

**Preliminary Comments from Members of the Chartered SAB on the SAB  
Draft report entitled *SAB Evaluation of the Effectiveness of Partial Lead  
Service Line Replacements (July 1, 2011 Quality Review Draft)***

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## **Comments from lead reviewers**

### **Comments from Dr. Cecil Lue-Hing**

#### **General**

The assignment is both interesting & challenging. Interesting because it concerns the potential for lead toxicity of large segments of the population, and challenging because of the complex nature of lead toxicity generally via public drinking water systems, and especially because of the disproportionate impact on children's health. The report is well written and structured to be easy to read. The report is comprehensive, in that it covers and incorporates all the readily available Peer Reviewed and other relevant studies on the subjects directly related to the Charge Issues.

The Panel deserves credit for a job well done

#### **Literature**

There is not a very extensive pool of literature available on the subject of partial lead service line replacement, and the associated five Charge Issues overall. On the specific topic of the "*impact of partial lead service line replacement on the blood levels in children,*" a major interest of the EPA in the study, there was only one peer reviewed reference available. This reference was provided to the SAB Panel by the EPA, and the Panel did not identify any other peer reviewed study on this specific topic. The EPA also provided a major portion of the other reference material, peer reviewed and otherwise, to be reviewed and utilized by the Panel.

#### **The Charge to the Panel**

The assignment is essentially a request by the EPA for a Peer Literature Review to be conducted by the SAB Panel, of research material predominantly identified by the EPA, plus other relevant material that the Panel may retrieve on its own for each of the Charge Issue topics. The specific charge to the Panel consists of five issues all structured around the central question/theme – *Does Partial Replacement of Lead Service Customer Lines in Public Drinking Water Systems Effectively Reduce Pb Exposure of Customers at the Tap?* This is stated more succinctly on page A-3 line 18, by the EPA – "*Lead service line replacement is the issue on which we are seeking SAB input.*" The specific Charge Issues require that the SAB review the following – 1) Studies Examining Associations Between Elevated Blood Lead Levels and Partial Lead Service Line Replacement (PLSLR), 2) Studies Evaluating PLSLR with Tap Sampling Before and After Replacements, 3) Studies Comparing PLSLR with Full Lead Service Line Replacement, 4) Studies Examining PSLR Techniques, 5) Studies Examining Galvanic Corrosion. While these studies combined cover the universe of lead service line replacement generally, they fall short with respect to some of the specific demands of the five Charge Issues, e.g., study design limitations, inadequate study period length, insufficient data, and sample size limitations.

It is obvious from reading the report that insufficient data was clearly an impediment to the conduct of the Panel's review, and its ability to offer a wider range of recommendations, findings or suggestions to the EPA on the subject of lead service line replacement. Thus, with the limited

amount of peer reviewed and non-peer reviewed literature available, it can be argued that, to the extent that the available literature permitted, the Charge Issues were all well researched by the Panel.

It is noteworthy also that with respect to Charge Issue #1 the EPA's interest is stated as "How does this study inform the available information on the effectiveness of partial lead service line replacement in reducing drinking water exposure to lead"? For Charge Issues 2 through 5, the EPA's interest is specifically stated as, "*What conclusions can be drawn from these studies --?*"

We have the opportunity here to offer direct answers to the EPA Charge Issues by arranging that the discussions on all 5 Charge Issues end with a Summary & Conclusion(s) or Conclusions, so as to better represent direct responses to the Charge Issues posed by EPA.

This format which includes conclusions was followed in the responses to Charge Issue #1, page 10, Charge Issue #3, page 16, Charge Issue #4, page 21. The same should be done for the responses to Charge Issues #2, and #5.

### **Letter to the Administrator**

The letter begins with the routine preamble that refreshes the Administrator about the issue of lead in drinking water obtained at the tap, the EPA's Lead Copper Rule, and the regulatory requirement to partially or completely replace lead service lines. The preamble then identifies the five Charge Issues, and proceeds to present a brief summary of the Panel's major comments and findings on the Charge Issues.

On page ii, line 2 of the letter reads –*The major comments and recommendations are provided below*. However, this reviewer could not identify any recommendations that are included in the five bulleted presentations that follow. The presentations are essentially comments and findings.

Suggest that – comments and recommendations in line 2 be changed to **comments and findings**.

The findings and comments accurately reflect those discussed for the five Charge Issues in the body of the report, and represent the information that should be brought to the attention of the Administrator. It should be noted also that for each of the five Charge Issues discussed and presented in the Administrator's Letter, the Panel indicated a lack of sufficient data to offer definitive conclusions – a major disappointment created by the limited available literature.

### **Executive Summary**

The Executive Summary is well organized, easy to read, and clearly written. It provides a short but concise preamble informing of the reason for the report, identifies the five Charge Issues, offers a few overarching findings, and then proceeds to address each of the five Charge Issues individually.

The findings on the Charge Issues are well summarized and presented. However, in those few instances where the Panel was able to arrive at a conclusion or made a recommendation, these

are generally buried in the text and not sufficiently highlighted, e.g., page 2 line 42, page 3 line 8, page 3 lines 35 to 40, and page 4 lines 5 to 9.

Suggest that these few conclusions and recommendations be better highlighted.

### **The Panel's Recommendations**

The Panel did not have the opportunity to offer many recommendations because of the lack of data that directly addresses some of the important aspects of the 5 Charge Issues posed by the EPA. The Panel was able to make a few recommendations, e.g., page 3 line 8, and page 8 line 37. These recommendations were generally a listing of future research needs for the EPA to consider pursuing.

### **Body of Report**

There is a recurring theme throughout the body of the report which characterizes the results of the Peer Reviewed studies as being generally inconclusive, or does not provide any evidence of benefit, or insufficient data, or the study design is not suited for the information sought, or the study is limited to a single utility, and therefore the data is not suitable for wider applications, or there is a lack of definitive studies on a particular aspect of a Charge Issue, or the presence of confounding factors render the data unreliable.

The available literature provided very few studies that were directly related to the topics of the Charge Issues, and this posed a serious handicap for the Panel. Unfortunately, the few studies that were topic specific suffered from deficiencies that impaired the value and utility of their data.

### **The Value of the Panel's Report**

Notwithstanding the limited nature of the database on which the Panel relied to conduct its work, I consider the Panel's report to be of value to the EPA for the following reasons; a) it brings to the fore the fact that the studies/data on which the EPA would normally rely to consider pursuing regulatory initiatives or advisories related to the replacement of lead service lines, are unreliable and need to be updated, b) it enabled the panel to offer a recommendation (one of very few) that the EPA should review and update some of its already published guidance material on the issue of lead service line replacement, c) it demonstrates conclusively that one of the key interest of the EPA, i.e., "*Associations Between Elevated Blood Levels and Partial Lead Service Line Replacements*" cannot be effectively addressed at this time because of data insufficiency.

These are all important advisories to the EPA.

### **Editorials Dealing with Recommendations**

Regarding belief vs. conclusions or recommendations

On page 4, line 2 of the report reads – *The Panel believes* that insertion of a lead-free dielectric is likely to have beneficial effects on Pb concentrations at the tap, albeit of uncertain magnitude

– This is followed on line 5 by – Given the relatively low direct cost of inserting such a device, *the Panel has concluded* that doing so would be an appropriate standard operating procedure in situations where the decision to implement a PLSLR has been made, provided that other issues (e.g., electrical grounding requirements, durability, and pipe-thawing practices) are adequately addressed.

It appears confusing to have *The Panel believes*, and *The panel has concluded*, in two consecutive sentences and in the same paragraph discussing the same issue.

**Question** – Is the Panel recommending the use of a lead-free dielectric?

The issue of Belief v. Conclusions or Recommendations appears again on page 13 line 33 regarding Sampling Methods – *The Panel believes this premise should be thoroughly re-evaluated, based on current information, for the following reasons:*

**Question** – Should the EPA assume that a recommendation has been made to re-evaluate the noted premise?

Again on page 15 line 6 regarding Sampling Methods – *There appears to be no simple solution to this problem, but the limitations of current sampling protocols should be carefully considered in future revisions of the LCR, in evaluating studies of Pb in tap water, and in assessing the potential impacts of tap water Pb levels on human health*

**Question** – Should EPA assume that this is a recommendation?

## **Other Editorials**

Letter to the Administrator, page ii line 18 – should PLSR be LSLR?

Note: From the List of Acronyms, LSLR means – *Lead Service Line Replacement* – PLSR is not included in this List.

Suggest that PLSR be included in the List of Acronyms.

## **Public Comments & Stakeholder Inputs**

It is not clear whether public comments or stakeholder inputs are required, or were solicited for this review. The report is silent on this issue.

## **Responses to the General Quality Review Questions**

Partial Answers to some of these questions are provided in the responses above.

*1 Were the original charge questions adequately addressed?*

Yes, all the original charge questions were adequately addressed within the limitations of the available data. The responses to the charge questions accurately reflect the data limitations.

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

I did not find any such issues

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

Yes, the Panel's report is clear and logical.

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

Yes, the few conclusions and recommendations offered are supported by the body of the report.

## Comments from Dr. Nancy Kim

Quality review – partial replacement of lead service lines

Nancy Kim

1. Were the original charge questions adequately addressed?  
The charge questions were answered. However, see comments under 2.
2. Are there any technical errors or omissions or issues that are inadequately dealt with in the Panel's draft report?

My comments center around the possibility that the Panel could add additional conclusions/advice to EPA since it has reviewed the existing literature on these issues.

### Issue 1.

The summary of the Brown, 2011 study states (page 10), “The results of Brown et al. (2011) provide no evidence of an effective drinking water Pb reduction via PLSLR in the short term (e.g., within approximately one year). Specifically, there was no demonstrable benefit as evidenced by a reduction in childhood BLL from having had a PLSLR compared to having an intact LSL. In fact, the study results provide suggestive evidence of the potential for harm (i.e. higher BLLs) from PLSLRs. In summary, the available scientific evidence regarding BLLs and PLSLRs, albeit limited, does not support use of PLSLR as an effective or safe measure to reduce short term Pb exposure of those served by LSLs. However, the long-term (e.g., over a period of years) relationship between PLSLRs and childhood BLLS cannot be determined from Brown et al. (2011).”

The report has a section about the limitations and caveats to the interpretation of the Brown study. It also contains a 5 page appendix suggesting how the study should be reanalyzed. This is the only study looking at BLL and PLSLR. It wasn't clear why, if the data were better or if analyzed differently, the lead levels might be lower or no different. Would the panel expect that if the data were reanalyzed as suggested, the results would lead them to the same summary and conclusion? If yes, the panel should probably state so. If no, the summary and the conclusion about the study on page 10, should recognize that the reanalysis may change the panel's conclusion. At a minimum additional information about the limitations of the panel's conclusions should be included in the two paragraph summary.

The analyses of the data stressed the no evidence of benefits from PLSLR and the potential for harm. I can understand why the panel would want to caution if lead exposure were increased, but if the data could provide evidence either way, both possibilities should be mentioned; cautionary statements could be added about the harm from increase Pb exposure.

If the Panel changes its summary and conclusion about the study, the paragraph about the CDC study in the letter to the Administrator should be reviewed and possibly revised.

### Issue 2.

For this issue, the conclusions are “The weight of evidence...clearly indicates that PLSLRs often cause tap water Pb levels to increase significantly for a period of days to weeks, or even several months. After this period the water Pb levels stabilize, sometime at levels below and sometimes at similar levels as those observed priori to PLSLR. It appears that the latter tends to be the case when the tap water PB levels are initially close to or below the AL.”

My interpretation of the conclusions for this section is that PLSLRs, after an initial increased in Pb levels, tend to be lower, especially if the initial Pb levels are higher than the AL. The closer the initial Pb levels to the AL before PLSLRs, the less benefit.

The response to this issue highlights the panel’s concern with the short-term increases in exposure with PLSLR replacement. PLSLRs occur for at least two reasons (compliance with LCR and maintenance problems). Can the Panel provide more specific conclusions about the potential benefits (e.g. reduction in Pb values if initial values are above the AL) and some practical guidance based on its analysis about the length of time short-term increases may occur to be used by those involved with PLSLRs? This guidance should be more concrete than days, weeks, several months.

The response to this issue also discusses problems with the sampling protocols (noting that the Pb results may be underestimated by the existing protocols). It would be helpful if the Panel noted if these concerns also apply to the pre-PLSLRs data.

Issue 3.

Second paragraph, beginning line 32 and continuing through line 36 on page 15. The three sentences in this section seem to be in conflict. Could the panel add something more to the sentence beginning on line 35 for clarification?

Page 16, line 5. Could the panel add a statement about how much the levels were reduced? This would help to characterize the results.

Page 16, second bullet. Could the panel further define or quantify reliably effective in some way, e.g. 25, 50, 75% of the time?

Page 16, 3<sup>rd</sup> bullet. Can the Panel add a time-frame (days, months) for the elevated lead levels?

Page 16, 4<sup>th</sup> bullet. In terms of education, additional information might be worthwhile providing. For example, is the benefit from flushing likely to be much better in the first few days or week and provide less benefit after a month? People may be more likely to carry out such a program than one that requires them to do something for a long time.

Issue 4.

See paragraph before comments on the letter to the Administrator under Issue 5.

Issue 5.

I liked the way the Panel dealt with this. On page 25, line 8, the Panel states, “Under the circumstances, the Panel believes that insertion of a lead-free dielectric is likely to have beneficial effects on Pb concentrations at the tap, albeit of uncertain magnitude. Given the relatively low direct cost of inserting such a device, the Panel has concluded that doing so would be an appropriate standard operating procedure in situations where the decision to implement a PLSLR has been made, provided that other issues...are adequately addressed.”

In this case, the Panel has provided concrete advice that is likely to reduce Pb concentrations/exposures and has qualified the advice. If the other issues could be dealt with in the same way, the Panel might be able to help to reduce lead exposures for those who have to undertake a PLSLR or LSLR.

Letter to the Administrator.

It might help to state that PLSLRs or LSLRs occur for two different reasons, reduce levels because of the LCR and because of maintenance issues. The report recognizes that. My impression is that the report and subsequently the letter to the Administrator and Executive Summary focus on the former rather than the latter. The guidance for the two reasons for PLSLRs or LSLRs may differ.

Executive Summary –

Page 3, paragraph beginning line 13 should be qualified because it appears to contradict the statement on page 4, line 5.

3. Is the Panel’s draft report clear and logical?  
Yes.
4. Are the conclusions drawn or recommendations provided supported by the body of the Panel’s draft report?  
See response to question 2.

## **Comments from Dr. L.D. McMullen**

I feel the Panel did a great job of not only reviewing and commenting on the studies identified in the charge questions but also studies that the Panel knew about that related to the charge.

1. I felt the original charge questions were adequately addressed along with additional comments for future research or studies.
2. I did not find any technical errors or omissions in the report or issues that are inadequately dealt with in the Panel's report.
3. I felt the Panel's draft report was clear and logical.
4. The conclusions drawn or recommendations given were provided with supporting material in the body of the Panel's report.

I have the following addition comments:

I feel the letter to the Administrator was good and did a good job of summarizing the report.

In the executive summary, the summary for charge issue 1 and 5 could be shortened. The second paragraph for issue 1 seemed long and could reference the section in the full report on the design limitations. The first two paragraphs in issue 5 could be combined and summarized. I also felt the third paragraph could be summarized a little.

Page 5 line 3 I think this sentence needs a reference

Page 5 line 17-18 this is redundant to line 14

Page 5 line 21 replace "at the tap" with "in tap water" This also occurs at other places in the report. I know that this is the shortcut notation for water at the tap.

Page 9 line 15-17 I think this needs a reference

Page 9 line 19 there needs to be some background on why the IEUBK Model is the best model to demonstrate childhood BLLs. This is not my area of expertise, but I would think an sentence stating why this model is the correct one to use may be of value to a reader that is not familiar with the Model.

Page 10 line 5 I liked the summary and conclusions section at the end of the charge question. However, it is not consistent with the other issues.

Page 10 line 13-15 I don't know that I agree with this statement. I would agree that if all other exposures were the same, BLL would be a good marker. However, in older homes there may be other exposures, such lead paint, that could be different and may have a greater impact on BLL.

Page 10 line 17-25 this seems to be a repeat of page 7 line 1-6.

Page 11 line 27 I think we may want to add "or lower" after "significantly higher" to be consistent with Appendix D

Page 13 line 43 we may want to add a reference

Page 13 line 46 we may want to add a reference

Page 14 line 9 we may want to add a reference

Page 16 line 1-3 we may want to say why one year is deemed a credible timing for effectiveness.

Page 21 line 28 we may want to add a short "In summary" paragraph to match the format for the other sections

Page 25 line 20 I feel we need to add a concluding paragraph that is a summary of the report, something like what is on page 1 line 14-20. Without that, the report seems to end and the reader is looking for the next chapter.

That is it. I think the Panel report should be of great value to EPA.

## Comments from Dr. John Vena

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

I extend my compliments to the Panel for their careful review of the literature and thoughtful development of conclusions and recommendations. The SAB was asked to evaluate the current scientific data regarding the effectiveness of partial lead service line replacements and centered around five issues: associations between PLSLR and blood lead levels in children; water lead level sampling data at the tap before and after PLSLR; comparisons between partial and full LSLR; PLSLR techniques; and the impact of galvanic corrosion. In my opinion each of the five issues were adequately addressed. Several edits and points of clarification are noted below.

2. Are there are 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?

The cover letter is concise and very effectively highlights the issues and responses. However, in paragraph one it would be helpful to give a brief statement of what actions are taken in a full vs. partial lead service line replacement.

The executive summary is well done and provides an excellent overview of the responses to each of the issues. A brief summary at the end of the conclusions and recommendations would be helpful to the reader.

In the cover letter and in the executive summary (page 1 lines 16-17) it is stated that PLSLR is generally associated with drinking water elevated lead levels. It should be stated how elevated. How much higher? 10%, 50%, 100%. This should also be stated in response to Issue 2.

Page 1 line 39 "measurement error in the assignment of BLLs". Should "assignment" be "quantification" ?

Page 2 line 27 "Several studies" state how many?

Specific comments on response to each Issue:

### ISSUE 1

The limitations of Brown et al (2011) listed on pages 7 and 8 are well done and comprehensive. Page 8 #6 line 16; Could the hypothesis also be that BLL would be lower in PLSLR than LSL? What was the power of the study to detect significantly lower odds ratios between the two service line groups?

Page 9 lines 1-7 and Appendix B. Excellent recommendations for reanalysis of Brown et al.

The public health implications and table 1 are excellent sections of the report.

## ISSUE 2

Page 11 lines 14-29. It would be good to provide a brief summary of the levels or quantification of the differences in the comparisons being made. Are the levels in PLSLR elevated by 10%, 50%, 100% or more??

Page 11 line 32. This is the first use of the term “galvanic corrosion” and at this point this term should be defined and the process explained.

The response to the issue is well written and recommendations are appropriate.

## ISSUE 3

Excellent Response- no edits or changes.

## ISSUE 4

The panel was comprehensive in considering all procedures used as “treatment techniques” as noted on page 17 lines 30-31.

Page 20 lines 20-21. Why does the time to realize the benefit from line flushing preclude any practical implementation of the technique?? (Especially if combined with public education?)

Page 21 lines 43-45 the panel makes an excellent point here that refraining from conducting PLSLRs is not practical as most PLSLRs are voluntary. (Perhaps this should be added to the cover letter and executive summary) I was myself curious why this was not a recommendation of the panel until I read this statement.

## ISSUE 5

Well done- no comments

A summary of conclusions and recommendations from all 5 ISSUES at the end of the report would be beneficial to the reader (as well as at end of executive summary?)

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

Yes. In my opinion the report is very well written, comprehensive in responses to the 5 ISSUES.

## **Comments from other SAB Members**

### **Comments from Dr. George Daston**

#### Quality Review for the Report on Partial Lead Service Line Replacement

I found this report to be well written, with clearly stated conclusions and recommendations. My only concern is that the data on PLSLR and blood lead levels come from a single study. While I agree with the report that the data from this study are consistent with other available information on water lead levels, and the plausibility of lead mobilization via a galvanic process, it is a concern that the data are so limited. My recommendation is that this limitation be clearly articulated in the letter to the Administrator.

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.

Question 2: I found no technical errors or omissions in the report.

Question 3: I found the report to be clearly and logically presented.

Question 4: I found the conclusions of the report to be well documented and supported. As noted above, my preference is to indicate in the letter to the Administrator that the data evaluating blood lead levels from PLSLR is from a single study, and that the report makes recommendations for re-analysis of these data. Because the data from this study are consistent with expectations based on water lead concentrations and a mechanism for lead mobilization, I do not think that the limitation in this data set should change any of the conclusions or recommendations that the committee makes. However, I think it is important that the Administrator understands that the database is limited.

## **Comments from Dr. David Dzombak**

Comments of David Dzombak on draft SAB report “SAB Evaluation of the Effectiveness of Partial Lead Service Line Replacements”

July 19, 2011

This is a well written and well organized report that responds to the charge questions clearly and comprehensively.

1. Were the original charge questions adequately addressed?

Yes, the original charge questions are addressed clearly and comprehensively.

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 recommend that the Panel modify some inaccurate language in the report in various discussions of point-of-use treatment. In various places point-of-use treatment is described via the common terminology “water filtration.” I recommend that this terminology be replaced with “point-of-use treatment” or “point-of-use treatment device”, as appropriate.

There are many types of point-of-use treatment devices, not all of which involve filtration. Further, a filter alone will not usually remove dissolved lead; it depends on the filter material, and whether any adsorption will also occur as water passes through the porous filter material. Point-of-use treatment devices for lead removal often involve a combination of filtration through an adsorptive medium containing activated carbon and cation exchange resin beads. Other kinds of treatment devices, e.g., membrane based systems, can also be used for lead removal.

Some specific locations where the recommended wording changes should be made are as follows:

Page 14, lines 38-39: replace “tap water filtration” with “tap water treatment” or “point-of-use treatment”.

Page 20, line 33: replace “a water filter” with “point-of-use treatment”

Page 21, lines 8 and 9: replace “a water filter” with “point-of-use treatment device”

Page 21, line 9: replace “filter is approved” with “device is approved”

Page 21, line 11: replace “filter device” with “point-of-use treatment device”

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

The draft report is well written and well organized. It responds to the charge questions clearly and comprehensively. I have some suggestions to improve clarity on some minor points.

Bottled water is mentioned as an option on page 20, line 33, and should be similarly mentioned among the options listed on page 14, lines 38-40.

On page 21, lines 3-5, and on Page 22, lines 12-14, the Panel discusses the limitations of and uncertainty about the effectiveness of flushing. The Panel may wish to state more clearly in the conclusions on page 22, and perhaps in the Executive Summary and letter to the Administrator, that flushing results are highly variable and that flushing thus has significant limitations as a primary line of defense. This practice is also in direct conflict with water conservation goals.

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

The conclusions and recommendations are adequately supported in the body of the report.

## Comments from Dr. Elaine Faustman

Quality Review of an SAB Drinking Water Committee draft report entitled SAB Evaluation of the Effectiveness of Partial Lead Service Line Replacements (June 1, 2011 draft)

SAB Reviewer --Elaine M. Faustman

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

The committee was asked to address 5 charge issues. Several of these issues dealt with the request to review one or more specific papers or reports. In addition the committee was asked in two cases to render an opinion on whether standard operating procedures could be instituted relevant for the issues raised in two charge questions.

This reviewer found this report to be detailed and generally on target however it was very, very difficult to follow and track the specific responses and conclusions of the committee.

The Executive Summary and body of the report adequately address the 5 charge issues however the letter to the administrator is difficult to follow as the issues are no longer numerically tracked. This reviewer would suggest specifically labeling the issues and clearly delineating each response to match the issue. For example point 5 which appears to be addressing charge question 5 starts on page ii line 42 and continues to page iii line 6 but does not say anything regarding the question from EPA regarding whether inclusion of a dielectric as part of an operating procedure? This is an example of the level of detail that was a part of the original issue raised that is lost yet addressing in the committee's report.

### 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 committee provides an excellent analysis of the Brown et al 2011 report and even includes a detailed Appendix B that provides an excellent rationale and recommendations for a re-analysis. Many of these details and thoughtful recommendations are lost in the report and definitely do not appear in the executive summary or administrator letter. I think some reference to this is needed. Likewise this reviewer found the summaries of the studies in Appendix C and sampling methods in Appendix D to again be very helpful and would merit further emphasis.

Given the details of the Committee's report this reviewer was surprised that more practical conclusions were not brought forth from the materials reviewed. For example, the committee would seem to be in a position to identify compliance times that could be recommended for PLSLR and intermediate health protective measures that would be recommended in the intermediate periods. Although the committee's report hints at these ideas several times it falls short of summarizing the available literature in a manner that would allow this. In fact the questions regarding the SOPs would appear to be the immediately obvious place to put such information. It would link these suggestions with the committees' statements about the public health significance of the short term elevations in lead that could be linked with a compliance based SOP to identify a practical solution. For example, "When PLSLR techniques are utilized this committee finds that the short-term to intermediate term levels of lead can pose a significant

health issue and with the un predictability of lead level during this period of replacement that the remedy for PLSLR requires a monitoring period until lead levels drop to (EPA can suggest this value) before it can be successfully be accepted as a remedy.” Would the committee feel comfortable with such an explicit monitoring based solution versus solely engineered options?

In the absence of such specific recommendations I think that the committee needs to come forth with a more distinct conclusion that connects their points.

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

In other reports the executive summary would state how and when the SAB deliberated—i.e. move forward the statement on page 5 lines 41 to 43 to state what was done.

The committee clearly discusses the issues of short term elevations of lead and the potential for significant health impacts. This is nicely summarized in the report on page 9, lines 10 to 33 and page 10 lines 1-5 however this important consequence is not mentioned in the executive summary and hence the reader is confused by the committee’s deliberations.

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

The conclusions are supported by the body of the Committee’s report however as noted above these conclusions are not fully brought forth into the two summary sections the executive summary and administrator’s letter in a consistent and comprehensive manner so it is difficult for a reader to obtain this conclusion.

Editorial comments—

Check the language of the document to be more certain-- For example page 24 line 15 the line states “In attempting to answer this question the Panel....” Change to “The Panel noted...”

## Comments from Dr. James Hammitt

Overall, I found this to be an excellent, clearly written SAB report. Below are my responses to the questions and a few additional comments.

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?

Not that I see.

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

Yes, although the claim (p. 23, l. 22-25) that a small area of corrosion can produce a significant risk to consumers "if that volume of Pb exits the tap in a small volume of water" seems overstated. While this scenario could yield a high Pb concentration in a small volume of water, it would not necessarily lead to a quantitatively important Pb exposure if most of the water consumed has a smaller Pb concentration. The risk also depends on the importance of acute vs. chronic exposure.

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

Yes, with some exceptions:

The conclusion and recommendation at p. 17, l. 1-9 seem stronger than supported by the preceding discussion. They seem to rely on only one study, which is presumably limited in its coverage.

The conclusion at p. 21 l. 16-19 does not seem to be supported by evidence in the report.

Other minor comments

p. 11 l. 20. Insert "is" in "it reasonable"

p. 13, l. 23-26. Is it possible to add a phrase to explain why this occurs (unless it is explained elsewhere)?

p. 19. l.3. Add "statistically" before "significant."

**Comments from Dr. H. Keith Moo-Young**

Were the original charge questions to adequately addressed?

Yes. The original charge questions were adequately addressed. The panel did a good job of putting together this report.

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

There are no omissions in the report.

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

Yes, The report is clear and logical.

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

The conclusion support the body of the report. Since many of the studies provided inconclusive data, it is the opinion of this SAB member that the report should emphasize the need for applied research in this area. In addition, STAR grants could be another source to further elucidate missing gaps in R and D.

Additional money to revitalize EPA's technology verification program would be another source of taking on the new technology evaluations.

**Comments from Dr. Eileen Murphy**

**Were the original charge questions to the SAB committee adequately addressed?**

Yes. This was a very well-written, concise and understandable report. Charge questions were clearly presented and addressed.

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

There were no technical errors or omissions apparent in the report.

**Is the committee's report clear and logical?**

The report was well-written, thorough and easy to follow.

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

Yes.

**Comments from Dr. Stephen M. Roberts**

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

I found the responses to the charge questions to be complete and thorough.

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 found no technical errors or omissions in the report.

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

The report is clear, logical, and well written.

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

The bases for the recommendations are clearly explained in the body of the report.

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**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

3. Is the Panel's draft report 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. James Sanders**

1. Were the original charge questions 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, to the extent that I can judge.

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

Yes. The report would benefit from another round of editing, as there are some repeated statements (such as lines 36. Page 13 through line 5, page 14 or lines 15-18 and lines 37-40 on page 18 or the material repeated twice in lines 19-25 on page 34). The Panel generally have used a format of general comments on each charge, followed by more specific comments. This format works well, but also had lead to repetition, for example the first paragraph on page 50 is largely repeated in lines 25-33 on the same page.

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

Yes.