UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

April 3, 2007

EPA-CASAC-07-004

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) Consultation on the 1st Draft Lead Renovation, Repair, and Painting (LRRP) Assessment

Dear Administrator Johnson:

The Clean Air Scientific Advisory Committee (CASAC or Committee), augmented by subject-matter-expert panelists, met on February 5, 2007 to conduct a consultation on EPA's *Draft Assessment to Support the Lead Renovation, Repair, and Painting (LRRP) Rule* (1st Draft LRRP Assessment, January 2007). The CASAC roster is attached as Appendix A of this letter, and the Panel roster is found in Appendix B. The Agency's charge to the Panel is contained in Appendix C to this letter, and Panel members' individual written comments are provided in Appendix D.

The SAB Staff Office has developed the consultation as a mechanism to advise EPA on technical issues that should be considered in the development of regulations, guidelines, or technical guidance before the Agency has taken a position. A consultation is conducted under the normal requirements of the Federal Advisory Committee Act (FACA), as amended (5 U.S.C., App.), which include advance notice of the public meeting in the *Federal Register*. As is our customary practice, there will be no consensus report from the CASAC as a result of this consultation, nor does the Committee expect any formal response from the Agency.

Nevertheless, the CASAC would like to underscore key points that were discussed at the public meeting. These issues are listed as follows, along with the names of those Panel members whose individual comments expand on these points. The CASAC recommends that EPA's technical assessment should:

1. Distinguish between uncertainty and variability (Dr. Cohen, Dr. Crawford-Brown, Dr. Russell and Dr. Schwartz);

2. Include secondary sub-populations such as the children of renovation workers potentially exposed to lead (Dr. Miller and Dr. Mushak);

3. Consider exposure assessment in a probabilistic framework (Dr. Goodrum);

4. Include wipe-based lead clearance testing (Dr. Mushak);

5. Use weighted regression techniques to convert dust loadings to house dust concentrations (Dr. Miller);

6. Use observed data, not model defaults, when possible; compare results from the empirical model with those from biokinetic models (*i.e.*, IEUBK, Leggett); and, to the extent possible, identify reasons for any differences (Dr. Cohen and Dr. Lanphear);

7. Use the term "renovation, repair, and painting (RRP) scenarios" to describe activity-specific environmental monitoring studies" (Dr. Fenske);

8. Clarify "activity" scenarios (*i.e.*, single versus multiple events) in residences with lead paint hazard history (Dr. Mushak);

9. Use clear and precise terminology in the LRRP proposed rule (*e.g.*, by: distinguishing between "training," "certification" and "accreditation"; acknowledging that this rule will apply to other buildings beyond housing structures; and carefully-defining terms such as "lead exposure," "lead dust hazard," and "dust lead levels"); and, importantly, more clearly specify the role that the Agency's implementation of this rule will play in attaining the Federal government's goal of eliminating childhood lead poisoning by 2010, *i.e.*, only three years hence, as stated in the Introduction to the 1st Draft LRRP Assessment (Dr. Cowling).

10. Pay particular attention to: assessment of risks posed to children who live in owner-occupied housing to ensure that EPA can appropriately address hazards linked with renovation and repair activities; characterize IQ loss on a population basis; and review the epidemiologic research linking renovation and remodeling with lead poisoning (Dr. Lanphear).

The CASAC was pleased to consult with the Agency on this important document and looks forward to conducting a peer review of the technical assessment this summer. As always, we wish EPA staff well in this important task.

Sincerely,

/Signed/

Dr. Rogene Henderson, Chair
Clean Air Scientific Advisory Committee

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

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

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

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

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

Dr. Frank Speizer, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

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Appendix B – Roster of the Panel for Review of the 1st Draft LRRP Assessment

U.S. Environmental Protection Agency
Science Advisory Board (SAB) Staff Office
Clean Air Scientific Advisory Committee (CASAC)
Panel for Review of the 1st Draft LRRP Assessment

CHAIR

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

MEMBERS

Dr. Joshua Cohen**, Research Associate Professor of Medicine, Tufts University School of Medicine, Institute for Clinical Research and Health Policy Studies, Center for the Evaluation of Value and Risk, Tufts New England Medical Center, Boston, MA

Dr. Deborah Cory-Slechta**, Director, University of Medicine and Dentistry of New Jersey and Rutgers State University, Piscataway, NJ

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

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

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

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

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

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

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

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

Dr. Randy Maddalena†, Scientist, Environmental Energy Technologies Division, Indoor Environment Department, Lawrence Berkeley National Laboratory, Berkeley, CA

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

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

Dr. Michael Rabinowitz**, Geochemist, Marine Biological Laboratory, Woods Hole, MA

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

Dr. Joel Schwartz**, Professor, Environmental Health, Harvard University School of Public Health, Boston, MA

Dr. Frank Speizer [M.D.]*, Edward Kass Professor of Medicine, Channing Laboratory, Harvard Medical School, Boston, MA

Dr. Ian von Lindern**, Senior Scientist, TerraGraphics Environmental Engineering, Inc., Moscow, ID

Dr. Barbara Zielinska**, Research Professor, Division of Atmospheric Science, Desert Research Institute, Reno, NV

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* Members of the statutory Clean Air Scientific Advisory Committee (CASAC) appointed by the EPA Administrator

** Members of the CASAC Lead Review Panel

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

Appendix C – Agency Charge to the Panel

Charge to the Panel for Review of the 1st Draft LRRP Assessment

Issue 1. Draft Assessment Plan

OPPT has developed a draft Assessment Plan. This is intended to provide an overview of the approaches that will be used for the hazard assessment, exposure assessment, blood lead modeling, and determination of changes in children's IQ.

Question 1. Please comment on the reasonableness of the approach outlined in the draft Assessment Plan.

Issue 2. Draft Hazard Assessment

EPA recently finalized its Air Quality Criteria Document (AQCD) for Lead, which was extensively reviewed by the CASAC. This document provides an all-encompassing analysis of the current lead literature. In an effort not to duplicate efforts, OPPT has adopted portions of the AQCD for the hazard section of the risk assessment for the LRRP rule.

Question 2. Please comment on the transparency and completeness of the draft hazard assessment.

Issue 3. Environmental Monitoring Studies

There are two existing studies and one ongoing study which contain environmental monitoring data on dust levels in buildings during renovation, repair and painting activities. The three studies are described below.

Issue 3a. Environmental Field Sampling Study (EFSS)

The purpose of the EFSS (USEPA 1997) was to assess lead disturbance and exposure associated with various types of RRP activities by measuring lead in air and dust before, during, and after RRP activities in housing units with confirmed lead-based paint. The EFSS had two components: one in which real world RRP jobs, such as carpet removal and window replacement, were monitored; and one involving a controlled study in which various RRP activities such as sawing, drilling, demolition, sanding, and duct removal were monitored on surfaces containing lead-based paint. The controlled study also investigated the degree to which settled dust-lead loadings could be reduced using either broom or standard vacuum cleanup on smooth, cleanable surfaces.

The EFSS demonstrated that significant lead loadings were generated by most of the RRP activities. Some important limitations of the EFSS include: most of the work activities were simulated RRP activities, not "real world" RRP activities; the housing units chosen for the study were generally vacant units in poor condition with high paint-lead levels.

Question 3a. Please comment on the usefulness of this study in the context of this particular exposure assessment.

Issue 3b. Lead-Safe Work Practices Survey Project Report. November 9, 2006.

The Lead-Safe Work Practices Survey was conducted by the National Association of Home Builders to measure the amount of lead dust generated during typical RRP activities and assess whether routine RRP activities increase lead dust levels in the work area and property. Both air samples and surface dust wipe samples were collected during RRP activities conducted in five separate residential properties included in the study. The Study's stated objectives were to answer the following three questions: 1) Do typical renovation and remodeling activities create lead hazards? 2) When applying EPA's lead-safe work practices to a set of typical renovation and remodeling activities, are surface lead hazards (>40 $\mu g/ft^2$ on floors, >250 $\mu g/ft^2$ on window sills), or airborne hazards (>50 $\mu g/m^3$ in the air) created? 3) Do modified lead-safe work practices reduce lead exposures below the PEL?

Some potential limitations of the NAHB survey include: 1) the properties in the study were old (approximate construction dates were between 1800 and 1950), and it is unclear to what extent the site preparation included cleaning; 2) the report is unclear about the difference between EPA/HUD Lead Safety Work Practices (LSWP) and Modified LSWP; we were unable to determine whether either of these was intended to be similar to the provisions of the RRP proposed rule; and 3) dust levels were only measured before RRP activities were conducted and after clean-up following the RRP activities. No measurements post RRP activity and pre-cleaning were taken.

Question 3b. Please comment on the usefulness of this study in the context of this particular exposure assessment.

Issue 3c. Characterization of Dust Lead Levels After Renovation, Repair, and Painting (Ongoing)

The OPPT Dust Study is currently in progress, and is anticipated to be completed in January, 2007. The OPPT Dust Study is investigating the comparative impact on dust lead levels from use of the lead-safe practices EPA has proposed, and from baseline activities. The study is also investigating the effectiveness of different components of the lead-safe work practices EPA has proposed. Specifically, for interior jobs, the study is investigating 1) using plastic coverings during RRP work and 2) using a more extensive clean up routine than that which is typically conducted by RRP workers. The four phases of the interior jobs to be completed are 1) use of plastic coverings and cleaning per the proposed rule after work completion, 2) use of plastic coverings and baseline cleaning after work completion, 3) no plastic coverings and cleaning per the proposed rule after work completion, and 4) no plastic coverings and baseline cleaning after work completion. For exterior jobs, a single phase will be used with plastic sheeting, and collection trays will be placed above and below the plastic to assess the differential amounts of lead. For interior jobs, settled dust wipe samples and air monitoring samples will be taken for each job, each cleaning step, and each cleaning verification step. For exterior jobs, dust wipe samples will be collected from collection trays placed underneath the rule plastic, on top of the rule plastic, and near the rule plastic.

Analysis of sample results will assess the impact of the proposed techniques for reducing lead levels of the dust left behind from RRP activities.

Question 3c. Please comment on the usefulness of this study in the context of this particular exposure assessment.

Issue 4. **General Approach for the Sensitivity Analysis in the Exposure Assessment**

As described in the draft exposure assessment, sensitivity analysis techniques are being used to examine the impact of sources of uncertainty on exposures. Assumptions have had to be made for a variety of parameters to apply these techniques. The indoor parameters include 1) post-activity cleanup efficiency, 2) percent house workspace, and 3) lead loading. The outdoor parameters include 1) background soil concentration, 2) lead loading, 3) percent of house perimeter involved in project, and 4) soil depth. At the moment, the sensitivity analyses suggest that cleaning efficiency is one of the most important variables in determining dust levels over time (see Issue 5 below). In addition, lead loading and percent of space involved (indoors and out) seem to be important. Most of the analyses conducted to date have assumed that cleaning efficiency is constant over time. However, an exploration of varied cleaning efficiency in kitchen remodeling indicates that the duration of elevated exposure may vary sufficiently to have an impact on the choice of the appropriate pharmacokinetic model as discussed in Issue 7.

The sensitivity of the estimated exposures to assumptions about different scenario conditions can reflect the differential scales in which those conditions are measured. Many of the assumptions are entered as percents, which have a limited range of values; some are lead concentrations, which are orders of magnitude greater. A sensitivity score is based on absolute units. OPPT has also chosen to express sensitivity by an “elasticity” measure, which normalizes the inputs.

Question 4a. Please comment on whether the appropriate variables have been evaluated in the sensitivity analysis. Please comment on whether the assumptions for other variables should be explored.

Question 4b. Please comment on OPPT’s plan to use both elasticity and sensitivity scores to evaluate the impact of changes in assumptions to likely exposures.

Issue 5. Cleaning Efficiency Considerations in the Exposure Assessment.

Review of the cleaning efficiency literature suggests that the most relevant factors for cleaning efficiency differences are the following: 1) floor type, e.g., hard surface and carpet; 2a) for the hard surfaces, the dust level, which varies by whether the dust has been added recently or has settled (i.e., been “ground-in”), and by the effect of cleaning iterations; 2b) for carpet, the cleaning iteration after RRP activity.

Generally, hard surfaces with recently added dust have higher baseline levels that correspond to higher cleaning efficiencies in the initial cleaning efforts. Efficiency results for hard surface floors with settled dust varied considerably. Different cleaning methods, floor types and floor conditions may be responsible for these differences. Initial effort carpet cleaning efficiency with recently added dust was quite variable, whereas settled dust initial efficiencies were similar.

Typical RRP activity may add lead dust to previously settled lead dust. This was the case for the EFSS 1997 hard surface study, which clearly shows differences in cleaning efficiency due to the baseline dust levels. For hard surface cleaning, we propose that cleaning efficiency values from the EFSS baseline-dust ranges be matched to the results of the Dust Study for the four test Phases, e.g., a Phase with results near 1000 µg/ft^2 would use cleaning efficiencies in the 25% to 68% range.

Neither different baseline levels nor added versus settled dust appear relevant for carpet cleaning efficiency. However, there are several studies with sequential cleaning results. Perhaps these could be combined and used to plot a function that could then extrapolate beyond the maximum of ten cleanings presented in the data.

Limited evidence suggests that lead flooring dust loading can increase over longer time periods because there will be a near-field reservoir that will contribute to lead dust gain, especially from carpet.

Question 5. Please comment on the proposed approach for establishing cleaning efficiency in the exposure assessment.

Issue 6. Conversion of Dust Loadings to Dust Concentrations

Appendix C of the draft exposure assessment describes the approach for converting lead loadings to lead concentrations. The relationship between house dust loading and lead concentration for the draft exposure assessment report comes from the ICF (2006) analysis of a data set developed as part of HUD's 1997 National Survey. The ICF (2006) analysis was used because it appears to use the largest, most nationally representative source completed to date of both house dust loading and concentration data taken simultaneously from the same households.

The regression analysis relating lead loading and lead dust concentrations in the exposure assessment differs from the Battelle (2005) regression analysis cited in USEPA (2006a). It is important to note that the ICF (2006) analysis was not complete prior to the development of the USEPA (2006a) report.

Question 6. Please comment on the adequacy of the method used in the draft exposure assessment to convert dust loadings to dust concentrations. Are there other methods that should be explored?

Issue 7. Blood Lead Modeling

The assessment will estimate blood lead level metrics for the specific RRP activities with and without the requirements of the LRRP, and will, to the extent possible, include characterization of uncertainty in these estimates. Three models are being considered to estimate blood lead levels in children, the IEUBK model (EPA, 1994), the Leggett model (Leggett et al., 1993), and an empirical model (Lanphear et al., 1998). The IEUBK model (EPA 1994) is a well-evaluated and widely used EPA model for predicting blood lead levels in children when exposures are expected to exceed 3 months to a year. The Leggett et al. (1993) model, which is also a biokinetic model, can accommodate shorter term exposures. An empirical model (the Lanphear model) for estimating blood lead levels in children is also being considered. The Lanphear model (Lanphear et al., 1998) uses a regression-based approach for predicting blood lead levels on the basis of environmental concentrations and other variables. Application of the Lanphear model, if undertaken, will not be parallel to applying the IEUBK or Leggett models.

The current draft exposure assessment indicates that exposures to lead following renovation activities are variable over time, and mostly occur for a time period less than one year. OPPT plans to use the Leggett model for these exposures of short duration and the IEUBK model for exposures greater than one year.

Question 7a. Please comment on whether the empirical model should be considered.

Question 7b. The draft exposure assessment indicates that exposures decline through time until background levels are reached. Please comment on the adequacy of using a mean (weighted or otherwise) or some other summary input of exposure to the Leggett or IEUBK models.

Question 7c. The IEUBK model yields activity-specific distributions of individual values at different (geometric) mean levels of blood lead. Please comment on how the level-specific upper tails and the variability can be determined when using the Leggett model.

Issue 8. Characterization of Changes in Children's IQ

The assessment will characterize IQ changes in children for the specific RRP activities with current cleanup conditions and those that would be in place following the rule. For each RRP activity, a distribution of IQ loss will be estimated, based on a log-linear model presented in the pooled analysis by Lanphear, et al. (2005). It is possible that the change in blood lead concentrations associated with each of the renovation activities will be small.

Question 8. If the analyses do indicate that the changes in blood lead concentrations are small, please comment on how to extrapolate the data from the Lanphear study at very low doses.

Appendix D – Comments from Individual Panel Members

This appendix contains the preliminary and/or final written comments of the individual members of the Clean Air Scientific Advisory Committee (CASAC) Panel for Review of the 1st Draft Lead Renovation, Repair, and Painting (LRRP) Assessment who submitted such comments electronically. The comments are included here to provide both a full perspective and a range of individual views expressed by Panel members during the review process. These comments do not represent the views of the CASAC, the EPA Science Advisory Board, or the EPA itself. Panelists providing review comments are listed on the next page, and their individual comments follow.

Dr. Joshua Cohen

Question 7 Modeling of Blood Lead Levels

EPA has requested guidance on three specific questions related to the use of either empirical or mechanistic models to estimate the blood lead levels associated with different renovation, repair, and painting (RRP) practices. Before addressing those questions, I will first comment on the assessment's handling of uncertainty and variability.

The assessment should clearly distinguish between uncertainty and variability

Section 1.1 of the December 2006 exposure assessment states (p. 1-1),

> *The approach for this draft exposure assessment is focused on developing a scientifically sound analysis framework and characterizing a reasonable range of results (considering both uncertainty and variability) using this framework.*

Although the analysis states that it addresses both uncertainty and variability, it does not sufficiently clarify how each is handled. The assessment specifies value ranges to be used in the sensitivity analysis, but it is not clear whether these ranges represent uncertainty (*e.g.*, plausible ranges for the <u>average</u> dust lead loading following a particular activity), or if they represent the range of values that would be observed in a sample of households undergoing that activity.

Whether the assessment should quantify variability or uncertainty depends on how the results will be used. For example, if the risk assessment results will be used to estimate aggregate population benefits and costs associated with the proposed rules, the average impact on lead exposure is important and the assessment should characterize the uncertainty in the estimated average. If the range of impacts is important (*e.g.*, identifying the greatest exposures associated with RRP activities), the analysis should characterize variability. There are methodologies for characterizing both uncertainty and variability (*e.g.*, "two-dimensional" Monte Carlo simulation). These methodologies can be adapted for use in sensitivity analyses. The key point is that the analysis needs to clearly identify which ranges represent uncertainty and which represent variability.

The assessment may not have addressed some important sources of uncertainty and/or variability

<u>Activity duration</u>

Duration of the repair activity appears to be an important factor influencing exposure because dust lead concentrations remain at their maximum until this activity ends. Although I may have missed it, the basis for the estimated durations were not obvious to me. Nor does there appear to be any discussion of uncertainty or variability for this potentially important assumption.

Conversion of dust lead loading to dust lead concentration

Exhibit C-1 illustrates the regression of dust lead concentration against dust lead loading. The figure visually indicates that there is a wide range of dust lead concentration values (about 4 natural log units, or a factor of about 50) associated with a fixed dust lead loading. This range of values is substantially greater than most of the ranges specified in the sensitivity analysis detailed in Appendix B. The assessment should describe the prediction interval for dust lead concentration if variability is important. It should describe the confidence interval for the mean prediction if only uncertainty is important.

Question 7a

Please comment on whether the empirical model should be considered.

EPA should describe estimated blood lead levels developed using the empirical model and compare those estimates to blood lead levels estimated using the mechanistic (IEUBK and Leggett) models. To the extent possible, the assessment should identify reasons for differences between the models. Residual differences that cannot be explained represent a source of uncertainty.

It is not clear to me what EPA means by the statement, "*Application of the Lanphear model, if undertaken, will not be parallel to applying the IEUBK or Leggett models.*" For reasons described in the preceding paragraph, I believe the assessment should consider both approaches together.

Question 7b

The draft exposure assessment indicates that exposures decline through time until background levels are reached. Please comment on the adequacy of using a mean (weighted or otherwise) or some other summary input of exposure to the Leggett or IEUBK models.

It is not clear if the question is referring to a temporal or spatial mean. It would be appropriate to use a spatial mean dust lead concentration, weighted by exposure.

Question 7c

The IEUBK model yields activity-specific distributions of individual values at different (geometric) mean levels of blood lead. Please comment on how the level-specific upper tails and the variability can be determined when using the Leggett model.

There seems to be no reason why the same approach used with the IEUBK model to characterize the range of blood lead values associated with a fixed exposure cannot also be used with the Leggett model.

Dr. Ellis Cowling

Dr. Ellis Cowling
North Carolina State University
January 27, 2007

Individual Comments prepared in advance of the February 5, 2007 CASAC Consultation on the Draft Assessment Plan to Support the Lead Renovation, Repair, and Painting Rule

Charge Question 1: Please comment on the reasonableness of the approach outlined in the draft Assessment Plan.

Our Federal government has established a very worthy goal — "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 refurbishment 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 buildings will be achieved during the next few years of the present Century. Thus it is important that the Office of Pollution Prevention and Toxics do its job very well!

Although many general features of the approach outlined in the Assessment Plan do seem reasonable, the specific wording of several parts of the Assessment Plan is neither clear nor reasonable. These semantic deficiencies include the vague, imprecise, and often confusing wording of:

1) The title of the proposed Rule itself,
2) The language used to describe the assessment and educational work to be done, and
3) The nature of the work that actually will be done by those who will do the training, certifying, accrediting, and planning for — and then accomplishing the labor of — the renovation and repair of buildings in which young children will spend a good deal of their time.

For example, although "painting" is a part of the title of the proposed Rule, the Assessment Plan does not deal at all with "painting" practices — the Plan deals only with "renovation" and "repair" processes and procedures. Thus, a more accurate title for the proposed Rule would be "Lead-Based Paint Renovation and Repair Rule" or "Lead Paint Renovation and Repair Rule."

Also, as now stated in the Draft Assessment Plan, the proposed Rule is intended to establish requirements for:

- "training renovators and dust sampling technicians;"
- "certifying renovators, dust sampling technicians and renovation firms;"
- "accrediting providers of renovation and dust sampling technician training;" and

- [doing something not now defined in the Assessment Plan about] "renovation work practices."

Similarly, use of the terms "target housing," "housing constructed before 1978," "0-bedroom dwelling," "rental housing," "owner-occupied housing," "owner's residence," and "residential location" all imply that it is home buildings [rather than school buildings, day-care center buildings, church buildings, or other buildings] in which the proposed Rule will be applied in order to achieve the goal of "eliminating childhood lead poisoning by 2010."

Another example of ambiguous language is the term "renovations for compensation performed in target housing." What does this mean?

The term "lead exposure" and "dust lead levels" are used on essentially every page of the Assessment Plan. There are a few places in the Plan where the distinction between air-borne dust and dust accumulated on solid cleanable surfaces after deposition from the air are discussed, but there are many places in the Assessment Plan where there is confusion about whether:

1) "lead dust hazard" or "dust lead level" means "measurements of lead concentrations in airborne dust" (presumably expressed as micrograms per cubic meter of air, or some such unit), or
2) "amount of lead in dust deposited on cleanable solid surfaces" (presumable expressed as micrograms per square centimeter of surface area, or some such unit), or
3) both of these indicies of exposure to lead?

In the next-to-last paragraph on page 3, what is actually measured when the phrase "measuring lead in air and dust" is used?

In the first full paragraph on page 4, I think I understand what is meant by the sentence "For interior jobs, settled dust wipe samples and air monitoring samples will be taken for each job." But it is not at all clear what is meant by the very next sentence which reads "For exterior jobs, dust wipe samples will be collected." Are these "dust wipe samples" taken from vertical surfaces such as the wood, metal, or vinyl siding now on the exterior of the building, or a horizontal or slanted surface such as a sidewalk or a window sill, or some other such surface?

In the third full paragraph on page 4, what is meant by the terms, "three cutouts" and "exterior LBP [lead based paint] removal"?

Similarly, in the first full paragraph on page 5, what is meant by the terms "background soil" dust soil/lead loadings," "dust exposure pathways," and "lead concentrations?"

What are the units of measurement (or what is the method used to determine) "exposure level" as stated in the first paragraph on page6?

What is meant by the statement "the user is required to supply estimates of total ingestion and inhalation pathway intake (administered dose)" near the end of the last paragraph on page 6?

It would be whole lot easier to say with confidence that the approach developed in this Draft Assessment Plan is "reasonable" if I better understood what this Plan was intended to tell us about the assessing, training, certifying, and accrediting, etc, that the Office of Pollution Prevention and Toxics will be doing!

In addition:

As we look forward to the time it will take for EPA to implement the proposed "Lead-Based Paint Renovation and Repair Rule," as I have suggested it be called, I could not help but wonder why CASAC is being asked to review this Draft Assessment Plan in February 2007 when the goal of our government is "eliminating childhood lead poisoning by 2010" – now only 3 years away!

When was this very worthy goal set?
What agency or group of agencies selected this target date?
Is there some good reason why CASAC's review of this Assessment Plan is just getting started — only 3 years before the intended deadline for accomplishing this very worthy national goal?

Dr. Douglas Crawford-Brown

Comments on the Lead Renovation, Repair and Painting Rule

Doug Crawford-Brown, January 2007

The focus of my comments will be on the Draft Assessment Plan, as that was my central charge. But I do have a few comments on the other sections, which I provide first. I end with some bulleted comments that summarize my main points.

Hazard:

I begin by noting that the third paragraph under Blood Lead as a Biomarker seems to me a bit confused, or at least ambiguous. It is not clear what blood lead is being used as a biomarker FOR. Part of the paragraph suggests it is a good biomarker for total body burden, which should reflect both current and past exposures. But the same paragraph suggests blood lead reflects environmental concentrations, and so presumably current exposures. I am not saying the paragraph is incorrect, but it does appear as if there is a lack of clarity as to whether blood lead reflects primarily current exposures or current body burden; these are two different concepts. Perhaps it reflects both adequately, but that isn't established in the document, and it calls into question what the measure of exposure or dose will be in the final analysis.

The section on neurocognitive effects summarizes fairly well the existing data, at least as these data are reflected in the two primary studies they use (which I would agree are the two of most relevance). The decision to focus on IQ changes as at least a measure of these effects is appropriate. Relating IQ changes to particular clinical effects that impact the quality of life is less straight-forward, and neither this document nor the Air Quality Criteria Document used to support it explain the transition from simple effect to adverse effect. This transition must be explained (i.e. why a particular IQ decrement constitutes an adverse effect).

The authors raise the issue of a potentially larger slope to the lead-IQ decrement curve with decreasing body burden. They are correct that this is observed in the data, even after accounting for confounding. It would be useful to understand the implications they will draw, scientifically, from this observation. One interpretation is that the curve is monotonic from zero body burden, rising through some function such as $A \times (1 - \exp(-BD))$, where A and B are constants and D is the dose or body burden. That would suggest that the slope gets larger as one goes to lower values of D, but IQ decrements would continue to be found even as the dose approaches 0. But another dose-response curve that has this same property of increasing slope as the dose is reduced is a threshold function. The authors don't specify which they will assume, although they appear to lean towards the former. They just need to be clear which they are going to assume, and then to provide a justification for a threshold if the latter approach is adopted. The selection of a threshold will be difficult to justify in the data they cite.

This ambiguity extends back into the AQCD, where on Page 6-326, the authors state that there is a "…steeper slope at lower than at higher blood lead levels…." They take this to be evidence that a threshold is unlikely to exist. Oddly, the same claim is made in the report by the Work Group of the CDC's Advisory Committee on Childhood Lead Poisoning Prevention, which may suggest the latter is the source of the claim in the AQCD. In any event, it isn't true that a steeper slope at lower doses implies a threshold doesn't exist.

There remains significant difficulty in drawing conclusions from the existing studies at low blood lead levels, although this is not reflected in the Hazard Assessment document reviewed here. The Work Group of the Advisory Committee on Childhood Lead Poisoning Prevention (mentioned previously), while supporting the claim that effects are noted in existing studies below 10 µg/dL, provides the caveat that (see page iv of their report): "Relatively few studies have directly examined relations of children's BLLs in the range <10 µg/dL, and many of these are cross-sectional studies in which data are unavailable on BLLs earlier in life and key covariates." They also note (see page 12 of their report) that "The work group concluded that collectively, these concerns and limitations on the available evidence preclude definitive conclusions about causation and leave considerable uncertainty concerning the magnitude and form of causal relationships that may underlie these associations." However, studies completed since the Advisory Committee on Childhood Lead Poisoning Prevention's review have increased the confidence that adverse health effects occur below 10 µg/dL, although my personal, subjective impression is that this confidence remains low at 5 µg/dL and below.

Aside from methodological limitations in ensuring that measured health effects are not caused by co-variates or unquantified sources of exposure, there is the issue of the trend in scores on intelligence tests over the past century. I'm not sure we would want to push too strongly on the following issue, but it is relevant. This trend has become known as the Flynn Effect, and is reviewed in the recent paper by Dickens and Flynn: Heritability Estimates Versus Large Environmental Effects: The IQ Paradox Resolved (*Psychological Review*, 108, 346-369, 2001). The conclusion of this longitudinal study of populations around the world is that IQ has been increasing steadily by several units per decade over the past century in most cultures. At first blush, this might be taken as evidence that reductions of environmental lead through regulatory control have in fact been effective, since if lead reduces IQ measures, the reduction of environmental lead should increase those measures. This would tend to support a link between reductions in lead exposures and improvements in IQ (a relationship that is crucial to EPA regulatory efforts). However, this slope has been consistent for at least 60 years, during which time exposures in the U.S. were at first increasing and then decreasing. And the trend is consistent even in countries that have not begun lead abatement. So clearly, there are large-scale temporal and geographic trends in the measures of IQ that cloud the picture of whether environmental exposures to lead are significant causes of changes in IQ noted in the existing studies.

Finally, I note that the Weight of Evidence section doesn't appear to me to be a weight of evidence assessment at all. It is instead a summary of the conclusions drawn by the authors and a mention of the information that leads them to those conclusions. My personal belief is that a WOE assessment should systematically compare the strengths and weaknesses of alternative bodies of data and interpretations, and then show how the overall body of data makes it reasonable to conclude that the summary of hazard included in the document is the most reasonable of those available. The current section fails to do this.

Exposure:

The structure of this exposure assessment, examining a pre-activity period, a period of the activity, and then a post-activity period in which concentrations return to background gradually, is correct in principle. Any problems that arise seem to me ones associated with getting the appropriate data to use in parameterizing the models, and here several problems arise. The most evident one is that the EPA plans to obtain data on actual measurements in air under these activities, and I wonder why they don't simply wait until these are available. Absent these data, they are forced to rely on the loading-to-concentration ratios mentioned, which leads them into problems defining the set of structures and activities under which these ratios were developed. I am not an expert in home characteristics or construction activities, but it seems to me that the ratios used by the authors stem from studies in a rather small number of homes with an unspecified relationship to a proper national sample of homes with lead-based paint. But I will leave it to someone else to determine whether the sample is representative.

I didn't follow the discussion of indoor dust (Section 3.1.1) and the selection of the 75th percentile as a "reasonable default estimate". I don't think it is awful to use that percentile, but it strikes me as almost completely arbitrary. In any event, no evidence is presented to support the claim that this percentile is somehow the most representative of the percentiles that could have been selected. And given that there are data on which to base a variability distribution, I don't fully understand why ANY particular percentile had to be used as representative. The same is true for outdoor soil. In fact, I have even more of a concern there because one would want to use soil to which children are exposed, and I get a sense from the document that the authors have used soil representative of that at the drip-line. I am unconvinced that this is the primary spot at which children would be exposed.

For both indoor air and soil, the authors appear to be assuming that an individual spends equal amounts of time in each room, and equal amounts of time in each grid block of a yard. I am not sure there are data available to make any other assumption, and this might complicate the assessment without much return on accuracy, but these assumptions don't seem to me justified.

Throughout the discussion of the sensitivity analysis, I was concerned about the lack of distinction between variability and uncertainty. It probably is infeasible to do something like a nested variability-uncertainty analysis (the distributions needed may be unavailable), but the sensitivity analysis conducted by the authors still needs to clearly separate variability and uncertainty.

Finally, the exposures through water, food, etc are problematic. The studies cited for water have a mixture of times during which the water samples were taken (e.g. first-draw, later in the day, etc), and there can be large variability between homes and times of sampling. I understand that it greatly simplifies the assessment to use a national average, but I worry this will obscure intersubject variability of non-air, non-soil exposures. At present, there is little empirical information on which to base judgments of the relative source contribution for lead from air, paint, drinking water, etc. The authors should contact authorities in the Office of Water and in the American Water Works Association for guidance to the water data.

Assessment Plan:

My primary comments here focus on the Draft Assessment Plan, although that plan can be no better than the data and models use in the Hazard and Exposure components. As written, it is difficult for the reader to follow completely the process that will be used in the assessment, but it appears to be:

1. Identify the adverse effect of interest; here it is neurocognitive effects as measured by IQ decrement.
2. Specify the background concentrations in air, water, soil, etc prior to the onset of activity. These are selected from a distribution of national values, using some pre-established percentile of those distributions (e.g. the 75^{th} percentile mentioned previously).
3. Calculate the exposures to lead in indoor air and soil during the period of the activity. For home air, these exposures are based on measured loadings onto surfaces in the room where the activity is found, followed by multiplication by an air-to-loading ratio developed empirically. The concentrations in the air of other rooms is then obtained through application of empirically-determined correction factors.
4. Calculate the temporal drop-off of air and soil concentrations after the activity has stopped. These concentrations return to background after some period of time.
5. Calculate the time-averaged concentrations (prior to, during and after the activity) over a 6 year period beginning at birth. From these concentrations, estimate the total exposure during that 6 year period.
6. From this total exposure, use the dose-response (IQ decrement) function to determine the IQ decrement in children living in these homes throughout the 6 year period. Unless I have missed something, the assumption appears to be that such children live in the same home throughout the 6 year period from birth.

The structure of this assessment plan seems reasonable. The focus on children in the first 6 years of life is correct. I worry that the plan examines exposure over the 6 year period without any information on differential effects during windows of development, but I also doubt that data are available to parameterize a dose-response model reflecting these windows. And the authors do at least mention this issue and so are aware of it. I also wonder whether the assessment will assume only one renovation event of one type for an individual child, or whether there might be multiple events in a home.

The use of the EFSS as the primary exposure database is appropriate given that it is the available study that is most developed, but it requires development of the air-to-loading ratios since a component of EFSS examined only surface monitoring. This is what leads me to conclude that the EPA might be wise to wait for the OPPT air monitoring study to be conducted. I suppose an argument here is that they can at least go ahead and develop the full computational methodology, and then just replace the calculated air concentrations with measured ones once they are available.

The link to blood lead is the more troubling aspect of this plan. The three biokinetics models (one of which is the empirical model) mentioned were reviewed when the EPA published the draft of the All Ages Lead Model (AALM). That review uncovered a number of issues, especially with the Leggett model that yields predictions that appear to be well above what one finds in data such as the NHANES database, and above the IEUBK model. This may be an issue of the model form, or it may simply reflect the need to select better parameter values from distributions of inter-subject variability (with the wrong selections from the distribution having been made in the original studies verifying and validating the models). I personally believe that the EPA has a significant amount of work to do to verify and validate these models, which are crucial in linking exposure and the epidemiological studies.

As mentioned elsewhere in my review, I believe the EPA needs to think much more carefully about the uncertainty-variability-sensitivity analyses proposed. It will be important to clearly separate uncertainty and variability, and nothing in this document suggests they will do that. While I believe it would be possible to do a fully nested variability-uncertainty analysis, I can also understand a position that claims the needed distributions are too poorly specified at present to make this feasible or defensible. So, the use of a sensitivity analysis using lower and upper bounds as well as central tendency estimates of all parameters can be at least partially informative. It will be necessary, however, to relate these three numerical values to some parts of the distributions, however loosely. Nothing in the document so far makes me comfortable that the EPA has a plan to do this, although they do have the staff with necessary skills to perform this step with rigor.

Specific Questions:

I consider here the specific questions asked by Cathy Fehrenbacher and Jennifer Seed in their January 2, 2007 memo. Most of the material for these answers is contained in my review above.

1. I commented above on the reasonableness of the assessment approach. Subject to the caveats I mention, the approach seems to me to be reasonable given the inherent difficulties in making estimates of exposure for activities that can vary so widely from site to site.

2. The documents make it clear how the assessment will proceed, although there is a lack of detail on the computational steps. But these steps will be better described in the final assessment, and they are routine calculations for the EPA. So I am comfortable that they know how these will proceed. There is less clarity on why specific parameter values were chosen from the underlying variability distributions (e.g. why they use the 75^{th} percentile in some cases). And the sensitivity analyses proposed are neither clear nor likely to be fully informative, as I discuss above.

3a. The EFSS provides the best available basis for the exposure assessment, and is about as good as one can find for the intended use. My only question is whether it might not be better to just wait for the OPPT Dust Study to provide direct measurements of air concentrations rather than using air-to-loading ratios. And I have some concern over the representativeness of the homes sampled in the EFSS database, especially given what is likely to be large variations between homes even under the same activity.

3b. I don't know much about the NAHB study and so don't feel qualified to address this question.

3c. The OPPT study will be quite useful once it is completed, which is why I continue to believe the final assessment must integrate these data into the calculations.

4a. The assessment plan is examining the appropriate parameters, but I have concerns over the justification for selecting particular values to represent low, central tendency and high values. This aspect of the methodology seems to me either poorly thought out or perhaps poorly explained.

4b. While elasticity and sensitivity scores are useful to partially inform the issues raised, I don't think they are sufficient to really understand uncertainty and variability issues. And the EPA needs to do a much better job of separating uncertainty and inter-subject (or inter-home) variability in conducting these assessments.

5. I don't know much about how cleaning efficiencies are measured or calculated, and so I can't comment significantly on this question. The one issue that strikes me as relevant is that existing data seem to reflect the cleaning efficiencies conditional on the cleaning procedure actually being employed. I was left wondering in the assessment plan whether the EPA will assume the procedures are applied in all homes, or whether there might be some probability that the cleaning procedure is needed but not employed.

6. The issue I see here is whether the sample is representative of all homes, or should be stratified by home type, home cost, etc. The reason for considering home cost is that this might reflect the ability of the home owner to hire companies that will take the extra steps needed to ensure reduced exposures. But I haven't worked with this NAHB database and so can't comment further on this.

7. I would use all three models and perform a sensitivity analysis around these three. I can see nothing in the Leggett model that is non-linear with intake, and so the use of a time-averaged exposure rate should be appropriate. There is, however, an issue concerning the age dependence of some of the key parameter values, and this age dependence would argue against use of a rate averaged over the entire 6 year period. I guess my final conclusion is that I would prefer to see the model run for each separate year during the exposure period rather than using the averaged rate. But this may be too much resolution given the uncertainties in the model and the variation in age-at-onset for the activities in a particular child's home.

As to the issue of activity-specific distributions, everything that has been done for the IEUBK can be done for the Leggett model, as they differ only in mathematical form and not in any of the essentials of the ways in which data are used to parameterize the models. The one exception is that the Leggett model contains additional parameters (above and beyond those for the IEUBK model), for which distributions may not be available. I would not be inclined to support an approach that selects "upper bound" values for these parameters independently, since selection of one particular parameter value can change the way in which the other parameter values are optimized. So there needs to be some sort of correlation structure determined for the parameter values, which has not been done to date (in fact, I don't believe it has ever been implemented properly even for the IEUBK model, although I could be wrong about this – I don't think I am).

8. I am very uncomfortable about extrapolations performed below 10 µg/dL, and could not support extrapolations below 5 µg/dL. I just don't feel the data support extrapolations below that level. But the same comment does NOT apply to an INCREMENT of 5 or 10 µg/dL sitting on top of a significant pre-existing BLL.

Summary Comments:

- Variability and uncertainty need to be much better separated in the report.

- The blood Pb biokinetics models need to be improved, especially the one by Leggett, before reliable estimates of blood Pb concentration from temporally complex exposures such as the ones considered here can be predicted.

- There needs to be significant improvement in the description of the computational steps and the assumptions underlying each step. There should be a flow diagram of these computational steps.

- The Weight of Evidence section must be improved significantly before it will meet EPA standards of practice.

Dr. Richard Fenske

Comments for the February 5, 2007 CASAC Consultation on the Draft Assessment in Support of the Lead Renovation, Repair, and Painting Rule

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Charge Issue 3: Environmental Monitoring Studies

The U.S. Environmental Protection Agency, Office of Pollution Prevention and Toxics (EPA-OPPT) is in the process of preparing an exposure assessment for lead dust generated during renovation, repair, and painting in residences and child-occupied facilities as a part of an assessment in support of the Lead Renovation, Repair, and Painting Rule. EPA-OPPT has provided CASAC with draft of this work-in-progress (December 2006).

EPA-OPPT plans to use environmental monitoring data gathered in one or more field studies, as discussed below. The activities included in this draft of the exposure assessment are

1. Kitchen renovation
2. Three cutouts
3. Replacing windows
4. Replacing exterior doors
5. Scraping lead-based paint, interior flat component
6. Scraping lead-based paint, interior door
7. Replacing fascia boards
8. Exterior lead-based paint removal

A number of other activities will be evaluated in the next exposure assessment draft.

This exposure assessment will eventually integrate intake rates with environmental media concentrations to produce exposure and dose estimates, and will then convert these to blood lead level estimates. The assessment will produce a "reasonable range of results", considering both uncertainty and variability.

This draft of the exposure assessment does not include child-occupied facilities (COFs), does not consider the age of the building, and treats inhalation exposures as unaffected by RRP activities. These elements will be included in the next iteration of the assessment.

Comment #1: The term "exposure scenario" is used to describe activity-specific environmental monitoring studies, but these studies do not characterize "exposure". Instead, they characterize air and surface lead levels related to specific RRP and control activities. I would suggest that EPA use the term "RRP scenarios" for these studies to avoid confusion. Exposure scenarios focus on specific human receptors, and include human activity data and/or assumptions to convert environmental media concentrations to exposure (contact), and ultimately to dose.

Comment #2. I would also suggest that EPA avoid the use of the term "exposure concentrations" to describe environmental media concentrations. Exposure is normally expressed as mass contacted by the receptor over a specific time interval, or as a rate (mass/time). What are the units of an "exposure concentration"?

Comment #3. I would agree with several other reviewers that our review may be premature, given the incompleteness of the exposure assessment. However, as a consultation exercise, we can hopefully provide some useful feedback so that the final assessment can be peer-reviewed in a thoughtful manner.

Comment #4. Part 1 of the exposure assessment does not provide a description of how contract rates will be determined. This section needs to include a sub-section that explains how human activities within residential and COF environments will be characterized.

Comment #5. Part 2 is entitled "exposure scenarios". But unique combinations of RRP activities and control activities do not represent exposure scenarios. See comment #1.

Comment #6. Section 2.1 does not provide a rationale for the selection of specific types of RRP activities. Why were the activities listed in Exhibit 3 chosen?

Comment #7. Section 2.2 does not provide a rationale for the selection of specific types of control activities. Why were these activities chosen?

Comment #8. Section 3.3.1 uses the term "default lead loading value". What is meant by "default"? Is this considered the central tendency of the distribution of values for lead loading in residences of concern?

Comment #9. Section 3.1.1 provides a default lead loading value, a low lead loading value, and a reasonable high-end estimate value. Are these values used to produce a distribution of values? Are there assumptions associated with the distribution of values?

Comment #10. Section 3.2 explains differences in the approaches used to estimate environmental media concentrations for the Economic Analysis and the current draft assessment. The second bullet states that "this assessment reconsidered many of the input values used in the Economic Analysis and revised these values where appropriate . . ." This statement is not helpful to the reader. I would suggest that the assessment delineate the input values that have been changed, and provide a rationale for each change.

Comment #11. Section 3.2.1.1 describes the steps taken to estimate indoor dust concentrations for the baseline control scenario. Do the authors mean the lead concentration in indoor dust? The first bullet is not clear. How were lead loadings estimated in the workspace based on the tasks specified for the RRP scenarios?

Comment #12. Section 3.2.1.2 talks about assumptions associated with the full rule implementation control scenarios. I must be missing something here. It is assumed that lead loadings in the workspace are 40 $\mu g/ft^2$. Why is this assumption made? Why is there a need for an assumption if measurements are being collected?

Comment #13. Section 3.2.2.1 discusses baseline control scenarios for outdoor soil. Bullet 2 states that converting lead loading to lead concentration is based on an assumed soil mixing depth and soil density. What are these values, and what is the rationale for using them?

Comment #14. Section 3.2.2.2 discusses the full rule implementation for outdoor soil. Similar to comment #12, it is not clear why it is assumed that the implemented controls are 100% effective in controlling lead loadings to soil. It would be helpful to have the basis for this assumption explained here.

Comment #15. The December 2006 "Exposure Assessment" document provided to CASAC is not, in fact, an exposure assessment. It is a discussion of how environmental media concentration data for lead will be used to compare the impact of different combinations of RRP and control activities on lead concentrations in dust. There is no discussion of how humans might come into contact with lead in residential environments, and no development of plausible exposure scenarios; i.e., scenarios that describe human interaction with the residential environment under particular conditions.

3a. Please comment on the usefulness of the Environmental Field Sampling Study (Lead Exposure Associated with Renovation and Remodeling Activities, Battelle, 1997) in the context of this particular exposure assessment.

This study focused on "typical unregulated R&R work" in an effort to be representative of R&R activities as currently (mid-1990's) practiced in the United States.

Comment #16. This study was conducted approximately 10 years ago. EPA may wish to consider if the study conditions at that time differ in any significant way with those found today.

Comment #17. One of the three recruitment criteria for this study focused on meeting "all requirements specified by EPA, Battelle and MRI's Human Subjects Committees". Section 4.4 of the report states that the work was "submitted to both the contractors' and EPA's Human Subjects Review Committee for review and approval". However, the report does not provide the names of these committees, nor any documentation associated with the review and approval. This information should be included in the study report. Also, it is my understanding that EPA did not have a Human Subjects Review Committee at that time. Please clarify.

Comment #18. The EPA should determine if this study will need to be reviewed by the Agency's Human Studies Review Board.

Comment #19. This study appears to have been conducted in a thoughtful and professional manner. Selection of sites and recruitment of subjects were described in detail, as were the sampling methods and analytical procedures. The environmental media concentration data appear to be suitable for use in the EPA's exposure assessment.

3b. Please comment on the usefulness of the Lead-Safe Work Practices Survey (National Association of Home Builders, 2006) in the context of this particular exposure assessment.

This goal of this study was to "measure the amount of lead dust generated during typical R&R activities, and assess whether routine R&R activities increased lead dust levels in the work area and property". The study aimed to evaluate "the most common jobs performed by renovation and remodeling firms". The R&R work was "performed by professional renovation and remodeling contractors from each of the communities where the properties were located". The report indicates that "all of the R&R workers who participated in this project had previously attended and successfully completed the EPA/HUD curriculum for *Lead Safety for Remodeling, Repair, and Painting"*. The investigators chose to include clean-up following RRP activities as an integral part of the RRP activities, so lead dust samples were collected only after clean up. The project was conducted in 2006 by Atrium Environmental Health and Safety Services, Reston, VA.

Comment #20. As with the 1997 Battelle study, this study appears to have been conducted in a thoughtful and professional manner. The sampling methods and analytical procedures were described appropriately. Selection of sites and recruitment of subjects were constrained by a number of factors. It is hard to determine from the information provided whether the sites were "typical" and whether the jobs evaluated were the "most common".

Comment #21. It is not clear what is meant by "professional" renovation and remodeling contractors. Table 3.1 provides a glossary of terminology, but this term is not listed. Does this simply mean that they were licensed contractors, or that they had special expertise in handling hazardous materials during R&R activities? Clarification of this point woud be helpful.

Comment #22. It appears that workers who participated in this study were among those in this workforce who were well attuned to the hazards of lead in residential environments, and the importance of minimizing contamination during R&R activities. Thus, it is not clear if they were a representative sample of R&R workers.

Comment #23. The narrative of the report gives the impression that the studies were carefully scripted (e.g., each activity was completed within one day), and well supervised by the research contractor. These factors raise a concern as to whether the study was able to capture work activities that may have been influenced by a need to hurry the work, fatigue, or other "real-world" conditions that are a part of normal R&R activities.

Comment #24. There is no mention in the report of a human subjects review prior to the study's commencement. Was such a review conducted, and did the investigators receive approval? The name of the Human Studies Review Committee should be provided, together with relevant documentation in the report.

Comment #25. The EPA should determine if this study will need to be reviewed by the Agency's Human Studies Review Board should the Agency choose to use the study in its exposure assessment.

Comment #26. The uncertainties associated with site selection, activity selection, and worker representativeness need to be considered in more detail before EPA integrates this study into its exposure assessment.

3c. Please comment on the usefulness of the ongoing study, Characterization of Dust Lead Levels after Renovation, Repair, and Painting Activities (Quality Assurance Project Plan, Battelle, 2006), in the context of this particular exposure assessment.

This project will be conducted to characterize dust lead levels after Low, Medium, and High RRP jobs in housing units and COFs with lead-based paint. Only the quality assurance plan has been provided for review.

Comment #27. There does not appear to be a section in the plan that describes subject recruitment and human subjects review and approval procedures. It is not possible to determine if the sites and workers selected for the study will be representative based on the information provided.

Comment #28. Appendix A provides a very helpful explanation of statistical procedures and power estimates.

Comment #29. This study protocol appears to have been prepared in a thoughtful and professional manner. The data provided by this study may be suitable for use in EPA's exposure assessment, but more information is required to make this determination.

Dr. Bruce Fowler

CASAC CONSULTATION ON DRAFT ASSESSMENT IN SUPPORT OF THE LEAD RENOVATION, REPAIR, AND PAINTING RULE (LRRP) RULE DOCUMENT

Bruce A. Fowler Ph.D., A.T.S.

I. GENERAL COMMENTS ON THE DRAFT DOCUMENT

As noted by a number of the CASAC Lead panel members, the current draft document is a bit difficult to follow and appears to rely on some rather simple assumptions regarding the presented scenarios. It is intuitively clear that there will be increased mobilization of lead during LRRP activities and that these concentrations should hopefully fall back to background levels at some point after these activities are complete assuming good housekeeping behaviors on the part of the housing occupants. Setting aside the assumptions underlying the loading factors for the various scenarios for the moment, there are a couple of more general public health practice questions that arise regarding this approach.

1) It appears that the LRRP rule is centered around child-occupied facilities (COFs) and that the proposed rule would not apply to housing containing adult occupants. If this understanding is correct, has any thought been given to the situation where a renovation or abatement has been conducted on adult occupied facility which is then occupied at a later point in time by children under the age of 6? It must be remembered that we live in a dynamic demographic society where young families are now moving back in to cities (with older housing stocks that have been previously renovated by adults) in order to avoid commuting issues. Such housing would be listed as renovated but might not be in compliance with LRRP rule.

2) It may be lack of background information but it might be helpful to address the issue of disposal of lead-contaminated housing materials / vacuumed dust / paint waste etc following LRRP activities. There will be tons of such lead -contaminated waste produced and some guidance regarding safe disposal of these materials would be useful to the reader. If such guidance or procedures are in already then simply citing the appropriate regulations or rules would be address this issue.

II. Response to Issue #8 - Question #8

As previously agreed by the CASAC Lead Panel, it is clear that a focus on children as the population at risk and loss of IQ points associated with various blood lead concentrations is the most appropriate and protective approach currently available for dealing with health effects associated with lead exposures. It is also increasingly clear that among children or adults some individuals are even more sensitive than the "average person" within a given age group such that there is <u>no</u> safe level for lead exposure (Please see NAS/NRC, 1993) for a discussion). The practical implications of this judgment with regard to extrapolating data from the Lanphear et al.,

(2005) studies to low lead dose levels or small changes in blood lead concentrations are that a linear dose-response model should be assumed for this endpoint in order to be protective of this highly sensitive subpopulation. A second related scientific issue is the value of evaluating ALA-dehydratase (ALAD) polymorphisms in exposed populations as genetic factors which will both influence blood lead concentrations for a given exposure level and internal lead bioavailability to sensitive biochemical systems. (Please see the meta-analysis studies by Scinicariello et al., 2007 for a review). Inclusion of these types of genetic evaluations in studies of children with low blood lead concentration may provide data of value in interpreting changes in IQ and helping to define those at special risk.

References

Lanphear, BP et al. Low level lead exposure and children's intellectual function: An international pooled analysis. Environ. Heath Perspect. 114:894-899, 2006.

NAS/NRC .Report of the Committee on Measuring Lead Exposure in Infants, Children and Other Sensitive Populations. Washington, D.C.: NAS/NRC Press, 1993, pp 337.

Scinicariello F, Murrary HE, Moffett DB, Abadin H, Sexton MJ, Fowler BA. Lead and δ-aminolevulinic acid dehydratase polymorphism: where does it lead? A meta-analysis. Environ Health Perspect. online 15 September 2006- Final - Environ Health Perspect.115:35-41, 2007.

Dr. Philip Goodrum

Individual Review Comments for CASAC Consultation on Feb 05, 2007
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CASAC Consultation on USEPA Draft Assessment in Support of the Lead Renovation, Repair, and Painting Rule (LRRP), December 2006

Question 3: Environmental Monitoring Studies. Comment on the usefulness of each of the following studies in the context of the Draft Exposure Assessment (USEPA, 2006. Exposure Assessment for Lead Dust Generated During Renovation, Repair and Painting in Residences ad Child-Occupied Facilities. OPPT. December).

1. Environmental Field Sampling Study (EFSS)
   USEPA, 1997. Lead Exposure Associated with Renovation and Remodeling Activities: Environmental Field Sampling Study, Volume I: Technical Report. Prepared by Battelle (Columbus, OH) for OPPT. EPA 747-R-96-007. May.

2. NAHB Survey Report
   National Association of Home Builders (NAHB). 2006. Lead-Safe Work Practices Survey Project Report. Prepared by Atrium Environmental Health and Safety Services, LLC. November 9.

3. OPPT Dust Study
   USEPA. 2007. Characterization of Dust Lead Levels after Renovation, Repair, and Painting Activities, Draft Final Report. Prepared by Battelle (Columbus, OH) for OPPT. EPA EP-W-04-021. January 23.

General Comments

The Draft Exposure Assessment is intended to provide estimates of the time course of surface lead loadings and lead concentrations in both indoor dust and outdoor soil that may be attributed to various renovation, repair, and painting (RRP) scenarios. Data from the environmental monitoring studies are intended to be used to support modeling assumptions and parameter values in the exposure assessment. From this perspective, general observations and recommendations are offered below.

1. Use the new data to improve the sensitivity analysis.

The data are also potentially useful for guiding the sensitivity analysis of the exposure models. The current sensitivity analysis is essentially a bounding exercise based on a series of alternative input parameters (low, default, and high). The range of point estimates seems to mix concepts of variability and uncertainty. Probabilistic sensitivity analysis (e.g., Monte Carlo simulation or

Probability Bounds Analysis) would be much more informative for several reasons: 1) inputs can be ranked based on their contribution to variance in the exposure model output; 2) inputs can be varied simultaneously in a single simulation; 3) variability and uncertainty can be characterized separately; and 4) correlations among inputs can be accounted for explicitly. Many of the "low" and "high" point estimates are derived from available data that support estimates of probability distributions; the newly released OPPT study will likely contribute additional information that can be used to define distributions and conduct a more comprehensive uncertainty analysis.

2. Conduct the exposure assessment in a probabilistic framework.

Lead risks are characterized by the likelihood that blood lead (PbB) concentrations among similarly exposed individuals will exceed a level of concern (i.e., 10 µg/dL). USEPA currently endorses the use of a lognormal distribution with recommendations for the geometric standard deviation parameter. The intent of the exposure assessment for these models is to estimate the geometric mean (GM) of the lognormal distribution. The underlying assumption of the exposure model is that the combination of central tendency input parameters for exposure variables, including the exposure point concentration, will yield the GM PbB concentration. However, from a purely mathematically perspective, the combination of arithmetic means and medians will most likely give, at best, a rough approximation of the GM, and more likely, an underestimate of the GM. One utility of a probabilistic approach such as Monte Carlo simulation or Probability Bounds Analysis would be to derive a confidence interval for the GM. If the exposure assessment is viewed in a probabilistic framework, then an important criterion for evaluating the dust studies is the extent to which data may be used to specify probability distributions that characterize variability or uncertainty.

3. Revisit the scenario assumptions.

The exposure assessment includes several important data gaps and "place holders" for modeling assumptions that are intended to be updated pending the evaluation of the OPPT Dust Study. More time is needed to provide a comprehensive and systematic review of the OPPT Dust Study; however, several specific observations are noted below in the detailed comments. Ideally, the information from the dust studies would resolve the following questions that I had as I reviewed the exposure assessment:

a. Can the regression equation used to relate lead loading to dust lead concentration be further explored in an uncertainty analysis? The regression equation approach is a simple solution to an otherwise complex modeling problem. To develop a reliable mechanistic model, the environmental studies would need to provide information on a wide array of factors that may all contribute to the variability in surface loading and concentration, including the concentration of Pb in the Pb-based paint that was applied, the number of times the surface was repainted (i.e., the average Pb loading, or mass per unit area), the extent of the surfaces previously renovated, the extent of the surfaces renovated during the study, etc. While it is unnecessary to quantify these sources of variability explicitly, the uncertainty in the regression equation should still be quantified. According to Appendix C, the data collected by HUD were stratified into four vintage ranges of pre-

1940 to post-1979 houses (presumably Pb paint-free). Yet only a single scatterplot and regression equation is shown (Exhibit C-1). Where do the post-1979 data fall within this scatterplot? How do the scatterplots for each vintage group compare with the combined data set (try regressions or side-by-side box plots). Are the sample sizes roughly the same for each category? What is the confidence interval on the regression line? To what extent are the data on dust loading from the empirical study included within the range of dust loadings from the HUD study?

b. For the Full Rule Implementation (Section A.2.2), the lead loading in the workspace is based on the EPA floor hazard threshold (40 $\mu g/ft^2$), rather than being a function of RRP activity. Why define this loading as a constant? Can't we expect that loading will vary even after the full rule is implemented?

c. Why not just remove the terms for percentage of house that is workspace and the percentage of house that is adjacent to the room? The parameter values seem very subjective and uncertain. For example, why would the percentage of the home constituted by the adjacent rooms be equal to the percentage constituted by the workspace? The real underlying assumption that isn't explicitly stated in the Exposure Assessment is that the child's hand-to-mouth activities that contribute to incidental dust ingestion can be equally divided among the entire house. This is unlikely to be true since the child will likely have favorite play areas, the surface loading material will be mixed throughout the house, etc. Lacking such information from even the best surveys, the approach to generating area-weighting averages is more complex and more uncertain than necessary. Recommend using a single variable and indicate that it is subjective: Fraction from source (i.e., the workspace area), which represents the contribution of the dust in the workspace to the average daily dust intake (workplace plus non-workplace), and use various scenarios for the fraction such as 5%, 20%, and 50%. Variables that can be more readily quantified using data from the dust studies include lead loadings and concentrations in the area of the workspace.

Specific Comments Related to Draft Exposure Assessment

Section 1.2 Sensitivity analysis should be reconsidered as discussed in General Comments above.

Section 1.2. First sentence of first paragraph seems to contradict the first two sentences of paragraph three. Could simply reword the first sentence of first paragraph, "Two types of buildings in which childhood lead exposure may occur include: residences with children, etc….."

Section 1.2 Last paragraph. Since vintage plays an important role, perhaps what's needed are separate regression models for separate vintage categories. As suggested in the general comments, some of the factors can be replaced by a subjective "fraction from source" term.

Section 1.3. Short-term inhalation exposures may be important if they introduce a significant spike in intake. Use the Leggett model (which accommodates short-term exposures) to determine the concentration in air that would yield a change in intake that is potentially significant. This risk-based screening level can be compared with the OPPT Dust Study data to determine if air concentrations are likely to be high enough to be of concern.

Section 1.4. Statement is misleading: “During the activity phase, exposure concentrations will be represented by the sum of the background dust concentrations and the estimated activity-related concentrations”. We don’t actually sum concentrations – for example two equally sized rooms with Pb concentrations of 2 mg/kg and 3 mg/kg would not have a combined Pb concentration of 5 mg/kg. What is intended is the weighted average Pb concentrations where the weighting factor could be based on relative floor space, activity patterns, etc.

Section 2.1. Identifies an uncertainty that is not addressed: “For some activities, it is possible that there are contributions to lead concentrations in both indoor dust and outdoor soil”. This could be tested – so should be looked for in the dust study sampling protocols or data sets.

Section 3.1.1 Use of the 75^{th} percentile of background lead loading values was justified because the HUD data set includes housing without lead-based paint. This is a reasonable estimate of the 50^{th} percentile of housing stock with lead-based paint since the lowest loading value (non-detect) is the 25^{th} percentile.

Section 3.2. A point is made that exposures should account for time-varying nature of concentrations and loadings. One question that should be addressed is the extent to which there is small scale variability in results. How do duplicate samples from the same sample event compare? To some extent, duplicates are indicative of measurement error and spatial variability. Is the variability in duplicates greater than or less then the temporal variability?

Section 3.2.1.1 Adding concentrations – see comment on Section 1.4 above. It is stated accurately in the last bullet of Section 3.2.2.1.

Section 3.4.1. Why not just use Monte Carlo simulation for a probabilistic sensitivity analysis (see General Comments above)?

Appendix A.2.3. Outdoor Soil – Baseline Controls. The area-weighted concentration is determined based on an estimate of the area of contamination (drip zone) relative to the area of the entire yard. The common assumption for residential scenarios is that the exposure unit is the residential lot and that the child has an equal probability of contacting any area. The proposed approach is consistent with risk assessment practice.

Appendix B. Exhibit B-5. Notes regarding efficiency control are important. This factor seems to be major, just by common sense. Cleaning efficiency will directly affect the dust remaining after the RRP job is completed. The timing of the study measurements is an important review criterion. In fact, this source of uncertainty could be easily tested by designing a sampling plan such that loadings and concentrations are monitored at specific time intervals throughout the RRP activity.

EFSS (USEPA, 1997)

The EFSS provides data associated with real world RRP jobs. It is a controlled study that can be used to define distributions of surface Pb loading and cleaning efficiency. Study design focuses on quantifying sampling variability and measurement error.

- Data are provided to develop a profile of the temporal variability in dust lead loadings at specific time points before, during, and after the RRP activity. Although the time course for sampling does not match for each property, this is not a major limitation since the results can all be plotted over time.
- Correlation matrix illustrating relationship between different dust sampling methods and dust lead loading measurements (referred to as “lead exposure estimates”)
- Personal air monitoring data;
- Major focus is on carpet removal RRP activities;
- Controlled study design appears to focus on one activity at a time; it would also be informative to understand how loadings may vary when multiple RRP activities are conducted. If there is no statistically significant difference, this would suggest that the overriding factors are the containment measures during the activities and the cleaning efficiencies after the RRP activities.

NAHB Study

The Draft Exposure Assessment (p. 1-1) indicates that the NAHB may be of particular interest for supporting modeling assumptions and parameter values. For example, both air samples and surface dust wipe samples were collected during RRP activities conducted in five separate residential properties in the study. Introductory materials provided to the CASAC panel suggested the following limitations:

1) The vintage of the properties (1800 to 1950) may not be representative on a more national scale. I am not convinced this is a severe limitation. While vintage may correlate with the type of lead-based paint used, what’s more important is the degree to which the surfaces have been renovated over time. A house from the 1930’s that was periodically painted may have less lead loadings than a house from the early 1960’s that was not painted as frequently.
2) Unclear information on site preparation. This may suggest that the background dust lead contributes to the post RRP measurements. The NAHB study was designed to simply evaluate pre- and post- RRP activity dust lead loadings. I do not view this potential double-counting as a major limitation because the RRP activities will generate much more material.
3) Unclear what lead-safe work practices were employed. I agree this complicates the classification of the study results according to the RRP activities.
4) No information on dust levels post RRP activity / pre-cleaning. Only information on post-cleaning. The study captured the most important information in my opinion – levels remaining after RRP and cleaning. I do agree that the study cannot provide reliable estimates of cleaning efficiency.

The sample size for the study is rather small (n=8 residences). Also, what appears to be missing from the NAHB study is a control group. The study suggests that for the majority of RRP activities, and for the majority of properties tested, post-activity dust lead loadings were lower than pre-activity dust lead loadings. The efforts to clean the workspace are clearly demonstrated. It would be helpful to have a control group in which the same cleanup activities are employed without actually performing the RRP activities. This would ideally be done on the same residence that later receives the RRP activities after enough time has elapsed for the dust reservoir to return to "baseline" conditions.

Dr. Robert Goyer

Comments by Robert Goyer on Draft Assessment Plan in Support of the Lead Renovation, Repair and Painting Rule
January 29, 2007

Response to Question 1: Reasonableness of approach outlined in draft

The two essential parameters chosen for the health risk assessment are blood lead as an indicator of exposure and measurement of neurocognitive effects in children. These parameters are entirely appropriate and the draft hazard assessment document provides succinct summaries based on evidence presented in the AQCD in support of these choices. The draft correctly points out that blood lead concentration reflects recent and current exposures to lead and is also in equilibrium with lead in body stores, soft tissues and bone, which may reflect past exposures. Blood lead concentration is the most commonly used indicator in studies the relate exposure to effect and indicates exposure to lead regardless of source, e.g. air soil dust etc.

Lead affects many other organ systems as discussed in the AQCD including cardiovascular effects (blood pressure) and renal effects but it is generally accepted that impairment of neurocognitive development in young children is the most serious health effect and that young children are the most sensitive population. It was also concluded in the AQCD that the Dose-Effect response was continuous, (has no discernible threshold), and is persistent into young adulthood.

One debate is the minimum level of exposure, (blood lead level) that results in a measurable effect. The document identifies the Canfield et al., 2003 and Lanphear et al., 2005 studies as evidence that there is an inverse, non-linear, relationship between blood lead concentrations below 10 µg/dl and IQ. I concur with these findings. Again, this evidence is succinctly presented in the document. I also agree that no threshold for this effect

The discussion of "influence of timing" concludes that that there is no definitive evidence supporting a "critical period or of cumulative exposure" that is most likely to be associated with a neurodevelopmetal defect. While studies by Bellinger et al., 2002 indicated importance of exposures within first few post natal years on long-term outcomes, the document also indicates that cumulative blood lead levels reflecting steady state exposures also serve as strong indicators of neurocognitive effects so I am not able to comment regarding the influence of timing.

The "Weight of Evidence" summary provides, in my opinion" an accurate summary of the relationship between blood lead level and neurocognitive effects.

Mr. Sean Hays

Comments on EPA's Draft Assessment in Support of the Lead Renovation, Repair, and Painting Rule
By: Sean Hays, Summit Toxicology
February 16, 2007

The following are bulleted comments for the various charge questions outlined by EPA.

Question 1: Draft Assessment Plan

- The document should discuss evidence used to justify not addressing potential breast milk exposures for this rule.

Question 6: Are there other methods that should be used for predicting dust loading rates?

- At least show the various options for transparency sakes and show how the shape of the model impacts the predicted dust loading predictions.
- Go gather the data. It shouldn't be that hard and would have been cheaper than assembling this CASAC panel.

Question 7a: Should the empirical model be used

- Only if the underlying data is applicable for acute high exposure scenarios. If the data underlying the empirical models is for chronic exposures, then it is not applicable for these types of acute, subchronic exposure scenarios covered by this rule.

Question 7b: Should mean exposure levels be used instead of time-varying lead levels

- No. Time varying levels should be used.

Question 7c: How should variability be used using the Leggett model?

- Better to use incremental increase in blood lead levels instead of absolute blood lead levels. The accuracy in predictions of an incremental increase are far better than a prediction of an absolute blood lead level.

Although not asked, I am going to comment on the use of the IEUBK model for this rule.

- The IEUBK is not appropriate for modeling acute, transient exposures.

This quote is from White et al. (1996)

"In the IEUBK model, a simplified approximation of bone lead kinetics was used to model the relationship between bone and blood in young children. The model was designed for applications where there are long periods of relatively steady exposure, not to acute or relatively rapid subchronic exposures, so that only the slowest transfer components affect kinetics on the time scales of interest. The cortical and trabecular compartments in the model provide the potential for long-term retention and storage of lead as an endogenous source."

The Conceptual Structure of the Integrated Exposure Uptake Biokinetic Model for Lead in Children
Paul D. White, Patricia Van Leeuwen, Barbara D. Davis, Mark Maddaloni, Karen A. Hogan, Allan H. Marcus, and Robert W. Elias
p. 1513

- EPA should consider using the lead PBPK model of O'Flaherty. It is applicable for children and for acute exposure scenarios.

2) Missing scenarios

    - Breast feeding mother and infant
        i. Either address this scenario or provide the evidence justifying why it is not an important/relevant exposure scenario/population.

Dr. Bruce Lanphear

Compilation of Comments on LRRP - Lanphear

Hazard Assessment
Overall, the summary outline of the Hazard Assessment was well written and accurate. I had only a few comments.

1. Page 2, 1st paragraph, last sentence: The draft should consider modifying this sentence to read, "Also, studies in humans and animals suggest that chelation treatment can transiently decrease blood lead levels – and presumably total body lead burden – but it does not appear to reverse or ameliorate lead-induced cognitive deficits or behavioral problems".

2. Page 3, 2nd paragraph: It is worth citing two more recent articles by Kordas (2006) and Tellez-Rojo (2006) that confirm the results of the pooled analysis using strict definitions for peak blood lead concentrations < 10 μg/dL.

3. Page 5, 4th paragraph: Considering modifying sentence to read: "Other limitations were also mentioned, such as the use of capillary finger-stick for early blood lead tests rather than venous samples *in one other study*".

Draft Assessment Plan for LRRP

Question 1: Please comment on the reasonableness of the approach.
In general, the approach outlined is reasonable with a few exceptions, as described below.

Page 2, 1st paragraph: The requirements may not be broad enough to protect a large and vulnerable population of children. As defined, the rule would not apply to families who own their homes and intend to become pregnant: "with respect to owner-occupied target housing, the person performing the renovation obtains a statement signed by the owner-occupant that the renovation will occur in the owner's residence and that no child under the age of 6 years resides there". Thus, this rule may inadvertently fail to protect a large group of children whose parents are buying a starter home and planning to become pregnant. I receive about 10 to 20 calls a year from new parents who inadvertently poisoned their child by renovating their housing unit before the birth.

Page 3, 1st paragraph: Of course the assessment should provide a characterization of IQ loss on a population basis. Why shouldn't it?

Question 2: Please comment on the transparency and completeness of the draft hazard assessment.

The Draft is transparent to the extent there are any details. There should be a review of the epidemiologic research linking renovation and remodeling with lead poisoning. There are numerous studies that should be cited from AJPH, MMWR, and the EPA Report from Wisconsin. The Plan should also include an overview of the relevant epidemiologic data on the relationship of dust lead loading and children's blood lead levels. This can be succinct because many of them are cited in the full report, but Staff should be particularly vigilant to make sure that the final recommendations are consistent with the empirical data, including the clearance levels.

Estimating Blood Lead:

The fact that the pooled analysis is only being considered as a compliment to the biokinetic models will inevitably lead to the same failure encountered in the NAQS Lead Report; an over-reliance on biokinetic models with limited data and ultimately no ability to validate the models with actual data. The Draft Assessment Plan must include an analysis of epidemiologic data to validate that the assumptions of the biokinetic models are reasonable.

Exposure Assessment for Lead Dust Generated During RRP

Page 3-3, 3.2.1.2: The reliance ion the EPA floor lead hazard level of 40 $\mu g/ft^2$ is unacceptable; epidemiologic studies have consistently found that about 20% of children will be expected to have a blood lead level >10μg/dL at this level. If the LRRP relies on clearance levels above 10 $\mu g/ft^2$ to 15 $\mu g/ft^2$ it will inevitably fail to protect children who live in housing units that undergo repair and renovation. A window sill standard of 250 $\mu g/ft^2$ is also not low enough to protect children.

The estimates in the exposure assessment document, which are all largely contrived, are not sufficient to set a standard. They offer a reasonable conceptual model, but little comfort that the results are grounded in reality.

Environmental Monitoring Studies:

The EFSS is a fine beginning to examine the extent of lead contamination from repair and renovation, but it is too limited with regards to the types of renovations. A review of the existing epidemiologic literature should be included with description of the extent of contamination that can result. There should also be an attempt to conduct epidemiologic analyses of repair and renovation using existing data sets.

It is imperative that the results of these studies are compared with the epidemiologic literature as well as the arbitrary dust lead standard promulgated for the residential dwellings.

Do these studies include measures of settled floor dust, sill dust *and* trough dust?

Issue 5: The cleaning efficiency is also largely dependent on condition (e.g., cracks that retain lead-contaminated dust).

Question: There is an existing study that has collected data on 170 housing units before lead hazard controls and after clean-up. It also examines how many times floors need to be cleaned to get dust lead loading values below 5 μg/ft^2. Contrary prevailing wisdom, it is feasible to achieve dust lead levels < 5 μg/ft^2 on floors, < 50 μg/ft^2 on window sills and < 400μg/ft^2 on window wells or troughs. The EPA should explore suing data such as this and the HUD grantee data to help validate their assumptions.

Question 7: The empirical model should not only be considered; it should be used.

Question 8: If the analyses do indicate that the changes in blood lad concentration are small, then you should question the validity of the biokinetic model or the assumptions (e.g., a floor dust lead loading value of 40 μg/ft^2 is adequate to protect children).

Dr. Randy Maddalena

Final Comments on Draft Assessment in Support of the Lead Renovation, Repair and Painting Rule

Randy Maddalena

February 5, 2007

The Exposure Assessment document describes a mostly empirical approach for estimating the total area weighted indoor dust lead concentration in buildings that are undergoing interior RRP activity and the area averaged soil lead concentrations in yards from exterior RRP activities. The document considers a variety of "scenarios" but the term "exposure scenario" is used to describe only the release scenarios. There is no discussion of human activities and/or behaviors, such as where a child is likely to spend time in the dwelling and how they will come into contact with the Pb dust from the RRP activity. This part of the exposure assessment may be in the biokinetic models or it may be beyond the scope of the assessment but either way *the report should provide an explanation of how the results from the release scenarios will be linked to the blood-lead model(s).*

In my view, all three of the environmental monitoring studies are useful for supporting the assessment. The studies provide task specific Pb loading rates in different rooms of residence undergoing specific RRP activities. In addition, the studies provide useful information about changes in these Pb loadings resulting from different methods of workspace cleaning and the effectiveness of plastic sheeting and general cleaning. I agree that there may be issues regarding the representativeness of the houses used in the studies and the limited number of structures and activities but overall these studies provide a very useful and relevant dataset. I do not have a concern about the age of the houses used in the field studies or the fact that the houses were not occupied during the measurements. Taken together, the three monitoring studies provide an opportunity to develop a release scenario model that combines specific RRP activities to simulate complete RRP "jobs" or "projects" and to verify the lead loading models. I see the older Battelle study and the ongoing OPPT studies as providing the detailed information for constructing the release scenario model where the NAHB study provides field data for verification of the model. Given the level of detail in these studies *I recommend a probabilistic framework for the release scenario model such that loading values for a given project are presented as a distribution*.

As indicated above, I agree with the approach of modeling a full RRP project or job by combining the individual tasks. One thing the monitoring studies all agree on is that it is difficult to find representative properties to study so empirical data on all aspects of RRP activities will continue to be limited. I think that if the approach of combining specific tasks is adopted for use in future assessment (i.e., a release scenario model), there will be no need to include full jobs such as "renovating kitchen" except for verifying the performance of the model. Unfortunately, the document is not really clear on whether they are really going with the idea of characterizing individual RRP tasks to simulate RRP projects and predict total loading. For example, Exhibit A-1 seems to provide a good start for this approach but Exhibit 3 includes "renovating kitchen" as one of the activities. I think that not only the "renovating kitchen" but also most of the other major renovation projects listed on pages 4 and 5 of the "Draft Assessment Plan" can be characterized within an acceptable range of uncertainty by combining individual RRP tasks given an understanding of the housing stock and an understanding of construction/remodeling process. The existing field monitoring studies provide a great opportunity to develop a release scenario model for lead loading and this should be a priority for moving forward with the assessment.

The "universe of included building types" is critical to the exposure assessment but very little information is provided in the document on the important characteristics of the "target housing" other than the expected relationship between age of the structure and the elevated levels of background lead contamination compared to the general housing stock. Are there other characteristics of these structures that may impact Pb exposure concentrations (floor area, room layout, yard area, ground cover, floor coverings, HVAC systems, etc.) or impact the regression model that relates loading to blood lead? Ultimately the draft exposure assessment only considers a generic residence. The report indicates that more building types including COFs will be included in the revised assessment but no information is provided about how this will be done and what characteristic might be important for modeling release scenarios. Discussion on the important characteristics of this target housing should be provided. The results from a sensitivity analysis based on a probabilistic analysis will help in this discussion.

Details on the exposure pathways are very sparse. The assessment focuses on calculating exposure concentrations and not actually calculating potential dose. These pathways may be captured adequately if the Agency chooses to use the regression model to relate loading to blood lead but there needs to be better justification for excluding pathways beyond just a lack of available data if a multi-pathway exposure assessment is used. For example, the approach ignores the potential for dust tracking from the yard and/or from room to room and resuspension of this dust into the breathing zone, particularly for children. There is also no discussion of hand-to-mouth exposures for children in the remodeled building. A significant amount of knowledge has come out of the pesticide exposure assessment research and could help in developing these exposure pathways for dust but again, the regression modeling approach may already capture these pathways. If the semi-mechanistic models (IEUBK and Leggett models) are used then discussion of exposure pathways is needed along with a justification for using the average household dust/soil concentration without any spatial resolution?

The five temporal phases that are used to characterize individual RRP activity specific exposure concentrations provide sufficient detail if the goal is to demonstrate the effectiveness of a given control/cleanup method. If the Agency is mainly interested in exposures then some of the phases may be excluded because children are not likely to be present for example during the actual construction phase in the property.

The approach used to derive background media concentrations seems to ignore the fact that only a small fraction of the housing stock is relevant. Selecting a high percentile from the overall U.S. housing stock to represent the fraction of homes that are likely to have lead-based paint seems arbitrary and the low level selected seems entirely irrelevant to the assessment. If this range is simply to provide a bounding estimate for the sensitivity analysis, it probably doesn't need to be so formal (default value +/- 1% or 10% is often adequate for the one-at-a-time sensitivity analysis although, as indicated above, I would suggest moving to a probabilistic framework for the sensitivity analysis). The selection of background soil concentrations from the distribution of all U.S. houses also seems arbitrary when measurements could have been collected on site at properties included in the field monitoring study.

Setting the "Full Rule Implementation" dust concentrations to the EPA floor lead hazard level of 40 ug/ft^2 seems optimistic at best. That assumption needs to be confirmed with the field monitoring studies and a more relevant *distribution* selected rather than a specific value.
The area weighting approach used in the assessment concerns me because it requires an assumption that the child will be equally likely be spend time digging in any part of the yard and/or spend equal amounts of time in each room of the house. Diluting the exterior source into the top 3 cm of soil is also somewhat arbitrary. One would expect it to be retained at the surface unless there was some active mixing of the soil. There is not enough information provided in the current draft to judge whether these assumptions are a problem. Specifically, it is unclear whether what loading-to-dose model is going to be used and if that will need more spatial resolution in the exposure concentration values.

The contribution of exposure from other sources is based on average U.S. values for drinking water and food. This again ignores the importance of the age (and typical locations) of the homes that are relevant to the assessment. If this is an "other sources" important variable in the assessment (and I am not sure that it is) then representative values for air and water concentrations should be derived for "vintage" homes and more representative areas rather than the complete U.S. housing stock. Using a dietary intake that is representative of the U.S. population should be okay.

The changing cleaning efficiency over time is an important factor in the assessment. It is unclear to me whether this change in efficiency comes about because the lead that is there is more difficult to pick up (in which case it would also be less bioavailable) or is it simply that the lead dust is replaced by "clean" dust so for a given cleaning you pickup a constant amount of dust but the fraction of lead removed with the dust is reduced by dilution over time. Some indication or discussion of the reason for this change in cleaning efficiency should be provided and as indicated above, this model input should be characterized as a distribution and modeled in a probabilistic framework.

The percentage of house that is workspace in Exhibit B-3 seems very high for the Replacement of Exterior Door.

If interested in relevant dwellings, why pool the data used to develop the regression in Exhibit C-1. The data was originally stratified into four age groups for the houses, which begins to provide useful information about the effect of different buildings but this is lost when the data is pooled. Also, the variability (several orders of magnitude) in this conversion from lead loading to lead dust concentration is lost in the regression and uncertainty in the prediction is not discussed. Is there going to be an effort to capture this uncertainty and variability in the revised assessment?

More important, the data pairs used to develop the regression may not be relevant to the dust composition and conditions that exist during an RRP activity. It is unfortunate that the field monitoring studies did not collect this information in the houses studied during RRP activity. I suspect that the composition of house dust will be very different when looking at converting background lead loading to dust concentrations than when converting the lead loading that is generated by an RRP activity to house dust concentration. This model needs to be verified for use in converting RRP activity generated Pb loadings to dust concentration.

Dr. Frederick J. Miller

Fred J. Miller, Ph.D.
February 16, 2007

CASAC Consultation on EPA's 1st Draft LRRP Assessment

Question 6. Please comment on the adequacy of the method used in the draft exposure assessment to convert dust loadings to dust concentrations. Are there other methods that should be explored?

The method for converting dust loadings to dust concentrations is presented in Appendix C of the document entitled "Exposure Assessment for Lead Dust Generated During Renovation, Repair, and Painting in Residences and Child-Occupied Facilities". Basically, a log-log regression model is used to represent the relationship wherein the independent variable is dust loading and the dependent variable is house dust lead concentration.

Importantly, if regression analysis is being used in order to be able to convert dust loading values to house dust concentrations, then our "calibration " curve needs to be a function that, in my opinion, explains a great deal more than 52% of the variation in the data. To pick the best function, can we incorporate information on the Pb particle size distribution and therefore suspension time to argue for a mathematical function that might be suitable to fit to the data?

Using a log-log model removes two inflection points in the relationship between dust loading and house dust concentration. If the relationship is truly linear, then the logarithmic conversion imparts curvature. From Appendix C, it is clear that constant variance is not present as one goes across the range of dust loading data. This indicates that weighted regression techniques should be used. Were they? Weighting could be done using the variance of subintervals or the reciprocal of the number of observations within an interval.

A statistical correlation has been introduced by double sampling 21 homes (i.e., 7.4% of the data), which violates one of the assumptions required for using linear regression techniques. One way to eliminate this problem is to use the average of the two values for these 21 homes.

The document provides no indication of the comparability of the 284 homes from the viewpoint of: what location in the home was sampled, air-exchange rates and whether the windows were open or not, the season of the year the sample was obtained, etc. Some discussion of these variables is needed to allow the reader to determine if an R^2 of 0.52 is about as good as one can expect.

The bottom line is that I am not convinced that Exhibit C-1 represents the best mathematical relationship that can be obtained between dust loading and house dust concentration.

Dr. Maria Morandi

Draft Assessment Plan To Support the Lead Renovation, Repair, and Painting Rule
Maria T. Morandi

Preliminary Comments (general and Question 3)

General comments

The approach appears reasonable overall but the Agency needs to provide more explicit rationale and justification for specific inputs. The document should provide a clear description of the findings that inform the draft assessment, not just refer to AQCD. One of the difficulties in evaluating the document in its present form is that one of the environmental studies is not yet available to the reviewers. Presumably, there will be a follow up review that will include these studies.

The selection of neurocognitive effects in young children as the most susceptible end point for health risk assessment is appropriate. Although epidemiology studies of these effects under the current blood Pb guidelines are limited and subject to uncertainties, the special sensitivity children and societal implications support judgments and decisions in favor of the precautionary principle. Although the Agency is under pressure to show the impacts of its regulations on public health, this reviewer has some concern (in part because of clarity in the document) about the apparent intent to establish a quantitative linkage between blood Pb increases resulting from exposures during RRP activities and IQ decrements. The document needs to provide a more detailed description of the scientific basis and rationale that support the dose-response modeling approach. Given the uncertainties inherent in these, it would appear judicious to describe the underlying assumption in each of these and then select the one that fits the current application best. In this context, the document would benefit from some revisions to improve its clarity and usefulness:

1) The Draft Assessment refers to the Pb AQDR or even not yet published studies to support assumptions, dose-response models, etc. This approach results in a briefer narrative but diminishes clarity regarding major technical and scientific findings that support the assessment because the reader is referred the more lengthy descriptions in say the AQDR. The Draft Assessment should be as much as possible a self-contained document that succinctly presents the pertinent scientific findings from the AQDR (i.e., which specific data are selected for baseline values, dose response models, etc.) and importantly why those values are chosen for the specific application to RRP activities. Summary tables of pertinent studies would improve readability.

2) The potential pathways of exposure for children vary significantly by age but the document does not explain if and how this is taken into consideration in the assessment. One would presume that the assessment incorporates the variability in pathway of exposures by developmental stage at the time the renovation activity occurs, but this is not stated anywhere in the document. It is not clear, for example, if the Agency incorporates purposive and non-purposive consumption of non-food items as part of the dietary route, including hand-to-surface

to mouth activities and food-to-surface-to mouth. It would appear that the impact on exposure from RRP activities that occur at different developmental stages should be part of the assessment.

3) Related to item (2) above, was the distribution of dust particle sizes associated with the RRP activities considered?

4) The document would benefit greatly from development and inclusion of a glossary of definitions and consistency in the use of these definitions throughout the document...

Issue 3. Environmental Monitoring Studies
General comments on the two first environmental studies:

The two available environmental studies are very different in terms of design, worker skills and training and safety practices (independent of how consistent these practices are with the proposed rule), so the results are difficult to compare strictly. The EFSS can be described as a more realistic scenario in a less regulated environment, comparable to the results expected when the untrained homeowner undertakes remodeling or hires workers to do the job. The NAHB survey was performed under tighter practice control conditions and, as would be expected, resulted in lower concentrations of the dust and lead releases associated with the activities. These differences are typical of what one would expect in industrial hygiene practice, and each of the studies is useful for different purposes. Workers that have a higher level of training (both in their specific profession and/or in safety) also perform their tasks more quickly than those with less training. In addition to the skills of the worker, the types of tools used, and the measures adopted to control dust generation (misting, for example) would be expected to result in different levels of Pb dust release and exposures. The differences between the two studies illustrate the importance of worker skills and workplace practices in reducing both the emissions and exposures. There are, however, clear qualitative similarities as to the activities that result in the highest levels of lead dust, that is window replacement and abrasive surface preparation which is important in the development of scenarios.

Issue 3a. Environmental Field Sampling Study (EFSS)
The purpose of the EFSS (USEPA 1997) was to assess lead disturbance and exposure associated with various types of RRP activities by measuring lead in air and dust before, during, and after RRP activities in housing units with confirmed lead-based paint. The EFSS had two components: one in which real world RRP jobs, such as carpet removal and window replacement, were monitored; and one involving a controlled study in which various RRP activities such as sawing, drilling, demolition, sanding, and duct removal were monitored on surfaces containing lead-based paint. The controlled study also investigated the degree to which settled dust-lead loadings could be reduced using either broom or standard vacuum cleanup on smooth, cleanable surfaces. The EFSS demonstrated that significant lead loadings were generated by most of the RRP activities. Some important limitations of the EFSS include: most of the work activities were simulated RRP activities, not “real world” RRP activities; the housing units chosen for the study were generally vacant units in poor condition with high paint-lead levels.

Question 3a.

The EFSS was mainly directed at evaluating inhalation exposures experienced by workers performing renovation activities. The study provided information on activity-related dust/Pb emissions and deposition on indoor surfaces and constitutes one of the few sources of such information potentially useful for the present assessment. The level of training and experience of the workers was highly variable. One of the difficulties in relating the results of the study to its use in the current assessment is that the EFSS reported releases for specific activities, including:

1. Surface preparation
3. Removal of large structures
4. Window replacement
5. Enclosure of exterior painted surfaces (i.e., siding)
6. Carpet or other floor covering removal
7. Wallpaper removal
8. HVAC (central heating system) repair or replacement including duct work
9. Repairs or additions resulting in isolated small surface disruptions
10. Exterior soil disruption
11. Major renovation projects involving multiple target activities.

There were differences in the levels of contamination associated with each of these activities, with those involving abrasive sanding of surfaces been the highest. The difficulty in relating the results of this study to the assessment, however, is that the current document does not provide information on how these data were used to derive emissions for each of the scenarios. It would have been useful to present a descriptions of the specific activities and their that form part of each scenario, including assumptions about important variables such size of rooms and wall surfaces and the duration of each activity. It would also be illustrative to discuss the results and implications of clean up evaluation done in the EFSS because it bears directly on the implementation of full rule. The EFSS also points out that (1) multiple rather than single activities occur during renovations, (2) the extent of contamination beyond the specific area been worked on varies by type of activity, and (3) particle size and bioavailability are important variables that can impact exposure pathways as well as the effectiveness of clean up procedures. Clearly, these considerations would be important in any uncertainty analysis, but the document does not present a description or discussion of these considerations, or how they were incorporated in the exposure scenarios.

Issue 3b. Lead-Safe Work Practices Survey Project Report. November 9, 2006.
The Lead-Safe Work Practices Survey was conducted by the National Association of Home Builders to measure the amount of lead dust generated during typical RRP activities and assess whether routine RRP activities increase lead dust levels in the work area and property. Both air samples and surface dust wipe samples were collected during RRP activities conducted in five separate residential properties included in the study. The Study's stated objectives were to answer the following three questions: 1) Do typical renovation and remodeling activities create lead hazards? 2) When applying EPA's lead-safe work practices to a set of typical renovation and remodeling activities, are surface lead hazards (>40 µg/ft^2 on floors, >250 µg/ ft^2 on window

sills), or airborne hazards (>50 µg/m^3 in the air) created? 3) Do modified lead-safe work practices reduce lead exposures below the PEL?

Some potential limitations of the NAHB survey include: 1) the properties in the study were old (approximate construction dates were between 1800 and 1950), and it is unclear to what extent the site preparation included cleaning; 2) the report is unclear about the difference between EPA/HUD Lead Safety Work Practices (LSWP) and Modified LSWP; we were unable to determine whether either of these was intended to be similar to the provisions of the RRP proposed rule; and 3) dust levels were only measured before RRP activities were conducted and after clean-up following the RRP activities. No measurements post RRP activity and pre-cleaning were taken.

Question 3b.

Since the homes were relatively old, the content of Pb in paints and surfaces, as well the level of deterioration of these materials would be expected to be worse that for newer homes. It is also likely that these homes had multiple coatings of paint, and that surface preparation between coatings was not consistent with current practices. While the report may not be clear as to the consistency of the work practices with the proposed rule, the NABH demonstrates that the levels of dust generated by skilled workers who have received safety training. Assuming that this study represents a "best scenario" under controlled practice conditions, and understanding that there were post measurements were only done after cleanup, the results would be useful for comparison with predicted estimates form the various scenarios under the current assessment.

Issue 3c. Characterization of Dust Lead Levels After Renovation, Repair, and Painting (Ongoing.)

The OPPT Dust Study is currently in progress, and is anticipated to be completed in January, 2007. The OPPT Dust Study is investigating the comparative impact on dust lead levels from use of the lead-safe practices EPA has proposed, and from baseline activities. The study is also investigating the effectiveness of different components of the lead-safe work practices EPA has proposed. Specifically, for interior jobs, the study is investigating 1) using plastic coverings during RRP work and 2) using a more extensive clean up routine than that which is typically conducted by RRP workers. The four phases of the interior jobs to be completed are 1) use of plastic coverings and cleaning per the proposed rule after work completion, 2) use of plastic coverings and baseline cleaning after work completion, 3) no plastic coverings and cleaning per the proposed rule after work completion, and 4) no plastic coverings and baseline cleaning after work completion. For exterior jobs, a single phase will be used with plastic sheeting, and collection trays will be placed above and below the plastic to assess the differential amounts of lead. For interior jobs, settled dust wipe samples and air monitoring samples will be taken for each job, each cleaning step, and each cleaning verification step. For exterior jobs, dust wipe samples will be collected from collection trays placed underneath the rule plastic, on top of the rule plastic, and near the rule plastic.

Analysis of sample results will assess the impact of the proposed techniques for reducing lead levels of the dust left behind from RRP activities.

Question 3c.

Since the study is not available for review, the only comments that can be made are on the overall objectives and study design described in the preamble to the question. Given the lack of information, the design appears appropriate for determining the efficacy of plastic sheeting for reducing deposition on building surfaces as well as the efficacy of cleaning procedures with and without use of plastic coverings for reducing post activity lead levels. The results can be use to evaluate the outcomes of the modeling scenarios proposed in the assessment document.

Dr. Paul Mushak

2/5/07 CASAC CONSULTATION: PRE-MEETING COMMENTS ON THE OPPT DRAFT DOCUMENTS FOR THE PROPOSED LRRP RULE

Reviewer: Paul Mushak, Ph.D.

I have both general and specific comments on the provided drafts. It appears that the main substantive document provided at this time is the exposure assessment, main text plus four appendices.

I. GENERAL COMMENTS

The CASAC Panel is to review and consult with OPPT on a set of documents for a proposed rule that has been years in the making. The proposed LRRP rule, to control lead paint hazards associated with renovation, repair and painting activities that will disturb lead-based painted surfaces, has a number of problems that are addressed below. The proposed rule affects many children. EPA estimates that 1.1 million children under age 6 will be affected per year from RRP activities [71 (6) FR at 1626].

A lot of the material one needs to really review the LRRP's scientific elements, such as they are, is in the underlying Federal Register notice of proposed rule making. It would have been helpful to have had the FR notice in hard copy provided as part of the documents, instead of having to chase it to get a .pdf copy. The notice is lengthy in html, which is what you get from the URL provided by OPPT. The .pdf version can be accessed via the EPA "Laws, Regulations, and Proposed Rules" link or, alternatively, the direct FR route also works: 71(6) FR 1588, January 10, 2006.

There are a number of difficulties with this draft. It is quite difficult to read. The terminology in the writing is itself confusing. Furthermore, much of the preliminary draft materials are contingent on material still in preparation or will be subject to modification after more material is obtained. In addition, the principal elements describing the "activities" toward RRP work appear quite deficient compared to the real world of renovation and repair or painting.

The CASAC Panel is arguably being prematurely presented with material for consultative review. First, the OPPT dust lead study seems to be the main underpinning report but it is still a work in progress. OPPT makes general reference to use of biokinetic models for Pb-B modeling but states little about any specifics. The hazard assessment is basically the rationale for what health risk metric will be used, with no details about methodology intended for use or the interfacing of the modeling outputs and the risk characterization distributions. In the parlance of conventional human health risk assessment, what OPPT has provided in the draft documents for the proposed LRRP rule is either hazard characterization and dose-response, or modeled media lead levels for dust and soil lead. The exposure steps in the form of biokinetic model Pb-B outputs and associated risk characterization estimates (IQ loss) are to be done in the future.

A major deficit with this assessment is that the various “activity” scenarios being described and roughly quantified are presented as unrealistic and unlikely individual events rather than multiple activities occurring simultaneously. I have rarely seen cases in the literature or in many years of experience where one only has to do one of the activities in the absence of any others. A residence with a chronological and lead paint hazard history typically has multiple home areas and components within those areas with lead-based paint. These areas are as currently defined in the January 5, 2001 lead hazard rule.

It is highly unlikely that a residence with lead paint hazards only needs to have a kitchen replacement, or an interior door scraped, etc. Many or all of the indicated types of activities typically would be required simultaneously. That, necessarily, means multiple activities done at one time in the interest of cost effectiveness and minimum child resident risks.

Did OPPT intend to mean that some or all of the seven classes of activities can occur simultaneously in a given residence but such activities can each be characterized as to lead exposures individually followed by risk assessments merely done additively?? If so, that appears equally unrealistic. If a kitchen is being refurbished next to a room that has walls and trim being LBP-scraped, which is next to a room having door scraping, which occurs next to, or in, a room also having the lead-painted windows replaced, much of the spatial and contamination assumptions in this exposure draft become quite simplistic and uncertain and, therefore, of limited use.

The proposed LRRP rule text in **71(6) FR at p. 1611** recognizes that the scale of renovation, repair and painting will vary and could be extensive. However, there are not enough details presented in the notice to make it clear what is being proposed in this draft Exposure Assessment in terms of individual “activities” that would permit the level of precision implied in the various Figures, or for that matter, assumptions on levels of dust.

My impression of the various scenarios and their resulting modeled dust lead and soil lead levels is that of an overall approach that is simply too trusting of subjective ad-hoc procedures versus scientific procedures. The procedures, as a consequence, are too unwieldy to be useful to either Rule validation or for routine use. Rather than a smaller number of worksite-specific laboratory testings, the Rule opts for a contractor’s detailed comprehension of exacting protocols to minimize occupant lead exposure risks. Science is being swapped for a wish list of hopeful assumptions and expectations.

Background dust and soil lead values are taken not on a site-specific basis using Pb measurements but use a generic set of values taken from the 2001 National Housing Survey (HUD, 2002). Baseline controls (not to be confused with OPPT’s parallel use of baseline lead content and loading for interior dust and soil) are laid out with estimating piled on estimating. Full rule controls are equally simplistic, and tout the unrealistic message: the Rule is always effective and will always give the residual dust loading indicated in the numerous Tables and Figures of the draft exposure assessment.

My parallel impression of the Exposure Assessment draft approach and the underpinning draft Rule in the FR is also that of proposed controls that are having to be detailed and cumbersome because scientifically valid post-activity clearance-type testing will not be done. Such clearance testing for lead paint abatement or LBP interim controls is required. Clearance testing is a performance standard with legal implications for contractors.

A major flaw in the proposed LRRP Rule is dependence of the protocols on statistical modeling instead of generation of hard data. Each renovation, repair or painting project to be covered by this rule will not take objective measurements. In lieu of clearance testing (**71(6) FR at p. 1614**), which involves laboratory measurement of lead content of wipes and is codified as enforceable regulations by EPA for lead abatements [40 CFR Part 745: Subpart D] and as guidelines by HUD for "interim controls," the draft rule spells out a series of "cleaning verification" steps, none of which actually entail any lead measurements.

The scenarios are simplistic and rigid with respect to the temporal projections for each of the constituent phases of each of the scenarios. If one in fact has to do multiple activities in close proximity, how would these time frames even begin to be plausible? Keeping in mind that the estimates provided in such places as Appendix D for the numerous dust Pb levels have to be input to one or more exposure-predictive models, the Pb-Bs being generated become numerous.

A related question for multiple area renovation and repair is how would the numbers change in Tables D-1 to D-9 in Appendix D? These tables are single activity based.

The OPPT terminology for what constitutes "exposure" seems to be both confusing and at odds with the more specific definition adopted by EPA sister offices and the larger scientific and health communities. A concentration of Pb in dust is an environmental lead measure.

The exposure assessment draft also makes some simplistic assumptions about post-activity dust and soil lead levels. The "routine" clean-up phase of the five-phase sequence for lead paint and lead dust maintenance is assigned to the residents. I find it very hard to believe, based on the literature, that residents who are not lead abatement professionals can do effective continued dust Pb control. I have not seen this capability in my own experience nor does the published literature support the effectiveness of reliance on residents to do long-term routine dust maintenance. See, for example, the article of Lanphear et al. on the ability of residents to deal with interior dust lead exposures:

Ref:

Lanphear BP, Howard C, Eberly S et al. 1999. Primary prevention of childhood lead exposure: a randomized trial of dust control. Pediatrics 103: 772-777.

Certain literature information relied upon by OPPT needs to be checked by the authors. This includes the HUD report, "National Survey of Lead and Allergens in Housing." For example, in Table 5.6 of the main report, the figure of background dust lead loading of 2 $\mu g/ft^2$ for the 75th percentile is only for floor lead loading, with the corresponding figures for window sills and window troughs being 37 and 462 $\mu g/ft^2$ respectively. Similarly, for the 25th percentile, the respective values are 2.0 and 18.0 µg/ft^2. However, the proposed rule calls for cleaning verification to include window sills, etc. through visual inspections, wet cloth wiping and use of a "cleaning verification card." The question then arises as to what is the reference background value to which the post-renovation/repair/painting activity process is to return??

Table 6.5 of the main HUD report shows 130.7 ppm as the smaller of the two dripline soil Pb levels, not 103.7, stated in the OPPT draft. Why was the mid-yard soil Pb used as the lowest, 25th percentile, value for yard soil Pb when driplines were used for the 75th percentile? This seems nonsensical. Mid-yard soil Pb does not capture a mainly lead paint source, but a mix of some exterior Pb paint and ambient air lead fallout from, e.g., past leaded gasoline use and local industrial sources. The two 25th percentile dripline values are 11 ppm (rounding).

The biokinetic modeling proposed employs the Leggett model. This is the only one of the two models (the IEUBK is the other) that can be used over the short "activity" time spans. The IEUBK model is a "steady-state" model in terms of its computational construction and would not respond as reliably to short-term potential exposures of the sub-year durations being projected in the Exposure Assessment. However, failure of the routine cleaning expectations as part of the overall scheme would mean longer-term exposures to dust and appropriate use of the IEUBK model.

How exactly do the authors plan to use inputs to the Leggett model with whatever exposure module is attached, if multiple activities are continuing simultaneously and producing different numbers than in the Appendix D Tables?

Have the authors assembled an exposure module for use with the Leggett core biokinetic module, and if so, how was that done? Was there simply use of the interim All Ages Lead Model currently under development?

I do not see, anywhere in this document, any reference to secondary lead exposure, i.e., take-home exposures, of young children of renovation, repair or painting workers. Is this handled through worker protection practices in the FR notice sections? Those appear to address OSHA's worker requirements. If so, are the protocols adequate to avoid take-home leaded dusts? The FR notice (p. 1630, Sec. 745.85, Work practice standards) merely states that personnel should not carry leaded dusts off the worksite. How exactly do workers avoid this? Take-home lead exposure is a potentially serious aspect of the likely exposure universe for young children in these residential activities.

II. SPECIFIC COMMENTS

p. 1-3, Secs. 1.3, 1.4 The absence of the actual results from the OPPT dust study limit the scope of this consultation. The dust study document online is basically Battelle's QA project plan for the field study plus two short amendments. In Section 1.4, Exposure duration, I don't understand the mixing of the terminology for child "exposure duration" and each "scenario"? Does this mean there is an assumed one or more renovation or repair incidents over a child's six years of residency? For just the first six years of life? That the total time impact of a renovation or repair or painting activity is six years? Needs rewriting and explanation. It is unlikely that residents' routine cleaning efficiency will prevent dust Pb levels rising above background. As noted earlier, there are data on this problem.

p. 2-2, Table 3 What is the basis of the range of RRP activities in this table being the universe of scenarios? Exterior doors are expensive. One would expect that scraping LBP from exterior doors is more likely than their replacement. Does the full LRRP rule bar scraping of existing exterior doors versus their replacement?

p. 3-2, Sec. 3.1.2 The 25th percentile figure seems quite low, when compared to other data sets, such as those listed in the Pb AQCD ranges of soil Pb values. There may be something about the methodology, but that's not obvious. The soil collection was of the top 0.5 inch but vegetative cover may not have been completely removed.

p. 3-3, Sec. 3.2.1.1 Conversions of lead loadings to lead concentrations is based on the assumption that (1) the 1997 HUD national survey data capture the universe of dust Pb loading-concentration relationships and that the confidence bounds around the regression line reflect the universe of housekeeping hygiene in terms of total dust mass (lead and non-lead fractions). Have the authors compared this approach with that used by EPA's NCEA in development of the All-Ages Lead Model (AALM), where a conversion factor was used to convert from dust Pb loading to concentration? Consult the AALM manual for description of this part of the Leggett retrofitted exposure module. Have the authors considered the difficulty of lead removal from carpets in these calculations?

Ibid, 3.2.1.2 I don't understand this at all. What is the origin of the assumption that the 40 $\mu g/ft^2$ figure applies from initiation of the activity through its completion. What constitutes completion? The loading figure before cleaning and cleaning verification immediately after the Rule-based renovation, etc.?

p. 3-4 et seq., Sec. 3.3 What is the actual empirical evidence that the decay rates for dust lead for the various activity scenarios in the background control approach are as they are shown in Figures 3-4 to 3-9?

III. RESPONSES TO ISSUE # 5: CLEANING EFFICIENCY

1. I do not believe the cleaning efficiency outlined in the proposed rule is anywhere near scientifically rigid enough to prevent lead exposures of children subsequently occurring. The text of the FR notice dealing with public responses and EPA changes indicates cleaning and cleaning verification steps appeared to evolve for reasons of convenience and economics rather than for protection of children from toxic lead exposures.

2. The proposed cleaning scheme and cleaning verification should be either scrapped, or should include wipe-based clearance lead testing for a baseline for starting any of the activities envisioned.

3. In my opinion, these "cleaning verification" approaches are too flawed to be protective of occupant health. A central part of the cleaning sign-off is the use of a "cleaning verification card," wherein workers compare dust wipe surface smudge results to pictures of "cards" that depict various levels of lead dust. The visual appearance of a wipe, when compared to pictures of different degrees of soiling with dust, will guide progress in "cleaning verification." How exactly does one compare cards with white wipes for white lead paint dusts?

4. Has EPA done any field testing of the card(s) to validate the stability of visual interpretation across remodeling and repair workers with varying levels of visual acuity and interpretive skill? This is the sort of stuff people did before there were any testing instruments. A second concern on cleaning efficiency is "visual inspection" for surface dust presence. How well can this criterion be used to ascertain dust lead accumulation or dust lead escape from plastic sheet containment? White dust on white surfaces? Blue dust on blue surfaces?

5. Use of wet wipes for leaded dust clean up is one of the key components of the cleaning verification. How well does wet wiping perform with steady use? The only index of effectiveness is that the wipes be damp to the touch.

6. The proposed LRRP rule actually permits use of lead-measured clearance testing [71(6) FR at 1616e] as an option. However, only a certified worker can collect the samples for the clearance tests. Failing clearance tests, e.g., floor Pb > $40 \mu g/ft^2$, requires recleaning.

Mr. Rich Poirot

CASAC Consultation on the Draft Assessment in Support of the Lead Renovation, Repair and Painting Rule: Comments on Draft Hazard Assessment R. Poirot, 1/30/07

Please Comment on the transparency and completeness of the draft hazard assessment.

The draft hazard assessment presents a concise summary of the hazard posed by lead exposures to the cognitive development of young children. To avoid "duplicate efforts," many sections of the hazard assessment are taken directly from the Lead Criteria Document. Emphasis is placed specifically on: blood lead as biomarkers of both lead body burden and exposure; neurological effects of lead in children; and on results from recent epidemiologic studies which show quantitative inverse relationships between lead blood levels in children (both concurrent and lifetime) and cognitive function as measured by IQ test scores.

Especial emphasis is placed on 2 recent studies (Canfield et al., 2003 & Lanphear et al., 2005) that show neurocognitive deficits in children at blood levels below 10 µg/dL (a level previously considered to represent a lower threshold below which effects were uncertain). In fact, both studies, which are consistent with each other and several other recent studies, show greater <u>relative</u> reductions in IQ scores (<u>per µg Pb/dL</u>) at blood levels below 10 µg/dL than at higher concentrations. The hazard assessment also considers the potential influence that the timing of lead exposures might have on effects, although no clear evidence is provided that there are specific periods of childhood development which are most sensitive to lead exposures.

The hazard assessment is clearly written, logically argued and fully "<u>transparent</u>" — in the sense that major points of emphasis are accurately documented by, transcribed from and cited to the recent literature (as reviewed in the Pb CD). If the intent is to convey the points that: a current hazard exists (at lower blood lead levels than previously believed); that children's blood levels are good indicators of concurrent and historical Pb exposures; and that IQ scores quantitatively reflect neurocognitive effects of Pb exposures (as reflected in blood lead levels) — then yes, I think the hazard assessment statement is reasonably <u>complete</u>. If these are the objectives, the brevity is commendable and I certainly don't encourage adding any unnecessary discussion.

However, it does seem as though you define the hazard more with an intent to zoom quickly in on quantitative metrics (I.Q score deficits) to assess or describe the risk posed by Pb exposures from certain activities or for evaluating the efficacy of specific control measures, and less with an intent to provide a description of the hazard posed by current Pb exposures — as may be further increased or decreased by specific renovation, repair and painting and clean-up activities.

For example, although quantitative relationships between lead exposures, children's blood lead levels and IQ test scores are relatively well established, these effects represent, and could be described as, only one "indicator" of many short-term and long-term adverse toxicological effects of lead contamination. Also, while you illustrate clear quantitative relationships between blood lead and IQ scores, you provide only a very qualitative statement that blood lead levels directly reflect exposures — from lead in air, dust and soils. It might be useful to at least provide some citations for the "several recent studies" referred to in the 4th paragraph on page 1 that show how blood lead levels reflect environmental exposures. Providing examples of quantitative relationship between LBL and household dust Pb would seem important to your arguments. Your summary letter "scope of assessment" indicates intent to implement the resulting rule in a prioritized manner beginning with older housing "where a child with increased blood lead levels resides". Historically, I believe the term "increased blood lead level" has been used to mean > 10 µg Pb/dL, so unless you propose a new definition, the proposed implementation would seem somewhat at odds with your "hazard statement" emphasis on effects at lower blood lead levels. I'm not suggesting your proposed prioritization is flawed, but rather that you should make clear in your hazard statement that your emphasis on the recent Canfield & Lanphear studies illustrates (not a more adverse effect at lower levels but) that the "hazard" is more widespread and of greater magnitude than previously supposed, emphasizing the urgency of moving quickly and extending any possible protection to children with even lower blood lead levels.

Another aspect of the nature of the "hazard" which might be discussed here — and might in turn affect the details of your proposed rule — is that many of the children who are most at risk are currently living in older, low income housing where historical and continuing lead dust exposures — regardless of any new future renovation, repair or painting activities — already represent a serious hazard (& have likely been a major contributing cause of "elevated blood lead levels" in your target population). According to the 2002 CDC Report on "*Managing Elevated Blood Lead Levels Among Young Children: Recommendations from the Advisory Committee on Childhood Lead Poisoning Prevention*": **"**Direct and indirect exposure of children to leaded paint that has deteriorated because of deferred maintenance is likely the major factor in the increased risk for EBLL associated with poverty and living in older housing" (emphasis added).

Thus, "deferred maintenance" of older, low-income housing units has contributed to the current hazard, and you don't want to impose restrictions that will provide financial disincentives to timely repair & renovation work that would ultimately lower exposures. I assume the intent is to encourage the work to be done – but with best practices, precautions, clean-up, etc. There is some indication in your docket & proposed rule on fairly substantial HUD grants that have been provided for targeted Pb remediation programs in the past. Hopefully similar future subsidies will provide clear incentives to continue new "clean" renovations and maintenance activities.

The section on "Influence of Timing of Exposures on Risk" doesn't seem to provide much useful information – unless it is that there appears to be no logical basis to try to prioritize the timing of renovations according to the developmental stages of resident children. For example, should older housing units with children under 2 years old be given top priority? I would think a related topic that might be considered is the influence of the "episodicity" of the exposure. Does it matter whether young children accumulate a little lead every day or see much higher concentrations over a few week renovation project? Doing nothing continues the chronic exposure; improper renovation techniques will make the problem temporarily much worse; while best practices may not cause a sudden spike and may also reduce future chronic exposures

Minor Comments:
Page 1, 4th para, last line: I would state this in the inverse order or passive sense, i.e. that Pb levels in air, soil & dust are "reflected by blood led", rather than that these environmental exposures "reflect blood lead".

Page 6, para 3, 5th line: should be “exposures…were” or “exposure …was”.

Dr. Michael Rabinowitz

Comments by Michael Rabinowitz January 2007

On Lead Renovation, Repair, and Painting Rule

Issue 1. Draft Assessment

Question 1.

Regarding the reasonableness of this approach, I suppose it is realistic and sound enough. It looks like a 3 step process: 1) Find the environmental impact of a "renovation", 2) convert that to a change in blood lead and 3) convert that into an IQ decrement.

A renovation will release lead to the extent there is lead in the paint, which can range from negligible to very high. That combined with the episodic nature of renovation means that the child's exposure may well be acute or spiky, of brief, but perhaps repeated, duration. In that blood tends to time-average exposure over a time scale of weeks and months, the changes in blood lead will less abrupt.

It may be worth considering if under conditions like this, where the lead arrives in pulses, rather than a constant, chronic exposure, might not whole blood lead values under-estimate the impact of the brief exposure, because a relatively larger fraction of the dose will go to the brain, via the plasma, compared to near steady state exposure. I am asking those more familiar with the workings of these biokinetic models if the brain lead/ whole blood lead ratio is different under conditions of quick, repeated exposures, rather than chronic elevated exposure, and if that matters. Does the same blood lead value imply the same risk regardless of if the exposure was chronic or a bolus? In principle the biokinetic models should be able to account for this if the step size is short enough.

Regarding the conversion of changes in blood lead to changes in IQ, I suggest that for an initial presentation consider only a linear relationship, for your first analysis. Although large studies have now confirmed the details of the relationship to be non-linear, just to proceed cautiously, I'm asking you to consider first try the linear approximation. If that result looks reasonable, then try non-linear conversions. It may well develop that children with lower initial blood leads will be harmed more for a given event because of this non-linearity.

The final product ("deliverable" in contractual terms) of this effort needs to provide not only a numerical estimate of the IQ decrement, but also some sort of range or other estimate of the uncertainty in that estimate. As indicated in your last paragraph, we have scanty information about many of these underlying uncertainties. Despite the limitations you cite, any point estimate requires a range.

Allow me an additional reflection. At an EPA meeting some decades ago in the hallways of some Washington hotel I witnessed responsible men discussing responsibility for residential lead paint. Some, even at EPA, opined EPA's mandate would not allow them into a home. EPA was confined to the great outdoors. Crossing a citizen's threshold was beyond the role of the

EPA. Radon issues changed those attitudes, and the passage of time. Today the public looks to the EPA to set standards that could be applied to the inside, as well as the outside, of their homes.

Issue 2. Draft Hazard Assessment

Question 2.

It is adequate to the task. I suppose it is not necessary to state that IQ in children was chosen from among all of the many effects of lead because it has been observed at the lowest ranges of exposures. I concur with the remarks on page 6 about the ages of vulnerability. There are physiological, developmental windows and also age-dependent exposure pathways. So using both blood lead metrics seems appropriate. I share your doubt of resolving the issue of which blood metric will be more sensitive most of the time.

Issue 3.

Question 3a. EFSS

Questions3b. Lead-Safe

Question 3c. OPPT

All seem useful. Of course, I wish I could see more of the presentation. Side-by-side tabulations from these 3 would be illuminating.

Issue 4.

Question 4a.

Yes, I suppose so. I can not think of any others.

Question 4b.

No comment.

Issue 5.

Question 5.

I have no suggestion.

Issue 6.

Question 6.

I know of no other methods to convert from lead loading to concentrations. I sure we all realize that any conversion is highly dependent on the surface and how the samples are collected. Vacuum, wet wipe, and dry wipe protocols each provide samples that vary in their efficiencies on different floor surfaces. It may also be that if the lead is from a primary or secondary smelter or from deteriorating lead paint, or wind blown roadside debris, the particle characteristics, and hence any conversion factor, might well be different.

It is worth remembering dust lead is usually the strongest predictor of blood lead.

An editorial point: - C-1 the equation in the text and in Exhibit C-1. Please adjust the number if significant figures to a more realistic value. This display of 4 and even 7 digits is not warranted. I suggest r- sqr= .52. y=.6x+4 or = 4.0 ± .8 + 0.6 ±.2 X (I surmised these values from the data, but I'm confident you have them.

Also, please show us not only the best fit line, but also the 2, almost parabolic, error curves. That level of complexity of presentation would not be a problem.

Issue 7.

Question 7a

I would give it a lower priority, because the two other models are adequate. What might it add? Many more cases would be useful.

Question 7b

I suppose there is some way to vary the environmental inputs in these models over time, perhaps as a step function with an exponential decay. Using the mean may not be adequate.

Question 7c.

I have no idea.

Issue 8.

Question 8.

The small increments should not been claimed to cause large effects because, by themselves, they fall low on the non-linear dose-response. The slope for that increment needs to correspond with what the pre-increment lead level was.

These problems are avoided by reverting to a linear association, with a fixed slope that was chosen to be as near as possible the area of interest. The problem of extrapolating the non-linear model downward is the steeping slope at lower doses, which can not be sustained indefinitely.

Overall Comments:

It seems another way to approach this is to generate a baseline blood lead distribution and then offset it upward by the amount a renovation would cause. This yields two blood lead distributions. Each of those has an attendant IQ distribution. One of those would be offset compared to the other. So, the effect of renovation on IQ would be the difference between those two IQ distributions. Would that not yield an equivalent estimate of the IQ decrements from a remediation event?

Good Luck

Dr. Armistead (Ted) Russell

Review of Exposure Assessment for Lead Dust Generated During Renovation, Repair, and Painting in Residences and Child Occupied Facilities

Section 3.4 Sensitivity Analysis

Ted Russell

As part of the LRRP Exposure Assessment, EPA has conducted a preliminary sensitivity analysis to assess to which parameters the calculated Pb exposures are most sensitive. This is done, in part, as a first step towards an uncertainty analysis.

My first comment reading through this section is that one needs to clearly distinguish between uncertainty and variability. They note the difference in 3.4.3, though it would be good if they provided greater discussion of how they differentiate at this point. There will be a range of exposures resulting from RRP activities, indeed, likely a very wide range, depending on the specific activity, the Pb loadings, the conduct of the activity, the cleanup, etc. Thus, variability may be extremely large, as will uncertainty. EPA will have a difficult time differentiating the two down the road. For now, they have conducted a sensitivity analysis that does not rely on making a distinction between uncertainty and variability. Given the early stage of this analysis, this is appropriate. Indeed, the level of uncertainty analysis that is reasonable will be guided by the findings of the initial assessment and the sensitivity analyses. Before embarking on a more comprehensive uncertainty analysis, it is first reasonable to determine if the results of such an exercise are likely to be of importance. It would be good, and very instructive to the reader, decision maker and others if a discussion of what level of uncertainty would be considered important were to be given, noting the application of the analysis.

One limitation of the analysis is that the default chosen was a100% control efficiency. While very efficient, this is too high, and as noted drives much of the results to showing zero sensitivity. This is a reason to use a more robust sensitivity and uncertainty analysis.

At this juncture, EPA has chosen to do a parametric, min-max-baseline assessment. This is an extreme approach, but fine at this initial stage. One would look for them to get a bit more involved if policy considerations suggest that the sensitivities (and implied uncertainties) warrant such. For one, a Monte Carlo approach is not much more involved, and while it requires assumed distributions of the inputs and parameters, those can be provided with appropriate caveats to allow such. Such a method can also be used to calculate sensitivities.

A question that is asked is if presenting the sensitivities as elasticity and sensitivity score is sensible. Again, if the results at this stage do not suggest that a more comprehensive approach is necessary (e.g., stratified Monte Carlo or similar, followed by regression), this is fine, but the results will need to be adequately caveated to note that any non-linear interactions are not accounted for, and thus the results may over or underestimate the range of uncertainty and variability one would actually experience.

As they work through the following rounds of their assessment, it would be good to provide a discussion of what would constitute an important level of uncertainty and variability. Without more background, it is difficult to assess what more is needed.

Dr. Joel Schwartz

Comments on OPPTS Document

1. Use of IEUBK Vs Regression modeling

I disagree with the mantra that regression models can only be used on the population they were fit to, whereas IEUBK models are apparently generalizable to populations whose values for many underlying parameters in the model could differ considerably from the populations from which those parameters were drawn. The issue is the same. I would like to see both approaches used. This is particularly important for remodeling, where the house dust generated is precisely the kind of housedust for which the HUD pooling project obtained regression coefficients. We do not have to deal here with different bioavailability of mining wastes, we are talking about lead paint dust, and we have coefficients for that. If the two approaches give similar results, I would be pleased, if they differ, than EPA must address these differences, try to understand them, and either generate a good argument for why one is better in this specific case, or do the health risk assessment as a range running from one to the other.

2. I agree with Dr. Cohen on the need to distinguish uncertainty from variability and the relevant importance of the two, depending on the goal of the analysis. Given that we have seen evidence that lead uptake varies considerably among individuals depending on diet, behavior, and genetics, I would argue that just addressing average effects is insufficient, we need to know if there will likely be a noticeable fraction of the population with much greater impacts. In this regard I would note that it is a characteristic of models that they do a better job estimating means than variances, and usually underestimate variability about the mean. This tendency needs to be addressed, perhaps in the context of Monte Carlo analysis of the distribution of effects.

3. Regarding the Question on Adequacy of the Hazard Assessment, I think the focus on IQ in children is appropriate, the summary of the literature (taken from the CD) is reasonable. I agree that the evidence suggests higher slopes at lower doses. Indeed, I think every published paper has this result. I would add that since the results of Lanphear, there has been a new publication from the Mexico City Cohort, showing a significant effect in children whose blood lead levels were always below 10 µg/dL (Tellez-Rojo MM, Bellinger DC, Arroyo-Quiroz C, Lamadrid-Figueroa H, Mercado-Garcia A, Schnaas-Arrieta L, Wright RO, Hernandez-Avila M, Hu H. Longitudinal associations between blood lead concentrations lower than 10 microg/dL and neurobehavioral development in environmentally exposed children in Mexico City.Pediatrics. 2006 Aug;118(2):e323-30). Once again, the coefficients were considerably larger for the children who never exceeded 10 µg/dL than for the children with higher blood leads. Moreover, there were 294 children in this study who never exceeded 10 µg/dL, significantly increasing the total number of children evaluated at these lower levels, compared to just relying on the Lanphear data. Hence this strengthens the association.

I would also like to address the question of thresholds. If there is a threshold in the data, within the range of variation observed in the study population, then the observed slope when fitting a linear model is the weighted average of the true slope above the threshold, and the true slope below the threshold; the latter being zero. Hence, if there was a threshold where a significant fraction of the population's exposure lay, we would expect the coefficient to decrease as we truncated the distribution by eliminating children with higher blood lead's from the study. Of course, this does not mean that there is no threshold at a level where few or none of the subjects' blood lead levels lie. But the more recent studies have a fair number of subjects down to quite low blood lead levels, and the ever-increasing slopes argues that any thresholds that might exist are at levels too low to be of concern.

Regarding my comment above about the need to use the regression coefficients that relate house dust lead to blood lead, it would obviously be appropriate to address these studies in the Hazard Assessment phase. They also will qualitatively support the use of the IEUBK model, since they provide further evidence that a relation with dust lead is not just an assumption of a model, but empirically documented.

From a risk assessment perspective, one key issue is that remediating a housing unit reduces future exposure of future residents. Since low income families change residences frequently, this is an important benefit. How will this be factored in? In particular, should we prioritize housing units we expect to be around for a long time over ones we expect will be demolished and replaced?

I believe that the data in published epidemiologic studies provides no firm evidence for periods of exposure that are more critical. Indeed the pooling project suggests (weakly) that concurrent exposure, even after age 6, is most important. So I agree that we cannot base a risk assessment on timing currently. A sensitivity analysis could look at effects on older children, however.

I am confused by what the prioritization means. Is OPPTS proposing to initially have one set of guidance on how to remediate homes with a child with "high" blood lead levels (whatever that means, and it is not clear), and another set of rules for other apartments? This does not seem like an approach a contractor would like. They have to learn two sets of rules, and apparently, know the child's blood lead.

Dr. Frank Speizer

Consultation on EPA Draft Assessment to support Lead Renovation, Repair, and Painting Rule (LRRP) Dec 2006, for meeting 2/5/07

Question 4: General Approach for Sensitivity Analysis in Exposure Assessment

Exposure Assessment for Lead Dust Generated During
Renovation, Repair, and Painting in Residences and
Child-Occupied Facilities

Section 1.2, page 6 This exposure assessment is focused on lead exposures in two types of buildings: residences with children under six years of age, and COFs. For the purposes of this assessment, COFs are defined as a building, or a portion of a building, constructed prior to 1978, visited regularly by the same child, under age 6, on at least two different days within any week, provided that each day's visit lasts at least 6 hours and the combined weekly visit lasts at least 6 hours, and the combined annual visits last at least 60 hours.

Issue not considered seems to be the nature of maintenance of space over years prior to 1978. Repeated painting over many years with and without prior scraping could lead to quite variable lead build up. Ditto previous renovations. Would suggest that an 1890 house with an updated kitchen or bathroom could have log differences in lead in wall paint depending upon nature of updating and repair.

Note further that although age is recognized as important not considered in this draft and is indicated that will be considered in next draft. ***How good will the info coming in to deal with this variable?***

Figure 7, page 18, suggest replace of exterior door has same time sequence as replacing windows or kitchen. Not clear why the replacement isn't a one day affair of taking the door off its hinges and replacing with a new door and thus "no" exposure.

In all the scenarios it would seem that prior activities in "distant" past might affect background levels. The indication here is that, for example outdoor painting background goes to new background level that is average level. But if already at higher background because of previous distant past activities, won't new activity be on a higher baseline and be at least additive to what is already there?

Page 27, definition of elasticity: this definition may be too narrow. A one percent change suggests more data than one is likely to have. The changes may be one to 3 orders of magnitude larger than 1% and the measure calculated at 1% change is likely to be linear and not predictive of the potential log changes or differences.

Defining the sensitivity score which weights the elasticity by the coefficients of variation may be a more realistic approach.

Although not mentioned in this document there will need to be an estimate of the number of children who are actually exposed. For example in rental households, there may be local ordinances that prevent rental of households that have not been de-leaded to families with small children. Thus, the proportion of households with children under 6 may vary. Second there is testing of children in most states (or cities) and removal from household may be the outcome while renovation takes place. Not clear what the numbers for these variables would be.

Second the assumption of minimum vs. maximum appropriateness of abatement procedures may vary by region, and whether professional, handyman, vs. homeowner are doing the work.

DRAFT HAZARD ASSESSMENT FOR CASAC CONSULTATION MEETING, FEBRUARY 5, 2007

Document summarizes well finding from the CD. Expression of effects noted below 10μg/Dl seems to minimize the importance of effects noted below this level, whereas ~18% of population have levels below 10μg/dl (5-95%ile population levels 2.4-30μg/dl), with what appears to be a linear relationship on IQ. *Would be useful to have estimate of % population below 5μg/dl in order to estimate degree of effect of lower levels in terms of population for margin of safety.*