Leggett (1998) who compared predictions from the Leggett model with the deterministic predictions of blood Pb levels generated by the IEUBK model, using the IEUBK default inputs. In addition, the relative difference between the two models seems to be similar for single and multiple RRP activities. Please comment on whether both the IEUBK and Leggett models should be used to estimate blood Pb levels for all of the houses and COFs that will be "built" for the economic analysis.

4. Estimates of IQ Change

This document describes the use of two strategies to address the limitations and uncertainties associated with the log-linear IQ model. Please comment on the strategies EPA has used to address limitations and uncertainties. Have these limitations and uncertainties been accurately and transparently described? These include the use of a log-linear model with a "cutpoint" of 1 µg/dL blood Pb and the use of a piecewise linear model. Both models are drawn from Lanphear *et al.* (2005). The coefficient for the piecewise linear is derived from concurrent blood Pb levels. Both models, however, are being used with lifetime average blood Pb values in the context of this document. Please comment on the strengths and weaknesses of the models. Please comment on whether both the log-linear IQ model and the piecewise linear model should be used for all of the houses and COFs that will be "built" for the economic analysis.

5. Adaptation of Approach for Child-Occupied Facilities

With the range of potential COF configurations, the fact that children may spend most of their time in a limited part of the COF, and the fact that there may be multiple children under age six (6) in different rooms of the same COF, there is no simple way to develop a COF-wide loading estimate. The proposed approach would estimate the Pb loadings in three different types of rooms in a COF (workspace, adjacent, and rest of COF) by assuming that all RRP activities take place in the same workspace. It is proposed that loadings in each room would be estimated for each type of activity individually and then composite loadings would be estimated for each multiple activity scenario by summing the relevant activity-specific loadings for each type of room. The estimated loadings for the workspace would therefore represent the high-end exposure scenario, the rest of COF would represent the low-end exposure scenario, and the adjacent room would represent the mid exposure scenario. Please comment on the strengths and weaknesses of the overall approach for COFs.

6. Adaptation of Approach using Age of Housing

The HUD surveys of lead-based paint in housing indicate that the level of lead in paint will vary by the age of the housing and housing component. The OPPT Dust Study included houses dating from around 1920 and a school built in 1967. The lead levels in the lead-based paint in the OPPT Dust Study varied considerably. The Approach uses lead loadings from the OPPT Dust Study as a proxy for lead loadings in newer houses. Please comment on: (1) whether it is appropriate to adjust the lead loadings from the OPPT Dust Study downward based on the age (*i.e.*, vintage) of the building for newer buildings; (2) a suggested approach for making the adjustment, if recommended; and (3) the application of such an adjustment for COFs in public or commercial buildings, as well as for residential buildings.

7. Adaptation of Approach for Exterior Renovation, Repair, and Painting

The examples provided in the Approach are for interior renovation jobs. The proposed rule also addresses exterior renovation, repair, and painting. When the Approach is used to build the houses for the economics analysis, exterior jobs will be represented. Modifications or enhancements may be needed to the approach to account for lead exposure from exterior jobs. In particular, lead dust created by exterior jobs may be tracked into a housing unit or COF or otherwise enter the unit or COF, and contribute to the indoor dust loading. Please comment on: (1) the extent to which the approach should consider this “tracked in” dust contribution to the indoor dust loading of a single property, and provide suggestions for incorporating it, if recommended; and (2) how to estimate potential lead exposures to occupants of neighboring dwellings from exterior renovations and for occupants of neighboring units in multi-family housing from interior renovations.

8. Adaptation of Approach for Other Contributions

The Approach was developed to consider the range of permutations and combinations of exposure scenarios and houses/COFs that would need to be built for this rulemaking. Please comment on whether any potential exposure scenarios and/or housing/COF considerations have been overlooked and should be considered when building the houses for this rule-making. Please comment on any additional issues with building houses in which many low or high dust generating activities are used (*e.g.*, small repairs or power sanding).

Charge to the CASAC Panel for the Review of EPA-OPPT's *Draft Final Report on Characterization of Dust Lead Levels After Renovation, Repair, and Painting Activities* (OPPT Dust Study, January 2007).

Organization of the Report

Chapter 1 covers background and study objectives. Chapter 2 includes a brief summary of study conclusions, and addresses the peer review of the study design and the human subjects review. Chapter 3 summarizes the study design. Chapter 4 summarizes the field work. Chapter 5 contains the statistical analysis plan. Chapters 6 and 7 present the analysis of the data. Chapter 8 summarizes study quality assurance. Chapter 9 presents the study conclusions in detail.

Appendix A provides details on the individual jobs in the study. Appendices B to H contain plots of study data. Appendices I to O provide more detail on the data analysis in Chapter 7.

Issue 1. Study Objectives

The study was designed to meet several objectives. The study objectives were determined through consultations with the ultimate users of the data, who would conduct the risk approach and the economic analysis. The study objectives are listed on pages 1-2 and 1-3 in Chapter 1 of the report.

Question 1. Are each of the study objectives objectively and transparently addressed in the data analyses and conclusions in the report?

Issue 2. Study Conclusions

The study conclusions are presented briefly at the beginning of Chapter 2, and in detail in Chapter 9. The conclusions are based on the analyses of the data that was collected in the study.

Question 2. Is each of the study conclusions in the report supported by the data analyses and other information in the report? If you do not agree that the conclusions are supported by the data and analyses, please discuss your concerns and if possible, provide specific language to describe the conclusions.

Issue 3. Range of Data

Data collected from field studies tend to be variable due to a number of factors. That was the case in this study.

Question 3. Do the tables, graphs, figures and other information in the report objectively and transparently convey the range of the data in the study?

Issue 4. Report Organization and Clarity

The report was written to support rule development, and is likely to be read by persons who do not necessarily have a technical background, but who are interested in the final rule.

Question 4. Is the report logically laid out, consistent, and easy to follow?

Issue 5. Data Collection and Descriptive Analysis

The study design has been peer reviewed previously. There has been no other external peer review of the data analyses in the report.

Question 5. Are the descriptive analyses in Chapter 6 for interior and exterior jobs appropriate for the study objectives and the collected data? Have the collection and the descriptive analyses of the data been objectively and transparently described in Chapters 3, 4 and 6?

Issue 6. Statistical Modeling Results

In addition to the descriptive analysis in Chapter 6, the report includes statistical modeling in Chapter 7.

Question 6. Please provide any specific comments on the modeling analyses in Chapter 7. Are the statistical methods appropriately applied to the data? Are the methods objectively and transparently described?

Appendix D – Review Comments from Individual CASAC Panel Members

This appendix contains the preliminary and/or final individual written review comments on the Agency's Draft LRRP Activity IQ-Change Methodology and the OPPT Dust Study from those members of the Clean Air Scientific Advisory Committee Panel for Review of EPA's LRRP Activities who submitted such comments. The comments are included here to provide both a full perspective and a range of individual views expressed by Panel members during the review process. These comments do not represent the views of the CASAC, the EPA Science Advisory Board, or the EPA itself. Panelists providing review comments are listed on the next page, and their individual comments follow.