UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

August 30, 2007

EPA-CASAC-07-006

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) convened 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); and met again on August 7, 2007 via teleconference to hold further deliberative discussions concerning this letter. 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. Panel members' responses to those Agency charge questions are provided in Appendix D, and Panelists' individual written comments are attached as Appendix E.

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* (1st 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 (RRP) 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.

Overall Evaluation

The CASAC Panel is pleased to review and provide advice to the Agency on this topic. 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, which OPPT developed to support the benefits assessment in the economic analysis required for "significant regulatory action[s]" such as the LRRP rule-making. The Agency authors are to be commended for the significant 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 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. Nevertheless, as detailed below, *the Panel's overall conclusion was that the available experimental or empirical data are limited and that the modeling procedures and analyses are inadequate to support the proposed modeling approach for estimating the IQ changes in children exposed during renovation procedures. Therefore, the modeling approach in its present form would not adequately support a rigorous cost/benefit analysis. Accordingly, while the Panel believes the overall concepts in the proposed methodological approach are reasonable, the CASAC Panel cannot endorse the specific steps, procedures, and data analyses contained in the draft Agency methodology document.*

Furthermore, the Panel had two other overarching concerns beyond the review of these documents:

- Although the topic is not strictly related to the review of the draft methodology, the Panel questions whether it is appropriate to conduct economic analyses on each increment of exposure to a *multimedia* pollutant such as lead (*e.g.*, during a 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.
- EPA should give much greater priority to this effort of developing improved processes for lead RRP activities so as to decrease childhood lead exposures in homes and other child-occupied facilities (COFs) in various parts of our country. Since 2000, when the Agency joined with other Federal agencies in establishing the worthy and, indeed, critical goal of eliminating childhood lead poisoning within 10 years, the evidence suggests that EPA has to date given only limited emphasis to developing a reliable means to decrease

exposure of children to lead used as pigments in many of the interior and exterior paints applied during the original construction and renovation of homes, schools, day-care centers, and other buildings that are frequently occupied by children. In particular, the CASAC 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, and control of existing, dust lead exposures. Repair and renovation of homes and COFs where lead-based paint surfaces are present require practices that minimize dust lead exposures to 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.

With respect to its review of the two Agency documents, the Panel was concerned about both regulatory and methodological issues, as follows:

Regulatory Concerns

- OPPT's draft methodology is likely to underestimate IQ loss because blood lead levels of concern for adverse health effects are based on the exposure-response information underlying the current lead national ambient air quality standards (NAAQS) that are presently under Agency review. The CASAC has recently recommended that the Lead NAAQS be lowered substantially (see the CASAC's letter to you [EPA-CASAC-07-003] dated March 27, 2007). In the CASAC's opinion, these standards need to be strengthened in view 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. In addition, while setting maximum allowable cleanup concentrations is a reasonable approach, benefit estimates must take into account benefits that accrue from decreasing environmental exposures to lead below those concentrations, which any reasonable cleanup protocol will do much of the time (see the individual written comments of Panel member Dr. Joel Schwartz on page E-48).

Methodological Concerns

- The cleaning procedures employed are inadequate, such that post-cleaning lead levels do not even meet the existing EPA standards. Moreover, the qualitative and simplistic method used to verify the effectiveness of these cleaning procedures — *i.e.*, the "white cloth verification tests" — 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, which are used as input into the biokinetic models, most likely do not represent a statistically-valid sample of housing at the *national* level. On the one hand, the estimated risks may overstate what might be encountered on average nationally because the examples studied likely represent high-hazard scenarios reflective of the upper tails of the distribution. On the other hand, several modifications in the study design falsely diminish the estimated risk of lead hazards due to repair and renovation activities, *e.g.*, excluding eight out of 35 housing units because they were in poor condition; excluding housing units with floors in poor condition; use of sample trays in place of window sills because of inability to achieve clearance standards; and the use of plastic sheeting on some tool and observation rooms. In order to use the OPPT data, EPA must quantify the extent to which the factors just mentioned, as well as others, might lead to either an overestimate or an underestimate of risk, and hence an overestimate or underestimate of the regulation's benefits.

- In both the draft IQ-Change Methodology and the Dust Study, there is no indication of the variability of the findings (*e.g.*, standard deviation, range, *etc.*), which should be given in the main body of each document.

- High uncertainties are associated with the use of the biokinetic lead models, especially for episodic exposures. The Integrated Exposure Uptake Biokinetic (IEUBK) model for lead in children is unsuitable in this exposure scenario because it does not allow use of episodic exposure data input and is only concerned with steady-state conditions. As a result, unless it is decided that the exposure-response function can use a time-weighted average exposure rate over some significant period of time that includes pre- and post-cleanup, and that shorter-term temporal patterns of exposure are not important, the IEUBK model will not be suitable. The Leggett model does allow use of episodic exposure data, but predicted blood lead concentrations appear to be biased high when compared to the IEUBK and O'Flaherty models applied to the same steady-state exposure scenarios. Therefore, it is unclear if Leggett model is biased high when applied to an acute or episodic sub-chronic exposure scenario. Moreover, the use of biokinetic models for episodic exposure creates additional uncertainties because of short-term variations in behavioral, dietary, and biokinetic parameters that broaden the distribution of expected blood lead concentrations. Accordingly, the Panel recommends use of the Leggett model with an uncertainty analysis that identifies and quantifies sources of potentially high uncertainty associated with the model estimates. *The CASAC Panel also strongly favors greater use of empirical data for estimating blood lead levels following exposure to lead dust during renovation activities, to aid in the evaluation of the usefulness of the biokinetic component of the Leggett model.*

- There is a lack of consideration for the activity patterns of children as a sensitive subpopulation. The Panel felt that changing the geometric standard deviation (GSD) from 1.2 to 1.6 would, in part, alleviate this problem. However, a GSD of 2.0 or 2.1 is probably most appropriate given all of the uncertainties in the analyses to be performed. A more scientifically defensible approach, and one used routinely in other regulatory analyses, would be to develop separate distributions of activity patterns for children, with their own central tendency and GSD values.

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

Comments on 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 relative to both regulatory issues and study methodology:

Regulatory Concerns

- 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 underlying exposure-response information reported in the forthcoming Lead NAAQS documents that are presently undergoing Agency review, public health will not be adequately protected.

Methodological Concerns

- It is problematic 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).

- 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 by discoloration 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 other problems associated with it as well, including the fact that some forms of lead are white and that the cleanup solution (*Simple Green*®) sometimes discolored 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.*

- The limited data from residential housing units and COFs included in the Dust Study, which are used as input into the biokinetic models, most likely do not represent a statistically-valid sample of housing at the national level. On the one hand, the estimated risks may overstate what might be encountered on average nationally because the examples studied likely represent high-hazard scenarios reflective of the upper tails of the distribution. On the other hand, several modifications in the study design falsely diminish the risk of lead hazards due to repair and renovation activities, *e.g.*, excluding eight out of 35 housing units because they were in poor condition; excluding housing units with floors in poor condition; use of sample trays in place of window sills because of inability to achieve clearance standards; and the use of plastic sheeting on some tool and observation rooms. In order to use the OPPT data, EPA should quantify the extent to which the factors just mentioned, as well as others, might lead to either an overestimate or an underestimate of risk, and hence an overestimate or underestimate of the benefits of the regulation.

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 E.

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

OPPT developed the Draft LRRP Activity IQ-Change Methodology to support the benefits assessment of the economic analysis required for "significant regulatory action[s]" such as the LRRP rule-making. 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." To support this economic analysis, OPPT developed a proposed 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 significant 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, among the CASAC Panel's major concerns is 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 by the three steps of the approach:

- <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, this limitation is a critical issue that EPA should address either by quantifying the extent to which this factor and others may result in either the overestimation or underestimation of risk. In addition, 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. Thus, while the document does a good job of noting its limitations, there are no suggestions of how to improve on or eliminate those limitations.

- <u>Step 2</u>: 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 IEUBK model and the Leggett model for use in predicting the blood levels of children exposed during renovation activities (see, in particular, the response of Panel member Mr. Sean Hays to Charge Question #3 found on pages D-22 & D-23). 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, and so would be inappropriate if used in conjunction with exposure-response data that employ short-term exposure measures. 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.

The Panel recommends that the Leggett model be used as the biokinetic model of choice for modeling of childhood lead exposures occurring during LRRP activities, because: (1) the IEUBK model is inappropriate for acute, short-term lead exposures of children; and (2) time does not allow substitute use of the potentially-better O'Flaherty model. The Leggett model has a positive bias to its output (*i.e.*, blood lead) when compared to blood lead outputs of the IEUBK and O'Flaherty models applied to the same steady-state exposure scenarios, but the size of that bias *in absolute terms* is not precisely known, especially for episodic exposures. Therefore, the uncertainty associated with use of the Leggett model must be described. The use of the Leggett model also has the advantage that it is less likely to underestimate blood lead levels and subsequent health risks.

As also mentioned during the CASAC's February 2007 consultation with OPPT, *the Panel strongly favors greater use of empirical data for estimating blood lead levels following exposure to lead dust, which will aid in evaluating the usefulness of the biokinetic model predictions.* At least one set of published data was suggested for this: Rabinowitz *et al.*, *Amer. J. Public Hlth*, 1985. (In addition, see the individual written comments of Panel member Dr. Paul Mushak found on pages E-35 to E-41). This dataset provides quantitative data relating dust lead loadings in houses with children's blood lead levels and shows that repair and renovation activities result in elevations of these blood lead levels. The article does not, however, relate dust lead loading during renovation/ construction with changes in blood lead levels. Therefore, this dataset will primarily be useful for estimating children's *steady-state* blood lead levels associated with post-renovation dust lead loading clean-up standards and as a "reality check" for the Leggett model predictions of the respective blood lead levels. Unfortunately, no quantitative data are available that relate changes in dust or air lead loadings from repair and renovation activities with acute changes in children's blood lead levels. Therefore, the Leggett model will need to be relied upon for predicting transient changes in children's blood lead levels as a function of dust levels during renovations.

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 a 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. Such an empirical model could be used in conjunction with the Leggett model. (For additional detail, see the individual written comments of Panel member Dr. Bruce Lanphear found on pages E-20 & E-21).

- 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 exposure-response characteristics underlying current standards for lead toxicity, but these characteristics are out-of-date due to recent epidemiological data. These data extend the dose-response relationship between blood Pb and IQ loss to even lower Pb lead levels than those underlying the current standards, and, importantly, demonstrate 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 most recent 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 responses of Panel members Dr. Robert Goyer and Mr. Sean Hays to Charge Question #4 found on pages D-20 & D-21 and D-23 & D-24, respectively). 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 amino-levulinate 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. While this approach is used commonly in risk assessments, we can see no scientific basis for the use of such assumptions in the current case (or at least no basis is provided in the document), and so the Monte Carlo simulations are suspect.

- Another assumption — that children occupy the entire house or yard equally during a renovation project — is simply not realistic. *Activity patterns for children as a sensitive subpopulation should have been included in the analyses.* Changing the GSD in the biokinetic model from 1.2 to 1.6 should, in part, alleviate this problem. However, a GSD of 2.0 or 2.1 is probably most appropriate given all of the uncertainties in the analyses to be performed. In addition, a sensitivity analysis can be performed using a GSD in the range of 1.6 to 2.1 (see the response of Panel member Dr. Fred Miller to Charge Question #2 found on pages D-27 & D-28). In any event, the best approach would be to develop a child-specific distribution with central tendency and GSD determined from child-specific data. 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 quantified 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 Panelists' individual written comments (Appendix E).

The CASAC Panel was pleased to be of service to EPA in its review of these two documents related to the avoidance of lead exposures 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

Appendices (A–E)

cc: Marcus Peacock, Deputy Administrator

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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Mr. Richard L. Poirot, Environmental Analyst, Air Pollution Control Division, Department of Environmental Conservation, Vermont Agency of Natural Resources, Waterbury, VT

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

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

MEMBERS

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Dr. Ellis Cowling*, University Distinguished Professor-at-Large, North Carolina State University, Colleges of Natural Resources and Agriculture and Life Sciences, North Carolina State University, Raleigh, NC

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Dr. Richard Fenske†, Professor, Department of Environmental and Occupational Health Sciences, School of Public Health and Community Medicine, University of Washington, Seattle, WA

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

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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

Dr. Frederick J. Miller**, Consultant, Cary, NC

Dr. Maria Morandi†, Assistant Professor of Environmental Science & Occupational Health, Department of Environmental Sciences, School of Public Health, University of Texas – Houston Health Science Center, Houston, TX

Dr. Paul Mushak**, Principal, PB Associates, and Visiting Professor, Albert Einstein College of Medicine (New York, NY), Durham, NC

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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 – Panel Members' Responses to Agency Charge Questions

This appendix contains the preliminary and/or final individual responses to EPA charge questions on the Agency's Draft Lead Renovation, Repair, and Painting (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. These written responses do not represent the views of the CASAC, the EPA Science Advisory Board, or the EPA itself. The names of the panelists who provided written responses to Agency charge questions comments are listed on the next page, and their individual responses follow.

Dr. James Crapo

James D. Crapo, M.D.

Comments: An Approach for Estimating Children's Health Risk (IQ) Changes Associated with Dust Lead Generated by RRP Activities

Charge Question #1: Overall approach and utility

The approach used by the EPA for estimating IQ change from LRRP activity is appropriate, and the work done to date is important in identifying how these models could and should be used as well as the inputs that are necessary to support these models. Unfortunately, the draft approach for estimating changes in children's IQ from LRRP activities has sufficient problems with lack of adequate data for model input and a lack of model validation that it cannot be reliably used at the present time to estimate health or economic cost-benefits and should not be used to determine national regulatory standards.

There is insufficient data for input into the biokinetic blood lead level models, and work validating the models is completely absent. This approach cannot be reliably carried out and completed at the current time. The OPPT Dust Study provides important data to address questions regarding the extent of lead dust generated from LRRP activities and provides some of the important activity-required inputs for the IEUBK and LEGGETT models for estimating blood lead levels. Unfortunately, substantial additional work is necessary to provide the necessary inputs to these models and to validate the model results. This work needs to be completed before either of these models are used for cost-benefit analyses and the results considered in the development of national regulatory standards.

A substantial amount of data is currently available to guide regulatory decision making and which can provide an adequate base for regulatory decision making. What is known is that:

- Lead exposure results in elevated blood lead levels with children being at primary risk because of their activity patterns.
- Elevated blood levels effect neurocognitive development including IQ.
- The effects of blood lead levels on neurocognitive development are particularly strong below levels of 10 µg/dL.
- All lead exposures contribute to the blood lead level.
- Room floor dust is a substantial factor in determining blood lead levels in children with the key factor being lead loading or µg Pb/ft^2.
- Renovation, repair and painting activities in older homes can lead to substantial increases in house (floor and window sill) lead levels post renovation and can mobilize lead into various media including air, flood, house dust and soil.
- Standard cleaning of older residences post RRP activities can result in high residual lead levels in the home (elevated 5- to 6-fold according to the OPPT Dust Study).

- Enhanced protection and cleaning as studied in the OPPT Dust Study can substantially reduce the risk for lead exposures in homes post activities. (Floor lead levels are decreased up to 80% following cleaning under the proposed rule change compared to standard cleaning.)

The above data and the supporting documents in the OPPT Dust Study provide adequate support for rule making to reduce lead exposure post renovation, repair and painting activities in older homes. I would recommend that the EPA support additional research activities to enhance and validate biokinetic models of blood lead levels that can be used for future analysis of the effectiveness of interventions to reduce lead exposures to children. Critical studies that would enable the application and validation of these models include:

1. Measurement of blood lead levels before and after RRP activities. This should be done in children and adults living in the home and should include assessment of the impact of lead exposure on workers carrying out RRP activities in older homes. Both short- and long-term follow-up should be included.

2. Measurement of home (floor and window sill) lead levels before and after RRP activities in older homes with follow-up for multiple years to determine the duration of potential lead exposures following RRP activities. These measures should be done with and without the proposed rule change in lead prevention and cleaning standards.

3. The impact of the proposed rule change on lead prevention and cleaning in homes undergoing RRP activities should be assessed on homes of differing age ranging from pre-1920 construction to post-1970 construction.

The IEUBK and LEGGETT models should be validated based on their ability to accurately predict measured blood lead levels in relationship to the RRP activities described above. Only after validation should these models be generalized for cost-benefit analyses.

Dr. Douglas Crawford-Brown

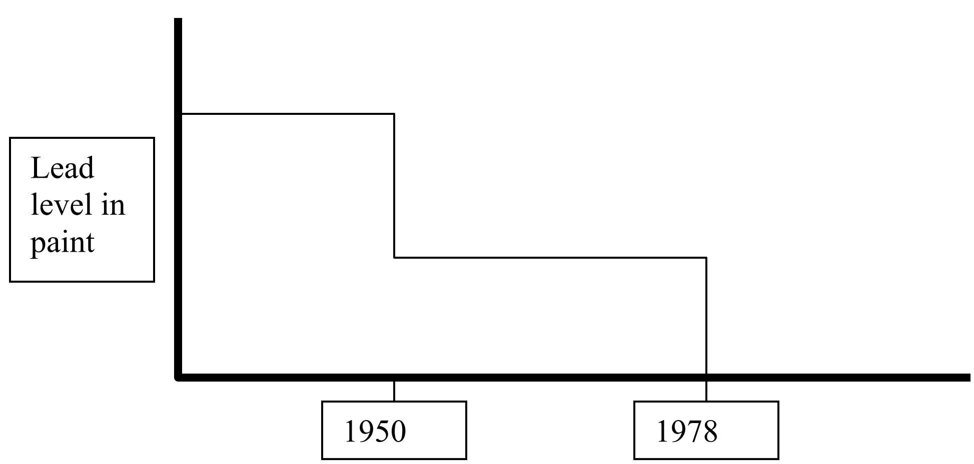
Doug Crawford-Brown (6-23-07)

Addressing Question 6: Concerning the potential correction for the fact that homes sampled were all 1920s vintage.

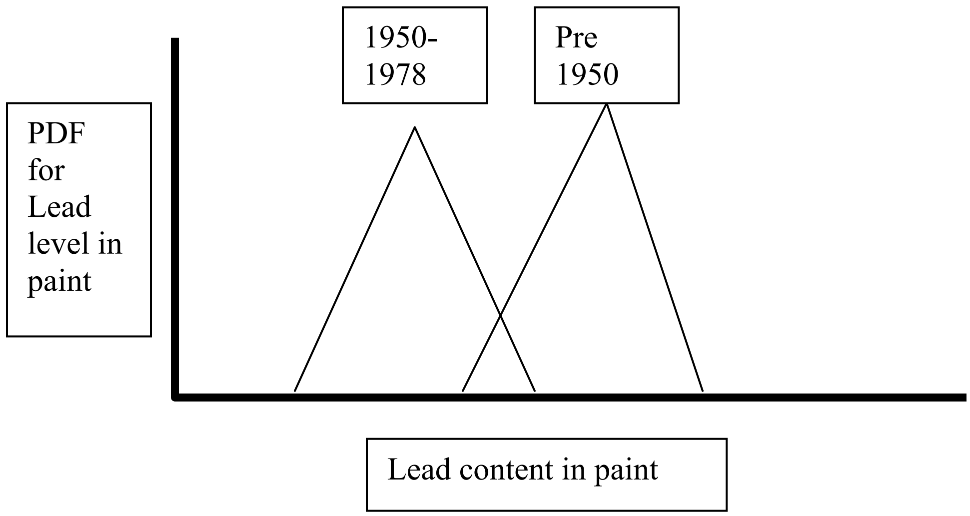
The issue arises here because (1) the lead content of paint has changed historically, with reductions in 1950 and then again in 1978, (2) all homes in the OPPT study were of 1920 vintage and, hence, were first painted when the controls on lead in house paint were not in place and (3) the EPA wishes to extend the results of the Dust Study to a national sample of homes, which would include homes built between the 1920s and today.

The proposed solution in the IQ Change document is to use the results of the OPPT study (on 1920s vintage homes) for all homes in the national sample. The justification given is first that data necessary to make a correction for newer homes are not available. The second justification is that the distribution of lead in the paint chip samples from the OPPT study homes was wide (although it was only a GSD of 1.5 to 2, which is not a particularly large dispersion). I suppose the argument is that this wide distribution would in some way "cover" the post-1920s homes, including post-1950 homes.

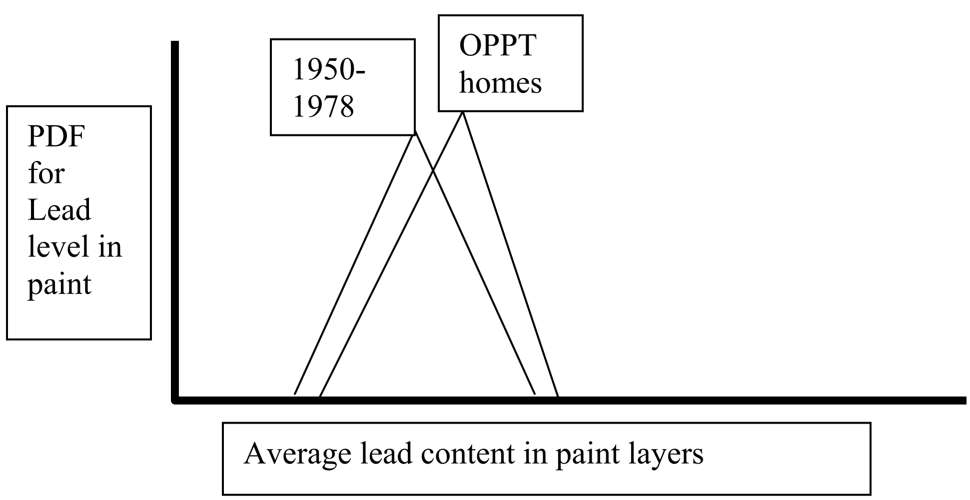
Let me begin by saying that I don't know the actual distribution of lead content in paint sold prior to 1950, between 1950 and 1978, or after 1978. I assume after 1978 the lead content is negligible, and in any event these homes don't seem to be the focus of the proposed rule anyway. But it is safe to say that paint produced between 1950 and 1978 would contain a lower lead content than paint produced before 1950, and certainly the paint first used in the OPPT homes. So, we should have a curve (Figure 1 below) that looks something like this (and I am not drawing this to scale, since I don't know the values):



So, if this curve is correct in some sense, we might imagine that homes painted entirely with pre-1950s paint and homes painted entirely with 1950-1978 paint might have some sort of distributions of lead levels in paint as follows (Figure 2 below):



But homes in the OPPT sample would have multiple layers of paint that accumulated over the years, including paint from all three periods of time (pre-1950; 1950-1978; post 1978). So in a sense, the paint scraped from the OPPT homes would have an average lead content represented by the average of the layers of paint that had accumulated. The only effect this would have would be to "push" the Pre-1950 curve to the left. So the argument of the EPA (the second justification I mentioned) is that this existence of multiple layers of paint would produce something like this (Figure 3 below):



This does seem qualitatively to make some sense. Whether it does quantitatively depends on three factors:

1. How far apart the two distributions in Figure 2 lie (their degree of overlap).
2. How many paint layers have been applied to the OPPT homes
3. The timing of those paint layers

We should be able to state with confidence that use of the OPPT study for all homes will tend to overestimate risk from the activities, which I suppose could count as a kind of conservatism (even if I am not a believer that conservatism necessarily leads to optimal protection of public health). But it also will then overstate (for the same reasons) the benefits of the rule practices in post-1950 homes (i.e. overstate the benefit-cost ratio).

We can be a bit more mathematical about this (which doesn't necessarily mean more quantitative unless we can get the needed parameter values), in the following way. Let's assume there is some time, L years, between paint layers, and that L does not depend on when the home was built. Let's further divide the time at which a home was built, TB, into three periods:

TB1 is pre 1950
TB2 is 1950 to 1978
TB3 is post 1978

TB1, TB2 and TB3 are the date, in years (e.g. 1925)

During these three periods, based on Figure 1 above, the lead content is:

C1 in TB1
C2 in TB2
C3 in TB3

Finally, let TR be the time of the renovation (e.g. 2007).

Now, any given home will have some number of layers of paint on the walls. We will assume each layer of paint uses the same amount of paint. The fraction of the layers at C1, C2 and C3 will be proportional to the fraction of the total time period between TB and TR represented by each time period. Since L is assumed constant through the three periods, it will drop out of the math here.

Let's let Caverage be the average lead content in the wall paint, averaged across the layers. There are now three cases:

1. If TB falls in TB3, then

Caverage = C3

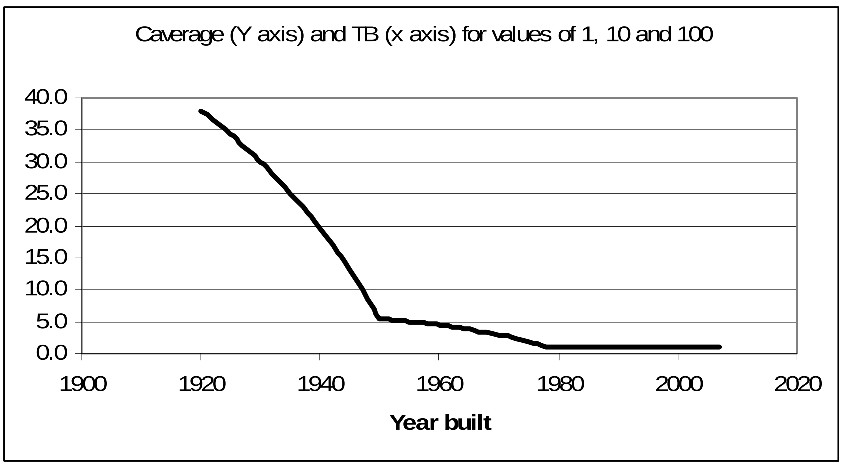
2. If TB falls in TB2, then

Caverage = [C3 x (TR-1978) + C2 x (1978-TB)] / (TR-TB)

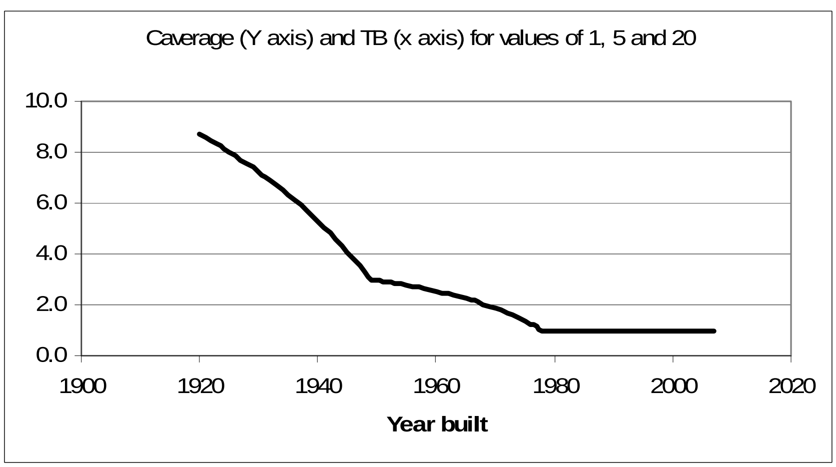
2. If TB falls in TB1 (as in the OPPT study) then

Caverage = [C3 x (TR-1978) + C2 x (1978-1950) + C1 x (1950-TB)] / (TR-TB)

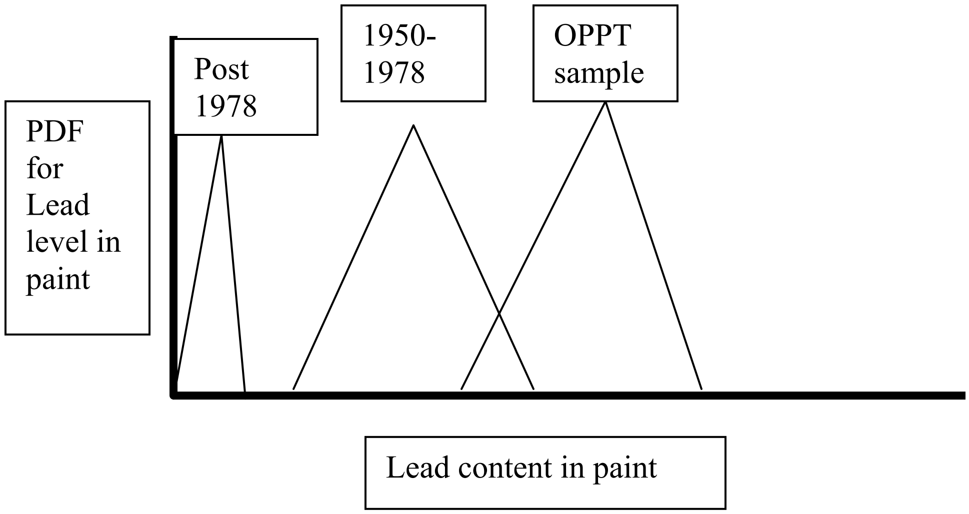
I made a simple EXCEL sheet to calculate these three values. I will assume that C3 is negligible, so it is 1 (that can be corrected in the attached EXCEL sheet). The figure below shows how Caverage changes with time if C2 is 10 and C1 is 100.



The next figure below shows how Caverage changes with time if C2 is 5 and C1 is 20.



From these two figures, it seems clear to me that there can be a rather large overestimate of paint lead levels using only the OPPT values for all ages of homes. From this analysis, I would guess that the PDFs for the different periods of homes are closer to those of Figure 1 than Figure 3:



I recommend that the EPA find reasonable values of C1, C2 and C3; place these into the attached spreadsheet (or equivalent); and apply the resulting correction factors. Absent this, some mention must be made of the likely magnitude of the over-estimate of the risk reduction benefits for 1950-1978 homes and post 1978 homes.

We can discuss these issues further at the July meeting.

Spreadsheet for calculating the average lead content of paint layers in homes of different vintage.

TR =	2007	TB is the build year
C1 =	20	
C2 =	5	The units on C are arbitrary here, since we are interested in relative values
C3 =	1	

For homes where TB > 1978, Caverage = 1.00

For homes where 1950 < TB < 1978, Caverage =

TB	Caverage
1978	1.00
1977	1.13
1976	1.26
1975	1.38
1974	1.48
1973	1.59
1972	1.69
1971	1.78
1970	1.86
1969	1.95
1968	2.03
1967	2.10
1966	2.17
1965	2.24
1964	2.30
1963	2.36
1962	2.42
1961	2.48
1960	2.53
1959	2.58
1958	2.63
1957	2.68
1956	2.73
1955	2.77
1954	2.81
1953	2.85
1952	2.89
1951	2.93
1950	2.96

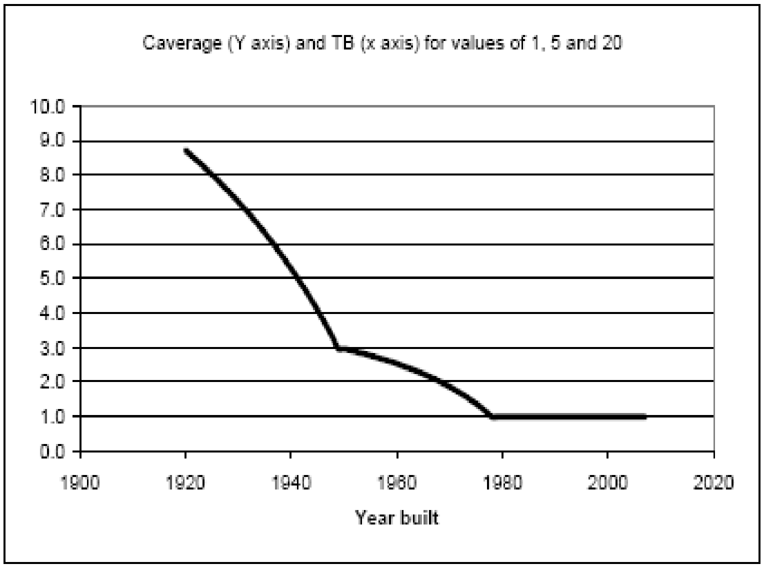
Composite:

TB	Caverage
2007	1.0
2006	1.0
2005	1.0
2004	1.0
2003	1.0
2002	1.0
2001	1.0
2000	1.0

For homes where TB < 1950, Caverage =

TB	Caverage
1950	2.96
1949	3.26
1948	3.54
1947	3.82
1946	4.08
1945	4.34
1944	4.59
1943	4.83
1942	5.06
1941	5.29
1940	5.51
1939	5.72
1938	5.93
1937	6.13
1936	6.32
1935	6.51
1934	6.70
1933	6.88
1932	7.05
1931	7.22
1930	7.39
1929	7.55
1928	7.71
1927	7.86
1926	8.01
1925	8.16
1924	8.30
1923	8.44
1922	8.58
1921	8.71
1920	8.84

1999	1.0
1998	1.0
1997	1.0
1996	1.0
1995	1.0
1994	1.0
1993	1.0
1992	1.0
1991	1.0
1990	1.0
1989	1.0
1988	1.0
1987	1.0
1986	1.0
1985	1.0
1984	1.0
1983	1.0
1982	1.0
1981	1.0
1980	1.0
1979	1.0
1978	1.0
1977	1.1
1976	1.3
1975	1.4
1974	1.5
1973	1.6
1972	1.7
1971	1.8
1970	1.9
1969	1.9
1968	2.0
1967	2.1
1966	2.2
1965	2.2
1964	2.3
1963	2.4
1962	2.4



1961	2.5
1960	2.5
1959	2.6
1958	2.6
1957	2.7
1956	2.7
1955	2.8
1954	2.8
1953	2.9
1952	2.9
1951	2.9
1950	3.0
1949	3.0
1948	3.3
1947	3.5
1946	3.8
1945	4.1
1944	4.3
1943	4.6
1942	4.8
1941	5.1
1940	5.3
1939	5.5
1938	5.7
1937	5.9
1936	6.1
1935	6.3
1934	6.5
1933	6.7
1932	6.9
1931	7.1
1930	7.2
1929	7.4
1928	7.6
1927	7.7
1926	7.9
1925	8.0
1924	8.2
1923	8.3
1922	8.4
1921	8.6
1920	8.7

Dr. Richard Fenske

"Draft Final Report on Characterization of Dust Lead Levels after Renovation, Repair and Painting Activities"

Response to Charge Questions
July 9, 2007

Richard Fenske
University of Washington

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

The report provides six objectives, as well as a seventh objective ("Objective X"). The objectives are presented in an unusual format, as they are posed as interrogatives rather than as specific aims. It would be helpful if the objectives were stated as declaratives rather than interrogatives. Several of the objectives contain multiple questions (Objectives 2, 3 and 4). Each question should be restated as a specific aim.

Objective "X" is a bit mysterious. The report states that there are six study objectives, but it seems that an additional objective has been added. Please make objective X a numbered specific aim, or omit.

The **first** objective is focused on the effect of low-, medium-, and high-level RRP on post-work and post-verification dust-lead levels. This objective is not addressed directly in Section 9 of the report. The conclusions presented in Section 9.1 appear to address the mysterious objective X. Please revise the report so that the conclusions address the objectives clearly and sequentially.

The **second** objective is focused on the ability of heavy-duty polyethelyne sheeting to reduce lead levels. This objective is addressed directly in section 9.2. In that section it is stated that "Figure 6-3 indicates that use of plastic did not consistently result in lower geometric mean work room floor lead levels across job types at the post-cleaning phase." While this statement is generally true, no statistical results are included in Figure 6-3, so it is hard to understand the extent to which plastic sheeting did or did not reduce lead levels. The geometric means are presented, but the geometric standard deviations are omitted. It might be more helpful to plot the results as distributions, using percentiles; e.g., lead levels would be the x-axis and number of samples would be the y-axis.

The **third** objective focuses on a comparison between the proposed rule cleaning method (HEPA vacuum and wet mopping with cleaning solution) and the baseline cleaning methods. Section 9.3 of the report addresses this issue directly. The report states that the "differences in cleaning method is [sic] focused on the Work room, as little impact of cleaning method was observed in either of the two non-work rooms." The reader is referred to a table in Appendix C (Table C2.7a). However, this table does not provide a statistical test of geometric mean differences. The reader is then referred to Figure 6-4 and 6-9, but no statistical analysis is provided for either of these figures. Jumping from the main report to appendices and back again is quite difficult for the reader. It is recommended that that final report present all of the key findings within the main body of the report.

The **fourth** objective focuses on lead dust migration from the Work room to adjacent rooms. This objective raises three separate issues related to dust migration: the effect of different levels of RRP work, the use and non-use of plastic, and the use and non-use of proposed cleaning methods. This objective is not addressed directly in Section 9.

The **fifth** objective focuses on the use of plastic ground coverings to reduce the amount of lead falling on the ground during exterior work. Section 9 does not provide a succinct response to this issue.

The **sixth** objective focuses on the lead levels remaining after the two steps of the cleaning verification process; i.e., the wet cloth step and the dry cloth step. This objective is not addressed directly in Section 9.

Question #2. *Are 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.*

Yes, but the data could be presented in a more reader-friendly format. For example, Tables 9-1 and 9-2 provide no results of statistical analyses. It should not be necessary for the reader to consult the appendices to review key information.

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

No. The graphs present mean values, but do not include variability; e.g. standard deviations, geometric standard deviations, or 95% confidence intervals. It is recommended that the key tables be presented within the report, rather than in the appendices.

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

In general, yes. But there is a disconnect between the objectives and the conclusions. It is recommended that the objectives and conclusions be linked in a direct manner, and that key information currently relegated to the appendices be included in the main body of the report. This recommendation holds true for all sections of 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 data collection and the descriptive analyses of the data been objectively and transparently described in Chapters 3, 4, and 6?*

Figure 6-1 is a scatter plot of disturbed area and average post-work workroom floor lead loading. It seems that this figure should be revised such that disturbed area is the predictor variable (x-axis) and lead loading is the outcome variable (y-axis). The explanation for the change in pre-work goals for lead levels (Section 6.3) is not satisfactory. The 4-fold increase in pre-work lead dust level goals needs further justification.

Again we have the situation in which the reader is asked to consult an appendix (appendix G) in order to verify assertions that are presented in the main body of the report. Key findings should be presented in the main report.

Figure 6-2 does a poor job of illustrating differences across jobs. The use of a log-scale for the y-axis is not discussed. The use of this scale makes it hard to see differences. It would probably be more effective to present these data in a table. Statistical differences for the different jobs are not provided.

There is a lack of statistical analysis in Section 6. In most cases the reader is referred to the appendices. The key findings should be documented in the main body of the report.

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?*

It would be more effective to consign the modeling analyses to an appendix, and to bring more of the empirical findings and statistical analyses into the body of the main report.

Dr. Bruce Fowler

Bruce Fowler

Pre-meeting Comments on Charge Question #3

The primary focus of Charge Question #3 is whether to use both the IEUBK and Leggett models for predicting blood leads in children living in or around housing stock that is undergoing lead renovation, repair and / or painting. It seems to me that this would be the pragmatic thing to do because if EPA chose to use one model and not the other there would likely be many questions and criticisms. I also think it best to use both models so that future decisions regarding relationships between lead in dust and soil and predicted blood lead values will have the benefit of a complete perspective.

In addition, I would like to again point out that blood lead values represent an established surrogate for a target dose of lead to sensitive organ systems such as the brain, kidneys and the hematopoietic organ system. It is also known that there are subgroups within the general population (on the basis of ALAD polymorphisms for example) who may react in a more sensitive manner to a given blood lead value than others. It is my hope that as the agency evolves its LRRP Rule that it will take into account these sensitive subpopulations and consider the issue of predicted blood lead values by whatever models in this context. It is my view that such an approach will help the EPA in the long –term to provide more precise risk assessment values in this important area by taking advantage of the most modern available science.

Dr. Philip Goodrum

CASAC Consultation on "Draft Final Report on Characterization of Dust Lead Levels after Renovation, Repair and Painting Activities"

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General Comments

Overall the report is well written and provides enough detail to support the study conclusions. My comments focus on areas in which additional information could be added to improve the readability. Also, some shortcuts were taken in the statistical analysis; a more rigorous data exploration and analysis would strengthen the overall presentation, but I suspect the overall conclusions would not change.

This study focuses on the relationship between lead content on interior surfaces prior to RRP activity, and lead content on floor and sill surfaces within 1 hour of the activity as well as after cleaning. The study does not address the difference between lead loading and dust loading. In terms of compliance with standards, the choice to measure dust lead loading makes sense. Likewise, exposure models will generally require information on contact rates (square feet per time) and lead content per square feet. However, to better understand and explain differences in dust lead loadings associated with different experimental conditions, as well as to generalize the results to other jobs, it would be informative to present information on dust loading. A moderate correlation was observed between lead concentrations in paint and post-cleaning lead loadings on floor and sill surfaces. To what extent is the variability in lead loadings due to variability in dust loading? This component of the variability cannot be quantified without including dust loading in the statistical models. Presumably, containment and cleaning practices that are most effective at reducing dust will, in turn, be most effective at reducing dust lead loading.

Recommend including a definition for dust lead loading in the glossary.

The analysis focuses on data collected at discrete points throughout numerous RRP experiments. A figure should be presented early in the introduction of the study design to more clearly delineate a generic timeline of sampling activities relative to stages of the experiment. Points on the timeline would include stages of the experiment: cleaning, RRP activity, cleaning, and verification. Sampling events would include: pre-experiment test, air sampling during RRP activity, air sampling after RRP activity, dust sampling after RRP activity, dust sampling after cleaning, dust sampling for verification.

RESPONSES TO CHARGE QUESTIONS

Issue 1: Study Objectives

Q. 1. Are each of the study objectives presented objectively and transparently?

Yes. Although I would recommend adding a paragraph to explain that the study is not designed to investigate the relationship between experimental conditions and dust loading (see general comment above).

Issue 2: Study Conclusions

Q. 2. Are each of the study conclusions supported by data?

Yes, although the Chapter 2 summary is reduced to one paragraph each for interior and exterior jobs. It may be helpful to expand the summary to include bullets of the main points from Chapters 6 and 9. Specifically address factors that have a primary influence on dust lead loading – is it the conditions of units prior to RRP activity (e.g., paint lead concentration, surface area remediated), the level of dust generated by a job, or the containment and cleaning practices?

Issue 3. Range of Data

Q. 3. Do the tables, graphs...in the report objectively and transparently convey the range of data...?

No. Most comparisons of subsets of data focus on differences in the geometric mean (GM). For example, almost all figures in Chapter 6 present side-by-side bar charts of GMs. But there are no tables in main text or supporting appendices that convey the corresponding variability. For example, Figure 6-3 compares post-cleaning work room floor lead levels by job with and without plastic use. None of the box-and-whisker plots in Appendix C illustrate the variability for the same subsets of data. Same observation for Figure 6-4 (post-cleaning work room floor lead levels by job and cleaning method (proposed rule vs. baseline). Information should be presented in summary tables in Chapter 6 (or an appendix) to include both the GM and measures of variability (e.g., standard deviation, interquartile range, min/max).

Issue 4. Report Organization and Clarity

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

Yes. There is a lot of information to present, and good choices were made to move many of the supporting graphs and tables to the appendices. Summary bullets are helpful. Table of contents should be proof read – Section 9 TOC does not match titles of sections/sub-sections in text.

Issue 5. Data Collection and Descriptive Analysis

Q. 5. Are the descriptive analyses in Chapter 6...appropriate? Have the data collection and the descriptive analyses...been adequately described...in Chapters 3, 4, and 6?

Yes, although implications of some simplifying assumptions need to be investigated.

1. Goodness-of-Fit (GOF) testing. Section 5.2 indicates that data were evaluated for both normal & lognormal distribution using the Shapiro-Wilks test. Appendix B (p. B-1) indicates the statistical significance of GOF is attributed to p-value < 0.001. Text should introduce how the GOF testing was used (to support log-transformation; to evaluate underlying assumptions of subsequent statistical analysis, etc). Should note that p-value of 0.001 is much lower than standard $p < 0.05$, effectively relaxing the test (will less often reject the null hypothesis that data are normal/lognormally distributed).

2. Units. All tables and graphics in appendices should include units; graphics should include x-y axis titles. Particularly confusing was Table C1.1 which appears to provide information on loadings ($\mu g/ft^2$) when in fact it is sample sizes.

Issue 6. Statistical Modeling Results

Please provide any specific comments on the modeling analyses.

The R^2 of regressions can be strongly influenced by including non-detects. Recommend excluding NDs, or conducting a separate analysis on detects only, especially for regressions that involve comparisons to clearance levels (e.g., Figures C3.2a – C.3.2c; Figure F3.2a; Figures G1.12 and G3.12)

Dr. Robert Goyer

July 3, 2007

From: Robert A. Goyer, M.D.

Response to Charge Question 4. *Estimate of IQ change*, draft document "An Approach for Estimating changes in Children's IQ from Lead Dust During Renovation, Repair, and Painting (LRRP) Rule ----.

Chapter 4 provides an overview of the uncertainties and limitations associated with the log-linear IQ model. The discussion is logical and transparent.

<u>Choice of Blood Pb metric</u>
With regard to the choice of blood-Pb metric, reports in the literature do suggest that blood –Pb concurrent to IQ testing may be a better indicator of future IQ than lifetime average but I do agree with the decision for the purpose of the LRRP rule that lifetime, thru 6years, takes into account the renovation exposure activity of children of all ages avoiding problem of high concurrent levels of children with renovation activity ages 5 or 6 years old.

<u>Input data and Assumptions</u>
The limitations of small sample size variation in cleaning efficiencies will contribute to data uncertainty as discussed. However, the most difficult uncertainty to account for will be the amount of time children spend in different locations in buildings and time out of doors and variation in activities. Both of these uncertainties are likely to be significant and vary considerably from child to child. Maybe the variations will cancel out reducing the uncertainty.

<u>Choice of biokinetic models</u>

As discussed there are a number of uncertainties common to both the IEUBK and the Leggett models but the fact that the IEUBK model is more consistent than the Leggett model, I tend to favor selection of the IEUBK model. But I really do not know which to choose. A problem for me is that the results of the two models sometimes differ greatly.

<u>Choice of Strategies to Overcome Limitations of the Log-linear Model:</u>
The two strategies proposed to overcome limitations of the log-linear model are the application of a 1 µg/dl cutpoint or the use of a piecewise linear model. It was helpful to include the examples comparing results of the two models. The 1 µg/dl cutoff model not allowing estimates of IQ loss with blood Pb levels below 1 µg/dl seems most appropriate because there were few B-Pb measures below the 1 µg cutpoint and the log-linear model goes to infinity at zero blood Pb which is not realistic.

Which model is most realistic?

The 1 µg/dl cutoff model seems most realistic.
The demonstration exhibits show that the piecewise model results generally in smaller IQ loss per µg/dl exposure than the log cutoff model. Exhibit 6-10 shows that the piece-wise model results in lower IQ deficits in newer vintage homes which seems realistic to me.

Should both models be used for all homes to be built for economic analysis?

No, that doesn't seem practical. Any later decisions based on the economic analysis would have the problem of deciding which result to use.

Mr. Sean Hays

Comments on "An Approach for Estimating Changes in Children's IQ from Lead Dust Generated during Renovation, Repair, and Painting in Residences and Child-Occupied Facilities"

Prepared by:

Sean Hays
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165 Valley Rd.
Lyons, CO 80540

July 10, 2007

Charge Question # 3: Blood Lead Modeling

1) The IEUBK model is not scientifically valid for the application intended for this LRRP rule.
    a. IEUBK is only valid for steady-state exposures (see White et al., 1998). "The [IEUBK] model was designed for applications where there are long periods of relatively steady exposure, not to acute or relatively rapid subchronic exposures" quoted from: *The Conceptual Structure of the Integrated Exposure Uptake Biokinetic Model for Lead in Children* (1998) Paul D. White, Patricia Van Leeuwen, Barbara D. Davis, Mark Maddaloni, Karen A. Hogan, Allan H. Marcus, and Robert W. Elias, p. 1513 (http://www.ehponline.org/docs/1998/Suppl-6/1513-1530white/abstract.html).
2) The Leggett model is the only model of the two that is valid for predicting changes in blood lead levels associated with short-term/acute exposures.
    a. Leggett model was not validated against environmental exposure scenarios for validation of predicting absolute blood lead levels (hence the high estimates for background)
    b. However, the model should be valid for incremental increases in blood lead levels associated with incremental increases in environmental exposures.
    c. I applaud EPA for conducting an analysis of incremental increase in blood lead levels for the various scenarios. This incremental increase analysis is more valid and reliable.
3) The O'Flaherty PBPK model should be used along with the Leggett model
    a. This will help to make modeling uncertainty more transparent
4) Dose Metrics: Concurrent versus lifetime average (0-6 years of age)
    a. Must be paired with appropriate IQ decrement model
    b. Currently, it appears EPA has used lifetime (0-6 years) average blood lead modeling and paired it with Lanphear IQ analysis which relied on concurrent

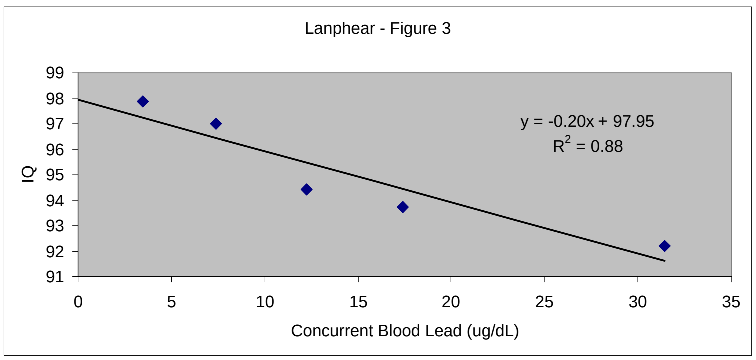
blood lead levels. EPA should clarify this? The dose metrics from the lead modeling and the IQ versus blood lead concentration (PbB) relationship provided by Lanphear et al. (2005) must match to be scientifically valid.

c. It would provide additional context for risk management purposes if EPA would provide a plot similar to Exhibit 5-11 but showing the PbB profiles expected for each of the example control measures.

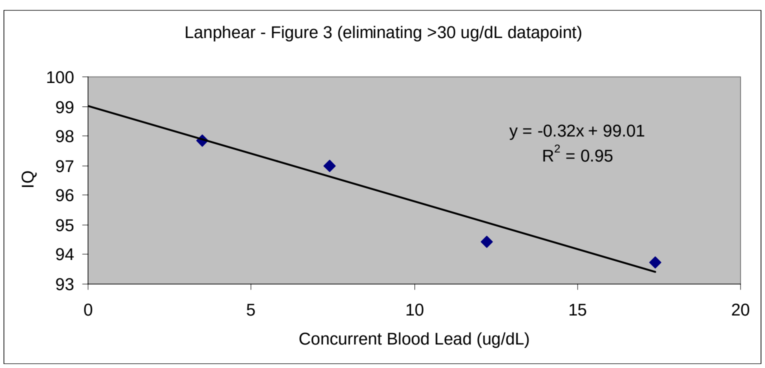
d. The EPA should consider using incremental increase peak PbB as the dose metric of concern for the risk assessment rather than lifetime average (0-6 years of age).

Charge Question # 4: Estimates of IQ Change

1) Reliance on the recommended dose metric, incremental increase in peak PbB, requires the use of a single linear slope describing the relationship between IQ decrement and PbB. A re-analysis of Lanphear et al. (2005) data should allow the use of a single linear relationship.
2) The following examples show the type of analysis which could provide this relationship.



Constant slope allows for a constant IQ decrement per incremental increase in blood lead levels. If blood lead levels < 30 µg/dl is the region of relevance,
IQ decrement = Loss of 0.2 IQ points per 1 µg/dl increase in blood lead levels



Constant slope allows for a constant IQ decrement per incremental increase in blood lead levels. If blood lead levels < 20 µg/dl is the region of relevance,
IQ decrement = Loss of 0.3 IQ points per 1 µg/dl increase in blood lead levels

3) Some additional benefits of relying on incremental increase in blood lead and IQ decrement
   a. Less uncertain for blood lead modeling results
   b. Alleviates issues/uncertainties about knowing what region of the blood lead vs. IQ curve one is at.
   c. Alleviates the issues with "cutpoints" for blood lead levels and IQ
   d. Likely to substantially simplify cost-benefit analysis

4) It needs to be considered whether the Lanphear analysis, which relies on observing IQ and blood lead levels among children mostly at steady-state, is valid for use in predicting IQ loss following acute/transient increases in blood lead levels. While it may not be scientifically valid to make this extrapolation, it may be the only available approach. This should be recognized in the text.
5) There is some consideration of using empirical relationships between dust loading and blood lead levels in children. However, these types of relationships should only be considered applicable for the LRRP Rule is the empirical relationships have been developed in homes undergoing renovations/remodels and paired children's blood lead levels. These empirical relationships are NOT applicable if they were derived for homes not undergoing renovations (i.e., both the home's dust lead loadings and children's blood lead levels were at steady-state).

Charge Question # 8: Adaptation of approach for other contributions

1) I recommend EPA consult with the building/construction/remodeling trade associations for advice on this issue. They are in a better position to advise on issue related to the types of construction activities that are most likely to result in dust generation.

Dr. Bruce Lanphear

Comments on "Draft Final Report on Characterization of Dust Lead Levels after Renovation, Repair and Painting Activities"

Bruce Lanphear

RESPONSES TO CHARGE QUESTIONS

Issue 1: Study Objectives

Q. 1. Are each of the study objectives presented objectively and transparently?

With two important exceptions, the objectives were presented objectively and transparently. The first exception was the validation step, which was presumably a stealth approach to using the white glove technique that was soundly criticized at the February CASAC meeting. This technique or "verification" is a non-scientific and foolhardy attempt to minimize the costs of the LRRP. This criticism is consistent with the understated conclusions in the Report (see p. 9-6, part 9.4), which states:

"The cleaning verification process as stated in the proposed rule resulted in decreases in lead levels, but under the conditions of the study *was not always accurate* in identifying the presence of levels above EPA standards for floors and sills. Factors such as floor condition, contractor performance, job type, and dust particle characteristics impacted the cleaning verification process in the study."

The second exception is the decision by US EPA staff to ignore scientific evidence indicating that it is necessary to achieve settled dust lead loading values considerably less than 40 $\mu g/ft^2$ to protect children from lead hazards. If the EPA staff chooses to ignore or deny this evidence, they should **boldly declare** this in the introduction of the document and take full responsibility for denying its existence.

Issue 2: Study Conclusions

Q. 2. Are each of the study conclusions supported by data?

Yes, except for the conclusions about the verification method and the reliance on dust lead standards described above. Still, the report fails to make several important and directly relevant conclusions. For example, the study confirms that regulations are needed to protect children from lead hazards. This conclusion should be prominently described. This conclusion is justified because the lead hazards generated by repair and renovation using baseline practices consistently produced dust lead levels in excess of levels shown to be associated with children having blood lead levels > 10 µg/dL; produced significantly higher dust lead loading values than the rule practices in the Work Room; led to marginally significantly lower dust lead levels in the

Observation and Tool Rooms; and they often exceeded US EPA residential dust lead standards. The proposed rule's procedures consistently – if not always statistically significant - led to significantly lower post-renovation dust lead loading values.

Issue 3. Range of Data

Q. 3. Do the tables, graphs...in the report objectively and transparently convey the range of data...?

No. The tables and graphs are overwhelming and overly complex. The titles and footnotes do not fully or accurately describe what is being presented. It would have been easier to understand if the report focused on the primary analyses and results, preserving the extensive output for the appendices. Instead, the reader must wade through the document numerous times to read and then re-read to verify the information presented.

Issue 4. Report Organization and Clarity

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

No. The report is overly complex. It would have been easier to understand if the report focused on the primary analyses and results, preserving the extensive output for the appendices.

Issue 5. Data Collection and Descriptive Analysis

Q. 5. Are the descriptive analyses in Chapter 6...appropriate? Have the data collection and the descriptive analyses...been adequately described...in Chapters 3, 4, and 6?

Yes.

Issue 6. Statistical Modeling Results

Please provide any specific comments on the modeling analyses...

3. The results of the statistical modeling should be presented more simply. The results should also explore the proportion of various dust lead loading values achieved by use of plastic, proposed rule cleaning, and baseline cleaning (e.g., < 10 μg/ft^2, < 20 μg/ft^2, < 30 μg/ft^2, and so on). Achieving floor dust lead loading values of 40 μg/ft^2 and sill dust lead loading values of 250 μg/ft^2 only provides an illusion of safety.

Dr. Frederick J. Miller

Input on Charge Question 2 for the CASAC Panel letter to the EPA Administrator

2a – As a strength, a sufficient number of appropriate variables were chosen for sensitivity analyses. However, there are a number of weaknesses in the implementation of the sensitivity analyses for the two examples studied. Among these were: (1) studying only a 10% change in the value of input variables, (2) not providing how this 10% change relates to the standard deviations of the variables, (3) computing elasticity but providing no explanation of the importance in the range of computed outcomes, and (4) not putting the sensitivity scores into perspective so the reader could adequately judge which input variables provide the most variability in predicted outcomes. Given that the two examples studied reflect probably the minimum and the maximum amount of renovation that will be done, there is no need to conduct separate sensitivity analyses for each of the houses and COFs that will be "built" for the economic analysis.

2b – The framework for the Monte Carlo analyses that were performed was fine. However, the outcome of these analyses is of limited value because of deficiencies such as those noted above. The Panel does not feel that separate Monte Carlo analyses need to be conducted for each of the houses and COFs that will be "built" for the economic analysis.

2c – There probably is not a need for an additional Monte Carlo analysis as a way to account for the variances in the dust study. The non-monotonic results that were seen across increasing Control Options is probably an artifact due to the way non-detectible sample values were handled and the failure to use statistical methods for left censored distributions. Clearly, the dust levels should decrease across the increasingly rigorous Cleaning Options. A failure to do so reflects poor or inadequate data.

2d – The use of a geometric standard deviation (GSD) of 1.2 in both the IEUBK and Leggett models is inappropriate and has contributed to the sensitivity analyses showing that most input variables are not important for dust loadings (and subsequently dust concentrations). A GSD between 1.6 and 2.1 should be used as a value in this range incorporates some of the uncertainties in estimating mean blood Pb levels. An additional Monte Carlo step between the application of the blood Pb model and the IQ change model would be quite useful.

2e – Some assumptions bases on deterministic data are imparting variability that is not really of interest for the project objectives. For example, the dietary Pb intake values for ages 2 to 6 vary up and down by an amount that is not likely to be biologically significant. Setting the dietary level to the average across these ages would eliminate this factor, which is not of interest here. The deterministic value used for lung deposition fraction is outdated and needs to be replaced by age-specific lung deposition fractions. The current analyses ignore head deposition of particles, which is going to be a major source of Pb input to the G.I. tract. The use of a GSD of 1.2 in the blood Pb modeling is not appropriate and needs to be increased. If the type of corrections mentioned above were made, the assumptions that were incorporated in a deterministic fashion would probably be fine. As noted earlier, except for the possible use of additional Monte Carlo analyses for the blood Pb and IQ change modeling, other Monte Carlo modeling beyond the types already being done is not necessary nor is it necessary to apply them to each of the houses and COFs that will be "built" for the economic analysis.

Dr. Ian von Lindern

Clean Air Scientific Advisory Committee
OPPT RRP Lead Rule Consultation July 9-10, 2007
Post-meeting Response to Charge Questions
Ian H. von Lindern

Charge Question 1   Clarity and Transparency of the Document.

Overview: The problem is well presented from the immediate perspective of the EPA regulatory need to produce a document to support cost-benefit evaluations. The analyses, strategies, and systematic approach to the problem are well laid out and supported by appropriate graphs and Tables. However, the ultimate questions to be answered, and how the Agency and OMB will be informed by these analyses, are not well defined. It is unclear exactly how the outputs will be used in decision-making.

The discussions are brief and well edited for the reader looking for findings and conclusions at the various stages, and the document flows well. However, the details are difficult to follow into the appendices. Many procedural and data use implementation decisions have to be accepted at face value, although the appropriate caveats and rationale are usually there, the numbers are not so easy to access and assess. There is no doubt, however, that it will always be a difficult task to either present or follow the numbers through a document containing so many mathematical models in different systems.

The data discussion is straight-forward, concluding that there are few sources available to support these analyses and none specifically designed to its needs. This perennial complaint of, at least, some critics of every study, seems to be true in this case. There are few studies and data to rely on, and as a result, considerable uncertainty in the outcomes.

The model structures are sound and have been used successfully in past regulatory and scientific activities. The outcomes of each step are, for the most part, appropriately conveyed to the next. However, the limitations imposed in each step may constrain the analyses in succeeding steps, and at times, lead to erroneous interpretations. The sensitivity analysis is well conceived, but it inadequate to the task as presented. The Monte Carlo application add some useful information, must be presented in manner that does not imply it increases the quantifiable nature of this sparse data set.

The parameter selection process tends toward simplicity, that is proper, given the reach that must be extended to develop the estimates necessary to support the models, and even more so, the Monte Carlo analyses. However, the range of parameter values that should be accommodated in the blood lead modeling and sensitivity analyses is inadequate.

Overall, the significance of these short-comings is not sufficiently illuminated nor well-enough echoed in the late stage uncertainty discussions. It is unlikely that an unqualified conclusion and quantitative answers can be provided to the economists, given the overall degree of uncertainties. The committee was obviously uncomfortable with endorsing the scientific validity of these analyses unless some corrective measures are undertaken, and the results presented in the context of the significant uncertainties and how those unknowns must be treated in extended analyses.

Risk Assessment Concerns: Despite all the caveats, the greatest problem with this analysis is that it could lead to an erroneous conclusion and ultimately subject children to significant risk that might otherwise be avoided. This is in contrast to the current flavor of the document that seems to suggest these are transient exposures, will result in short-term spikes in blood lead levels, with little or no significant IQ decrement.

Much of the frustration indicated by the committee, I believe, comes from the committee's collective understanding that:

1) the levels of lead generated in the RRP activities can cause substantial increases in household dust levels,

2) exposure to these dusts could result in dangerous spikes in blood lead levels, that put children at risk of significant IQ loss,

3) extraordinary measures (relative to current state-of-the-art practices) must be undertaken to minimize these exposures,

4) even the most stringent controls proposed will result in increased exposures,

5) as a result, the rule should advise and promote every reasonable pre-caution,

6) reasonable pre-cautions likely translate to containment of dust and isolation of children during construction, extensive (frequent and aggressive) and repeated cleaning afterward, and a reliable clearance test.

The difficulty is that, after all the modeling, this document could be leading to the conclusion that only small IQ decrements result, and many committee members fear that an economist may find that the costs associated with implementing these precautions are excessive in relation to the small IQ decrement. Much of this confusion, in my opinion, is that the presentation of resultant blood lead and IQ, respectively, as an increment and decrement to baseline can be misleading.

The problem is complex, and the complexities multiply through the series of non-linear systems. This is difficult to grasp conceptually and describe mathematically. There are problems with lack of data and uncertainty associated with parameter selections. However, the modeling effort is comprehensive and most of the components have been peer-reviewed and utilized successfully in past scientific and regulatory activities. The process and the results should be informative in assessing the risk and outcomes. Doubtless, some significant aspects and factors are left out, but the analyses should aid in making a better decision.

Lead Health Policy Concerns: The analyses of the modeling results, however, neglect two of EPA's critical mandates and much of what we have learned about lead poisoning over the years. EPA's mission is to:

1) eliminate lead poisoning by 2010,

2) protect the most vulnerable members of the population, and

Because lead is a potent multimedia toxin, eliminating lead poisoning will only be accomplished by addressing all sources of lead. Evaluating each source of lead as an increment to all the other sources could (in the extreme) lead to the conclusion that no individual source is significant while it is clear that the combination is harmful.

Purposefully, allowing increases in children's exposures is counter to the federal strategy to eliminate lead poisoning and promote lead-safe housing.

I believe it is because the modeling approach masks the most significant effects by the manner in which the increments are evaluated.

As I understand the approach, the model assumes a "background" or baseline dust concentration for each vintage home and then estimates outcome blood lead levels for this "background" situation. Then an incremental dust exposure associated with the RRP is added to the mean background dust exposure and a second outcome mean blood lead level is estimated. IQ deficits are then projected for both these total blood lead levels and the difference is attributed to the RRP. A GSD of 1.2 is applied to the blood lead means to estimate 5th and 95th percentile blood leads and the same increment/decrement calculation is performed.

In effect, the model assigns the same baseline blood lead level (and hence IQ deficit) to every child that lives in a housing strata. The procedure then calculates various distributed blood lead increments and calculates IQ deficits for children. This effectively is operating only in the upper portion of the distribution, where it is assumed the most vulnerable children are found, consistent with the theory that those children with the highest blood lead levels are at greatest risk. As a result, the largest overall IQ deficits identified are associated with the children with the highest combined background and RRP increment. However, when the IQ deficit attributed to "background or baseline" is subtracted out, a smaller decrement is noted.

This process misses another vulnerable segment of the population for these analyses. That is the child with a low baseline or background attributable blood, (left side of the background distribution) that is then exposed to high RRP sources (right side of the RRP dust lead distribution), responds with a high response rate (right side of the individual blood lead dose-response distribution) at the low end (highest slope) of the IQ/blood lead dose-response curve. This is the child will that will see large IQ deficits, that otherwise may have been avoided by controlling the RRP exposure. This child could be teased out with modifications to the sensitivity analyses.

Summary: Overall, I believe the analyses are well structured and can, with modifications inform the decision-makers in their respective activities related to characterizing risk. I do, however, have reservations regarding the quantitative reliability and the exact nature of the deliverable to the economists. From a risk assessment perspective there are three critical elements missing from this document. Those are:

1) presentation of the number of children whose blood lead levels will be elevated above the 10 µg/dl threshold currently considered unacceptable in all other agency programs (also currently under serious review as being inadequate to protect children). This critical consideration seems to be lost in the rush to provide economists with numbers to crunch. Allied to this is the suspicion that the rule is insufficient to protect children without lowering the residual floor dust loading to, at least, half the current acceptable value.

2) Identification of, and descriptions of the potential effects on, the susceptible populations. Which segments of the national population will suffer the greatest harm from not implementing the rule, and what is the effect at the individual child level?

3) Qualitative discussion of the uncertainties in terms of the error effect on outcomes and determinations need to substantially augmented. Do these analyses, the critical parameter selections, assumptions, and model forms lead to false negative or false positive determinations. At the end of the day are we more likely to make false positive (impose unnecessary precautions in the rule and waste resources) or false negative (leave children at risk) conclusions.

Charge Question 2 Sensitivity and Monte Carlo Analyses

Sensitivity Analyses: The sensitivity analysis is well developed, but is applied to a limited portion of the overall modeling effort and is incomplete in some key areas. These analyses, in my opinion, are among the most important in the document. There are, as noted through out the document and the Committee's findings, large uncertainties that result from the limited database. These uncertainties are compounded through this chain of calculations performed largely with non-linear models. The sensitivity analyses should be accomplished with both negative and positive increments in key variables. The increments employed should be larger and in line with the known or anticipated range in expected values. Runs, at least, should be made at double and half the typical values; or with larger differences if one and two standard deviations are substantially greater than the double and half scenarios. It would not be necessary to display all these results, but it should be discussed whether the model sensitivity breaks down or implodes with values in the extremes of the distributions.

The current analysis provides some good information with respect to the dust lead concentration estimations. However, the parameter selections must be extended toward 1 to 2 SDs from the typical values in the model and the elasticity measurements evaluated accordingly across this range. The elasticity and sensitivity indices provide insight about the model's behavior and performance, but it is even more important to use these sensitivity analyses to convey information regarding the effects of the uncertainties on outcome. For example, what are the consequences in blood lead and IQ increments and decrements if the dust lead prediction equation is off by a factor of two? This is critical information to those who intend to use this output. This should be followed with a discussion concerning the probability of this occurrence and whether it leads to overstating or understating the true outcome.

Sensitivity analyses should be conducted on dust, blood lead, and IQ outcomes.

Non-monotonic Results: The lack of monotonic results in the outcomes could trace back to non-monotonic input from the RRP studies. This well could be due to the data points for different strata not reflecting mean or median observations within these distributions. That is, not enough data points were collected in each strata to obtain a consistent typical or central tendency values for modeling analyses. This is not a fatal flaw, but it must be recognized in the uncertainty discussions that neither the variance nor an effective mean has been identified.

Monte Carlo Analyses: This is especially true for the Monte Carlo analyses. The reader should be cautioned that these analyses don't lend to better quantification of the outcomes, but can be useful in qualitatively assessing the uncertainty in results derived from the limited data base. There has long been caution offered regarding adopting probabilistic front ends to the IEUBK to avoid using an empirical overall GSD in evaluating tail effects. Much of this caution relates to the inability to specify the variance in the input factors with more informed guesses. Multiple guesses on the front end of the model won't improve on an aggregate guess based on observed data in the backend.

Similarly there are several instances where no-detects and background, baseline or fixed variables tend to "freeze" or truncate the left-hand portions of the distributions. These fixed or informed guesses could have important artifactual effects on subsequent analyses, particularly with random sampling techniques. These analyses must pay attention to both tails of the distributions, as the most vulnerable children will be affected by both the low and high end distributions. For example, the traditional use of IEUBK is to evaluate effects and relationships at the mean and project the percentage of outcomes in exceeding critical levels in the upper tail. When considering incremental analyses, the greatest affects may be observed in children moved from the left tail to the right side of the distribution due to the incremental exposure. This doubly true when considering the delta IQ, as this child will be responding in the steepest portion of the IQ/blood lead relationship.

Additional Monte Carlo analyses will not be helpful if it is disengaged from model results. All of these types of models must appropriately describe how they inform the treatment of uncertainty. It must be pointed out that without an effective description of variance in the input parameters the Monte Carlo results are qualitative or, at best, semi-quantitative. The imputed variance must be discussed is in context of other unknowns and uncertainties and the discussion must be informative of variance and parameter, model or decision rule uncertainty.

Charge Question 3 Blood Lead Modeling

Choice of Models: The blood lead estimates are well-presented and the contrast in model results between the two primary models is demonstrative of a lack of consensus regarding the capability to project children's blood lead levels following short-term exposures. These differences are probably not as glaring as this document would leave a regulator to believe. The Leggett model, as pointed out in the document, is known to predict higher blood lead levels than the IEUBK. Some of the over-prediction may be to absorption factors for soil and dust. For the most part, however, the Leggett model is likely showing spikes that are collapsed in the longer-tem averages captured in the IEUBK. In all likelihood, the appropriate value for use in these analyses lies between the IEUBK and Leggett estimate. Bracketing the analyses by both these estimates, likely captures this value.

The best blood lead level to utilize in the IQ model, however, is not clear because little is known regarding the effect of short-term excursions in blood lead levels. Both concurrent and lifetime average values have been shown to be related to IQ deficit, but there are questions regarding which would be better applied in these analyses. In either case, the effect is likely related to some cumulative measure of elevated blood lead. In this document that cumulative blood lead excursion is best illustrated in the time-series curves shown in Exhibits 5-10 and 5-11. The area under these curves shows the combined attenuation in exposure and predicted blood lead level that leaves small children at risk for significant periods of time, even considering the "spike" in dust concentration. The greatest concern evident in those figures is the area under the curve for 1-3 year old children, who would be the most vulnerable due to their habits, hygiene and physiological predisposition to adverse effects. This could lead to the suggestion that the IEUBK 2-year old blood lead estimate be used. The best course of action is probably to conduct the analyses using the highest and lowest estimates and convey the outcomes and associated uncertainties to the decision-makers in informed discussion.

Selection of GSD: There are difficulties with the manner in which variance in blood lead estimates were handled in these analyses. There is a fundamental error in the use of the 1.2 GSD. This value fails to account for several sources of variance in blood lead distributions. Typically, most blood lead populations show GSDs in the range of 1.5 to 2.0 and greater. EPA has recommends 1.6 as a typical value when evaluating lead contaminated hazardous waste sites. NHANES national strata data indicate values near 2.0. These GSDs are empirical and reflect several sources of variance in blood lead response, ranging from differences in media concentrations, accessibility, exposure, intake, absorption, individual blood lead response, bio-kinetics and SES factors. When large national populations such as NHANES are assessed, all of these factors show large variation and resultant overall GSDs are generally 2.0, or greater. Conversely, when some of the exposure and population factors are limited, such as at an individual hazardous waste site where the primary sources, pathways, media concentrations, bioavailability, SES factors, etc. are known or constrained, lower GSDs are appropriate.

In this report, the selection of the GSD is not a simple determination. Evaluation of a single constructed home would suggest a GSD near 1.6. However, to apply the results across the national population the aggregate GSD should reflect the NHANES findings of near 2.0. Most probably the 1.6 should be applied and the results of all homes when aggregated should reflect the increased variance in response noted in NHANES.

Because the GSD is driven to a large extent by the population-wide variance in exposures and SES, the GSD for this case should be selected to describe the variation in the "background" population. That population(s) should be the appropriate NHANES stratification relative to the housing vintage under consideration. This GSD will likely be much larger than the 1.2 value used and will result in significantly higher 95th percentile estimates. Because this is also the population to which the increment must be applied, the same GSD should be used in assessing the increment.

Consideration of the Most-vulnerable Children: In these analyses, the ultimate need is to assess an IQ increment associated with RRP exposure. The current approach does calculate a mean and distribution for the "background" case and then adds a dust exposure increment to intake, resulting in a blood lead increment. This is accomplished at the mean in both models and then the extremes of the response distribution are assessed by applying the GSD. However, this method 1) underestimates the extreme blood lead levels by not using the appropriate GSD, and 2) implicitly estimates the increment by subtracting each point in the RRP distribution from its respective point in the background distribution. The latter is discussed in response to Charge Questions 1 and 2. As a result, using a larger GSD and investigating the potential impact for the most vulnerable child will likely show a much larger potential IQ deficit for those individuals.

There are two distinct populations that could be considered most-vulnerable in these populations. Those are 1) the children who (under current guidance) would see an increase in blood lead levels to above 10 µg/dl, that would not otherwise be at risk of exceeding this criteria, and 2) those that would experience the greatest IQ deficit, that would have otherwise not have suffered this result (even if their blood lead level did not exceed the 10 µg/dl threshold). The former should be evaluated in this analysis as these are the children that conventional lead health risk assessment would identify. If large numbers of children are identified as experiencing excess absorption (>5% under current criteria) by these analyses, then the efficacy of the rule should be re-examined in light of the findings. Current empirical evidence is suggestive that the rule will be ineffective in protecting these children, unless the post-activity loading criteria are significantly reduced. In the case of those children who would suffer significant unintended IQ deficit but remain below 10 µg/dl, these should be explored by the sensitivity analysis suggested in Response to Charge Question 2.

IEUBK Sensitivity Analyses: The IEUBK model clearly has the disadvantage that it is not designed to estimate short-term blood lead levels and the resultant inapplicability to this problem must be pointed out. However, this weakness is clearly biased toward under-estimation of risk and the IEUBK can be used as a reality check for the overall analyses and to assess the potential of other uncertainties to over- or under-estimate risk. The IEUBK can inform these analyses by performing "sensitivity" runs to:

1) Aiding in selecting a GSD that describes the population variance as described above.

2) Estimating the percentage of children put a risk of exceeding the10 µg/dl threshold.

3) Estimating the blood lead increment seen by children at risk for the greatest IQ decrement (i.e. by performing a "sensitivity " run for children from a low background soil and dust home that sees a maximum dust lead increase due to RRP.

4) Examining the blood lead effect of repeated RRP activities over a number of months or years.

5) Examining the effect of different "background" or other source contributions to blood lead levels and the "area under the curve."

Charge Question 4 Estimates of IQ Change

Please see the response to Charge Questions 1 and 3 with regard to where in dose-response curve the IQ decrement is calculated, particularly with respect to the overall decrement that is attributed to background blood lead levels. See also the discussion in response to Charge Question 3 under **Choice of Models** as it pertains to the appropriate blood lead level for estimating IQ decrement and the "area under the curve" in time series blood lead exhibits.

Charge Question 5 Adaptation of Approach for Child-Occupied Facilities

I believe the application is sufficient provided the approach is consistent with the rule as it will be applied.

Charge Question 6 Adaptation of Approach using Housing Age

My understanding of this question relates to the observation that the OPPT (Battelle) Study dust lead loadings (that provides the data to estimate dust concentration estimates for use in blood lead modeling) were observed from renovation work performed only on older vintage homes. The concern expressed is that these loadings, and hence the concentrations developed may be overestimated when used as surrogates for newer vintage homes, This could lead to overestimating the blood lead increment , IQ decrement, benefit, and cost. Initially, this seems to be a straight-forward question with a straight-forward answer. There is more lead in older homes, and likely more lead in dusts generated from RRP activities that is likely reflected in lead loadings from RRP debris. This would lead to the conclusion that using the older results for newer homes likely over-estimates risk and should be viewed as a "conservative" or protective uncertainty factor consideration in decision-making. At the end of the process this would translate to there being a greater probability of making a false positive (protect children not needing protection) rather than a false negative (waste money and resources) determination. The policy risk managers would be so informed. This is my understanding of how the question would be handled in the current version, although I don't specifically see that discussion in the text. The issue thus far, was raised only in the charge questions.

However, there is reason to suspect that risk may be overestimated for newer homes because there is more lead in older homes and background dust loadings and concentrations are higher in older homes (HUD and others). This is known from XRF surveys and dust lead measurements. One alternative would be to develop an "adjustment factor" to reduce this uncertainty and try to incorporate the belief that lower lead loadings result in lowered dust concentrations and down-the-line outcomes. The uncertainty discussions would then need to reflect the level of knowledge and evidence supporting the parameter selections, models and assumptions incorporated in the "adjustment".

The first question to ask is whether the surrogate levels are inappropriate. There are considerable uncertainties in these data, even for the older homes. This is a single data base, relying on few observations, with no corroborating evidence, and little to build meaningful variance estimates. It's unlikely that the uncertainty can be quantitatively improved by developing additional adjustments, as high, low and mid estimates need to be developed to support the probabilistic analyses. However, the understanding of the level of protectiveness in the outcome could be improved, depending on the reliability of the "adjustment".

In the absence of RRP data generated from newer vintage homes, any adjustment parameters would likely be developed from the XRF and loading / concentration observational database. It seems that none of the available data are RRP activity specific, or even related to RRP activities. As a result, the adjustment would likely be a "scaling factor" related to relative "background" or XRF loading factors. Whether these are more or less appropriate for each RRP activity is unknown. I suspect appropriate, but not constant values could be developed for each vintage. The use of lead paint and the lead content of the paint varied by vintage and component. Such factors, as demolition of lathe and plaster verse types of wallboard or textured surfaces etc. might have some affect on bulk dust, and as such, concentration levels.

Most important, however, is recognizing that the variable being constructed for use in predicting outcomes, is dust concentration. Corrections for vintage are made in the conversions applied in this document. Moreover, the conversions use the same variables that would likely be used in an adjustment factor. Statistical analyses of the HUD database showed that the dust concentration was related to house age, XRF loading and outdoor soil. However, the correction selected was univariate using only house age. This form subsumes the XRF and soil variables and accounts for these in the intercept. As such, the adjusted correction may have already been accommodated in the dust conversion equation.

Additionally, the second Battelle report provided shortly before the meeting dated June 29, 2007 suggests that there is little significant difference in XRF lead loading in paints in various interior housing components by vintage (for homes that show readings >1.0 mg/cm^2). Should these analyses be accepted in peer review, the adjustment for vintage is likely not needed, provide the homes exceed the 1.0 mg/cm^2 criteria.

Charge Question 7 Adaptation of Approach for Exterior RRP.

Outdoor soils are implicated in both outcome blood lead levels and as contributors to house dust lead concentrations. As such soils have the potential for longer term residual impact on blood lead, IQ and residual dust lead levels. The significance of exterior RRP on these soils should be included in the analyses.

Charge Question 8 Adaptation of Approach for Other Contributions

Please see the discussion regarding children at-risk and incorporate the findings of the sensitivity analyses in the houses to be built so as to appropriately include these children in the risk assessment and cost-benefit studies.

Dr. Barbara Zielinska

Barbara Zielinska

Comments: An Approach for Estimating Children's Health Risk (IQ) Changes Associated with Dust Lead Generated by RRP Activities

Charge Question #8: Adaptation of approach for other contributions.

I understand that the question is if the methodology developed in this document could be used in any other exposure scenarios and houses/child occupied facilities (COFs) that it may be necessary to examine these in a subsequent economic analysis. In my opinion, this document is very comprehensive and well written and could be adapted to other combinations of exposure scenarios, providing that certain changes and corrections, as discussed at the CASAC meeting on July 9-10, 2007, are made. The goal of this document is not to show the efficiency (or lack of efficiency) of the proposed LRRP rule, but rather to develop an approach that would allow for building multiple exposure scenarios in different residences or COFs in different geographical areas and to estimate changes in children's IQ from lead exposure due to these scenarios. In this respect, I have only a few general comments:

1. As discussed in Section 7.1, the approach developed in this document relies heavily on the experimental data derived from the OPPT Battelle Dust Study, which was rather limited in scope. The small sample size, limited geographical area, lack of evaluation of different control options for the same activity in the same building, limited list of possible RRP activities makes the model input data rather uncertain. A more comprehensive data set would be required to make the approach developed in this document universally applicable.

2. The important limitation of this approach is that it does not account for the child's activity pattern in a building and an adjacent yard that undergoes renovation. Children may spend more time in different areas or be removed from the building for the duration of renovation and in these cases their exposures would be significantly different. This is especially important in the case of multiple activities and COFs– it is rather unlikely that children would be left in the building during the major renovation activities. The post-renovation Pb level would be the most important in this case.

3. As noted in the document, the assessment of the cleaning efficiency after renovation is also very limited. The supplemental material "Cleaning Verification Extract" that describes the methods used for assessment of cleaning efficiency makes it clear that these methods do not provide real Pb-loading data. Since the buildings may not be even occupied during the renovation activities, the cleaning efficiency may be very important in terms of the Pb exposure.

4. Since the two biokinetic models used in this document give very different blood Pb concentrations, it would be necessary to resolve the question which of these two models

is appropriate to use for LRRP analysis before the more general application of the developed methodology. Although the Leggett model seems to be more appropriate for the RRP activities since it can accommodate the shorter exposure span, it generates values that are much higher than the observed blood levels. However, the higher estimates of Pb blood levels may be more consistent with the protection of children's health. I think that the empirical data should be used for model verification. Perhaps IEUBK model could be used for estimating the background concentrations and Leggett model for incremental changes resulted from RRP activities.

5. Since the estimated incremental IQ changes due to the major renovation activities were rather small (Chapter 6), I don't believe that the approach developed in this document could be applicable to low dust generating activities, such as small repairs. Due to the high overall uncertainties of this analysis, low exposure scenarios would generate rather unreliable results.

Appendix E – 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 CASAC 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. The names of the Panelists who provided review comments are listed on the next page, and their individual comments follow.

Dr. Joshua Cohen

Comments on the sensitivity and Monte Carlo analyses

The description of the sensitivity analysis and Monte Carlo analysis should be revised to help better convey several important issues.

1 Quantify Impact of Uncertainty and Variability Separately

EPA's report does not describe the purpose of the sensitivity and Monte Carlo analyses. Is their purpose to characterize variability or uncertainty? The first sentence of Section 4.6.1 (the overview of the sensitivity and Monte Carlo section) reads in part, "*it is important to characterize the impacts of this variability and uncertainty on the estimated dust concentrations.*"

The analyses include a large number of parameters, but the results do not parcel out how much of the estimated variation is due to uncertainty, and how much is due to variability.

Variability represents differences between different members of the population (or, in this case, different dwellings) that cannot be reduced by the collection of additional information. That information can help determine the extent to which the proposed intervention might better be targeted at those dwellings where they yield the largest benefit. There are conceivably several important sources of variability that were not, as far as I could tell, explicitly addressed. These sources include differences in: 1) building condition; 2) lead paint coverage on surfaces that will be disturbed; 3) type of renovation; 4) number of children living in the dwelling, among other factors. It is possible that the net benefit of the proposed rule will vary substantially. In some cases, it could conceivably be negative, while in other cases, more intensive measures might be justified.

Uncertainty, on the other hand, indicates that there is a range of plausible results because of a lack of knowledge. Quantification of uncertainty helps decision makers understand if the knowledge base is sufficiently robust to support rule making, and if it is not sufficiently robust, it helps identify those sources of uncertainty that are most important to resolve. The sensitivity and Monte Carlo analyses should quantify the extent to which an outcome of interest varies depending on the assumptions used. EPA reports the extent to which various outputs change in response to an arbitrary change in the input quantities (*e.g.*, a 10% change), yielding a response elasticity. This information does not, however, account for how uncertain each input quantity is. Two assumptions can have the same elasticity, but one may be more uncertain than the other and therefore make a larger contribution to the overall uncertainty of the output.

2 Use of Dust Lead Concentration

Use of dust lead concentration as a measure of exposure is problematic because it introduces substantial uncertainty, and the analysis does not sufficiently quantify its impact on the results. Tables A-5, A-6, and A-7 in Appendix A do a reasonable job laying out the assumptions used in the sensitivity analysis and Monte Carlo analysis. The treatment of the load-concentration slope coefficient is not clear, however. The central value in Table A-6 is 0.5 and no hi and low values are listed. The footnotes read:

- "*The Load-concentration Intercept and Load-concentration Slope were determined through ICF analysis. Please see Appendix C for a more detailed discussion of this analysis.*"

and

- "*There were no low and high values for the Load-concentration Slope, however a CV of 2 was deemed too high. Therefore, the Load-concentration Slope CV was estimated by setting the CV equal to the Load-concentration Intercept CV.*"

Appendix C (referred to in the first footnote passage above) describes the regression analysis, which indicates that the estimated dust lead concentration is very uncertain, spanning a bit more than e^3, or a factor of about 20.

The second footnote passage does not help. Section D1 explains that "*If no low and high values were available, then the variable was assumed to be normally distributed and was assigned a default coefficient of variation of two, representing a conservative estimate of the variability.*" Why was CV = 2 deemed too high in this case? If it was deemed to be too high, then there must be an alternate value that makes more sense. Using the CV from the intercept does not make sense and probably understates uncertainty because the intercept is probably more certain than the slope coefficient. In any case, there is no reason to believe that the CV for the intercept is a good proxy for the slope's CV.

It appears that EPA used concentration (µg lead/g dust), rather than loading (µg lead/ft^2 floor space) because the biokinetic models require a concentration value. This conversion introduces uncertainty by using an uncertain relationship to replace an empirical measurement (loading) with a proxy (concentration). Comments from Bruce Lanphear indicate, moreover, that even without consideration of this additional uncertainty, concentration is an inferior predictor of blood lead than the original loading measurement. EPA would be better off if it could use loading as an input to its biokinetic model, rather than concentration. I briefly describe several approaches.

The simplest approach would be to compute background blood lead and the increment associated with exposure to RRP-generated dust lead separately, and then to add the two together. The background could be computed using NHANES data or the IEUBK model, as discussed in the July 9-10 meeting, while the increment could be taken directly from the relationship between dust lead loading and blood lead described in Bruce Lanphear's 2005 paper (I do not have the cite, but he showed me the paper during our meeting). The shortcoming of this approach is that the relationship described in Lanphear *et al.* (2005) is based on a chronic exposure to lead. A second approach uses a biokinetic model to address this limitation. Let us assume that the Leggett model is used for this purpose because it can model the impact on blood lead of short time scale changes in lead exposure. EPA should determine the chronic change in dust lead concentration that increases blood lead levels by the same amount that the Lanphear *et al.* model predicts a given change in dust lead loading will produce. This mapping should be computed for a range of incremental dust lead loadings. Note that Lanphear *et al.* (2005) use a log-linear relationship to predict blood lead as a function of dust lead loading, so the impact on blood lead depends on both the beginning and end dust lead loading. The numbers in the table below are fabricated but illustrate the approach.

Start Loading	End Loading	Change in PbB (GM) Predicted by Lanphear (2005)	Corresponding Dust Lead Concentration Increment Producing Same Increase in PbB in the Leggett Model
0	10	2	200
0	20	3	300
0	30	3.5	350
…			
10	20	1	100
10	30	1.5	150
…			
…			

Note that I am assuming that in the Leggett model, the relationship between dust lead concentration and blood lead is roughly linear.

The next step is to produce the appropriate dust lead concentration time series that will be input into the Leggett model. EPA should assume that the same dust lead concentration values that reproduce the Lanphear relationship for chronic exposure will also work for short term exposure. For example, suppose that the assumed background dust lead loading is 10 μg/ft^2, that the immediate post-RRP level is 30 μg/ft^2, and that after 1 week, the level is 20 μg/ft^2. The dust lead <u>concentration</u> time series to be entered into the Leggett model would then be:

Time Point	Assumed Baseline Dust Lead Loading	Measured Incremental Loading	Corresponding Dust Lead Concentration Increment Producing Same Increase in PbB in the Leggett Model
Before RRP	10 μg/ft^2	0 μg/ft^2 (by definition)	0
Post-RRP	10	20	150
0	10	10	300

3 Results Display

Exhibit 4-14 in the main report illustrates key percentile values for week 0 dust lead concentrations for each of the four control options evaluated in this study. This quantity is not, however, what is important for two reasons. First, what we are interested in is the difference between the impact of the control options. Because all of these sources of uncertainty affect the impact of each control option to a similar degree, the uncertainty across control options is correlated. As the figure suggests, the differences between control options are probably not as the uncertainty within each control option. It is not clear exactly how correlated the different control options are, however. It is also likely that the quantities that influence individual control option results contribute more to uncertainty of the differences between the control option cleanup levels than do assumptions that influence all of the control options. Second, we are interested in the uncertainty in the estimate of exposure aggregated over the entire remediation process. This quantity serves as a good indicator of the impact of remediation on blood lead levels, which in turn serves as a good indicator of the impact of remediation on IQ. The results in Exhibit E are likewise uninformative because they report week 0 and week 10 dust lead concentrations, and the number of weeks it takes for dust lead concentrations to return to background.

4 Use of "Conservative" Assumptions in Monte Carlo Analysis

The Monte Carlo analysis involves a mix of distributions and, in some cases, conservative estimates for parameters. "Conservative" estimates are used the decay constant for air lead (p. 56), and assumptions related to child access to the work area (p. 87). Because the analysis is designed to evaluate an intervention, rather than the burden associated with the presence of a chemical, it is not clear what "conservative" means in this context. If we overestimate the size of the risk (the burden), we end up overestimating the benefit of the intervention. It can be argued, though, that a "conservative" evaluation of an intervention would underestimate its net benefit.

5. Addressing Report Limitations

It is not clear that the sensitivity analyses and Monte Carlo analysis addressed the most important sources of uncertainty. Both sections 3.5 and 4.7 of this report list important limitations to the analysis. These sections are very useful. The limitations can be addressed in a number of ways. It may be possible to dismiss some limitations as not having an important impact on the results of the analysis – *i.e.*, they introduce unimportant sources of uncertainty. If that is not the case, it would be best to attempt to quantitatively account for these limitations in the sensitivity and Monte Carlo analyses. Short of that, the report can explain how these limitations qualify the results. Perhaps the findings cannot be generalized to a certain class of dwellings. If even that is not possible, the report should explain what sort of data should be collected to overcome the limitation.

While listing limitations is useful, it is insufficient. Without somehow addressing the limitations, they become reasons for dismissing the usefulness of the analysis entirely. From my perspective, the most important limitations are those that relate to the quality of the data. In particular, it is not clear to me how a convenience sample of 12 residential dwellings and 3 child occupied facilities can be used to represent the range of building types and conditions that will be encountered in the U.S. At the very least, the uncertainty inherent in such an extrapolation should be addressed. Without doing so, it is not clear how meaningful the results the results of this analysis are.

Dr. Ellis Cowling

Dr. Ellis Cowling
North Carolina State University
July 23, 2007

Post-Review-Meeting Comments on the EPA Report titled:
"An Approach for Estimating Children's Health Risk (IQ) Changes Associated with Dust Lead Generated by Renovation, Repair, and Painting Activities"

Several of my colleagues on CASAC are much better prepared by experience and scientific expertise to provide very constructive comments on specific details of the approach described in this EPA report on "Estimating Children's Health Risk (IQ) Changes Associated with Dust Lead Generated by Renovation, Repair, and Painting Activities". My natural predilection as a member of CASAC, and also my assigned task in our recent review of this report, was to focus on the most general aspects (Charge Question 1 – Overall approach and utility) rather than more specific aspects of this report and its proposed methodologies for estimating IQ changes related to lead exposure in residential housing and other "child occupied facilities."

Charge Question 1: Overall approach and utility

Various agencies of our Federal government have established a very worthy goal for environmental protection — "eliminating childhood lead poisoning [in the United States] by the year 2010" — [now only 3 years away!].

In this connection, EPA has proposed new requirements aimed at decreasing the exposure of children to the lead used mostly during various decades of the 20th Century as pigments in many of the interior and exterior paints applied during the original construction and renovation of homes, school buildings, day-care centers, churches, and other buildings that frequently will be occupied by children in the early years of the 21st Century. These requirements will affect the manner in which renovation and repair of already existing child occupied facilities will be achieved during the next few years of the present Century. Thus it is important that EPA's Office of Pollution Prevention and Toxics do its job both very well and in a very timely way!

Many aspects of the general approach outlined in this EPA report seem very reasonable. Unfortunately, however, the report contains few, if any, references to indicate how the approach and resulting estimates proposed by the USEPA will be related to and pursued in conjunction with the activities and responsibilities of other federal agencies whose leadership and resulting actions also will be necessary to achieve the noble goal of "eliminating childhood lead poisoning by the year 2010."

As we look forward to the time it will take for the USEPA to implement the approach outlined in this report, I could not help but wonder why CASAC was asked to review this approach when the goal of our government is "eliminating childhood lead poisoning by 2010" – is now only 3 years away!

During CASAC's recent review of this report, we asked and learned that:

1) This interagency goal of our federal government was established in 1992,
2) EPA promulgated its first regulations with regard to renovation, repair, and painting of child-occupied facilities in 1996,
3) EPA provided its first guidance for implementation of these rules and regulations in 1997, and
4) Until very recently, relative little further actions were taken by the USEPA with regard to reconsideration and implementation of these rules and regulations.

This very brief and no doubt inadequate chronology of events within the USEPA led to further inquiry into the long-term history of both governmental and private sector actions and activities with regard to lead pollution in the United States and other developed countries around the world.

The attached references indicate that the currently proposed actions and reports regarding lead pollution and resulting lead poisoning in the United States are long overdue. We commend the present administration of the USEPA for undertaking their presently renewed interest and actions with regard to lead pollution and poisoning and hope that the USEPA will do its important and appropriate part -- together with other federal agencies – and thus help our country make further progress toward our national goal of "eliminating childhood lead poisoning – [hopefully] by 2010," if not by then "as soon thereafter as may be possible. **Better late than never!**

<u>References</u>:

1) Childhood lead poisoning prevention. Too little, too late. B P Lanphear. J Amer Med Assn. 2005 May, 293(18):2274-2276.

2) "Cater to the children": The role of the lead industry in a public health tragedy, 1900-1955. G Markowitz and D Rosner. Am J Public Health. 2000 January; 90(1):36–46.

3) The secret history of lead: How General Motors, Standard Oil and Du Pont colluded to make and market gasoline containing lead—a deadly poison—although there were safe alternatives. Abetted by the US government, they suppressed scientific knowledge that lead kills. Still sold in countries all over the world, leaded gasoline continues to poison the planet. J L Kitma. The Nation. March 20, 2000: 11-44.

4) Warnings unheeded: A history of child lead poisoning. R Rabin. Am J Public Health. 1989 December; 79(12):1668–1674.

5) "A 'Gift of God'?: The public health controversy over leaded gasoline during the 1920s." D Rosner and G Markowitz. Am J Public Health. 1985 April; 75(4): 344–352.

Dr. Douglas Crawford-Brown

Review of An Approach for Estimating Changes in Children's IQ…, Draft for CASAC Review

Doug Crawford-Brown

General Comments

I begin by noting that this is a mature document that lays out quite clearly (in most instances) how the assessment will proceed. I found the organization of the document, including the use of the flow diagrams for computations (and the sub-diagrams for specific subsections) particularly useful in keeping track of the discussion. The authors are to be congratulated for their organization.

I found throughout that (for the parts where I feel I have the necessary expertise) the authors have chosen the appropriate studies and models to use, including the appropriate parameter values for the models.

Before getting into specific comments, and then answering the Charge Questions, I do have one quibble. It relates not to the way in which the assessment will be done for a specific activity or set of activities in a home, but rather to how the EPA intends to use any results. The proposed methodology is no different in kind from the methodologies used for any number of national assessments, such as that of incinerators. In the latter case, however, there is a distinct set of sources with a defined (however well or poorly) emissions inventory. In the current case, I don't think we can specify the distribution of activities that will be conducted, unless we assume that the future distribution is the same as the distribution of activities that have taken place so far. And I doubt this will be a valid assumption.

So it seems problematic to me to produce anything like a national variability distribution of IQ loss over the potentially exposed population. But then this may not be the intent in the first place. The intent might be to produce inter-subject variability distributions of IQ loss for hypothetical populations exposed to each specific activity and some representative subset of complexes of activities. The goal might then be to say something like: *For the following activities and complexes of activities, the inter-subject variability distribution of IQ loss is acceptable if the contractor uses the Rule Procedures, and for the remaining activities and complexes of activities even the Rule Procedure is insufficient to provide adequate protection of public health*. There could even be some subset in which the Rule Procedures are not needed to protect public health (although the data in the OPPT Dust Study suggests this is unlikely).

The concern I raise here doesn't affect the methodology proposed. That methodology remains sound. I simply, as a reader, was not completely clear how the assessment results would relate to specific public health decisions that needed to be made.

Some Specific Comments

1. The flow diagram on Page 10 has a step termed …convert dust lead loadings to dust lead concentrations. It doesn't say concentrations in what. I presume air (indoors) and soil (outdoors), but this could be made more clear. Also, there are hints throughout the document that at least some of the OPPT Dust Study results contained air sampling, and that these air samples might be used directly. This would remove the need to estimate air dust from dust loadings. However, there also are places in the document where I received the distinct impression that all indoor air concentrations would be estimated from loadings. This needs to made more clear for the reader.

2. In the section on the epidemiological studies, it at first worried me that the studies do not adequately characterize prenatal exposure to Pb. There are legitimate arguments to be made for prenatal exposure being quite important. But then as I thought about it further, I became less worried. That is because one might assume that prenatal exposure is in part (perhaps even in large part) correlated with post-natal blood lead levels. If the infant has high blood lead levels that are maintained throughout the first 6 years, this probably indicates exposure in the home, and the mother might be expected to have received similar exposures during pregnancy. So perhaps this is not such as major weakness of the epidemiological studies. Just a word or two to this effect might alleviate concerns.

3. Again in the epidemiological study section, it would be an improvement to include the Lanphear et al data in some sort of dose-response graphical form. I find it unsatisfactory to just note (as on Page 17) that there was a "…decline of 6.2 points in full scale IQ for an increase in concurrent blood lead levels from less than 1 to 10…:" Since essentially all of the "action" in this document is applied at blood lead levels between these 2 values, there is a pressing need to see what the D-R curve looks like in there. Absent this, the later assumption of a possible 1 µg/L threshold appears arbitrary, as does the assumption of linearity, piece-wise linearity, etc.

4. The authors note that their use of the word "Phase" (see Page 22) differs from that in the OPPT Dust Study report. It would be better if this difference could be resolved. It has no implication for the results of the current report, since the authors make the translations correctly. But it struck me as odd at first having just reviewed the OPPT Dust Study report.

5. I noted in Figure 3-7 that there is no mention here of people ingesting dust from surfaces. The last box ends up being concentrations. Later in the document, the authors note correctly that there will be dust ingestion (or at least they mention ingestion of dust lead and suggest some

fraction is due to ingestion outdoors and some fraction to ingestion indoors). This discrepancy needs to be cleaned up.

6. On Page 33, the issue of background levels of indoor air is raised. There seems to be the suggestion that this will be estimated from outdoor, ambient, air. Perhaps this is the best that can be done, but I find it hard to believe the penetration factor for the indoor microenvironment is 1, and that indoor sources don't elevate the indoor air above outdoor air concentrations in the kinds of homes being considered here. Are there no data from the OPPT Dust Study or the HUD study (mentioned on Page 34) that can be used to improve on this assumption?

7. Page 36, Section 3.3.2.2 has a statement that I don't believe can be correct. It says that "…values below 0.375 µg/ft2 set equal to 0.375 µg/ft2, which is equal to one quarter of the detection limit". But if 0.375 is one quarter of the detection limit, that limit must be 0.375 x 4 = 1.5 µg/ft2. So how can there be ANY measurements down below 1.5 µg/ft2 if that is the detection limit? Or is this an artifact of the measurement method, which produces results down to 0 (and even below 0 when background is subtracted) even if ones below 1.5 µg/ft2 are not to be considered statistically significant detects? But if the latter is the case, then the procedure should be … values below 1.5 µg/ft2 set equal to 0.375 µg/ft2, which is equal to one quarter of the detection limit. I am at a loss here to understand this paragraph.

8. On Page 36, near the top, the authors state that "…the increased ventilation in the outdoor environment as compared to indoor ventilation would likely reduce the effect". But "reduce" and "make insignificant" are not the same things.

9. On Page 43, on about the 11^{th} line, the authors state that "…geometric means…correct for positively skewed data…." I don't understand what they mean by "correct for" here. There is no "correction" being made. The median is simply more stable with respect to extreme values in the tails. This doesn't make it a better estimate of, or correction for, the mean.

10. Also on Page 43, the authors introduce the idea of using 10% of the window sill loading to add to the floor loading. This value comes out of no where. I can see no justification for it. And surely it would depend on the ratio of window sill area to total floor area.

11. On Page 43, the last paragraph begins by saying that Exhibit 3-13 contains the loadings. No such loading values are provided in that table. I assume the authors mean that Exhibit states WHICH loadings will be considered representative in specific cases.

12. On Page 45, I was not clear whether it will be assumed that children play on the outdoor plastic sheet during the Rule Procedure.

13. Between Pages 45 and 46, the bridging sentence appears to suggest that if the yard is divided into the three areas, the soil value used will be the median of the three medians. Perhaps I have

misread this. This doesn't strike me as an areal-weighted average unless the three kinds of areas have the same surface area (which they don't).

14. On Page 54, the assumption is that a person spends an equal fraction of time in each square foot of the house. This may be the best one can do for now, but if there are data on fraction of time spent in each room, that might be more appropriate. But again, such data may not be available and the suggested approach is at least an approximation.

15. On Page 55, I cannot understand why Equation 4-2 contains the denominator of n. I would assume the air concentrations contributed by separate activities would be additive. Imagine a home with just one activity that yields a concentration of 10 (choose your units). Are the authors saying that if the contractor chooses to do a second activity that releases NO lead, the new air concentration will be (10 + 0) / 2 = 5? That makes no sense. I am missing something here.

16. On Page 76, I like the areal weightings applied to a yard, but I don't see any information on the national sample that will be used to establish these weightings. And it needs to be a sample tailored to the kinds of homes being remediated, since I suspect these have smaller than average yards. Or is there really no areal weighting, but rather the procedure I mention in Comment 13?

17. On Page 77, Exhibit 4-11 contains values that are not described as medians, means, 95^{th} percentiles, etc. Which are they? And it will be important to ensure that whatever statistical value is used, it meshes with the assumptions employed from the OPPT study and other aspects of the methodology in the current report.

18. Beginning on Page 91, I began to have some questions about the Monte Carlo analysis. The authors propose a reasonable methodology, but I was not clear as to how an individual would be followed over multiple years. Once some parameter value is selected (e.g. air inhalation rate) for an individual, is that same value used for that individual throughout that year? And when the next year occurs (and the age has changed), will a completely random value from the underlying inter-subject variability distribution be selected, or will it be chosen at the same Z-value as for the first year? For example, if an individual is at the high end of inhalation rates for the first year, will they also be at the high end for subsequent years? The decision here will influence the variance of the final inter-subject variability distribution for IQ loss.

19. In Exhibit 5-3, Page 94, the authors refer to "inhalation absorption fraction". I presume this includes both the deposition fraction and the fraction transferred to the bloodstream?

20. In the same Exhibit, the "water consumption rate" is given. Is this solely tap water? And does it include only direct ingestion or also use in food and drink preparation? I assume the latter.

21. The comment 18 above also applies to the Monte Carlo approach to blood lead modeling. I was not clear as to whether for a given individual, one value of a parameter is chosen and applied

throughout multiple days of simulation, or new samplings were done many times for a given individual. I assume the former. But then it strikes me that NO Monte Carlo analysis will be done using the model. Instead, the national distribution of blood lead levels will be used in a post-processing mode. I support this latter approach.

22. Throughout the comparison between Leggett and IEUBK, there is an unstated issue about the difference between what the two central compartments mean in these models. It is evident that the IEUBK model compares better to the NHANES data, but this MAY be because the Leggett central compartment is not the same biological medium as is sampled in the NHANES study. It could be that the Leggett model is predicting concentration only in some sub-compartment of what the NHANES study uses as the sampled medium, in which case the Leggett values would go down if they were averaged over the entire medium being sampled in NHANES. I don't know the answer here, but someone should look at that issue.

23. On Page 109, the authors state that "This methodology is intended to give a conservative estimate of IQ changes…" I cannot understand why it would produce conservative estimates. This requires some explanation.

24. I am not sure how I feel about Exhibits 6-2 and 6-3. They purport to show IQ losses due to background exposures to Pb. The problem I have with this is that everyone in the epidemiological studies was exposed to background. I don't see how these studies can measure anything other than the incremental loss of IQ due to incremental exposure above background. I suppose these two Exhibits simply assume that the dose-response curve above background extends down below background, and these Exhibits are predicting what the effect would be if even background exposures to Pb were removed from the environment. But I am not convinced this is a valid use of the epidemiological studies. I am ready to be convinced otherwise by our epidemiological colleagues.

Specific Charge Questions

1. My comments on the overall methodology are provided in the previous section. Applying them to the economic analysis will be more difficult since one must hypothesize some distribution of the kinds of renovations that will be done. But this problem is avoided by doing a benefits analysis only on specific renovation scenarios, rather than for the entire nation. As I mentioned earlier, I am not clear as to which is to be the application here.

2a. I believe the sensitivity analysis done so far indicates the most important factors to consider, and will be applicable over a large range of modeled scenarios.

2b. I think doing a separate Monte Carlo analysis for each house is both a waste of resources and likely to be inaccurate anyway. The parameter distributions used are difficult to relate to a specific house (and many are difficult to relate to a specific scenario), and so they are better applied to broad categories of houses and scenarios. I think a different Monte Carlo analysis for each house would be over-interpreting the data.

2c. I don't think there is any way to account for uncertainty and variability properly when making the transition from the Dust Study to IQ change results. The temporal pattern of exposures in these case studies is simply too different from those in the epidemiological studies to make any reasonable or defensible corrections. You are already doing the best that can be done.

2d. I do not recommend a separate Monte Carlo step. The epidemiological results already INCLUDE the effect of differences in the biokinetics of individuals in the population (i.e. the slope factors already reflect this variability), and it would be inappropriate (in my opinion) to apply these differences again in the proposed study through a Monte Carlo biokinetics model.

2e. I am comfortable with the way the probabilistic and deterministic aspects are melded in the current approach.

3. I would not use both until you can be sure that the central compartment model in which blood lead levels are calculated in the Leggett model are the same as those used in NHANES and in the epidemiological studies. See my earlier comment on this.

4. It is essential that the blood lead indicator (concurrent or lifetime average) be the same in the epidemiological study and the application. Given that lifetime average will be calculated for the case studies, it is appropriate to use the results of the epidemiological studies based on lifetime average.

5. I think the approach recommended is the best that can be done at present. I would not recommend changes.

6. This is outside my area of expertise.

7. Again, this is outside my area of expertise.

8. I believe you have chosen the correct ones. The one caveat I would make here is that I did not see any explicit mention of kids gnawing on window ledges. I had thought that was an issue.

Review of Draft Final report on Characterization of Dust Lead Levels After Renovation, Repair and Painting Activities

Doug Crawford-Brown

My first, and most general, comment is that this is quite an extensive study. Given the vast variability that exists between structures, and the variability between the way different individuals conduct any given task and even in the way the same individual will conduct the same task at different locations, study design was a particular challenge. The result is a lot of variability in results, not just in magnitude of change with and without rule practices, but even at times in the direction of change. Having said this, there really isn't anything the researchers could have done to reduce this variability, and one would expect this kind of variability to exist in practice anyway. As a result, I am comfortable with the overall design and conduct of the study.

My second general comment concerns a statement (and it is a key one) on page 2-2: "The study results may underestimate the levels of dust that would result from a renovation job due to the absence of these "real world" factors, but the study will achieve its goal of providing comparative data on the differences in dust lead levels when lead-based paint is disturbed under proposed versus baseline work practices". There is an implicit assumption here, often made in both experimental and modeling studies, that missing factors, or uncontrolled factors, might change the magnitude of results for a given part of the study, but not the RELATIVE magnitude of different parts. In this case, the assumption is that these missing factors won't change the relative magnitude, and hence the ratio, of dust lead levels with and without the rule procedures.

I don't buy this idea in general, and it becomes particularly less tenable as the ratios get closer to 1. I'm not saying the research design was flawed, because I believe the best approach to the study WAS to simplify matters by getting furniture, etc out of the building. I would go further to say that any responsible remediator of a home should clear the entire room before doing anything. And by having bare rooms, the study in effect removed a major source of variability that would have complicated the picture even further. But the authors need to do a slightly better job of explaining why the particular conditions of the study leave the results valid, rather than having this implicit assumption that their inclusion would not have changed the ratios of results for rule and baseline practices.

Homes were selected in part on the basis of the lead content of paint, which is appropriate. I even agree with the criterion, or cut-point, used for selection. But it would also have been good to show where the particular homes selected, with their specific lead concentrations (or fractions by weight), fall within a national distribution. I doubt there are any implications for study interpretation, but as a reader I just kept wondering how representative the levels are of homes that might need remediation in the future. I don't think this would have affected the ratios of floor, sill and/or soil lead levels (rule over non-rule practices), however.

At the beginning of the report, the authors are quite clear that there was a lot of variability in the background lead loadings on floors and sills in the various homes, even after the cleaning that took place prior to work. But then I can't see any place in the report in which these differences are reflected in the rule to non-rule comparisons. I would expect, for example, that the ratio of rule to non-rule lead loadings on floors might get closer to 1 as the pre-work loadings increase, since then the loading due to the work would become a smaller fraction of the overall loading. Perhaps I missed it, but I have looked several times for some sort of way in which this was accounted for. It could be accounted for by using the difference between pre and post loadings as the measure of impact, or it could be done by stratifying the results according to pre-work levels. At least some mention of this issue would be helpful.

I never fully understood the chosen length of time between the end of work and the taking of floor samples. It was about an hour, and this surely was selected based on the settling velocity of the lead in the air, but this wasn't made clear quantitatively. A simple graph showing the expected RATE of settling (grams per minute) in an originally contaminated air sample would have been helpful. That would show the decrease in airborne lead over time, and show that most of the airborne lead was gone by 1 hour, 2 hours, or whatever time was used (and presumably, therefore, present on the floor and sills). I also note that on Page 4-7, it mentions that there were times when this was as short as 30 to 40 minutes. Again, a curve would help clarify whether this is or is not a large issue.

A minor quibble: On page 4-3, the authors list the four Phases. Phase III says "No plastic covering and rule cleaning after work completion". It is not clear to the reader whether this means there was (i) no plastic covering but (ii) there was rule cleaning after work completion; or that there was (i) no plastic covering and (ii) also no rule cleaning after work completion. The same problem holds for the Phase IV description.

On Page 4-8 (and at a few other places, but 4-8 will illustrate the point), the authors state that at times, pre and post-work samples were not necessarily from the same spatial location. This occurred because a worker couldn't identify the precise location of the pre-work sample. This isn't troubling if there is not much spatial variability (on the scale of the difference between the two sample locations), but can be a large problem if there IS significant spatial variability. Something more needs to be said about this issue of spatial variability and its impact.

In a few places (Figure 6-1 is a good example), one of the axes in a figure has no units. In the case of Figure 6-1, the x-axis is unit-less. It is presumably the loading on the floor, but the reader doesn't know that.

I don't understand why Figure 6-2 shows only the floor loadings by job, rather than comparing with and without some sort of rule practice. Figure 6-2 just seems to aggregate results over too many dimensions for a given activity.

I realize I should be able to keep track of this myself, but I kept having to refer back to the text to understand the difference, in figures, between whether rule practices included BOTH plastic and cleanings. I kept feeling the headings should consistently describe what rule practices meant in all cases.

The bullet that straddles pages 6-13 and 6-14 confused me. I didn't think the job type or the amount of area remediated depended on the floor type. Are the authors suggesting that some types of jobs may have been disproportionately represented in homes that had wood floors, and especially in homes that had wood floors in poor condition? This would, of course, be problematic if true.

Figure 6-6 was the first figure where it struck me that error bars, or confidence intervals, really are needed in many of the figures. The two sets of bars are so close to each other in height that I began to wonder whether they had any significant differences. I realize this is dealt with later in the pair-wise statistical analyses, but the bars or intervals on these figures would have provided a better visual cue for me.

The third bullet on Page 6-23 mentions that air levels were higher when plastic is used on the floor. This may be due either to differences in the jobs conducted or the pre-work levels of lead (differences between rooms with and without plastic) or due to easier re-entrainment of lead dust when plastic is on the floor. Some comment seems warranted here.

In Table 6-10 on Page 6-27, the authors report results of dust loadings in trays. Presumably, this loading depends on the length of time the trays are exposed to the air. Is there a time associated with this sampling? Is it at some form of equilibrium?

The statistical analysis was well designed in my opinion, although there are so many analyses, on so few sample sites, I worry about the strength of any conclusions. But at least the results, summarized primarily in Figures 9-1 and 9-2 are consistent and suggest there is a beneficial effect of the rule practices. As mentioned previously, these figures would be improved by error bars on all bars of the graphs. It also would be good to show a horizontal line with the EPA target level (e.g., 40 $\mu g/ft^2$ for floors).

In tables such as 9-1, there is a value of the number of samples above a target value (e.g., the last column in that table). It would be useful to show the total samples collected for each row so the reader knows the fraction of samples above the target. The report doesn't explain whether compliance means NO sample is above the target, whether each part of a floor needs to be below the target, whether the target applies to the average of a floor area, etc. I realize that would be explained elsewhere in the actual rule, but it would be helpful for the reader to understand that here.

I wasn't clear whether Table 9-3 combines results across all categories of activities. I presume from Table 9-4 that this is the case, but the reader should be told this. And if this is true, is the conclusion therefore that in activities other than door planning and high heat gun, the rule practices are effective in reducing floor lead levels below the target? That seems to be a valid conclusion.

I now address the specific questions in the memorandum, although my answers are all contained at one point or another in the above:

Question 1. Yes, I understood the study objectives from the writing.

Question 2. Yes, I agree with the conclusions, although the discussion section could do a better job of explaining how the degree of inter-site variability in results produces some specific levels of uncertainty in the conclusions.

Question 3. Yes, subject to the comments I have above about axis labels and error bars and slightly improved figure headings.

Question 4. Yes, it was very well laid out. It was difficult to track through all of the various bodies of data, but that was because there were a lot of data and a lot of analyses of those data, rather than being due to any deficiencies in presentation.

Question 5. Yes, I found it easy to understand how the data were collected and how they related to the specific study objectives. I had to keep referring back to earlier sections to be sure I understood why a particular table or figure was important, but this is only natural in a report of this complexity.

Question 6. Statistical methodology is not my forte, so I can't comment on this.

Dr. Bruce Lanphear

Comments on "An Approach for Estimating Changes in Children's IQ from Lead Dust Generated during Renovation, Repair and Painting"

Bruce Lanphear

Most of my comments are to present an epidemiologic perspective to provide a reality check on the numerous assumptions underlying the two biokinetic models.

1. Page 92: The definition of hypothetical children and the time in their life when they are when they experienced the RRP activity is one reasonable approach, but many children experience more than one or even ongoing renovation or repair activities (see attached slide). It would be important to consider the impact on blood lead concentration and IQ when there is ongoing or > 1 renovation activities during a child's lifetime exposure.

2. Page 100: The estimated "Lifetime Average Blood Lead Levels" in Exhibit 5-6 are quite small across the Control Options. Since we know that much greater reductions in dust lead loading values can be achieved - and that the dust lead loading values can be quite high after renovation using baseline renovation and repair activities and cleaning procedures - the estimated reduction and subsequent benefits of the proposed rule dust is dramatically underestimated. Given these incorrect assumptions, it isn't surprising that there are small estimated differences in IQ scores by the various Control Options.

3. Page 107: The Report states, "Regrettably, there are little data available concerning the patterns of lead exposure of the NHANES participants." It is also regrettable that the US EPA didn't take advantage of the NHANES data set and insert relevant questions in NHANES because they collected blood lead levels and floor dust lead levels for housing units with children > 6 years of age. It if further regrettable that the EPA didn't plan ahead and fund the necessary epidemiologic studies in the mid-1990s, when Congress mandated the promulgation of this rule. Too often, there are delays in rule making until there is a lawsuit and then the EPA staff are given too little time and have too little empirical data to set scientifically-based health standards. This is an extreme example of a failure of leadership at EPA that has tremendous adverse consequences for the health of the US public.

4. The effects of IQ were apparently made only after accounting for background exposures. If so, you will underestimate the effects because renovation activities occur more frequently in owner-occupied housing in which children have lower mean baseline blood lead levels and because the greatest decrements in IQ occur at the lowest increments in

blood lead concentration and because children who live in owner-occupied housing are more likely to be exposed to renovation and repair activities and have lower baseline blood lead concentrations.

5. I would argue that the piece-wise analysis is more appropriate because the majority of children have maximal baseline blood lead 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 estimated -2.94 IQ decrement per 1 µg/dL should be used to estimate the effect of the proposed LRRP rule.

6. In addition to the current approaches, EPA staff should explore calculations to test whether the biokinetic models are valid or are in direct conflict with empirical data. One simple estimate of the impact of renovation and repair practices and the proposed rule on blood lead levels and IQ using empirical data is:

A. Begin with population mean blood lead levels for a cohort of 1 or 2 year old children from NHANES;

B. Estimate the increase in blood lead concentration due to renovation and repair activities using three values: 12.5% (Lanphear et al.) from unpublished research and by ~28-30% (from M. Rabinowitz, et al. AJPH 1985), and by about 20% (the midpoint of these two studies (i.e., a range of estimated increases in blood lead concentrations due to renovation).

C. Estimate the reduction in IQ associated with a increased in population mean blood lead concentration for the three scenarios (12.5%, 20% and 30%) using the -2.94 IQ decrement per 1 µg/dL from the piece-wise linear analysis for children with blood lead concentration < 7.5 µg/dL;

D. Estimate the range of estimated IQ benefits of the proposed rule (i.e., if the proposed rule reduces lead exposure and blood lead concentration by 25%, 50%, 100% or 150%) relative to the baseline practices. The estimated reductions in blood lead levels could use published reductions as well as the OPPT Dust Study. They should also include estimates of achieving dust lead loading values <10 µg/ft^2, as indicated by the HOME Study (Lanphear, et al. unpublished data). It should, as Rogene pointed out, result in a protective effect (i.e., an increase in IQ) for some children;

E. Use these empirical estimates to calculate the cost benefit of the proposed rule for a US birth cohort of 1 to 2 year old children.

Comments on "Draft Final Report on Characterization of Dust Lead Levels after Renovation, Repair and Painting Activities"

Bruce Lanphear

There are many aspects of this study that provide valuable data for the promulgation of a rule to protect children from lead poisoning after repair and renovation activities. Overall, for example, the results showed quite conclusively that the use of the proposed rule practices and plastic led to significantly lower dust lead loading values compared with baseline cleaning and baseline practice. I will focus my comments on the problems and limitations of the study.

Several decisions or exclusions described in this document will minimize or underestimate lead hazards created by repair and renovation. Similarly, they will underestimate the benefits of the proposed rule. This should be considered in the final rule. These include:

4. The draft report blindly accepts as truth that achieving floor dust lead loading values of 40 $\mu g/ft^2$ and sill dust lead loading values of 250 $\mu g/ft^2$ are sufficient to protect children, despite considerable evidence to the contrary. If the LRRP relies on clearance levels on floors above 10 $\mu g/ft^2$ or 15 $\mu g/ft^2$, it will inevitably fail to protect children who live in housing units that undergo repair and renovation. Any clearance levels in excess of 15 $\mu g/ft^2$ on floors and 50 $\mu g/ft^2$ on window sills should be justified in relation to existing epidemiologic data (see attachments for Lanphear, 1996, Lanphear 1998, Malcoe 2002, Lanphear 2002, Lanphear 2005). This is a problem throughout the document, but relevant examples can be found on 2-1, 1st paragraph and 3-4, 4th paragraph. Failure to account for the risk associated with floor dust lead loading values of 40 $\mu g/ft^2$ and sill dust lead loading values of 250 $\mu g/ft^2$ will result in a dramatic underestimate of the generation of lead hazards by renovation and repair activities.

5. Page 4-2, 3rd paragraph: Excluding 8 out of 35 housing units because they were in poor condition would tend to minimize or underestimate the generation of lead hazards from repair and renovation. Similarly, by excluding housing units with floors in poor condition, the differences in dust lead loading values between rule practices and baseline practices would be underestimated.

6. Page 4-7, 5th paragraph: Use of sample trays in place of window sills occurred because of inability to achieve clearance and insufficient sill surface area. Use of sample trays because of inability to achieve clearance would tend to underestimate lead hazards after repair and renovation.

7. Page 4-8, 3rd paragraph: The study design called for sampling to occur on actual floor surfaces, but plastic sheeting was used on some tool and observation room floors "because floors that were in poor condition were difficult to clean".

8. On the other hand, the use of procedures and practices that are prohibited (e.g., use of a heat gun > 1100º) and the inclusion of vacant housing units, may have exaggerated the lead hazards from renovation and repair of residential dwellings. Nevertheless, we can anticipate that many renovations and repairs will not be done using lead-safe work practice. Thus, I agree with the peer-reviewers of the OPPT Dust Study that adding these prohibited practices actually makes the study more realistic. Moreover, the cleaning done prior to implementing the study reduces the problem of including vacant housing.

Other comments:

9. As noted in the previous comments, there should be a review of the epidemiologic research linking renovation and remodeling with lead poisoning. This is particularly important because the limited sample size and questionable generalizability of the sample. There should also be a review of the epidemiologic evidence supporting the selection of floor dust lead loading values of 40 $\mu g/ft^2$ and sill dust lead loading values of 250 $\mu g/ft^2$.

10. Page 1.1, first paragraph: It would be useful if the report described how the paint lead levels and dust lead loading values in the LRRP studies compared with those in the National Survey of Lead and Allergens.

11. Page 4-8, paragraphs 4 and 5: Verification was not adequately defined nor was the description of post-verification floor lead sampling. Verification, which refers to a version of the "white-glove" test, is a misnomer. It is described by EPA as:

    > Disposable Cleaning Cloth/White Glove Study. EPA began looking for an alternative to dust clearance sampling that would be quick, inexpensive, reliable, and easy to perform. EPA conducted a series of studies using commercially available disposable cleaning cloths to determine whether variations of a ``white glove'' test could serve as an effective alternative to dust clearance sampling. White disposable cleaning cloths were used to wipe windowsills and wipe floors, then examined to determine whether dust was visible on the cloth. This determination was made by visually comparing the cloth to a photographic standard that EPA developed to correlate to a level of contamination that is below the dust lead hazard standard in 40 CFR 745.65(b). Cloths that matched the standard were considered to have achieved ``white glove.''

12. The problems identified in this Report highlight how ridiculous it is to try to replace a highly specific measure of lead in house dust (a dust sampling wipe test that quantifies the amount in lead in a uniform area and that has been extensively validated for its ability to predict children's blood lead concentration) with a simplistic and non-specific measure of discoloration. For example, during the study, the contractors found that using "*Simple Green"* could result in discoloration and that "some RRP contractors appeared more likely than others to consider discolored wet verification cloths to be clean, attributing discolorations to factors other than residual paint dust (with no apparent basis for such conclusions)". Finally, as noted in the Report, "*Overall, only 3 window sills failed the first wet cloth verification despite the fact that nineteen window sills had post-cleaning levels > 250 μg/ft^2.*"

    Despite these obvious problems and lack of firm evidence, the US EPA states: "EPA *believes* that adherence to this post-renovation cleaning verification protocol, in combination with the proposed training, containment, and cleaning requirements is a safe, reliable and effective system of ensuring that renovation activities do not result in an increased risk of exposure to lead-based paint hazards. In the great majority of cases, windowsills and floors that achieve post-renovation cleaning verification will also pass dust clearance sampling."

13. Page 6-1, Table 6-1 and page 6-5, 1st paragraph: Interior paint lead levels ranging from 0.8 to 13 percent (average = 4%) by weight seemed low. How do these values compare with the National Survey XRF values?

14. Overall, the results showed quite conclusively that the use of the proposed rule practices and plastic led to significantly lower dust lead loading values compared with baseline cleaning and baseline renovation and repair practices. Although this wasn't statistically significant across all rooms (e.g., observation rooms), the lack of a difference were likely due to small sample sizes.

15. Page 9-5, paragraph 3: The differences in dust lead loading values with and without the use of plastic sheeting (41, 43 and 39 μg/ft^2 for post-work, post-cleaning and post-verification compared with 51, 61 and 79 μg/ft^2) in the tool room, for example, were described as "small". I disagree. These differences are quite substantial on a population level, especially in view of the high dust lead loading values. The mean values will also mask exposures of some children to considerably higher dust lead loading values.

16. Page 9-6, 3rd paragraph; Of particular concern, "nearly half of the experiments ended with average work room floor lead levels above 40 μg/ft^2" - a level of settled lead-contaminated house dust associated with about 20% of children having a blood lead concentration > 10 μg/dL. Not surprisingly, the majority (20 out of 29) of floors that exceeded 40 μg/ft^2 were in housing units that had floors in poor condition. This finding

indicates that further research and more extensive cleaning will oftentimes be necessary to make housing units safe after renovation and repair.

Dr. Frederick J. Miller

An Approach for Estimating Changes in Children's IQ from Lead Dust Generated during Renovation, Repair, and Painting in Residences and Child-Occupied Facilities

General Comments:

The 2nd draft of this document is much improved relative to the presentation of the methodology. Staff have laid out the most important aspects of the factors to be considered in support of the analyses of the impact of renovation, repair, and painting activities in residences with lead-based paint or in child-occupied facilities.

For the types of analyses needed in support of the proposed rule, the Leggett model would appear to be more appropriate than the IEUBK model to use. Staff repeatedly phrase sentences towards use of the IEUBK model because the predicted blood Pb levels are lower and tend to agree more with values from NHANES. However, using NHANES as the baseline for comparison is equivalent to comparing apples to oranges as the NHANES survey had a large number of homes that did not have lead-based paint. Moreover, the stratification according to various demographics in the NHANES study argues that the overall population value not be used. Hence, it is quite likely that the upper tail NHANES data are the values that one should be comparing the blood Pb modeling results with. Discussions during the July 9-10 meeting with CASAC brought out the point that the IEUBK model did pretty well at handling the trends in the blood Pb data and most likely provides a lower bound on expected blood Pb values. It is also clear that the Leggett model results probably provide an upper bound on expected blood Pb values. I endorse using both models and letting comparisons with experimental data provide the decision point on the final answer as to which model provides the most relevant estimates for the exercise being undertaken here.

The document still has some technical errors that need to be corrected. One of the most egregious of these is a failure to use newer data on the deposition in the respiratory tract of children of various sizes of particles that will be present in indoor dust after Pb renovation activities. The result is an under prediction or an over prediction of lung mass absorbed depending upon particle size and age of the child. In addition, the models and methods do not appear to account for deposition in the head following inhalation of indoor dust, and yet this source likely accounts for more than 220 µg of Pb (assuming an indoor air level of 10 $\mu g/m^3$) that is transferred to the G.I. tract on a daily basis, which would be a value about 80-fold higher than what is input from the diet on a daily basis. Some way needs to be developed to incorporate head deposition in the inputs to the blood Pb models.

The authors of this document seem to have combined the concepts of uncertainty and variability into one lumped category. Variability stems from differences in the population being studied with respect to any number of factors such as type of housing, inhalation rate, ability to clear Pb from various organs, etc for which no additional data can be obtained to delineate among the individuals. Uncertainty, on the other hand, reflects the fact that the choice of variables or the use of methods, models, etc can lead to plausible different answers about risk, some attribute like blood Pb, etc. As such, the sensitivity analyses need to focus on whether a variable or factor imparting uncertainty can make a difference in the "bottom line" outcome.

While on the right track, the sensitivity analyses that were performed are not sufficient to provide a sense of the importance of the input variables that were allowed to vary relative to estimating dust concentrations. Specifically, all input variables were allowed to vary only by 10% and the resulting elasticity and sensitivity statistics computed. Without knowledge of the standard deviations about the mean for all of these input variables, one would have to suspect that not enough variation in the input variables was studied. For each input variable, does a 10% change correspond to a standard deviation, two standard deviations, $1/4^{th}$ of a standard deviation or what? This review suspects that for most input variables, the 10% change is far less than a single standard deviation from the mean and therefore, is not sufficient to really establish whether the input variable contributes significantly to estimations of dust concentration. Discussions at the July 9-10 meeting with CASAC clearly reinforced the above comments.

It would be helpful to the reader if the authors would include a discussion of how far the elasticity and sensitivity statistics need to depart from zero before one should conclude that the calculated deviation is indeed significant, if not statistically, then from a data interpretation viewpoint. Without such a context, one can not really identify which input variables are the most important drivers of changes in the Pb dust concentration changes.

The Monte Carlo simulations that were done for uncertainty in indoor dust Pb concentrations are described briefly in the text and more explicitly in Appendix D. The text description of how the Monte Carlo simulations were done glosses over the major distributions assumption that is explained in Appendix D. The authors state in this appendix how the low and high values for the variables listed in Exhibit 4-13 were used to determine whether a normal or a lognormal distribution was more appropriate to use in the simulations if a standard deviation was not given for one of the input variables. The authors simply state the assumption without any defense of it. The assumption was that the low observed value represents two standard deviations below the mean and the high value represents two standard deviations above the mean. There is no scientific basis to defend this assumption, which makes the Monte Carlo simulations suspect as to what extent uncertainty in Pb dust concentrations has indeed been captured.

For the Monte Carlo simulations, Appendix D states that a coefficient of variation (CV) of 2% was used if no low and high values were available and also that the variable was assumed to be normally distributed. Discussions at the July 9-10 meeting brought out that the 2% was really supposed to be 200%, which is more than satisfactory as a default CV. Other assumptions, such as assuming children occupy the entire house or the entire yard equally during the renovation project, are not justified and weaken this reviewer's confidence in the Monte Carlo modeling results. Also, the use of 1.2 as the GSD in the Pb lead models is a gross underestimation that minimizes variability in the predicted outcome variable, and as noted during the July 9-10 meeting needs to be between 1.6 and 2.1 to capture uncertainties in this part of the analysis. Furthermore, since the real issue is the extent to which the indoor air dust concentrations of Pb impact blood Pb levels and thus IQ, more attention should have been given to Monte Carlo modeling that extended to the final endpoint – estimated impact on IQ changes due to the various types of renovation projects.

Specific Comments:

Page, Line #	Comment
Exhibit 3-6	The use of black and grey does not come through very well in this exhibit and in others. Perhaps the steps that are discussed in Chapter 4 should be italicized instead.
Sec. 3.3.1.3	The assumption that the background indoor air concentration equals the background ambient air Pb concentration is not reasonable. From the PM CD, we know that not all outdoor particles penetrate indoors and that the percent that do penetrate is a function of particle size. Thus, the 0.025 µg per m^3 is too high and should be adjusted downward.
Sec. 3.3.2.2	The practice of setting values below the detection limit to a level of 1/4th of the detection limit is not really defensible. Staff should be using the statistical methods developed by EPA (Dr. John Creason) for left censored distributions. The authors should indicate what percentage of data comprising Exhibit 3-9 is reflected by values below the detection limit. The fact that 5/9ths of the cells in Exhibit 3-9 are values below the detection limit compounds the error being made by not using the statistical methods for left censored distributions.
Sec. 3.3.3.2	What was the method used to determine outdoor soil values and how could the concentrations be < 0? No defense is provided for setting values to 5 µg/g when the measured value is < 0. The authors should describe how frequently this type of adjustment had to be made.
Sec. 3.4.3.1	In the first paragraph of this section, the authors refer to the geometric mean, minimum and maximum concentrations as being labeled mid, min and max, and they state that Exhibit A-4 gives these indoor air concentrations. Only the mid value appears in Exhibit A-4. What is the range of sample size associated with the various combinations for which geometric means were generated? If the Ns are small, this presents a major problem for the subsequent analyses and models that use the indoor air concentrations of Pb.
p. 43, line 6	A geometric mean of geometric means is described here, but the calculated mean should be a weighted geometric mean unless the sample sizes are essentially the same for all of the combinations being averaged.

p. 44	It is noted that loading values for the Rest of Building increased between the post work and post cleaning measurements, from 1 μg/ft^2 to 1.5 μg/ft^2. This is probably an artifact of the arbitrary decision to make values equal to 1/4th of the detection limit.
Sec. 3.4.4	How did staff come up with the example scenario of multiple renovations? Some discussion of this selection is needed.
p. 48, line 15	The paragraph states that it is unclear whether the assumption of indoor air concentrations being equal to outdoor air concentrations produces either a positive or negative bias in estimated blood Pb levels. Indeed, since not all particles penetrate inside a home, a positive bias should be expected.
Eq. 4-3	Shouldn't the term in the exponent of e have a negative sign in front of it? Otherwise the decay constant must be negative because the equation is relating to estimating concentrations during the Settling phase and the air concentration should decrease.
Exhibit 4-3	If I understand this table correctly, the base control option, which includes no special cleaning or plastic placement measures, produces the lowest Pb air concentrations. What am I missing?
Exhibit 4-4	Same comments as for Exhibit 4-3.
Eq. 4-5	What is the adjusted R^2 for this equation? This is needed so the reader can judge just how good the model fits the data.
Exhibit 4-9	This reviewer does not see where Option 3 is plotted.
Exhibit 4-11	This exhibit gives non-water dietary Pb intake estimates. Beyond the first year of life, the values go up and down by year and only vary between 2.6 and 2.99 μg/day. The question arises as to whether these values are really different from each other. In addition, their use in the blood Pb models imparts variability that is not of interest and that is probably not biologically significant. Consider using the overall average for years 1 to 6, which is 2.76 μg/day
Exhibit 4-14	The reader can not currently tell which is Control Option 2 and which is Control Option 3. One would assume that the last bar in each set of 4 is Control Option 3, but the reader should not have to assume anything.
p. 85, line 21	The statement is made that the approach (no effort made to ensure that children remain outside the work area during renovation) gives a conservative estimate of exposure. To the contrary, this ensures that a liberal exposure scenario is used. As an aside, given our societal knowledge about the harmful effects of Pb, it is unthinkable that a parent would not ensure that a child is removed from the area while major renovations are being implemented.
Sec. 5.1	Why isn't the O'Flaherty model discussed here? It certainly has more positives that the IEUBK model for this particular application.

Exhibit 5-2	This exhibit is not needed. The text adequately describes the exposure patterns for the 6 children example.
Exhibit 5-3	The absorption factor for the lung given in the exhibit is 0.42 based upon a 1989 USEPA publication. This absorption fraction only holds for total deposition of particles that are 0.5 μm in size. Lung deposition for children is typically much less than this. There are more recent estimates of the respiratory tract absorption of particles in children that should be used (e.g., the MPPD model available from the Hamner Institutes for Health Science). This reviewer pointed this out for the Pb CD and is including a table at the end of these comments appropriate for a 3-year old child. There is no excuse whatsoever to not use the correct absorption fractions as a function of age and of the particle size distribution that the indoor air will contain when renovations occur. Moreover, the renovation activities will lead to a great amount of larger particles that will deposit in the head. I see no place where URT deposition is taken into account. The Leggett model should be able to be adjusted to incorporate URT deposition.
p. 99, line 3	The NHANES data are not appropriate for use as a benchmark to determine which model (Leggett or IEUBK) provides the most appropriate modeling results unless the data relate to specific strata from NHANES. One is comparing apples and oranges here because probably most of the NHANES houses did not contain lead-based paint.
Sec. 5.5	The discussion about dust ingestion rates and GI absorption likely being important contributors and sources of uncertainty, while appropriate, begs the question on a major source of uncertainty that is not being addressed anywhere – namely deposition in the head of most of the dust from the renovation projects and the quick translocation of this material to the G.I. tract.
p. 109, line 8	While it is correct that the log-linear model produces unrealistic results at a blood Pb of zero, the model should never be applied there. Given the uncertainties in the analyses being conducted here, the models should not be used at low Pb blood levels (i.e., < 0.5 to 1 μg/dL.

	Regional Deposition Fraction for a 3 Yr-Old Child[a]			
Particle Size (μm)	**Head**	**TB**	**P**	**Total**
0.5	0.208	0.047	0.164	0.419
1	0.243	0.047	0.167	0.457
2	0.264	0.064	0.269	0.597
2.5	0.27	0.077	0.312	0.659
3	0.243	0.047	0.167	0.457
5	0.332	0.178	0.313	0.824
7.5	0.443	0.317	0.133	0.894
10	0.562	0.324	0.027	0.912
12.5	0.647	0.245	0.0027	0.895
15	0.686	0.167	1.5 E-4	0.853
20	0.649	0.074	7.0 E-7	0.723

[a] The deposition values are from the MPPD model, which is available from the Hamner Institutes for Health Science, 6 Davis Drive, Research Triangle Park, NC

Dr. Maria Morandi

Characterization of Dust Lead Levels after Renovation, Repair, and Painting Activities (OPPT Dust Study)

Preliminary comments for July 9 meeting.

Maria Morandi

General Comments:

The report presents a detailed description of the objectives, rationale, practical (operational) limitations due to field constraints over initial protocols, sample collection, and data analysis. The description of actual field conditions and deviations from original protocol presented in Chapter 3 and the field experiments in Chapter 4 is detailed and a strength of the Report. Appendix A is very helpful in providing further detail, as are the rest of the appendices. However, there is a sense of too much information so that sometimes it is difficult to keep in mind the essential objectives of the study.

Given the nature and amount of the data collected, it would be useful to have summary of results and conclusion beyond the very brief Summary presented on page 2-1. My suggestion is to move the May 24 – June 11, 2007, peer review from the main body of the Report and perhaps place it in an Appendix together with any subsequent peer reviews. The Summary section should be expanded in a manner that provides the findings addressing each of the objectives listed on pages 1-2 and 1-3, followed by a paragraph presenting limitations and caveats.

While the conclusions of the study are generally correct in that the rule package did result in overall lower post-job levels than the baseline conditions as determined from analysis of the log-transformed data, but there was variability among contractors, workers and jobs, with the differences not been uniform. These results raise the question of how (and if) the Dust Study differences may underestimate variability upon rule implementation given the broader universe of contractors and owners that will not be knowingly part of an experimental study and subject to the typical time pressures “to get done with the job” Obviously, this could have implications for the estimation of blood lead levels and IQ decrements.

There is a concern that when the post-job or post-cleaning Pb values do not achieve the EPA guideline, the values tend to be somewhat dismissed either because of some alteration of the protocol or housing condition. This is problematic because it is likely that these are highly likely to occur during actual abatement implementation. The main objective of the rule is to assure appropriate and safe abetment for all Pb contaminated housing, so if the proposed rule is not effective for certain activities or residential/building condition, it would be advisable to determine what additional modifications to the rule or further modifications need to be undertaken.

The response to the prior reviewers of the report accurately indicated that analyses of workers Pb exposures as part of the report was not done because it was not contemplated in any of the study objectives. However, this is a weakness in the report. As we all know, there were serious concerns about worker exposures in the asbestos abatement program and it would seem appropriate to address the potential for excessive occupational exposures, bearing in mind that PPE principles were probably more strongly adhered to than it would likely occur once implementation of the rule takes effect, as the Report indicates on page 3-8. It is not quite convincing that these data cannot be used because of IRB stipulations since the data analyses and presentation can be done using personal de-identifiers which is a standard approach for reporting such findings. It seems a waste of potentially important information from an occupational health stand point not to use the exposure data, obviously a new IRB application would be required for secondary use of the personal data.

Charge questions:

Issue 1) Study Objectives

Question 1) Are each of the study objective objectively and transparently addressed in the data analysis and conclusion of the report?

The study objectives are addressed in the report. However, because of the profusion of data and their analysis it would be advisable to provide an objective by objective conclusion in the Summary. I addition, it would help the reader if the pertinent sections of the report are cited under each of the objectives (following the same format as in the last paragraph of page 5-3, or Chapter 7, for example).

Issue 2) Study Conclusions

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.

In general yes, except when the post cleaning levels do not achieve the target levels, then the data are dismissed.

Issue 3. Range of Data

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?

Yes. I found the graphs especially useful.

Issue 4. Report Organization and Clarity.

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

The layout of the report is logical and consistent. Given the amount of data and analyses presented, it cannot be described as an "easy read", but it is clear and can be followed and probably clearer that most reports of this type.

Issue 5. Data Collection and Descriptive Analysis

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 data collection and the descriptive analyses of the data been objectively and transparently described in Chapters 3, 4 and 6?

As indicated earlier under General Comments, the description of the data collection and field activities, especially the deviations from the original protocols, are strength of the report and the authors should be commended for that.

As much as possible, descriptive statistics on paint Pb content should include some indicator of distribution, as is done in a limited way for other information such as the duration of activities or cleaning times. The scatter plots are especially illustrative.

Issue 6. Statistical Modeling Results

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

The methods are described in a manner that is understandable. What are less clear are the assumptions used for the choice of statistical analysis or models? /**-*-y concern is that given the variability in the post-data, modeling based on geometric measures of central tendency may not be the best approach to evaluate if adoption of the rules will meet the intended objectives.

Dr. Paul Mushak

POST-MEETING COMMENTS: REVIEWS OF THE EPA-OPPT DUST STUDY AND DRAFT DOCUMENT ON AN APPROACH FOR IQ CHANGES DUE TO LRRP ACTIVITIES

Reviewer: Paul Mushak, Ph.D.

There appear to be two Panel review positions, judging from the mix of submitted comments and views expressed at the 7/9-10/07 meeting. Some members favor setting aside or greatly adding to this draft. Others favor making enough interim repairs to the draft to make it at least minimally acceptable for cost-benefit analyses. The repair camp appears to focus on just getting the draft materials to a certain point, albeit with flaws. The trade-in group focuses on whether the approach will be adequate for reliable use throughout the nation.

I am more or less in the trade-in camp, but I'm quite prepared to be convinced otherwise. I still see high barriers to acceptance of the draft approach. Furthermore:

- I admit I still don't quite follow what we're being asked to do for this draft approach review.

- We first have the general and underlying problem of communication. OPPT seems to be talking to the Panel in "reg-speak" and "law-speak" while the Panel is talking to OPPT in "tech-speak." This gets into dialogue problems of non-aligned vocabularies that complicate effective peer review.

- OPPT appears mainly interested, and has repeatedly reminded the panel of that interest, in getting the Panel's take on the conceptual and qualitative virtues of its approach. OPPT is seemingly less interested in the specific outputs of the methodologies in that approach. OPPT presenters appeared frustrated in the meeting by the Panel's continuous framing of the dialogue through a battery of quantitative criteria it considered necessary for review.

- Is the principal need for review of the OPPT's draft approach simply that (1) OPPT needs the Panel to say whether the approach is feasible or not, rather than (2) the Panel needs to conclude that the approach can only be judged feasible if it is judged to be case-accurate or even case-reasonable?

- I believe the Panel generally accepts the notion that adherence of the OPPT methodologies to quantitative criteria is the critical prerequisite to review sign-off. How rigid the applications of those quantitative criteria have to be appears to define the bifurcated views of the Panel. Nonetheless, I don't see how either OPPT or the Panel can escape the link between conceptual validity of some approach and quantitative criteria for validating the concepts.

- If the above indivisibility for validation does not govern, then how would one advise OPPT on any revised approach strategy, not just the one at issue? How could one tell OPPT that if the end results of the OPPT formulas and potions in the review draft or revised version do not make quantitative scientific sense, there is still conceptual validity to the approach?

- I suspect that the Panel would have a more unitary view as to advising OPPT if, at the end of the day, it concluded *(i)* one could harvest enough RRP field data relevant to national scenarios, *(ii)* one could generate plausible and reliable environmental media lead data sets for biokinetic modeling, *(iii)* one had access to reliable biokinetic, mechanistic models into which these reliable data sets could be input, and *(iv)* one could generate quantitatively reliable health risk dose-response relationships as IQ changes. One can question whether the first three of these elements are even present. That is, it is not a matter of the Agency and the authors merely doing a better conceptual structuring and presentation of existing data.

Differing views and perspectives can perhaps be better represented to the various consumers of the review by a simpler illustration. Consider a parcel shipping approach instead of a health risk causal chain approach. If one asks in broadest terms whether one can have delivery of a parcel to Seattle by sending it from New York the answer is obviously yes. One also answers yes to questions that address a set of specifics. Can one get a parcel delivered from NY to Seattle by shipping via FedEx or UPS Air? UPS/FedEx Ground? U.S. Postal Service? Someone in NY actually taking it to Seattle by flying there? Driving there? Someone going by ship with the parcel from NY through the Panama Canal to the Port of Los Angeles and taking a train to Seattle? And so forth.

- All the above approaches are qualitatively feasible but obviously differ in such quantitative characteristics as overall cost, effort and temporal uncertainty as to date of delivery or knowing all of the variables that operate and have to mesh to assure delivery.

- For purposes of cost-benefit analysis, any one of the above scenarios within the overall goal can be monetized. So, the real question for the shippers is which scenario is governing, if any?

- One can then elevate the role of uncertainty in the process by saying that (1) the parcels contain valuable but perishable contents, and (2) if the delivery is not timely, the contents spoil and the parcel is worthless. We have specified the nature of the parcel at issue, regardless of how it's shipped. We then have to stratify the level of uncertainty, i.e., get quantitative, because the risk of contents becoming worthless increases with the increase in uncertainty about delivery being prompt enough to prevent the contents becoming worthless.

- We readily conclude that the odds for preserved value of contents are greatest using an air express overnight shipment. That is, this choice will result in the least likelihood of a spoiled, worthless shipment because it is the most temporally certain of the options. Inasmuch as the other alternatives for delivery of the valuable but perishable contents have increasingly greater uncertainty, their usefulness for the purpose at hand C assuring delivery of contents that have not perished and retain their values declines significantly.

- A panel of parcel shipping experts advising on various shipping options would be able to address qualitative feasibility straight away but certainly would not see simple questions of feasibility as those that are ultimately governing. They would focus on the best way to preserve value and utility of perishable shipments. They would never argue that the method of shipment is irrelevant because the level of temporal uncertainty is irrelevant to preservation of a parcel content's value. They would particularly never argue that shipments whose stability and utilitarian value are time-sensitive do not require any more certainty about beating the clock than those that are not time-sensitive.

In the case of this Panel review, another broad aspect the Panel needs to wrestle with is the atypical nature of the RRP activity to be regulated vis-à-vis the proposed approach. This was not communicated very well to the Panel. The proposed RRP Rule, as I understand the Rule's regulatory purpose, addresses a situation that is the flip side of typical TSCA or even other regulatory rule making on lead (CERCLA, RCRA, CAA NAAQS for Pb, the Lead-Copper Water Rule, etc). Specifically, much of lead hazard control rule-making in the Federal government confronts situations where a lead exposure/health hazard already exists and the point of the rule is to oversee discernible reduction of the hazard, e.g., lowered 95th percentile or median Pb-B levels.

In cases of Superfund site evaluations, one of the areas I've been involved with, one includes a human health risk assessment for the no-action option ("Baseline" risk assessments). That is, one quantifies hazards to risk populations if an already-existing hazardous waste site is not cleaned up. For lead, the relevant cohort of exposure children at the site will typically have a log-normal distribution of Pb-B values and one is especially focused on the most exposed children. That is, the focus is on those in the upper tail of the exposure (Pb-B) distribution.

The RRP Rule has to address the atypical scenario where an activity, RRP jobs involving lead-painted surfaces, will produce or potentially significantly increase lead hazards and some level of associated lead exposures of children rather than reducing them. As Ian von Lindern correctly noted, the RRP scenario is one where children in older housing with relatively low Pb-

B levels are at risk to have more exposure, not less, with lead dust-generating RRP work. Taking Dr. von Lindern's point further, the purpose of the Rule becomes preventing increased blood lead for those kids in the lower tail of the distribution as much as it is preventing increased Pb-B levels of children in the upper tail of the distribution.

Toxicokinetically, moving children in the lower tail who have low Pb-B values to higher Pb-B concentrations not only produces higher health risks but induces higher risks along a portion of the dose-response curve for IQ loss that is the steepest, i.e., most robust for blood lead maximal impact. For example, if RRP activities increase a child's Pb-B from 2 to 6 µg/dl the impact on incremental IQ point loss is comparatively more than IQ change in the upper but shallower portion of the Pb-B versus IQ loss curve.

Other serious flaws in the draft approach exist. Collectively, virtually all assumptions used in the approach have had the net impact on the methodology outputs of understating health hazards, specifically reduction in IQ, with RRP activity intensity and multiplicity.

The inclusion of sensitivity and similar testings, e.g., Monte Carlo analysis, are useful in direct proportion to the amount of empirical data available for crunching. The size of the data sets used here versus the needs of the approach are so disparate that it's not clear how much value accrues to such analyses. A number of the Panel members also made it clear in writing and meeting comments that incorrectly used constraints on parameter specifications for doing the sensitivity and related analyses in the draft report created a host of artifactually predetermined responses to parameter tweaking.

The two biokinetic models selected for simulation of lead exposure of the target children are themselves limited for the purposes to which they were put. The IEUBK model, on balance, is ill suited kinetically and mathematically to the type of body lead changes arising from transitory changes in lead intakes from RRP activities and would not be recommended for that purpose.

Note that the absolute and incremental values for Leggett versus IEUBK models tabulated across the various Chapter 5 Tables track in about a 3:1 Leggett/IEUBK ratio. That does not validate the utility of IEUBK for very short-term Pb intakes from RRP activities. That ratio is simply an artifact of the IEUBK model not differentiating between acute/sub-chronic intakes/inputs to the models and stable, steady-state inputs. That is, with dust lead, inputting a daily dust Pb intake of X µg to the IEUBK for a three-day Pb intake at that level is perceived by the model as being the same as a steady-state 6-months of daily dust Pb inputs. It will produce Pb-B simulations that assume input stability. One fools the model by ignoring the model's assumption and requirement of stable, steady state lead inputs for proper use. The model's exposure module does not filter or censor for temporal stability of environmental inputs.

The IEUBK model is still valid for background Pb-B from preexisting (pre-RRP or stable) dust lead based on its close match to the relevant NHANES III, Phase 2 Pb-B descriptive statistics for Pb-Bs of U.S. children 1-5 years of age in variably-aged housing.

The Leggett Model also presents problems for this particular OPPT draft approach. One problem is that the Leggett model starts with the background, pre-RRP Pb-B distributions at too high a value, based on the above relevant strata of NHANES data. Leggett also shifts incremental changes in Pb-B with various RRP activities to the shallow higher portion of the Pb-B vs. IQ curve, i.e., > 10 µg/dl. We then have an artifactually created lower IQ vs. Pb-B relationship compared to the curve segment below 7.5 µg/dl Pb-B. Sean Hays is correct that the increments from Leggett are not the absolutes from Leggett, but the increments from Leggett are numerically higher for some Pb intake change than the increments from the O'Flaherty and IEUBK models when applied to stable, steady-state conditions. The comparison is evident from the text material evaluated by the EPA All Ages Lead Model evaluation Panel where all three models are compared and contrasted with empirical data.

On balance, we cannot say that the actual Pb-B is bounded by the two model estimates. There are no reliable bookends and, even if there were, the models would be bracketing outputs as Pb-Bs that are derived from modeled, not measured, data. Also, the bracketed modeled Pb-B values would have a range that is arguably very small when superimposed on the overall huge uncertainty to Pb-B values propagated from start to finish in the derivation of both Pb-Bs and the IQ changes from those Pb-B changes.

Use of More Empirical Data

The Panel would probably be more comfortable striking a compromise if OPPT used more empirical data at the various steps along the way, either to augment the modeling or, more appropriately and typically, to serve as higher priority for uses in the approach. Modeling is typically validated and calibrated with empirical data, rather than vice-versa. This is not inviolate. One explanation of disagreement between measured and modeled data, as I noted in a 1998 paper in EHP, is that in fact both are wrong, but each is wrong for different reasons.

The Panel discussed some empirical data options for either expanding the draft approach or giving it higher priority. Attention was given to more use of the Lanphear data that have within the measurements useful information about remodelings.

I believe the best choice for determining background Pb-B for variably-aged housing are the relevant NHANES III, Phase 2 values. One cannot use NHANES national strata or aggregated overall snapshots of national lead exposures for specific geographic and demographic segments of the nation, e.g., for children who live in Baltimore or Atlanta, but one can use the strata in the national NHANES picture for comparisons to OPPT approaches that are also for national strata. GM values (Table 1) and % exceedences. 10 µg/dl (Tables 1 and 2) in Pirkle et al., 1998 for housing in the age bands “< 1946”, “1946-1973”, and “After 1973” give the corresponding NHANES GMs for 1-5 year old children of all races, income and urban status: 3.8, 2.8 and 2.0 µg/dl respectively.

Ref:

Pirkle JL, Kaufmann RB, Brody DJ, Hickman T, Gunter EW, Paschal DC. 1998. Exposure of the U.S. population to lead, 1991-1994. Environ. Health Perspect. 106: 745-750.

I would suggest the OPPT authors also have a look at two papers that described lead dust control steps as part of interim lead paint hazard controls on a national rather than localized basis. These would be equivalent to the no plastic/Rule cleaning, i.e., Control Option 1 for the draft approach but would reach to national results.

One focused on interior repainting of deteriorating lead paint areas and window replacement as used in multiple programs around the nation as part of the HUD Lead Hazard Control Program described in Galke et al., 2001. The national research projects summarized as to hazard reduction activities and their impacts on Pb-B over time were not lead paint abatements per se. That is, the projects in Galke et al. would have useful information about lead dust control options for RRP activities.

Galke et al. reported on Pb-B versus dust lead changes longitudinally for 1212 dwellings around the nation. The most common interventions in their Table 1 included repainting or repainting in combination with window replacement. This was followed by cleaning equivalent to the Rule cleanings. The changes in dust lead loadings with types of activities are given in their Tables 2 and 3.

Ref:

Galke W, Clark S, Wilson J, Jacobs D. et al. 2001. Evaluation of the HUD Lead Hazard Control Grant Program: Early Overall findings. Environ. Res. 86: 149-156.

The second paper is that of Ettinger et al., 2002, where a professional interior dust lead cleaning protocol was employed to reduce interior dust lead levels using HEPA cleaning and two-bucket mopping with wipe cleaning afterwards. Again, it’s equivalent to the no plastic/Rule cleaning or Control Option 1 in the draft. A total of 765 homes were given dust lead clean-ups, and 213 of these were tested for pre-and post cleaning dust-lead loadings. Cleanings were especially effective where pre-cleaning lead loadings exceeded the EPA and HUD dust lead standards for floors and sills (and troughs for clearance testings).

Ref:

Ettinger AS, Bornschein RL, Farfel M, Campbell C, et al. 2002. Assessment of cleaning to control lead dust in homes of children with moderate lead poisoning: Treatment of lead-exposed children. Environ. Health Perspect. 110: A773-A779.

Dr. Michael Rabinowitz

Review by Michael Rabinowitz of
"DRAFT FINAL REPORT ON CHARACTERIZATION OF DUST LEAD LEVELS AFTER RENOVATION, REPAIR AND PAINTING ACTIVITIES" Jan 23, 2007 Draft

General Comments:

Overall, this report convincingly shows that lead contamination and exposure from old lead paint is more severe from some activities than others, and that some appropriate work rules can significantly reduced that exposure. The series of sites and measurements that comprise the data, their analyses, and presentations all were executed in a way that should bring real useful clarity to our understanding of this topic. It was clearly written, although I offer below a few suggestions.

It might be helpful to know to what extent the specific sites studied here are representative of the range of situations found across our nation. Climate, land use patterns (lot size and zoning, for example), historic use of lead paint and building stock (type, materials, age, for example) all vary even more widely than the variability studied by Battelle here. I raise this not to in any way invalidate this study but rather to ask if we can expect similar results as these proposed rules are applied nationwide.

I can only guess the variability and magnitude of the results if they were to be collected across sites nationwide. How effective one method or another might be in reducing risk might depend on humidity or how air tight or well ventilated a home might be or proximity to their neighbor. But I would also guess that these would be relative minor effects compared to the main findings here. The over pattern of risk reduction with rule implementations demonstrated by this Report likely do apply nationwide.

Lead containing paint is a hazard. Over time, as it disintegrates slowly or rapidly from RRP, it generates toxic dust. Since some of the RRP methods appear to generate much more of this dust, one might ask if it would not be better to leave intact paint alone rather than perform the RRP in a way that causes a short-term problem. To avoid answering this affirmatively we should be sure the recommendations for RRP rules are sufficiently rigorous to mitigate any harm.

Some Specific Responses to the Text:

Page 1-1 line 5 For what its worth, allow me to note a further, perhaps un-necessary, description : Because of formulation changes in American paints, not only was lead paint more common among the older homes (as is noted in the text), but the lead content of that lead paint was much higher. For example, white ready-mix house paint in 1940 averaged 4.1 pounds of lead per gallon compared to 2.1 pounds per gallon in 1948. (Larson, L. P. and J.H. Calbeck Comparison of Pre-and Post- War White Outside House Paints, Paint, Oil & Chemical Review, June 9, 1949, vol. 112, p25-50). Older paint formulations from the 1920's and 30's tended to be even higher in lead content, and during the 1950's the fraction of lead in the lead pigments continued to drop.

Page 1-2 This list of Objectives is admirable. I look forward to seeing it in the conclusion as list of these along with the findings.

Page vi " Lead-based paint" are defined here as anything above ½ percent lead by weight. I recognize that this is well accepted jargon, even in statute. However, with a view to accuracy I feel compelled to object (likely fruitlessly) to this wording.

To me "Based" means "made of" or "fundamental to". The term does apply when lead was the major ingredient, more than half of the mass of the liquid paint, maybe four pounds per gallon. Lead was the only or major source of the paints opacity and hiding power as well as a white base to which colors or tints could be added. Lead also acted as a drying agent and gave the dried film its longwearing, waterproof plastic body. However, when paint is found with less than a few percent lead, as when some yellow or green lead based pigments or when lead napthenate drier are used, it does not meet my criteria for being " lead-based". Lead is a minor ingredient. I would have preferred "lead–bearing" or "lead-rich" paint, or "lead paint". But using the broad term "lead-based" is so imbedded in our usage and recognizing it is only a matter of semantics without substantive difference, I am close to surrender on this point. I would be pleased to see the term "lead-based paint" replaced with "lead paint".

Page vii Specialized cleaning- Regarding the wet moping- Is it worth noting somewhere that neither phosphate not EDTA wash waters were used. Perhaps the use of these has been addressed elsewhere?

Page 2-1 line 2, between ….results in ____ lower……
I would invite you to add here a descriptor of the magnitude of the reduction such as "Somewhat", "slightly", "much "(my favorite), or "markedly " or ….

In chapter 9 where this appears again on page 9-1, a descriptor of magnitudes would be useful. So much is said about p values and statistical significance, something more about effect size would be welcome.

Page 3-3 Ambient Air Sampling- it looks like air volumes were so small that detect-ability becomes a concern. Because generally air values were shown to be low, this is of less importance. I am curious what the limiting factor was. Could the air flow rate or the sampling time be increased? Were the Samplers to noisy?

Page 3-9 Worker blood lead monitoring was required for worker protection. However, unless the workers were generally assigned specific jobs (some always sanded, others always door planed…) I suspect nothing would be found that might help us assign risk to each task or rule. Still, I would be curious what the impact of this de-leading work was on the workers, how much, if at all it went up as a group, and if any individual's stood out. I hope not.

Section 4 was especially well written. It seemed all reasonable. I particularly like the section starting on page 4-6 about occasional deviations from the protocol. It gives the reader a much clearer idea about what actually happened and a sense of the complexities.

Page 5-2 Fourth paragraph. Can you tell us what fraction of the environmental samples required imputation? It may have been very low for the dusts but much higher for the airs. Could be also addressed in Section 8?

Section 6
Is it worth making a multiple regression model of dust lead using paint lead, area of work, remediation method (job), and phase, for example?

Page 6-6 Figure 6-1 If the independent variable is the area disturbed, why not have that on the x, horizontal axis? The line would curve up sharply and then more to the right and become flatter.

Page 6-10 Tables 6-5 and 6-6 I could use to illustrate one of my own personal peeves, the fear of rounding off. Do we really need 5 or even 8 significant figures? I would not think any less of Battelle's precision if they reported the total average lead wipe as 23.7 mg or 23,800 µg instead of 23,770.7 µg. It is a form of clutter to me. Also, the tabulated precision exceeds by orders of magnitude the analytical precision on which this is all based. So, I suggest rounding off to 3 significant figures.

Figures 6-2, 6-3, 6-4 , and 6-5 present some of the most significant findings in a clear manner, so I would assume they would be selected to be carried forward to any summaries. How can they be improved? Is a sub-title appropriate, with information, taken from the text, that might allow this figure to stand on its own more? Something about N's? Maybe some error bars? Reminder that they are logs?

This repeats in Figures 9-1 and 2, page 9-1. I want to encourage the authors to elaborate more if they like.

Page 6-23   Third bullet point: Would you speculate that the smooth plastic surface encourages re-suspension compared to a rougher surface?

Page 9-6 section 9-3 line 2. Again I'd encourage a word about the magnitude of the effect size. …. Yielded much (?) lower lead levels…

Responding to the Specific Questions of the May 23 Memorandum:

Question 1. This could be better, making it easier for the more casual reader. Section 1.3 clearly listed the objectives. Could this list of these questions be duplicated with corresponding answers to the questions in Section 9? Maybe as a Table?

Question 2.   No, none came to my attention. I could have missed one.

Question 3.   Yes, generally they are up to the task.

Question 4. Yes, this was one of the report's strengths.

Question 5. Yes, I think they are. Was there any more they could get out of the data? No.

Question 6. This is outside my area of expertise, but I would ask if it is worth making a multiple regression model of dust (or soil) lead using paint lead, area of work, remediation method (job), and phase, for example.

After-Meeting Comments by Michael Rabinowitz

17 July 2007

The Dust Lead and RRP Study

1) Regarding the "white glove test":

Although it was an easy target of ridicule, having a simple field test to see if lead contamination remains after clean up would be a major component of the national de-leading effort.

A variety of colorimetric field test kits for lead are available. Check your closest hardware store. They are the size of small crayons and disposable. Many are based on dithizone and give a color change from green to red, others using sulfide give a black reaction to lead. As consumer products they have been tested for specificity and sensitivity, and the sulfide method is generally disfavored. These kits are especially for lead in paint, rather than soil lead.

My recommendation is that before deleting the whole verification step, consider using these spot tests to visualize the lead, then mark any hot spots with bright orange spray paint.

2) It is worth re-iterating:

Lead containing paint is a hazard. Over time, as it disintegrates slowly or rapidly from RRP, it generates toxic dust. Since some of the RRP methods appear to generate much more of this dust, one might ask if it would not be better to leave intact paint alone rather than perform the RRP in a way that causes a short-term problem. To avoid answering this affirmatively we should be sure the recommendations for RRP rules are sufficiently rigorous to mitigate any harm.

3) Regarding air-lead:

We heard a lot about how the missing values were and should have been handled, but I wish we heard more about why the air samples were lacking. Was the pump too noisy? Too low a flow-rate? Too short a sampling time?

<u>The Dust Lead from RRP and IQ: Proposed Methods</u>

1) Overall, I was heartened by the skepticism of the panel towards this undertaking.

2) Modeling Blood Lead:

a) Period of Vulnerability:

There seems to be some growing consensus that it is the contemporaneous or current blood lead level that best correlates with these subtle neuro-cognitive deficits found at these lower levels of exposure, aside perhaps from the perinatal period of increased vulnerability. The matter is still murky because we must rely on longitudinal surveys of children and most children's blood lead levels tend to track within the same exposure category. So it is hard to resolve a specific time of vulnerability if one existed.

b) Fetal red blood cells:

The perinatal period is unusual because of both the staging of the development of the central nervous system at that time, and the higher affinity of fetal hemoglobin for lead compared to adult hemoglobin, which appears soon after birth. The brain competes with red blood cells for circulating lead, so the higher affinity of fetal blood and the higher hematocrits at birth mean that a given numerical value for whole blood lead at birth over-estimates the brain lead level compared to the same blood value at a later age. Despite this distortion, which would give a falsely low estimate of brain lead for a given fetal blood lead, an increased more persistent vulnerability has been reported for this age.

c) Modeling brief exposures:
RRP can cause a pulse or spike in lead exposure and lead absorption. Have we adequately addressed the question of if the mathematical models for IQ loss, which are based on blood lead prediction, apply well enough to the situation of short burst of lead exposure? I ask this because with brief exposure more of the dose goes to the brain than under more steady state conditions, because the plasma lead levels are briefly elevated? Does our choice of bio-kinetic model take this into account?

3) Using Older Data:
Glad some older studies of blood lead in residences will be utilized to see if the proposed modeling of RRP and blood lead perturbations gives reasonable values, according to the lead level in the paint.

4) Assigning an Age to a House:
Whether it is based on the age of the foundation or of major structural additions, I suspect HUD might have some general rules they used for NHANES and other surveys. You need only do the same and follow their guidelines.

Dr. Joel Schwartz

Comments of Dr. Joel Schwartz
Professor of Environmental Epidemiology and Director, Harvard Center for Risk Analysis
Harvard School of Public Health
Boston, MA

August 17, 2007

I would just like to emphasize a few points.

a) For regulatory purposes, EPA needs to set clearance levels so that there is a target for renovation. That is quite distinct from assuming that there is a threshold at those dust concentrations in a benefits analysis. Since children with a wide range of baseline blood lead levels will come into contact with this dust, even if there were a threshold blood lead level below which no benefits of further reduction in exposure occur, this would not be the case for dust lead. Hence the benefit analysis should never assume a threshold dust lead level. This should be clarified to EPA, and reflected in their benefit analysis for OMB. The point is that if some of the time, the application of appropriate clean up standards produces dust lead concentrations that are below the clearance level, that will produce additional benefits. Since clean up techniques are presumably targeted to meeting the clearance standard almost all the time, they will in the majority of cases produce these additional benefits, which need to be quantified and set off against the costs.

b) We need to note that there are additional sources of variation that occur when one applies the Leggett model to episodic exposure. There is considerable variation from day to day in many of the parameters, both behavioral as well as physiologic, which determine lead uptake. Variations in hand to mouth activity, iron status, febrile status, etc. These all average out when applying a biokinetic model for a longer period. But when the exposure is episodic, there is a wider distribution in the population of all of these factors, both related to intake as well as the parameters of the model. Hence while the Leggett model may adequately predict the mean of a group of children exposed, to predict the 90th percentile, a wider range of variation of all parameters will need to be assumed. The results of the empirical studies we cite could be helpful in determining that range, since they give distributions of blood lead levels, not just means.

c) I support the idea of Dr. Lanphear on how to use the empirical studies to do a benefit analysis.

d) I also support the use of the two linear slopes instead of the log-linear model.

e) I would like to see Monte Carlo analyses address not just uncertainty in the mean estimate of benefit, but be used to estimate the distribution of effects in a population with varying initial blood lead levels, varying dust ingestion, varying absorption parameters, varying lead kinetics, etc.

Dr. Frank Speizer

Draft final report on
"Characterization of Dust Lead Levels
After Renovation, Repair, and Painting Activities
January 23, 2007
Study and Report Background
May 23, 2007

Submitted by Frank E. Speizer
Date: June 21, 2007

General Comment: I found the report to be an excellent summary of a series of experiments that appear to have been well thought out and executed in manner consistent with a rather complex protocol. The experiments follow a basic design that has provided information that will be useful in setting up RRP guidelines and rules that should lead to protecting both contractors as well as less formally trained self home renovators. There are a number of minor issues, which should be discussed perhaps in more detail in the concluding chapter of the document. The only disappointment is that no results are reported on the blood work of the workers engaged in these experiments. I would assume the reason is that the study was deemed to not require Human Studies Approval (this would not have passed my IRB committee) and for this reason no personal exposure data or blood work information was retained. However, I believe that this was a mistake and surely lessen the value of the entire enterprise, particularly if the workers involved in this work carried out only this work during the periods of observation when blood was obtained pre and post exposure. Such blood lead changes that were found, and I assume were reported to the individuals as indicated page 3-9, could have been correlated with the air and wipe measures to estimate the impact of short term accumulated exposures in well defined settings. I would recommend that, if the data do currently exist, which I guess by IRB standards they should not, the investigators consider ways get IRB approval and make such data available.

Detailed questions:
Issue 1: Study Objectives: The objectives are well stated and seem to all have been met.

Issue 2: Study conclusions. The section of the report described here seem to be no more than an outline of what follows particularly in Chapters 6,7,9, with very little in the way of factual material. If it is meant to be an executive summary more detailed material needs to be included. The results of these experiments are impressive and important. Both here in Chapter 2 and in Chapter 9 rather than repeating some of the finding it would be useful to provide specific interpretive statements of what the experiment showed and how these results should direct both rule makers and renovators, not subject to rules, to change their practices. Regarding the final italicized comment in this section I strongly disagree with the reading of the 40 CFR rules in that this would have been true only if blood was not drawn. By drawing blood, the situation is no longer "usual work practices".

Issue 3. Range of Data: The study protocol is well described. On page 3.4 there is a statement on deviations. A brief table indicating frequency within each of the approximately 75 experiments and in which portion of the experiment the deviation occurred would be informative.

Issue 4. Report organization and Clarity: The tables are well laid out. I suggest to go along with section 4.5 on pages 4-6 and 4-7 a simple table by the 6 categories of protocol variations indicated that the number of times or samples that deviated from protocol be indicated. If the numbers are small the table might even have a "Comment" column giving details of the violations. Bottom of page 4-9, back to my general comment of why the investigators should have had Human Studies Approval.

Issue 5 and 6: Descriptive and Statistical analyses: There are quite a few tables and this seems ok. The data are very interesting but what gets lost is the magnitude of the impact of the potential revised rulings. Many of the graphs are log based and the differences between baseline and experimental settings and pre and post settings are described in the text in terms of p values. Whereas these are quite large changes in dust levels of lead and are important improvements (most appear to be at least log different). For the lay reader or rule maker it would be more impressive to indicate the magnitude of some of these changes rather than p values.

Pre-Meeting Comments on: "An approach for estimating changes in Children's IQ from lead dust generation during renovation, repair, and painting (RRP) in residences and Child-Occupied Facilities (COF)."

Submitted by: Frank E. Speizer

Date: July 3, 2007

This is a strong document that generally is well written and does, indeed, cover many of the issues and discusses quite well most of the uncertainties contained in what I would consider a totally flawed method. I think it is important that the document was produced, but I totally disagree with considering it as a basis for carrying out an economic analysis as part of the rule making procedure. Unless one finds it acceptable that "garbage in equals' garbage out" I do not see how what has been produced can be used in any further economic analysis. What is clear is that disturbing particularly older residences or other COF results in mobilizing lead into various medias (air, food, dust, soil, etc.). Lead exposure results in changes in blood lead levels in children. Elevated blood levels affect neurocognitive development. These are facts and it appears that the later effect is linear and particularly strong below levels of 10 µg/dL. On the other hand with regard to the effects of RRP the uncertainties described in the methods and the paucity of data that go along with those uncertainties described throughout this document along with the lack of generalizability of the examples used lead me to the conclusion that to use the data in any way other than qualitatively would be a disservice. Quite frankly, my reading of Fehrenbacher's cover letter to the Charge Questions suggests concern that the proposed methods may not be appropriate.

As pointed out throughout the text, there are uncertainties. For example, in using the results of the OPPT dust study at the end of chapter 3, the authors point out that the data included Pb loading for only a limited portion of the expected sources for each job. This clearly presents a problem in using the data. Further, in accepting the data from the selecting households for the OPPT studies, one is restricting the possible scenarios that might apply in different setting and different parts of the country. Houses built before 1940 (and still standing), may have undergone significant renovations in the past producing potential higher soil levels outside with perhaps totally eliminated indoor sources, and any combination of these scenarios. It is not clear that further renovations of such residences or COF will result in any addition exposure or more exposure. Thus to apply the data from the single and multiple renovations studies seems too simplistic.

As indicated on page 122, particularly with regard to the COF, the estimation of a single concentration for each building scenario makes unlikely assumptions about children's activities.

THE METHOD NOT DISCUSSED (for a future economic analysis). What is not contained in this document is a discussion of the effects of removing children from buildings designated for potential exposure during the duration of RRP and potentially for some time after completion of work. What would be the cost of taking children from one day care facility to another while the first is being renovated, and perhaps for a month or more after completion while dust control abatement is going on, rather than suggesting that they be in a "non-exposed" room next door to where the activity is going on?

BOTTOM LINE: My concern is that any use of these data for an economic analysis would be so flawed as to be discounted from both industry and environmentalists and thus it has no part to play in the rule making process.

I hope that the discussion of these documents at the CASAC meeting this next week can put the data in a more favorable light and I can be persuaded to be more positive about how the data may be used.

Post-meeting comments for potential inclusion in Dr. Henderson's summary letter.

From: Frank E. Speizer
July 18, 2007

I have reviewed Paul Mushak's Post-meeting comments and he summarizes well the problems we all faced in reviewing this material. My specific concerns, expressed in my original pre-meeting comments certainly are better expressed by Paul's comments. I remain essentially unconvinced that there exist enough data to carry out the kind of analyses proposed and to have any credibility given to those analyses. The analysis certainly can be done, but I fear it will end up with a series of numbers that will somehow be turned into a series of policy relevant economic statements with cost/benefit ratios attached and the degrees of uncertainty attached to those analyses will be lost.

In spite of all the work that went into gathering the data that will be used in these analyses, the technical people "turning the cranks on the computer" seem not to understand that the data they will be using was gathered in a convenience sample of selected homes in two cities with very specific characteristics, yet unknown histories of prior renovations, and there is no way that these data can be representative of what might be happening on a national sample of homes, renovation activities, or living arrangements. To then try to apply these data both to homes being renovated and then to other COFs (nurseries, day care centers, schools, etc.) where children less than 6 year old might be housed for varying periods of time from hours to days, is simply beyond the scope of the available data.

Note that as I read the text there is a general admission that there are insufficient data on COFs and that the plan to extrapolate from the residential data where a child's time is assigned uniformly to the whole building indoor dust and air concentrations and the whole yard outdoor soil concentration to characterize exposure can be modified for COFs by adjusting the media concentrations to account for where children spend their time when in a COF simply won't work. This would be appropriate if we had a reasonable handle on where children spend their time in the potential wide variety of COFs that exist, but I am afraid that such data simply do not exist.

From the discussion at the meeting it would appear that the marching orders given to this analysis group was to move ahead with analyses as planned and thus meet the "legal" obligations, so that something can move forward in the rule making process. The choice of having CASAC be the review body for this procedure is probably one that the OPPT group now regrets, as it is unlikely that they will be able to overcome our criticisms of the sources of data being used in the approach, as well as specifically which models to use in the approach. I remain open to be convinced otherwise, but thus far I am not. As Paul points out the existing models, even if they were all used would still not bound the limits of effects, and would still be a potential underestimate of effects.

I have great respect for the effort that went into both the gathering of the data by the Battelle group, and the way in which the data were written up. Further the discussion of the data and its potential use and uncertainties by the OPPT group is quite impressive and in and of itself is an important piece of work. However, by its own admission and the discussions in chapter 7 on pages 121-123, I believe the authors provide sufficient evidence that a **quantitative** use of the data is simply inappropriate and thus they must turn to more qualitative approaches based on the available empirical data.

Finally, the closing remarks made at the meeting left me somewhat disappointed. The suggestion was that we had been asked to comment on the methods as presented (not to offer alternative approaches). I am sure at that point everyone was tired and perhaps becoming somewhat 'testy". However, I believe we are all on the same side and want a final product that will withstand criticism both from the industrial trade groups as well as environmental activists. To get there will require EPA to be more creative in accepting our criticisms as a good faith effort to be constructive yet realistic as to what can and cannot be accomplished. Since there is not legal mandated deadline for the economic analysis, as there is for the rule making, I would suggest that a less formal economic analysis be done and the rule making move forward using more qualitative assessment techniques for establishing more qualitative risk/benefit ratios, perhaps using “willingness to pay” techniques.