

Pre-Meeting Comments from Members of the Chartered SAB on the report, SAB Review of EPA’s “Approach for Developing Lead Dust Hazard Standards for Residences (November 2010 Draft) and Approach for Developing Lead Dust Hazard Standards for Public and Commercial Buildings (November 2010 Draft)”

List of comments received as of May 17, 2011

<i>Comments from Lead Reviewers</i>	2
Comments from Dr. Elaine Faustman	2
Comments from Dr. Nancy Kim.....	5
Comments from Dr. Eileen Murphy	8
<i>Comments from other SAB Members</i>	9
Comments from Dr. Terry C. Daniel	9
Comments from Dr. George Daston.....	10
Comments from Dr. Costel Denson.....	11
Comments from Dr. James K. Hammitt.....	12
Comments from Dr. Bernd Kahn.....	13
Comments from Dr. Cecil Lue-Hing.....	14
Comments from Dr. L.D. McMullen.....	15
Comments from Dr. James R. Mihelcic.....	16
Comments from Dr. Jana Milford	17
Comments from Dr. H. Keith Moo-Young.....	18
Comments from Dr. Duncan Patten.....	19
Comments from Dr. Steve Roberts	20
Comments from Dr. Amanda Rodewald	21
Comments from Dr. James G. Sanders	22
Comments from Dr. Kathleen Segerson	23
Comments from Dr. John E. Vena	24
Comments from Dr. R. Thomas Zoeller	26

Comments from Lead Reviewers

Comments from Dr. Elaine Faustman

The SAB Lead Review Panel has produced a directed and “on-target” review of two related EPA lead dust documents. This panel consisting of leading scientists well recognized for their expertise in children’s lead exposure and effects included also a group of experts in exposure modeling, kinetic modeling and general public health and toxicology. This was an excellent choice for reviewing this document.

1. Were the original charge questions to SAB adequately addressed?

Since the charge questions given to the SAB were very similar between the document on developing lead dust hazard standards between Residence and the document on developing lead dust hazard standards for Public and Commercial Buildings, the SAB review panel chose to jointly address the two documents. They noted the very few instances when the charge questions were not quite identical. This reviewer feels that this was a very wise decision and one that made the recommendations consistent and poignant for both applications.

The review panel methodically reviewed and discussed each charge question and provided thoughtful and constructive responses. When the panel disagreed with the technical report recommendations, clear and well-documented responses and recommendations were made.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the Committee’s report?

The SAB lead review panel should request further technical detail and less editorializing. For example in reporting--Page 8 , 5th paragraph, lines 37-44—the panel response document captures a direct quote from the original document that discussed the impact of improvement in blood lead levels that various candidate dust lead levels would achieve. The Panel notes that the implication of the report is that setting dust standards would make little difference on blood lead no matter how low it is set. The SAB review panel rightly points out that these changes would be considered to be significant and requested reworking of this part of the document. The SAB review panel however failed to point out that the example text from the EPA document (see page 45 example) is “value laden” as such phrases such as “reasonable” ranges or “reasonable” input imply. The review panel should go further in encouraging the EPA to purge the document of such wordings and instead provide specifics about input and values used throughout.

This reviewer was surprised that the SAB Review Panel did not specifically state “daycare facilities” in discussing these two documents. Please be explicit about this due to the public health implications. If these are appropriately addressed under the non-residence status, then explicitly state this, if not then ask EPA to clarify and re-state in your review. This type of non-residence building is of importance and needs to be specifically addressed.

Although the SAB lead review panel documents discusses children, a few more sentences clarifying the SAB panel's view on EPA's adequacy of Adult lead level discussion should be added. (See expansion of comments below).

3. Is the Committee's report clear and logical?

Yes and the review panel deserve credit for pulling together a cohesive and directed review of these two documents that address important public health issues. However, this reviewer found that some of the "strength of the language" from section 3 of the report should be re-iterated in the letter to the administrator. This reviewer really liked the clear, targeted message of agreement with the basis but not the form of the EPA document as stated in the following text from page 7 lines 32 to 38 as it targets the bottom line agreement for protection of health. The statement says "The SAB generally supports the overall modeling approaches described in both documents and supports EPA's selection of target blood lead levels of 1 and 2.5 ug/dL for children. The SAB believes that a blood lead level of 5 ug/dL for children would not offer sufficient public health protection, due to recent studies indicating significant adverse health effects in children with blood lead levels well below 10 ug/dL. That being said, the SAB believes the current approach of evaluating a dust lead level that by itself would achieve a given target blood lead level is flawed, because lead is a multi-media pollutant.the SAB concludes that a simpler and more scientifically valid approach is to assess how changes in incremental dust lead levels result in incremental changes in blood lead levels, holding important covariates and other exposure inputs ...at either zero and/or at national averages." This reviewer believes that it is critical to state the concurrence of target levels of blood lead as this as historically hampered regulatory action and that this should also appear in the letter to the administrator. Note it is in the Executive Summary however this should also be in the letter due to its importance. This reviewer also would suggest adding something about the need for protection of the adults as that literature had also shown concerns in this same region of the dose response.

The seven bulleted comments and recommendations in the letter to the administrator reflect most of the comments discussed in the executive summary however there was some confusion in this reviewer's mind regarding the distinctions that the lead review panel was making regarding the use of empirical data and use of empirical models. Please clarify this in the second bullet point in the letter to the administrator (page ii, lines 22 to 29), pages 2-3 Executive summary and pages 9 to 13 in the review document.

This reviewer was appreciative of the details and suggestions provided by the panel (pages 21 lines 1 to 35) when they discussed the rationale and desired action by EPA for comparing the IEUBK models with modeling of the empirical NHANES data. The SAB lead review panel suggested including use of current EPA default parameters for the IEUBK model guidance as that would provide a much needed reference for the other model outputs.

The SAB lead review panel also considered who would be reading and using the document and offered clear suggestions on how to improve this aspect of the report. The review group seemed to appreciate how the document might be used and offered specific suggestions to document and standardize the package software—Survey—that is suggested for use in the QL modeling.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Again, the SAB lead review group deserves credit for pulling together the salient and "on-target" set of recommendations. Yes, the conclusions are supported with only the above listed clarifications needed. This reviewer especially appreciated the methodical analysis and rejection of the use of only blood lead levels in isolation and felt that the support for use of incremental blood lead changes provided a more useful and relevant reference for these two dust hazard standards.

Editorial comments

Consistency of the Letter to the Administrator, the Executive Summary and the body of the report.

Note that although the background document of the SAB review panel provides a nice summary of the documents to be reviewed and notes that the EPA has reached out for consultative advice on early drafts (with documentation) this reviewer noted that only Appendix A was referenced in this section of the report. Please also note the presence of all appendixes at the beginning (note that Appendix B is now not noted until page 12 line 31).

Typographical suggestions:

Page 9, line 12—remove double period.

Comments from Dr. Nancy Kim

The page numbers for the comments refer to the body of the report. However, some of the comments are relevant to the letter to the administrator and/or the executive summary.

1. Were the original charge questions adequately addressed?

Yes.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the Panel's draft report?

p. 14, line 3. Additional technical work may be necessary besides a more complete description and justification for input parameters. Would the model have to be validated in some way if the input parameters differed from the model guidance?

p. 16, line 17. The discussion of outdoor soil and dust particles with respect to lead concentrations may need to be modified. In places without a history of lead based paint, lead may only come from soil. It isn't clear in this case that the lead concentration would be any higher in dust than in soil.

Also, see some of the comments in the next section.

3. Is the Panel's draft report clear and logical?

Letter to the Administrator

p. ii, line 7. The letter states that, "For both documents, the SAB supports the overall modeling approaches and believes that they provide the best available means for establishing the quantitative relationship for predicting blood lead from dust lead levels. The SAB has a number of recommendations aimed at improving the application of several models discussed in the report." My reading of the report is that the Panel's concerns are more substantive than what the phrase "recommendations aimed at improving the application of several models discussed in the report" implies. A statement in the response to charge question 5, "Until then, the SAB is unable to concluded which modeling approach is most appropriate" (p. 23, line 12) illustrates this point. The Panel's discussion and concerns about other sources of lead and the recommendation to use an incremental risk assessment approach (mentioned in several places in the report, e.g. page 14, paragraph beginning on line 29) is another illustration of the Panel's position on the models and the approaches.

After reading the body of the report, I am not sure I would pick out the same recommendations/conclusions as the Panel selected to highlight in the letter to the administrator. Also, the Panel may want to consider focusing on 3 or 4 major recommendations/conclusions in the letter to the administrator.

Executive Summary

The paragraph in the body of the report that begins on page 14, line 29, makes a strong recommendation about the biokinetic models and other sources of lead. The Panel may want to consider including information in this paragraph in the executive summary of its report.

p. 4, line 14. This paragraph raises several different issues the Panel thinks is important. It might be useful to EPA for the panel to add additional specific recommendations.

p. 4, line 23. Should any additional phrasing be added to the end of this sentence such as to ask EPA to add additional language on how the different results should be interpreted or used in selecting target levels?

p. 4, line 34. Would it be helpful to add an additional phrase about EPA developing additional language about how the results of the different runs should be used or considered in selecting target levels?

p. 4, first paragraph under Choice of Model. The Panel endorses the use of the NHANES QL method, states that adequate justification isn't provided on the selection, expresses confidence in the Dixon model, and expresses concerns about the parameters used in the IEUBK model. After reading the paragraph, it isn't clear why the Panel is endorsing the NHANES QL model at this time without additional work being done on the other models.

Body of Report

p. 7, line 30. "pregnant woman who occupies a public or commercial building" The significance of the Panel's comments on the analyses of public or commercial buildings would be more apparent if the report clarified what this means. For example do these analyses apply only if a woman lives there or if she spends some time there? If it is the latter, does the amount of time matter or what she does there, etc.?

p. 8, line 22, sentence beginning with "If indicated." The recommendation in this sentence isn't clear. The words "if indicated" suggest that the panel is equivocal about the wording or inclusion of a conclusion across different models in the executive summary the panel is suggesting while the rest of the sentence is very direct about how it should be changed. See additional comment about modeling results.

p. 8, line 26. What the Panel is recommending isn't clear from the paragraph as written. This paragraph states that the documents do not provide an adequate description of how the standards would be used. It then continues to list and then elaborate on two principal uses of the standards. It isn't clear if EPA's document already lists these two uses, but doesn't provide any examples or if the document doesn't provide the two principal uses. If the Panel provided a specific recommendation of what should be added, the paragraph would be clearer. The report may be suggesting that the examples in the paragraph be added to EPA's document, but that isn't clear to the reader who hasn't read the two documents being reviewed.

Another related comment, the word standard in terms of regulatory actions implies something that is enforced and that is usually established after feasibility, costs, etc. are considered along with health risks. The Panel's report would provide additional context if it clarified how the word is being used in its report and/or in EPA's document. Panel's report begins to address this in its discussion of other sources of lead exposure.

4. Are the conclusions drawn or recommendations provided supported by the body of the Panel's draft report?

Yes, for the most part. Some of my comments under question 3 are also relevant to this question.

p. 22, line 33. Given the statements that follow the first sentence under the choice of the model for children, the support the SAB gives the NHANES QL doesn't seem valid. In fact, the last statement seems to contradict SAB support for NHANES QL.

Minor comments.

p. ii, line 19. I am not sure what is meant by the word approachability and suggest it be changed to something that would be readily understandable.

p. 2, line 10. Suggest changing the word "will" to "can."

p. 2, line 18. Insert and between Health and Nutrition

p. 2, line 35. Suggest adding a phrase to explain what context is needed.

p. 3, line 30. Remove the s from relates.

p. 7, line 35. Change "due to" to "since."

p. 11, line 14. Need a period at the end of the sentence.

p. 17, line 32. PbB is written out here and it is not the first time the abbreviation is used in the document. The document should probably be checked to see if PbD and PbB (and other similar abbreviations) are written out the first time and not subsequently.

p. 20, line 1. "hazard level required to effect..." The word effect should be affect.

Comments from Dr. Eileen Murphy

Charge 1: whether the original charge questions to Committee was adequately addressed:

The charge questions were addressed adequately.

Charge 2: whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report:

No technical errors appeared in the report. In fact, the committee identified some significant technical issues with the proposed modeling in the two reports and outlined approaches for EAP to address those issues.

Charge 3: whether the Committee's report is clear and logical:

The report is clear and logical and easy to follow.

Charge 4: whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report:

Yes. Examples were provided in most instances.

Other:

Letter to Administrator Jackson

P. 1, line 34: change "which" to "that"

P. 1, line 41: change "comparison" to "comparing" for grammatical consistency.

Executive Summary

P. 2, line 27: change "methods" to "method"

P. 3, need a space after line 2.

P. 3, line 27: first time we see PbB, so define first.

P.3, line 40: change "which" to "that"

Comments from other SAB Members

Comments from Dr. Terry C. Daniel

The SAB panel's review of the EPA's proposed approach for lead dust hazard standards seems very well organized and clearly written. The recommendations are specific and clearly stated and seem well founded in the body of the review. The suggestion to move to an "incremental risk approach" is especially well supported by the review and very clear recommendations are offered for implementing and evaluating that approach. The incremental approach seems very appropriate given the importance of lead sources other than window sill and floor dust. The modifications and comparisons of alternative models seem well considered and likely to enlighten the PbD to PbB relationships.

1. Were the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?

Yes

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the Committee's report?

None that this non-expert could determine.

3. Is the Committee's report clear and logical?

Yes, the Panel is to be complemented for a well organized report with clear and specific recommendations.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Yes, the Panel did an excellent job of establishing the foundations for their recommended revisions and comparisons of approaches.

While I rarely (probably never) have complained about insufficient use of acronyms in an SAB review, the use of PbB and PbD for lead concentration in blood and lead load (or concentration) in dust was not followed consistently in the review. For a reader unfamiliar with the relevant literature and science this caused some confusion in several places in the text.

Comments from Dr. George Daston

Overall, I found this report to be well written, with the conclusions well supported by the information contained in the review. It is clear that the review panel has a great deal of expertise in risk assessment methodology and their comments will improve an already good process developed by EPA staff.

We were asked to address four specific questions as part of the quality review.

1. whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed;
2. whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;
3. whether the Committee's report is clear and logical; and
4. whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

Question 1: The charge questions posed to the review panel were all adequately addressed in a very transparent way. Responses and recommendations were organized in a way that will facilitate revising the reports.

Question 2: I found no technical errors or omissions in the report, but there is one recommendation that should be justified a little more fully.

On p.19, lines 21-27, the committee recommends that the NHANES residential dust data be used for commercial buildings because there are no data to suggest that lead levels in dust would be different in commercial buildings. This may be the case, but it seems reasonable to me to assume that the source and composition of dust could be very different in an office, store or factory than in a residence. I think the potential uncertainties need to be stressed more.

Question 3: I found the report to be clearly and logically presented. The committee really knows lead and exposure modeling, and their review and recommendations were instructive.

Question 4: I found the conclusions of the report to be well documented and supported.

Comments from Dr. Costel Denson

General Comments

The letter to the Administrator is extremely well written. It is clear, direct, and provides un-ambivalent guidance in connection with the comments and recommendations.

1. Were the original charge questions to the SAB committee adequately addressed?

Yes. Five charge questions were presented for two related subjects

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the committee's report?

There are no technical errors or omissions that this reviewer detected.

3. Is the committee's report clear and logical?

The committee's report is laid out in a clear and logical way.

4. Are the conclusions drawn or recommendations provided supported by the body of the committee's report?

The conclusions and recommendations are appropriate and easily understood, and could be implemented in a straight forward manner.

Comments from Dr. James K. Hammitt

1. Were the original charge questions adequately addressed?

Yes.

2. Are there technical errors or omissions?

Not that I see.

3. Is the panel's draft report clear and logical?

Yes, though I found it a bit repetitious. E.g., some issues (such as the incremental risk approach) are discussed under the modeling questions (2 and 3) and again under question 4 about variability and uncertainty.

A few additional comments by page /line:

It might be worth clarifying that the three ways proposed to run the biokinetic models (4/31-34 and 21/1-36) serve different purposes. In particular, (2) is useful for evaluating goodness of fit to NHANES and (3) is useful for predicting effects of regulations.

7/34. It might be useful to mention how "sufficient public health protection" is defined in this context.

18/44-19/3. I find this passage counterintuitive and possibly inconsistent. I think the presence of unmeasured variables that affect blood-lead levels would tend to increase the estimated intercept and decrease the estimated slope of a model, and hence decrease the effect of a standard as estimated by that model. I do not think it would "attribute blood lead reductions to the hazard level that, in fact, are due to unrelated sources." It would be useful to add the word "estimated" before "effectiveness of a standard" at 19/3. I do not understand the phrase "would not be manifested in the real world" (19/2-3); clearly these background exposures are manifest.

4. Are the conclusions supported by the body of the report?

Yes.

Comments from Dr. Bernd Kahn

1. Were the original charge questions to the SAB committee adequately addressed?

Yes.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the committee's report?

No.

3. Is the committee's report clear and logical?

Yes.

4. Are the conclusions drawn or recommendations provided supported by the body of the committee's report?

Yes.

Other comments:

p.ii, 1.27: should the words 'than lead concentration,' replace 'are expressed as lead loading'?

p.1, 1.40: Since the values of the target blood levels are a significant topic of general concern but a side issue in this report, it may not be suitable for SAB to express its support for these target levels here in such a casual fashion.

p.9, 1.41-43 (also p. 2, 1. 21-23): The sentence should probably be "...SAB found many of the criticisms of the Dixon model not to be ..!". As it is written, the statement contradicts itself.

p.9, 1.10: Do the EPA draft standards actually propose a set of dust loading target values or just present some values that are outcomes of models? The SAB review should clarify this distinction.

General comments on 'loading' vs. 'concentration' of lead in floor and window sill dust:

1. Throughout the SAB Review, the words 'lead dust' should be followed by either 'loading' or 'concentration' to clarify the SAB comments.

2. How can 'loading' by itself be related to lead blood levels when the measurement surely depends on the time interval (i.e., the extent of lead accumulation) between the acts of house cleaning and measurement at the floor or sill location?

Comments from Dr. Cecil Lue-Hing

General Comments

The Panel has done an excellent job of reviewing the EPA reports, and of responding to the questions, comments, and recommendations received.

Specific Comments

Letter to the Administrator

The letter is well written and to the point. The letter clearly points out areas of SAB support for, and disagreement with the EPA's approach, and presents recommendations for improving the application of the tools/models developed by the study.

Executive Summary

The executive summary is well written, easy to read, and presents the highpoints of the report. It does a good job of highlighting the issues associated with the charge questions, and efficiently summarizes the level of SAB's support or concern related to the issues.

The Text

The text is well written and easy to follow.

Charge Questions

All charge questions were satisfactorily answered.

Comments from Dr. L.D. McMullen

1. I feel that the original charge questions were adequately addressed.
2. I did not find any errors or omissions although this is not an area that I'm an expert in.
3. I had a bit of a problem in understanding the different ways of discussing lead. For example on page 4 first paragraph, line 3 had "Pb-dust" line 5 had "dust Pb" line 6 had "dust lead" and in other parts of the report "lead dust" was used. I didn't know for sure if "dust Lead" was the concentration of lead in dust and "lead dust" was lead that was the size of dust particles that was 100% lead. Sometimes this understanding made sense and then other times it did not. Then other times they seem to be interchangeable and meaning the same. If they are different, I might suggest that "concentration" be added after "dust lead" to read "dust lead concentration" or " the concentration of lead in dust".
4. I feel the recommendations were supported by the report.

Comments from Dr. James R. Mihelcic

1. Were the original charge questions adequately addressed?

The charge questions were adequately addressed except that the Panel was not able to provide a recommendation about model selection (Charge Question 5) without the benefit of the additional modeling and inclusion of an incremental approach. I also do not support the high blood lead value of 5 µg/dL for the reason provided by the Panel.

2. Are there any technical errors or omissions in the report or issues that are inadequately dealt with in the Panel's report?

The draft report makes no mention of environmental justice which I assume plays a role in the topic being addressed. I just want to make sure that the Panel considered this issue into consideration when developing their detailed response to charge questions.

3. Is the Panel's draft report is clear and logical?

Draft letter to administrator is short and to the point, is organized around significant bullets.

However, the report's executive summary recommends that EPA continue to include the model results of the Dixon (2009) in comparisons between the various modeling approaches. The label of "Dixon" is used in many places of the draft report. However, I am not sure this point is made in the accompanying letter to Administrator Jackson.

The document uses wording "recommends" and "strongly recommends" throughout the document. It was not clear to me why some items were strongly recommended, versus just recommended.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

The conclusions and recommendations are supported by the body of the report.

Comments from Dr. Jana Milford

1. Were the original charge questions to adequately addressed?

Yes.

2. Are there any technical errors or omissions in the report or issues that are inadequately dealt with in the Panel's report?

The SAB panel mentions it does not support use of a target value of 5 ug/dL for children due to "recent studies" showing significant adverse effects at levels below 10 ug/dL. It would be useful if the SAB panel could provide citations to the studies to which it is referring.

3. Is the Panel's draft report is clear and logical?

Yes.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Yes

Comments from Dr. H. Keith Moo-Young

1. Were the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?

The original charge questions were addressed by the committee.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the Committee's report?

I did not detect any technical errors or omissions in the report.

3. Is the Committee's report clear and logical?

Yes. The report is logical and clearly written.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

The report amply supports the conclusions and recommendations drawn.

Comments from Dr. Duncan Patten

1. Were the original charge questions to adequately addressed?

The panel has addressed the original charge questions in a comprehensive fashion, allowing EPA to consider some major and minor options for rewriting the approach.

Because the panel has many comments that would alter a revised EPA document, it seems to me that the letter to the administrator, in addition to outlining the panel's concerns, should make some statement on need for level of revision (e.g., few changes and modifications to many).

2. Are there any technical errors or omissions in the report or issues that are inadequately dealt with in the Panel's report?

This is not in my area of expertise and thus I can't assess the SAB document for technical errors.

3. Is the Panel's draft report is clear and logical?

The SAB response appears to follow a logical approach, even including some combination of responding to charge questions. (e.g., residential vs public/commercial approaches which appear similar).

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

The discussion by the panel leads to some logical conclusions which are clearly supported by the body of the report.

Comments from Dr. Steve Roberts

1. Were the original charge questions adequately addressed?

Yes. Definitive answers were provided for all of the charge questions.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the Panel's report?

I found no technical errors or omissions in the report.

3. Is the Panel's draft report clear and logical?

For the most part, the draft report is clear and logical. Some of the text is redundant, however. In particular, the authors appeared to struggle with deciding where to place a recommendation to use an incremental rather than absolute blood lead target approach, inserting it into responses to charge questions 1, 3 and 4. Perhaps the report would be better served by making this an overarching recommendation at the beginning of the document, with a clear explanation of the rationale. Thereafter, in the responses to comments, reference to this recommendation could be made as appropriate rather than repeating the recommendation over and over.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Yes, the basis for the conclusions and recommendations are explained in the body of the report.

Editorial suggestions:

Pg ii, line 7: replace "are" with "is"

Pg 1, line 33, sentence beginning "The Public and Commercial Document ..." is too long and should be split after "biokinetic models."

Pg 2, line 26: should be "... using quasi-likelihood ..." [remove "a"]

Pg 8, sentence on line 28 beginning "The second is ...": Sentence structure needs to be fixed. Currently reads "... if dust lead levels ... has been adequate."

Pg 9, line 42: suggest phrasing "... lacking clarity and, in some instances, accuracy."

Pg 11, line 14: period at the end of the sentence

Pg 14, line 36: insert "analysis" after "sensitivity"

Comments from Dr. Amanda Rodewald

1. Were the original charge questions to adequately addressed?

Yes.

2. Are there any technical errors or omissions in the report or issues that are inadequately dealt with in the Panel's report?

No, not that I could find.

3. Is the Panel's draft report is clear and logical?

Yes.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Yes.

Minor comment:

Page 10, lines 16-18: The original text sounds somewhat sarcastic in tone to me: "EPA also seems to believe that the log-log Dixon analysis shows that blood lead decreases as floor dust lead increases at the upper tail of the empirical data distribution, which of course is not consistent with the idea that higher exposures should result in higher blood lead levels.". I suggest rewriting as "The wording suggests that the log-log Dixon..., which [strike 'of course']."

Comments from Dr. James G. Sanders

1. Were the original charge questions adequately addressed?

The charge questions were adequately addressed. The lead review panel have produced a report that folds the charge questions from the two different EPA documents into one. In most cases, the charge questions were identical, or very similar. The Panel's report concisely answers these questions.

2. Are there any technical errors or omissions in the report or issues that are inadequately dealt with in the Panel's report?

For the most part, no. However, there were a few statements that need further explanation, justification or reference. They are:

Page 7, lines 32-36. The draft report supports EPA's selection of target blood levels of 1 and 2.5 ug/dL. For what? Why are there two, what are they targets for? How were they selected? Are these for the two different types of models used, or for the two different documents (residential, public buildings)? Or for something else? And, what is the level of 5 ug/dL referring to? This entire section needs further amplification and justification, so that the reader can understand these levels and to what they refer. Finally, the Panel does not support the 5 ug/dL level, as "recent studies [indicate] significant adverse health effects..." (lines 35-36). This statement needs a reference.

Page 1, lines 40-43. The above discussed section also occurs in the Executive summary. The same comments apply.

Page 13, line 41. "The SAB believes that the Leggett model is less scientifically credible..." Why do we believe this? The Panel needs to further explain and justify this statement and the following recommendation.

Page 15, lines 3-4. "...the ALM produced more scientifically credible estimates..." How do we know this? Again, this statement needs to be fully justified.

3. Is the Panel's draft report is clear and logical?

Yes. With the exceptions above, the draft report is clear and concise.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

To the extent of my knowledge, yes.

Comments from Dr. Kathleen Segerson

1. Were the original charge questions to adequately addressed?

Yes, the report seems very responsive to the charge questions.

2. Are there any technical errors or omissions in the report or issues that are inadequately dealt with in the Panel's report?

I do not see any technical errors.

3. Is the Panel's draft report is clear and logical?

For the most part, the draft report is clear and logical. I have only some minor comments.

- The last bullet of the letter to the Administrator says that the SAB is not able to provide a recommendation about model selection, which is repeated on p. 5 (lines 3-4). Yet the statement at the bottom of pl 4 (lines 40-41) say that the SAB supports the use of the NHANES QL model. These two statements seem inconsistent. It would help to clarify this.
- In reading the executive summary, it appears that there are some points here that are more important than some of the things included in the letter but not included in the letter. For example:
 - o p. 2, lines, lines 11-12: "expanding the discussions on the degree of improvement in blood lead levels that different candidate dust lead levels will achieve, and providing an analysis of the differences between the different approaches" (not included in letter) seems more important than including an executive summary (included in the letter).
 - o P. 2, first paragraph in Empirical Models section: The first point here seems to be an important point but is not included in the letter. If this point is less important than subsequent points in this section (which are included in the letter), then perhaps it should be moved down in this section.
 - o P. 3: the committee seems to feel strongly that the Leggett model should not be used by EPA. At least this is the impression the reader gets here. But if this is a model that EPA is currently using and the SAB does not think it should be using this model, that seems to be an important conclusion that should be stated explicitly and included in the letter.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee's report?

Yes.

Comments from Dr. John E. Vena

1. Were the original charge questions to SAB Standing or Ad Hoc Committees adequately addressed?

The panel discussed two documents, one on the revision of the 2001 standard for residential buildings and the other on development of lead dust health standards for public and commercial buildings. I support their approach to an integrated written response document.

Yes, the panel very effectively addressed the clarity and transparency of the documents, empirical modeling, biokinetic modeling, analyses of variability and uncertainty, and choice of models for developing the lead dust hazard standards. The SAB panel found that the documents did not provide an adequate context for how the standards will be used. However, in my view the use of the standards is an issue that is beyond the scope of the charge questions.

2. Are there any technical errors or omissions in the report or issues that are not adequately dealt with in the Committee's report?

None that I can tell based on my expertise.

3. Is the Committee's report clear and logical?

I found that the letter to the administrator needs clarification on a few points. On page ii lines 19 and 24 "loadings" should be defined. On line 32 it is stated that SAB is concerned that the lower dust lead loads were not "evaluated". Perhaps a better term would be that were not "used" to establish the candidate lead hazard standards. On page ii line 38 the recommendation is to compare to other epidemiologic data. References should be inserted (see statement on page 12, Lamphear, 1996 and 1998.

The letter should define on lines 11-13, page iii of cover letter and on lines 1-4 of page 2 of executive summary the meaning of "incremental risk assessment approach". Perhaps refer the reader to page 15 lines 12-18 and page 18 lines 33-44.

Recommended clarifications in executive summary:

Page 1 line 41 When discussing target blood levels "high" blood lead values should term "recommended maximum" be used?

Page 2 line 17 "blood to dust lead relationship" should read "dust to blood lead relationship"

Page 2 line 28 define "dust loading"

Page 3 line 1 compare results to other epidemiologic data(as stated on page 12, Lamphear 1996, 1998)

Excellent recommendations on Page 4 lines 30-34 for running the biokinetic models and the summary gives straight forward and concise overview of the recommendations regarding choice of models for hazard standards.

On page 10 of report please define on line 8 “lead dust loading”

On page 11 lines 19-21 please explain the necessity for conversion of dust loading to dust concentration. Why do recommendations differ in use of the dust loading in QL model vs biometric modeling.

4. Are the conclusions drawn or recommendations provided supported by the body of the Committee’s report?

Yes. In particular, the recommendations to improve the modeling approaches are reasonable and sound.

Comments from Dr. R. Thomas Zoeller

Quality Review Question #1: whether the original charge questions to SAB Standing or Ad Hoc Committees were adequately addressed.

In general, the charge questions were clearly addressed.

2. Quality Review Question #2: Whether there are any technical errors or omissions in the report or issues that are inadequately dealt with in the Committee's report;

I did not detect technical errors or omissions.

3. Quality Review Question #3: Whether the Committee's report is clear and logical; and

The committee's report is clear and logical, but I did not get the impression that the full report was accurately represented in the letter to the Commissioner. While the general issues were well described in this letter, it was not clear from the letter that the SAB panel believed that there were major and substantive weaknesses in the report. While it is important to avoid unnecessary or harsh criticism, it is also important to portray the general tone of the report.

4. Quality Review Question #4: Whether the conclusions drawn or recommendations provided are supported by the body of the Committee's report.

The conclusions of the Panel are well described and justified in the report.