UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

DATE

The Honorable Lisa P. Jackson
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: SAB Evaluation of the Effectiveness of Partial Lead Service Line Replacements

Dear Administrator Jackson:

Lead exposure causes adverse health effects including impaired neurodevelopment of children, and hypertension and cardiovascular disease in adults. EPA's Office of Water regulates drinking water lead levels via the 1991 Lead and Copper Rule (LCR). The LCR established an action level for drinking water lead, above which water systems must install corrosion control treatment. If the action level is not met after installing corrosion control treatment, then lead service line replacement (LSLR) is required. Under the 2000 LCR revisions, water systems must replace only the portion of the lead service line that it owns. This is termed a partial LSLR. EPA's Office of Water sought SAB evaluation of current scientific data to determine whether partial LSLR (PLSLR) are effective in reducing drinking water lead levels. EPA identified several studies for the SAB to consider, and the SAB used additional studies for their evaluation.

The SAB was asked to evaluate the current scientific data regarding the effectiveness of partial lead service line replacements 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 lead service line replacements (LSLR); PLSLR techniques; and the impact of galvanic corrosion. The SAB Drinking Water Committee was augmented for this evaluation (hereafter referred to as the "DWC Lead Panel" or "Panel"). A public meeting was held on March 30-31, 2011 to deliberate on the charge.

Overall the SAB finds that based on the current scientific data, partial lead service line replacements have not been shown to be effectively reduce drinking water lead levels in the short-term. Indeed, PLSLR generally result in elevated lead drinking water levels for some period of time after replacement. Sufficient data to determine the long-term effectiveness of

PLSLR does not exist. The SAB response to the EPA's charge is detailed in the report. The key SAB comments and recommendations are provided below.

- The SAB evaluated a Centers for Disease Control and Prevention (CDC) study that examined associations between childhood blood lead (BPb) levels and PLSLR. Although the study had some design limitations, this study suggests that there is a potential for harm (i.e. higher BPb) resulting from PLSLR, and provided no evidence of a demonstrable benefit from PLSLR on reductions in childhood BPb levels. The available scientific evidence regarding BPb and PLSLR, while limited, does not support the use of PLSLR as an effective or safe measure to reduce Pb exposure of those served by lead service lines.

- The SAB evaluated several studies of tap water lead levels both before and after PLSR. They clearly indicate that PLSLR often causes tap water lead levels to increase, sometimes dramatically, for days to weeks or months, or perhaps even longer. Available data suggest that tap water lead levels tend to then decline over time, but often **only** to levels similar to those observed prior to PLSLR. The weight of evidence is that PLSR increases tap water lead levels in the short to medium term, and is not effective in reducing lead drinking water levels. However, data are lacking to evaluate the long-term effectiveness of PLSLR.

- In studies pertaining to comparisons between full and partial lead service line replacements (LSLR), the evaluation periods have been too short to fully assess differential reductions in lead drinking water levels. Nevertheless, for the time periods reported in the studies, in water distribution systems optimized for corrosion control, full LSLR has been shown to be effective and PLSLR has not been shown to be effective in reducing drinking water lead levels. Both full and partial LSLR generally result in elevated lead levels for a variable period of time after replacement, but the duration and magnitude of the elevations are generally greater with PLSLR than full LSLR. Insufficient scientific data are available to unambiguously identify the specific causes of the elevations in lead levels after LSLR.

- Studies examining different PLSLR techniques did not provide definitive information on the impact that PLSLR techniques can have on lead release. The SAB's ability to comment on this issue was limited by heterogeneity in the types of water studied, and changes in water quality during the studies. There is a lack of data on the role that water quality plays in optimal corrosion control and passivation of newly exposed pipe surfaces. Development of a Standard Operating Procedure for PLSLR techniques may be premature at this time.

- Galvanic corrosion associated with partial LSLR poses a risk of increased lead levels at the tap by increasing the corrosion rate and/or increasing the chance that corroded lead will be mobilized. This risk may persist for at least several months and is very difficult to quantify given current data. Insertion of a dielectric eliminates galvanic corrosion at the new pipe junction by breaking the electrical current between the new and old pipes, but it has no effect on depositional corrosion. The SAB believes that insertion of a dielectric will likely reduce lead levels at the tap, but it cannot confidently state the magnitude of the reductions because the contribution of galvanic corrosion and depositional corrosion to lead drinking water levels has not been quantified.

The SAB appreciates the opportunity to provide EPA with advice.

Sincerely,

Dr. Deborah L. Swackhamer	Dr. Jeffrey K. Griffiths
Chair	Chair
EPA Science Advisory Board	SAB DWC Lead Panel

NOTICE

U.S. Environmental Protection Agency
Science Advisory Board
Drinking Water Committee Augmented for the Review of the Effectiveness of Partial Lead Service Line Replacements

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ACRONYMS

BPb	Blood lead
EPA	United States Environmental Protection Agency
CDC	Centers for Disease Control and Prevention
LSL	Lead Service Line
LSLR	Lead Service Line Replacement
OW	EPA's Office of Water
Pb	Lead
PLSLR	Partial Lead Service Line Replacement
SAB	Science Advisory Board

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1. EXECUTIVE SUMMARY

This report was prepared by the Science Advisory Board (SAB) Drinking Water Committee Augmented for the Review of the Effectiveness of Partial Lead Service Line Replacements (hereafter "DWC Lead Panel" or "Panel"), in response to a request by EPA's Office of Water to evaluate the current scientific data to determine the effectiveness of partial lead service line replacements (PLSLR) in reducing lead drinking water levels. The charge to the Panel was centered around five issues. They were: associations between PLSLR and blood lead levels in children; water sampling data at the tap before and after PLSLR; comparisons between full and partial lead service line replacements; PLSLR techniques; and the impact of galvanic corrosion. The SAB DWC Lead Panel held a public meeting on March 30-31, 2011 and deliberated on the charge (see Appendix A). This Executive Summary highlights the Panel's major findings and recommendations.

Overall the SAB finds that based on the current scientific data, partial lead service line replacements have not been shown to be effective in reducing lead drinking water levels in the short-term. Additionally, PLSLR generally result in elevated drinking water lead levels for a variable period of time after replacement, suggesting the potential for harm rather than benefit. There is not sufficient data to determine the long-term effectiveness of PLSLR.

<u>Associations Between PLSLR and Blood Lead Levels in Children</u>

The Panel searched the current scientific literature and finds that Brown et al. (2011) is the only study that directly examines the relationship between childhood blood lead (BPb) levels and partial lead service line replacements. The results of Brown et al. (2011) demonstrate no evidence of demonstrable benefits from PLSLR on reductions in childhood BPb levels. In fact, the study suggests the potential for harm (i.e., higher BPb) related to PLSLR, among children living in households in which a PLSLR was performed. This finding is scientifically consistent with the observation that water Pb levels often increase after PLSLR (see Charge Issue #2).

There are a number of design limitations in Brown et al. (2011) that preclude reaching final and definitive conclusions about the relation of BPb levels with PLSLR. These include the following: a lack of information on both individual-level potential confounders and potential confounders related to houses that had PLSLR; not accounting for the timing of PLSLR relative to measurement of BPb levels; not accounting for the duration of residence in housing; possible ascertainment bias in the detection of elevated BPb; potential for measurement error in the assignment of BPb levels; low statistical power due to the limited number of children with elevated BPb in the subanalyses; limited BPb data for infants under one year of age; and limited ability to generalize the findings to other populations, communities, and water systems. The Panel has several recommendations to address these limitations, such as a reanalysis of Brown et al. (2011) using expanded data resources and improved methods. For example, even given the limitations of the data described above, a reanalysis of the original BPb levels in a more powerful ordinary least-squares regression would increase the power to detect significant increases in BPb associated with PLSLR, should they exist. In addition, fully utilizing available data (e.g., age of housing) and, where possible, acquiring additional administrative data (e.g., date of BPb testing and date of PLSLR) would improve a reanalysis of the data.

Water Sampling Data at the Tap Before and After PLSLR

The weight of evidence clearly indicates that partial lead service line replacement (PLSLR) often causes tap-water lead levels to increase for days to weeks or months, or perhaps even longer in some cases. Available data suggest that tap water lead levels tend to gradually stabilize over time following PLSLR, sometimes at levels below those observed prior to PLSLR, but often at levels similar to those observed prior to PLSLR. However, long-term data are sorely lacking. Therefore, it remains unclear how long it typically takes for lead levels to stabilize and how often tap water lead levels significantly decrease after an extended period of time.

The duration of elevated tap water lead levels following PLSLR may be influenced by the extent of disturbance of the LSL and the deposits within it, by the unique chemistry of the local water supply, by biological activity, by localized corrosion, and by other factors. Unfortunately, studies that have documented elevated tap water lead levels following PLSLR have generally not studied the mechanisms involved, so the reason for the increase in a given setting is generally not known with certainty. At present it is not known, nor is it possible to accurately predict, if or how high tap-water levels will increase following PLSLR in a given distribution system, or how long the increase will persist.

Comparisons Between Full and Partial Lead Service Line Replacements

The Panel evaluated several studies that examined comparison between partial and full LSLR. The Panel finds that in these studies, the time periods of evaluation of lead concentrations following partial and full LSLR have been inadequate to fully evaluate the effectiveness of reducing lead drinking water levels. Nevertheless, for the time periods reported in the studies, the Panel concludes that in water distribution systems optimized for corrosion control, full lead service line replacements have been shown to be an effective method of reducing lead drinking water levels. However, partial lead service line replacements have not been shown to be effective in reducing lead drinking water levels, at least in the time frames of the reported studies. In water distribution systems not optimized for corrosion control, the existing scientific data are inadequate to evaluate the effectiveness of partial lead service line replacements in reducing lead drinking water levels.

In water distribution systems optimized for corrosion control, both full and partial lead service line replacements generally result in elevated lead levels for a variable period of time after replacement. The duration and magnitude of these elevated lead levels are generally greater PLSLR than for full service line replacements. Insufficient scientific data are available to identify the specific causes of the spikes in lead levels.

PLSLR techniques

The Panel evaluated several studies that examined the impact that partial lead service line replacement (PLSLR) techniques can have on lead release, such as different replacement techniques, different cutting techniques, different joining techniques, the effectiveness of flushing, and public education. The Panel concludes that the studies do not provide definitive information on the impact that PLSLR techniques can have on lead release. The Panel finds that the different replacement techniques are either minimally invasive or involve limited physical contact with the service line, and therefore have minimal impact on post-PLSLR lead release. The studies that examined different cutting techniques are limited by sample size and do not clearly demonstrate a significant difference between the cutting methods. One study examined the use of heat shrink Teflon® sleeves as a joining technique, and the Panel finds that the results for this new technique are inconclusive. In the studies that examined flushing effectiveness, flushing of the pipe loop appears to provide some benefit, but the time to realize the benefit requires weeks and exceeds any practical recommendation for customer implementation. Additional data analysis of these studies might provide additional insights into the impacts of pressure transients and flushing.

Part of the PLSLR technique involves public notification and education. Informing the public about the risk of lead exposure is a critical component of a PLSLR program. While the agency has published guidance (last revised in 2002), there are no studies evaluating the effectiveness of these public notification programs or materials, yet these may be critical to reducing and minimizing lead exposure in PLSLR programs. The guidance does not address the issues related to PLSLR. Reviewing and updating of the public education guidance would be appropriate.

These studies point out that interaction of water quality parameters can play a critical role in lead release. Until this role can be better defined there will be inherent risks in any proposed solution to mitigate lead release following a partial LSL replacement. Lack of similar water quality between the different studies and changes in water quality during some of the studies (specifically switches in disinfection between chloramine and free chlorine treatment) limit their interpretation and broad applicability.

Generally, the techniques for PLSLR provide a good framework under which an SOP (standard operating procedure) could be developed. However, given the lack of definitive studies on the effectiveness of different procedures and approaches to PLSLR combined with a lack of information on the role water quality plays in optimal corrosion control and passivation of newly exposed pipe surfaces is a critical information gap, development of an SOP at this time may be premature.

Galvanic Corrosion

Several studies have been conducted to identify and quantify the significance of galvanic corrosion when partial lead service line replacements are implemented. The conclusions that have been drawn from the studies vary widely, in part because of the disparate procedures and metrics that have been used to assess the corrosion process, and in part because the process itself is complex and might proceed at vastly different rates in different systems. Despite some divergence of opinion as to the severity of the problem posed by galvanic corrosion, there seems to be widespread agreement that the electrical potentials and currents change when lead and copper are brought into electrical contact, and that the region over which these changes are substantial is confined to a few inches on either side of the contact point.

The available evidence strongly supports the contention that galvanic corrosion increases the corrosion rate of the lead pipe near the point of metal/metal contact shortly after the contact is made. It also supports the contention that galvanic corrosion can be significant for periods of at least several months thereafter. The time frame and magnitude of this increase are uncertain and probably differ among different systems, depending on the water quality and other local conditions. The panel is not aware of evidence suggesting that lead that is oxidized galvanically is more or less likely to be mobilized than lead that is oxidized by other mechanisms. The Panel therefore concludes that galvanic corrosion associated with partial lead service line replacement does pose a risk of increased lead levels at the tap, and that this risk might persist for periods of at least several months, but that the risk is unlikely to be uniform on either a temporal or spatial basis and is therefore very difficult to quantify given current information and the heterogeneity of water systems and conditions in the United States.

Insertion of a dielectric breaks the electrical connection between the new and old pipes, and thereby eliminates galvanic corrosion at the copper and lead pipe junction, but it has no effect on depositional corrosion or the galvanic corrosion that can subsequently ensue at the site of depositional corrosion. Because the relative magnitudes of galvanic corrosion at the pipe juncture and depositional corrosion have not been quantified, it is not possible to state with confidence how much galvanic corrosion will be reduced by insertion of a dielectric. However, there is no question that some reduction will be achieved. The panel believes that insertion of a dielectric is likely to have beneficial effects on lead concentrations at the tap, albeit of uncertain magnitude. Given the relatively low direct cost of inserting such a device, doing so would be an appropriate standard operating procedure in situations where the decision to implement a partial lead service line replacement has been made.

2. INTRODUCTION

Exposure to lead in humans has been shown to cause adverse health effects on the neurodevelopment of children, including seizures, as well as hypertension and cardiovascular disease in adults. Lead (Pb) in water is an established source of Pb exposure to the general population, including both adults and children. It has been estimated that 20% of children's overall Pb intake in the United States comes from Pb in drinking water (Lanphear et al., 2002). This value may vary widely depending on the source and volume of water consumed. Water may represent a much greater proportion of Pb intake for infants fed with formula reconstituted with tap water than for other children (Shannon and Graef, 1989). Indeed, high water Pb levels can be a singular cause of Pb poisoning in infancy (Shannon and Graef, 1989).

A key source of Pb in drinking water is Pb leached from materials present in water distribution systems, including Pb in service lines and household fixtures. There are a number of factors associated with the Pb leaching into water, including the types of chemicals used in water disinfection and water temperature and pH. The lead content of solder, fixture constituents and service lines themselves are also important factors.

EPA's Office of Water (OW) regulates lead drinking water levels through the 1991 Lead and Copper Rule (LCR) by establishing a treatment technique to minimize lead levels at the tap. The LCR established an action level for lead in drinking water, above which, water systems are required to install corrosion control treatment. If the action level is still not met after installing corrosion control treatment, lead service line replacement is required. Under the 2000 LCR revisions, water systems are required to replace only the portion of the lead service line that it owns. When a water system replaces only a portion of the lead service line (the portion it owns), this is referred to as a partial lead service line replacement.

EPA's OW requested that the Science Advisory Board (SAB) evaluate the current scientific data to determine the effectiveness of partial lead service line replacements (PLSLR) in reducing lead drinking water levels. In response to this request, the SAB Drinking Water Committee (DWC) was augmented with additional experts, hereafter referred to as the "DWC Lead Panel" or "Panel".

EPA's charge to the Panel, presented in Appendix A, is centered around five issues: associations between PLSLR and blood lead levels in children, water sampling data at the tap before and after PLSLR, comparisons between full and partial lead service line replacements, PLSLR techniques, and the impact of galvanic corrosion. EPA identified several studies pertaining to each of the issues for the Panel to consider in their evaluation, but the Panel was also encouraged to identify and use any additional studies for their evaluation. The SAB DWC Lead Panel held a public meeting on March 30-31, 2011 to deliberate on the charge. The Panel's response to the charge is detailed in the report.

3. RESPONSE TO EPA CHARGE

Overall Charge

EPA is seeking SAB evaluation of current scientific data to determine whether partial lead service line replacements are effective in reducing lead drinking water levels. EPA has identified several studies for the SAB to consider for the evaluation. The SAB may also consider other relevant studies for the evaluation.

3.1. Issue 1 – Studies Examining Associations Between Elevated Blood Lead Levels and Partial Lead Service Line Replacements (PLSLR)

A recently published study by the Centers for Disease Control (Brown et al. 2011) examined an association between children's blood lead level, lead service lines, and water disinfection in Washington, DC using data from 1998 to 2006. How does this study inform the available information on the effectiveness of partial lead service line replacement in reducing drinking water exposure to lead?

<u>Summary and conclusions from Brown et al. (2011)</u>

The SAB did not identify any other peer reviewed literature in addition to Brown et al. (2011) that explicitly addresses the relation of blood Pb (BPb) levels with PLSLR.

Brown et al. (2011) used administrative data from the Washington, D.C. Childhood Lead Poisoning Prevention Program (CLPPP) to characterize BPb levels among children under age 6 years between 1998 and 2006. Data obtained from the Washington, D.C. Water and Sewer Authority (WASA) were then used to characterize the water delivery system applicable to the child's listed address. Specifically, it was noted whether the address was served by a lead service line (LSL), a PLSLR, or a non-lead pipe delivery system prior to the BPb measurement. By matching CLPPP and WASA address data, the relation of childhood BPb levels with household water characteristics was assessed for 63,854 children. The study found that children with higher BPb levels were more likely to have an LSL; this relationship was stronger during the time period of November 2000 through June 2004 when chloramines, a relatively corrosive water disinfectant, were being used (Brown et al., 2011, Table 2). Key to Charge Issue #1, was the finding that, in a subset of 3,651 children with BPb measured between 2004 to 2006, residing in a household with a PLSLR compared to a household with an LSL not replaced, yielded a 1.1 increased odds (95% CI: 0.8, 1.3) of having a BPb between 5-9 μg/dL and a 1.4 increased odds (95% CI: 0.9, 2.1) of having a BPb ≥10 μg/dL compared to BPb < 5 μg/dL (Brown et al., 2011, right half of Table 3).

Thus results of Brown et al. (2011) demonstrate no evidence of a benefit to childhood BPb levels from a PLSLR compared to having an LSL not replaced. In fact, the study's results suggest the potential for harm (i.e., higher BPb) related to PLSLR, with a non-significant 1.4 increased odds of BPb ≥ 10 μg/dL (vs. < 5 μg/dL) among children living in households in which a PLSLR was performed. This finding is consistent with the observation that water Pb levels often increase after PLSLR (see Charge Issue #2).

<u>Limitations and caveats to the interpretation of Brown et al. (2011)</u>

There are a number of design limitations in Brown et al. (2011) that preclude reaching any definitive conclusions about the relation of BPb levels with PLSLR. These include the following:

1. Perhaps most important is that the administrative databases used did not include information on individual-level potential confounders, a common limitation of administrative data. For example, it is not known how children with PLSLR compared to those with an intact LSL with regard to potential confounding variables such as socioeconomic status, ethnicity, tap water Pb levels and consumption, alternative drinking water sources, point-of-use water treatment, or Pb paint hazards. The study used age of housing as a proxy for confounding by Pb paint hazards. However, age of housing was only available for a subset of the children and was not used in the analyses to assess the relation of BPb with PLSLR. Lack of accounting for such confounders could have biased findings. For example, if households with PLSLR filtered their drinking water in response to PLSLR, the observed relation of BPb with PLSLR would underestimate the true risk to BPb. This factor may have been of particular concern in Washington, D.C. during the time period of 2004 to 2006, when potential risks associated with Pb in drinking water were widely publicized in the media.

2. There was a lack of information regarding potential confounding factors associated with a household having a PLSLR vs. an LSL not-replaced. For example, it is not known whether PLSLR may have been preferentially conducted in households with the historically highest levels of water Pb. If so, it is possible that some children at PLSLR residences may have sustained higher chronic Pb exposure prior to the replacement, and this in turn may have influenced the comparison of BPb values between PLSLR and LSL not-replaced households.

3. The timing of PLSLR relative to measurement of BPb levels or the duration of residence in housing with an LSL were not accounted for and, except for timing between PLSLR and the BPb measures, presumably such information was not available via the study's administrative data. In the latter case, the authors reported that BPb levels were measured, on average, 10-11 months after PLSLR, a lag which may have attenuated any observed associations. Lack of accounting for such factors could result in exposure misclassification. Such misclassification, if non-differential, would attenuate associations but, if differential, would bias findings with the direction of bias dependent upon how such factors were distributed between children with PLSLR compared to those with an intact LSL.

4. Furthermore, there was possible ascertainment bias in the detection of elevated BPb. For example, the implementation of PLSLR at a household may have increased parental awareness regarding the hazards of childhood Pb exposure, and may have motivated a higher rate of BPb screening in children already subject to other risk factors for elevated BPb levels.

5. There was the potential for measurement error in assignment of BPb levels. Although many children had more than one BPb measure, analyses were restricted to one BPb value per child by using the lowest available finger stick (capillary blood) or the highest available venous value for a given child, an approach that may not fully capture a given child's BPb levels.

6. The PLSLR sub-analyses were based on a modest number of children with elevated BPb. Specifically, among children who lived in housing with a PLSLR, 598 had BPb < 5 µg/dL, 105 had BPb = 5-9 µg/dL but only 27 had BPb ≥ 10 µg/dL. In addition, due to the very unequal distribution of subjects in the two water service line groups (PLSLR vs. intact LSL), the use of categorical BPb outcome logistic analysis with low *a posteriori* probability of BPb exceeding 10 µg/dL, the power of the test of BPb lead in the two water service line groups was low. A post-hoc power analysis shows that with an alpha probability criterion of 0.05, there was only 25% power in the study to detect a significant OR of 1.36 (95% CI: 0.87, 2.12) (calculated from the frequency data in the right hand side of Table 3).

7. A significant limitation from the perspective of public health protection is that the CLPPP data had relatively little (13%) BPb data for infants under one year of age, the group most likely to be affected by water Pb levels via consumption of baby formula reconstituted with tap water.

8. Finally, given substantial local variability in water systems, the ability to generalize the Brown et al. (2011) findings to other populations, communities, and water systems may be limited.

Recommendations for future research

Some of the above limitations could be addressed by additional studies. For example, replicating Brown et al. (2011) in other communities could be of value regarding the ability to generalize the findings. Long term prospective studies assessing repeat BPb levels – including child and early infant levels as well as data on water Pb levels and consumption patterns – before and after PLSLR could provide valuable information regarding the relation of BPb with PLSLR over time. However, the most cost-effective and expeditious way of addressing the need for robust data relevant to Charge Issue #1 would likely be via a reanalysis of Brown et al. (2011) using expanded data resources and improved methods. For example, even given the limitations of the data described above, a reanalysis of the original BPb levels in a more powerful ordinary least-squares regression would increase the power to detect significant increases in BPb associated with PLSLR, should they exist. In addition, fully utilizing available data (e.g., age of housing) and, where possible, acquiring additional administrative data (e.g., date of BPb testing and date of PLSLR) would improve a reanalysis of the data. A request for access to the data used in Brown et al. (2011) for reanalysis is being made as part of this response to Charge Issue #1 as described in detail by SAB committee member, Dr. Stephen Rothenberg (see Appendix B: Rationale for reanalysis of the Brown et al. (2011) dataset).

Public health considerations

The short- and long-term consequences of PLSLR on BPb levels may differ. For example, children's BPb levels may increase substantially in the first few months following PLSLR due to short term elevations in water Pb concentration, a possibility not specifically investigated by Brown et al. (2011). Still, uncertainties regarding possible differences between short- and long-term BPb changes with PLSLR do not undermine the public health impact of short-term elevations in BPb, particularly in children for whom Pb is such a well-established and potent neurodevelopmental toxicant.

To demonstrate the role of water Pb elevations on childhood BPb, we used EPA's Integrated Exposure Uptake and Biokinetic Model (IEUBK) (USEPA, 2009), to estimate BPb levels for infants (ages 0-12 months) resulting from a moderate range of water Pb concentrations (Table 1). Our BPb predictions are based on a simplifying assumption that all of the infant's Pb exposure is from drinking water, consumed directly as a beverage and indirectly in the preparation of food and beverages (including infant formula). In addition, the calculations include the following inputs: first, that typically a formula-fed infant consumes approximately 500 ml of water/day but may consume up to 1500 ml of water/day (USEPA, 2008), and, second, that the bioavailability of ingested water Pb is approximately 50% in infants (ATSDR, 1995). For example, with water Pb levels varying from 10-30 µg/L and intake between 0.5 and 1.5 liters/day, the predicted geometric mean infant BPb levels resulting from water intake alone range from 1.2 to 8.2 µg/dL (Table 1), a range associated with demonstrable adverse impacts on neurodevelopment (Bellinger 2008; Lanphear et al., 2005). This model predicts that 34% of infants consuming 1.5 liters/day of tap water with a Pb concentration of 30 µg/L will have BPb levels in excess of 10 µg/dL (Table 1).

Table 1: Predicted infant BPb levels[1] by tap water Pb concentrations and water intake for formula-fed infants ([1]IEUBK model, US EPA, 2009)

Predicted geometric mean blood Pb (ug/dL): 0-12 months*

	Water Consumption (L/day)					
	0.500			1.500		
water Pb (µg/L)	Blood Pb (µg/dL) levels	% above 5 µg/dL	% above 10 µg/dL	Blood Pb (µg/dL) levels	% above 5 µg/dL	% above 10 µg/dL
10	1.2	0.0	0.0	3.3	18.7	0.9
15	1.7	1.2	0.0	4.7	44.7	5.4
20	2.3	4.7	0.1	6.0	64.8	13.7
30	3.3	18.7	0.9	8.2	85.6	34.1

* Absorption fraction (bioavailability) = 50%. Input parameters for all other sources of Pb set to zero.

Summary and conclusions

The task for SAB Charge Issue #1 was to assess how the available medical literature, in particular the study by Brown et al. (2011), offers information on the effectiveness of PLSLR in reducing drinking water exposure to Pb. There is well-documented and substantial population morbidity associated with low-level lead exposure in humans, especially for hypertension and related cardiovascular disease risk in adults, and neurodevelopment in children (Menke et al., 2006; Bellinger 2008; Lanphear et al., 2005). Thus, on the basis of well-established scientific literature regarding low-level Pb toxicity, the effectiveness of reduction of drinking water Pb exposure should be gauged by how well technologies consistently minimize or eliminate drinking water Pb exposure. The results of Brown et al. (2011) provided no evidence of effective drinking water Pb reduction via PLSLR. Specifically, there was no demonstrable benefit to childhood BPb levels from a PLSLR compared to having an intact LSL. In fact, the study findings suggest that there was a potential for harm (i.e. higher BPb) from PLSLR. In summary, the available scientific evidence regarding BPb and PLSLR, albeit limited, does not support use of PLSLR as an effective or safe measure to reduce Pb exposure of those served by lead service lines.

3.2. Issue 2 – Studies Evaluating PLSLR with Tap Sampling Before and After Replacements

There are a number of studies that evaluated partial lead service line replacement with tap sampling conducted both before and after the replacement (Britton et al., 1981; Gittelman et al., 1992; Muylwyk et al., 2009; Sandvig et al., 2008; Swertfeger et al., 2006; USEPA 1991a; USEPA 1991b; Weston et al., 1990). These studies use a variety of sampling protocols and the timing of sampling after replacement differed between studies. What conclusions can be drawn from these studies regarding the effectiveness of partial lead

service line replacement in light of the different sampling protocols and different timing of sampling? Please comment on the changes in lead concentrations in drinking water after partial lead service line replacements and the duration of those changes.

The weight of evidence clearly indicates that partial lead service line replacement (PLSLR) **often** causes tap-water lead levels to increase for a period of time that may range from days to weeks or months, or perhaps even longer in some cases. Available data suggest that tap-water lead levels tend to gradually stabilize over time following PLSLR, **sometimes** at levels below those observed prior to PLSLR, but **often** at levels similar to those observed prior to PLSLR. It appears that the latter tends to be the case when the tap-water lead levels are relatively low to begin with. However, long-term data are unavailable. Therefore, it remains unclear how long it typically takes for lead levels to stabilize and how often tap-water lead levels significantly decrease after an extended period of time. Nevertheless, it is clear that tap-water lead levels of significant concern from a public health standpoint can persist indefinitely following PLSLR and may continue to persist until the customer's LSL, and perhaps the piping within the home as well, is replaced. Furthermore, the lead concentrations to which consumers of unfiltered tap water are actually exposed following PLSLR may be significantly higher than the concentrations found using the sampling protocols specified in the LCR or other common sampling protocols.

The duration of elevated tap-water lead levels following PLSLR may be influenced by the extent of disturbance of the LSL and the deposits within it, by the unique chemistry of the local water supply, by biological activity, by localized corrosion, and by other factors. Unfortunately, studies that have documented elevated tap-water lead levels following PLSLR have generally not studied the mechanisms involved, so the reason for the increase in a given setting is generally not known with certainty. Some investigators have speculated that particulate lead is released into the water when lead-contaminated encrustations are physically or hydraulically disturbed. There is a substantial amount of good evidence from other studies that such disturbances can and do occur and that they do result in release of particulate lead. Other investigators speculate that galvanic corrosion occurs when the new line is connected and that lead levels decline as the new material is gradually passivated; and this possibility is discussed with Issue 5 below. In some cases, operational adjustments to the water chemistry (such as increasing the pH or adding orthophosphate to control corrosion) were made shortly before or after PLSLR, such that tap-water lead levels may have changed for reasons unrelated to PLSLR. At present it is not known, nor is it possible to accurately predict, if or how high tap-water levels will increase following PLSLR in a given distribution system, or how long the increase will persist.

In promulgating the LCR in 1991, EPA assumed that "partial removal of a lead service line will reduce … exposure … because there will be a smaller volume of water in contact with the lead service line" (USEPA, 1991a). EPA noted that this assumption was consistent with the results of a study of 2000 homes in the UK and with mass transfer modeling. In situations where the LSL is the dominant source of lead, most of lead is dissolved, and a significant fraction of the water consumed does not remain in the line long enough to reach equilibrium with respect to lead solubility, EPA's assumption is generally valid and it would be reasonable to expect PLSLR to significantly reduce exposure over time. However, it is now clear that there may be many cases where these conditions are not met and where PLSLR may be of little or no benefit.

Since 1991, a number of studies have documented the importance of particulate lead in drinking water lead exposure. It is now recognized that a large fraction of the lead in a given water sample may be present in particulate form, and that particulate lead is sporadically released from distribution or household water pipes into the water, especially as a result of sudden increases in flow rate (such as those caused by fully opening a tap), variations in water quality, seasonal changes in temperature, bacterial growths, and other physical or hydraulic disturbances to the system such as PLSLR and the water hammer phenomenon. Moreover, in homes that have (or previously had) lead service lines (LSL)s, the amount of particulate lead in a single sample or glass of water can be so high that it may pose an acute public health hazard.

If lead were associated only with LSLs and faucet fixtures, it might be reasonable to assume that exposure to lead would be reduced roughly in proportion to the fraction of the LSL removed (with actual exposure depending on use patterns, etc.). However, it is now recognized that large quantities of lead often accumulate in interior plumbing downstream from an LSL, especially in galvanized pipes. This phenomenon, referred to as “seeding” by some investigators, is caused by adsorption of lead onto scale deposits and corrosion products as they build up over decades of time in the system; by incorporation of lead into scales by precipitation and co-precipitation; and by capture of lead-bearing particles by various mechanisms. Thus, the entire plumbing system, not just the LSL, may be a significant (or even dominant) source of lead; and the encrustations may contain enough lead to pose a significant health hazard for many years (or even decades) after the LSL has been partially or even fully replaced.

Even in cases where particulate lead does not pose a problem, PLSLR may result in little or no benefit if most of the water consumed is initially stagnant in the customer-owned portion of the LSL for an extended period of time. Consumers who fail to flush their lines before drawing a glass of water, for example those who brush their teeth and take a drink of water before flushing the toilet or taking a shower in the morning, may be exposed to relatively high concentrations of dissolved lead. Those who flush their lines using water temperature as an indication that the water is now coming from the main may be exposed to high lead levels if the customer-owned portion of the LSL is significantly colder than room temperature.

Options for reducing exposure to lead remaining in a consumer’s plumbing system following PLSLR include tap-water filtration, preferably using a filter able to remove both particulate and dissolved lead; public education; full LSL replacement; and, where applicable, replacement of other plumbing materials encrusted with lead-bearing deposits. Although full LSL replacement is currently recommended, few home owners choose this option due to its cost. Options for increasing participation in FLSLR programs include public education and economic inducements such as subsidies, loan programs, and mandatory notification of prospective home buyers.

Several public commenters, as well as several panel members, noted that many PLSLRs are done by utilities on a voluntary basis. Some utilities voluntarily replace more LSLs than required under the LCR; and some have chosen to replace all those they encounter in the normal course of their operations as they repair leaks and replace mains. In most cases, such replacements are partial, since the majority of home owners choose not to replace the privately owned portion of the line. The consensus of the panel is that these PLSLRs pose a short-term health risk, since they are likely to result in short-term increases in tap-water lead levels. However, since such lines would be disturbed even if they were not replaced, there is no benefit gained by not replacing them; and there are likely to be significant cost savings involved because a work crew will already be on site for other reasons. Thus, these PLSLRs represent an opportunity for significant long-term risk reduction if properly managed. Options for risk reduction include public education, encouraging full replacements, recommending tap-water filtration while lead levels remain elevated, and recommending or requiring certain management practices such as line flushing. It appears that most post progressive utilities with LSLs already employ some or all of these practices.

EPA implemented the current LSL replacement program based on the premise that "lead is primarily of concern because of … chronic health effects, rather than acute toxicity" and the long-term benefits of PLSLR outweigh the adverse effects of short-term increases in tap-water lead levels (USEPA, 1991a). It can be argued that this premise was reasonable at the time based on what was then known about lead and PLSLR; and it may still be reasonable when PLSLR results in only a modest increase in lead levels in tap water consumed by adults. However, the validity of this premise is now in question for the following reasons: 1) tap-water lead levels observed following PLSLR are often high enough to be of concern from a human health standpoint, and they may remain elevated for longer periods of time than previously thought and stabilize at levels higher than anticipated; 2) young children are more vulnerable to lead than was previously recognized; 3) the lead levels to which consumers are actually exposed may be substantially higher than those determined using current sampling protocols, which tend to undersample particulate lead; 4) sporadic release of particulate lead into tap water from the wetted surfaces of interior plumbing materials can result in extremely high spikes in tap-water lead levels; and 5) consumers, including children, may be ingesting larger amounts of lead than previously recognized – not only by drinking tap water but also by ingesting food cooked in tap water and drinking beverages (or infant formula) prepared from tap water. Therefore, the relative importance of long-term versus short-term exposure to lead in tap water should be thoroughly re-evaluated based on current information. If the health risks associated with short-term exposure to lead following PLSLR are high enough, it may be possible to achieve significant risk reduction by modifying the LSL replacement requirements of the LCR.

Tap-water samples for lead analysis may be collected in a number of ways, each reasonably well suited for a specific purpose but having significant limitations when used for purposes other than its originally intended purpose. Sampling protocols used in recent studies include:

1) **First draw sampling** – required by 40 CFR 141.86(b)2 for monitoring lead and copper under the LCR, except for lead service line samples. A 1-liter sample of water that has been stagnant in the plumbing system for at least 6 hours is drawn from a cold-water tap in a kitchen or bathroom. First-draw samples are well suited for determining the concentrations of lead released from plumbing materials in and near the sink, which is useful in assessing water corrosivity and the effectiveness of a

utility's optimized corrosion control program. First-draw samples are not filtered, so they may contain particulate lead; but most of the particulate lead initially present will settle out while the water is standing and will therefore be significantly undersampled. First-draw samples do not provide a meaningful measure of tap-water lead levels in homes having full or partial LSLs because particulate lead, which may be the dominant form of lead in such cases, may be grossly undersampled and because the lead levels in the LSL may greatly exceed those present in standing water in the immediate vicinity of the tap.

2) **LSL sampling** – required by 40 CFR 141.86(b)3 for determining lead concentrations in water left standing in an LSL for at least 6 hours. The results are used to determine if a line is exempt from replacement (if all samples contain <0.015 mg/L of lead) and for the homeowner's information following PLSLR. Three options for collecting the sample are specified: i) wasting a volume calculated based on the interior diameter and length of the pipe between the tap and service line before collected a sample; ii) tapping directly into the service line; or iii) allowing the water to run until there is a significant change in temperature. For homes with LSLs, this protocol is superior to first-draw sampling in that an effort is made to obtain a sample from the LSL itself. However, all three sampling options are problematic and may lead to a gross underestimation of exposure. The volume wasted in the first sampling option may be miscalculated as a result of mathematical or measuring errors, or to failure to consider the volume of the pipe occupied by scale and corrosion products. A sample drawn directly from the LSL will be a standing water sample and particulate lead is likely to be grossly undersampled. If the third option is employed, a significant change in temperature could very well indicate the presence of relatively lead-free water from the main rather than water from the LSL.

3) **Profile sampling** – used to examine the lead concentration profile in household plumbing. A series of samples is collected, typically after the water has been left standing for at least 6 hours, with the last samples representing water coming directly from the main. This technique can be used to determine if elevated lead levels are associated with an LSL and perhaps, in some cases, with the connection between an LSL and a service line composed of copper or galvanized iron. The samples are usually drawn rather slowly, to minimize mixing and so the volume of each sample can be carefully measured. Using a low flow rate will also minimize erosion and resuspension of particulate lead, so this method is likely to result in gross underestimation of particulate lead. Another major disadvantage of this protocol is that a large number of samples must be collected and analyzed, resulting in higher cost.

4) **Random daytime sampling** – used to collect representative samples of tap water during the course of a normal day. Random samples can potentially provide a better estimate of human exposure than other types of samples. However, the concentrations of total, dissolved, and particulate lead are expected to be much more variable in such samples than in other types of samples; thus, a large number of

samples is typically needed to obtain meaningful results. Furthermore, random samples can produce biased results if the sampling schedule is not truly random or if the samples differ in some ways from those actually consumed. For example, if samples are not collected early in the morning for fear of waking up the residents, a representative number of first-draw samples may not be included and the results for dissolved lead may therefore be biased on the low side.

5) **Others protocols** – used by researchers for specific purposes. Examples include high velocity and particle stimulation sampling protocols designed to stimulate release of particulate lead. In this case, the lead levels in the samples are expected to exceed those to which consumers are normally exposed but may generate samples that represent worst-case conditions reasonably well.

The sampling protocols currently specified in the LCR have significant limitations, as do other existing protocols. The Panel recognizes that these protocols and the numerical limits associated with them were adopted primarily for pragmatic reasons. However, the Panel also recognizes that the results obtained using these methods are widely perceived as being useful for estimating the tap-water lead levels to which humans are exposed when in fact they may lead to significant underestimation of exposure. The limitations of current sampling protocols should be carefully considered in future revisions to the LCR, in evaluating the results of studies of lead in tap water, and in assessing the impacts of tap-water lead levels on human health.

3.3. Issue 3 – Studies Comparing PLSLR with Full Lead Service Line Replacements

There are a number of studies that compared partial lead service line replacements with full lead service line replacements (HDR Engineering, 2009; Sandvig et al., 2008; Swertfeger et al., 2006). What conclusions can be drawn from these studies regarding the relative effectiveness of partial lead service line replacement versus full lead service line replacement in reducing drinking water lead levels in both the short-term and long-term?

The Panel reviewed the following studies (HDR Engineering, 2009; Sandvig et al., 2008; Swertfeger et al., 2006) with specific focus on comparison between partial and full lead service line replacements (LSR). The Panel also read several other studies indicated below and also considered the public comments offered at the meeting of this committee.

In the study performed by HDR Engineering (2009), comparison of partial versus full LSR was based on particulate lead concentrations in households with galvanized premise plumbing. Full LSR did not substantially reduce the concentration of particulate lead in premise plumbing over partial LSR. The lead service lines were believed to have ‘seeded’ the galvanized premise plumbing with lead, and the lead released from the ‘seeded’ premise plumbing was believed to be as great or greater than the lead released from the service line.

In the study performed by Sandvig et al. (2008), corrosion control was identified as the most effective method of achieving LCR compliance. LSLR was recommended on a site-by-site basis. Lead service lines were found to contribute 50 to 75% of the lead mass at the household tap, with premise plumbing contributing an additional 20 to 35% of lead mass (likely from 'seeding' from lead service lines), and faucets 1 to 3%. Partial LSLR did not result in improvements in lead levels in the first liter collected during sampling, and resulted in only minimal improvement in total mass measured at the household tap over the entire duration of sampling. Full LSR reduced the total mass of lead measured at the tap during sequential sampling as well as the first liter lead level measured at the tap. The effectiveness of full LSR relative to partial LSR in reducing tap levels of lead is highly site specific. Both partial and full LSR generally result in elevated lead concentrations for site-specific durations after replacement.

In the study performed by Swertfeger et al (2006), a total of 21 houses participated in the study: (a) 5 houses performed a full LSR; (b) 5 houses performed a partial LSR; (c) 6 houses performed a partial replacement with Teflon® shrink wrap tubing around the cut section at the property line; and (d) 5 sites acted as control sites with no work performed on the lead service line. Lead levels measured at household taps were further compounded by corrosion control measures that were implemented in the distribution system at roughly the same time as partial and full LSR. Hence, comparison of lead levels in household taps immediately after partial and full LSR may be influenced by corrosion control measures. However, comparisons of lead levels after 1.5 years of replacement are deemed as a credible basis for comparing the effectiveness of partial versus full LSR. After 1.5 years of replacement, all 5 households with a full LSR had lead levels less than 5 μg/L, whereas 3 of the 5 homes with a partial LSR had lead levels less than 5 μg/L. Two of the 5 households with a partial LSR had lead levels close to the LCR action level of 15 μg/L.

The Panel also considered the following additional studies (Britton et al., 1981; Gittelman et al., 1992; Muylwyk et al., 2009; USEPA 1991a; USEPA 1991b; Weston et al., 1990) in generating its conclusions. The Panel notes that the study by Wujek (2004) was not considered due to the serious flaw of the disinfectant being changed from choramine to chlorine between the pre- and post-PLSLR sampling. In all the studies conducted to-date, the time period of evaluation of lead concentrations following partial and full service line replacements has been inadequate to fully evaluate effectiveness.

Based on review of the above mentioned studies, we have reached the following conclusions (lead levels are in reference to total lead, inclusive of both dissolved and particulate lead):

- In water distribution systems optimized for corrosion control, full lead service line replacements have been shown to be an effective method of reducing lead drinking water levels.

- In water distribution systems optimized for corrosion control, partial lead service line replacements have not been shown to be effective in reducing lead drinking water levels, at least in the time frames of the reported studies.

- In water distribution systems not optimized for corrosion control, the existing scientific data are inadequate to evaluate the effectiveness of partial lead service line replacements in reducing lead drinking water levels.

- In water distribution systems optimized for corrosion control, full lead service line replacements generally result in elevated lead levels for a variable period of time after replacement.

- In water distribution systems optimized for corrosion control, partial lead service line replacements generally result in elevated lead levels for a variable period of time after replacement. The duration and magnitude is generally greater with a partial lead service line replacement than a full service line replacement. Insufficient scientific data are available to identify the specific causes of the spikes in lead levels.

- For some undefined duration after replacement, both partial and full service line replacements may result in levels above the LCR action level. The duration is generally greater for partial service line replacements than full service line replacements. Insufficient scientific data are available to identify the specific causes of the spikes in lead levels.
- Following full service line replacement, household lead levels largely reflect lead from premise plumbing. In households with non-leaded household plumbing, lead levels in drinking water largely arise from lead precipitated in premise plumbing from lead service lines. The problem is most acute in households with galvanized plumbing.

- Management of elevations in lead levels following partial or full service line replacements should focus on not only comprehensive flushing of drinking water lines and monitoring, but aggressive occupant education. In the judgment of the Panel, both the flushing protocols and the extent of occupant education have been woefully inadequate and have therefore not been nearly as protective of the public health as is possible.

- The average percent contribution of mass of lead measured at the household tap during profile sampling is greatest from the lead service lines, followed by premise piping and then faucets. The contribution from water meters is negligible. For this reason, the loading order for reducing lead drinking water levels should focus on: (1) full service line replacement; (2) removal of lead precipitate in household-premise plumbing; (3) replacement of household-premise faucets. Removal of lead precipitate in premise plumbing may involve, but is not limited to, aggressive flushing strategies.

This issue, which relates to decreasing the population exposure to lead in water, needs to be discussed and incorporated into the larger document arising from the committee as a whole.

- The LCR action level should be reconsidered upon review of the effectiveness of partial and full service line replacement. Corrosion control is a highly effective method for maintaining lead drinking water levels below the LCR action level. Levels achievable under corrosion control may suggest a lower LCR action level. Corrosion control coupled with full service line replacement may represent a viable management strategy for achieving lead drinking water concentrations consistently less than the current LCR action level on a national basis. Modifications of the LCR action level may be achieved by either reducing the concentration level or decreasing the allowable percent of samples that exceed the concentration level.

- Changes in water chemistry can greatly impact lead concentrations in drinking water, even in systems well optimized for corrosion control. Increased monitoring of lead concentrations is recommend following any changes in water quality or control measures, inclusive, but not limited to, changes in disinfectant.

3.4. Issue 4 – Studies Examining PLSLR Techniques

Some studies have looked at other factors that can influence lead levels following a partial lead service line replacement, such as the pipe cutting, flushing to clear the lines and pipe joining techniques (Boyd et al., 2004; Kirmeyer et al., 2000; Sandvig et al., 2008; Wujek et al., 2004). What conclusions can be drawn from these studies regarding techniques that should be followed for partial lead service line replacements to reduce lead drinking water exposures? Please comment on whether a standard operating procedure can be developed to minimize spikes in drinking water lead levels after partial lead service line replacement.

Lead service line (LSL) replacement is one of two "treatment techniques" identified by EPA that can be used to achieve compliance with the Lead and Copper Rule (LCR) and is typically the last treatment technique available to a water utility to gain compliance with the LCR. By listing several techniques associated with LSL replacement in the issue statement, as "other factors," it would appear the intent of the issue is to focus solely on the physical techniques used to remove the service line. However, most water utilities follow a systematic procedure that involves several other steps when fully or partially removing an LSL. Some of these steps are required by regulation and some are outlined in EPA guidance, but not all involve physical contact with the service line, yet all are critical to the success of a LSL replacement program and necessary for reducing lead exposure.

The studies supplied with the issue statement provide limited insight on the impact that partial lead service line replacement (PLSLR) techniques can have on lead release.

- **Replacement techniques**: Kirmeyer et al. (2000) described the replacement techniques, but did not examine the impact on water quality after these techniques were used. However, the SAB believes these techniques are either minimally invasive or involve limited physical contact with the service line and have minimal impact on post-PLSLR lead release.

- **Cutting techniques**: The Wujek (2004) and Sandvig et al. (2008) studies examined the cutting techniques used to sever the service lines. These studies are limited by sample size and do not clearly demonstrate a significant difference between the cutting methods.

- **Joining techniques**: Swertfeger et al. (2006) examined the use of heat shrink Teflon® sleeves in their field study of full and partial LSL replacements. Results for this new technique were inconclusive.

- **Flushing effectiveness**: The Boyd et al. (2004) and Sandvig et al. (2008) studies examined lead release in pipe loop studies which provide insight into the complex issue of controlling lead release following a PLSLR. From these studies and others, there appears to be an information gap that EPA should address if recommendations on PLSLR are utilized. It is not clear that the role of water chemistry in lead release is sufficiently understood. For example, while the LCR requires optimized corrosion control, it is not clear that such control provides optimal passivation of newly exposed pipe surfaces. Flushing of the pipe loop appears to provide some benefit, but the time to realize the benefit requires weeks and exceeds any practical recommendation for customer implementation. Additional data analysis of this study might provide additional insights into the impacts of pressure transients and flushing.

- **Public education**: Part of the PLSLR technique involves public notification and education. This is a critical component of a PLSLR program. While the agency has published guidance (last revised in 2002), there are no studies evaluating the effectiveness of these programs or materials, yet these materials would seem to be critical to reducing and minimizing lead exposure in PLSLR programs. The guidance does not address the issues related to PLSLR. Reviewing and updating of the public education guidance would be appropriate.

These studies point out that interaction of water quality parameters can play a critical role in lead release. Until this role can be better defined there will be inherent risks in any proposed solution to mitigate lead release following a partial LSL replacement. Lack of similar water quality between the different studies and changes in water quality during some of the studies (specifically switches in disinfection between chloramine and free chlorine) limit their interpretation and broad applicability.

Generally, the techniques for PLSLR provide a good framework under which an SOP (standard operating procedure) could be developed. However, given the lack of definitive studies on the effectiveness of different procedures and approaches to PLSLR combined with a lack of information on the role water quality plays in optimal corrosion control and passivation of newly exposed pipe surfaces is a critical information gap, development of an SOP may be premature, however desirable it might be.

Upon review, the SAB believes the issue statement and scope omitted the critical subject area of water quality and its impact on lead release following PLSLR. The public comments, along with the reports and articles by Boyd et al. (2006, 2010a, 2010b) and Switzer et al. (2006), need to be compiled and reviewed to ensure the role water quality plays in lead release is understood. While the breadth and depth of these articles is extensive and controversial, the subject area is unquestionably germane to the scope of the PLSLR issue and can play an important role in what defines an SOP.

Details on the procedures and study results are discussed below. Replacement techniques for LSR and PLSLR are presented. The impact of pressure changes, such as water shut off, are included. Cutting, joining and flushing techniques are reviewed. Public education requirements and guidance are discussed.

Locating and Identifying LSLs

LSLs cannot be replaced until they are located and identified. Work by Deb et al. (1995) provided a summary that describes the techniques available for locating and identifying LSLs. A step-by-step list is provided in Table 2. Although some techniques used for locating service lines are minimally invasive, the direct methods used to identify the service line material require physical access and direct contact with the service line, but there is no evidence to suggest that these methods contribute to lead release following PLSLR. Some direct methods cannot be used in specific instances due to the physical layout of the connection between the service main and the household.

Table 2. The Primary Steps in Lead Service Line Replacement under the Lead Copper Rule.

1. Locate LSL
2. Identify LSL
3. Notify customer (or property owner); offer full LSL replacement at cost.
4. Educate customer on lead hazard
5. Schedule LSL replacement work
6. Confirm partial or full LSL with customer (or property owner)
7. Replace partial or full LSL
8. Attempt to contact customer on day of work; knock on door; leave a door hanger.
9. Shutoff water.
10. Expose work area
11. Cut LSL
12. remove LSL
13. Attach service line to main
14. Attach service to remaining service line or household plumbing
15. Check repaired connections
16. Turn service back on
17. Flush line at household entry point
18. Backfill construction

Locating and identifying LSLs by indirect methods requires a fairly extensive database of home age, plumbing materials, and renovation history. In general, the indirect methods are less accurate than direct methods leading to the misidentification and subsequent misclassification of LSLs,[1] but do not involve physical contact with the service line. Hence, these techniques should not contribute to lead release following partial LSL replacement.

[1] According to Deb et al. (1995) indirect methods of LSL identification were not 100% accurate. In their two case studies, the accuracy of identifying LSLs was 73.7% and 92.2%.

Replacement Techniques

The Kirmeyer et al. (2000) report identified the means by which lead service lines could be accessed for replacement or rehabilitated, but did not examine the impact of these replacement techniques on lead release during full or partial LSL replacement. The techniques used to access LSLs for replacement include: open trench, replacement on an existing route, and replacement on a new route. Unlike the open trench, which exposes the entire service line, replacing an LSL on a new or existing route involves minimal trenching. The LSL is replaced by following the existing service line, forcing it to expand and burst, then pulling (or pushing) a new line in through the existing hole and reconnecting the service at both ends. An alternative to bursting the LSL involves pulling a new service line into a hole bored along the same route following parallel to the existing line.

There is no evidence that any one replacement technique provides any greater benefit when used in either a full or partial lead service line replacement. The selection of the replacement technique is dependent on a number of variables, such as access restrictions, cost, and others. Generally, it is believed that unless the trenching technique involves direct physical contact with the service line, it is reasonable to assume that the act of replacing the service line will have minimal impact on lead release following partial or full lead service line replacement.

Unlike the replacement techniques previously mentioned, LSL rehabilitation is a process whereby the LSL is left in place, but the interior surface is covered or coated to prevent contact between the lead surface and the water. There are two processes that fall into this category described by Kirmeyer et al. (2000), slip lining and pipe coating. While both techniques were found to be fairly comparable in cost to the replacement techniques involving physical removal of the LSL, there were practical concerns that could adversely impact their use in the field. For example, trying to slip line or coat an LSL that was convoluted by the terrain could prove to be impossible, which would mean that physical removal (open trench) might be the only alternative. The existing scale in the pipe or plumbing connections would also make these techniques more difficult to apply. In addition, the inside diameter of the LSL would also be reduced, which could impact water pressure and flow inside the house.

Given the range of probable situations one could encounter when replacing a lead service line, it would be hard to justify excluding any practice that could minimize the period of service disruption for the consumer, without hard evidence to the contrary.

Water Pressure Changes

Since water is under pressure, it must be shutoff at the main or the main must be depressurized (disrupting flow to other parts of the distribution system) before work on the service line can begin. Water shutoff is a quick and efficient way to prepare the worksite and to return the site to service with minimal water quality impact and minimal service disruption. Absent any technique for removing a service line without stopping the flow of water from the main, the action of turning off the water cannot be avoided.

Water shutoff to the home, for a PLSLR, it is a one-time event, larger in magnitude than, but not as frequent as, the local mechanical actions of turning a faucet on or off. In Boyd et al. (2006), two pipe loops, from recovered LSLs, were operated with intermittent flow to simulate the opening and closing of a faucet. Two of the pipe loops, both operated with opening and closing of the valve with slow and rapid movement, showed continual releases of lead for over two weeks after startup. This study provides some insight on how normal pressure transients under low flow conditions could impact lead release after partial LSL replacement, but without specific data, it is not possible to determine if the lead concentration was a function of the length of the quiescent period. If such a correlation exists, it could be related to the rate at which passivation is taking place. Having the authors further analyze their data would be a potential means of gathering more information that could be employed in any future risk management decision. Flow rates characteristic of both high and low flow faucets were not used in this study; flows were lower than typically provided by home faucets.

<u>Cutting techniques</u>

Once the LSL has been located and exposed for removal and the water shutoff, the line must be disconnected from the main and the premise plumbing. Generally with a PLSLR, the service line is severed close to the curb stop or water meter. When a full LSL replacement is done the LSL will be severed near the shutoff at the house.

There are two studies (Sandvig et al., 2008 and Wujek, 2004) that have examined whether or not the method used to cut into the existing service line had an impact on lead release following a partial LSL replacement. The available techniques that were examined were using a hacksaw, pipe cutter, and pipe lathe. Both studies contained a very limited sample size for each pipe cutting method.

The Wujek (2004) study examined LSL replacements using a hacksaw (n = 4), pipe cutter (n = 1), and pipe lathe (n = 2) in a single distribution system. The study profiled the lead concentrations in the service line and premise plumbing following partial LSL replacement. All sample sets from these different cutting methods show a characteristic "bump" or increase in lead concentration in the 6^{th} through 11^{th} liter samples, indicating lead release from the service line.

The figures in the Wujek (2004) study show an attenuation in the peak lead concentrations following PLSLR when compared to the pre-PLSLR profiles. Since the partial LSL replacement samples were collected when a different disinfectant was in use and probably represent very different plumbing situations, an attempt was made to normalize the data by examining the ratio of the pre and post lead concentrations for each cutting technique. The ratio of pre-to post-peak lead concentrations are: hacksaw (52/14 = 3.7); pipe lathe (83/23 = 3.6) and pipe cutter (34/12 = 2.8). The pipe cutter has a lower ratio indicating a higher release of lead following partial LSL replacement, however, the similarities between the blade and manner in which the pipe lathe and pipe cutter operate lead to the conclusion that the two techniques would not be significantly different in a larger study. The small difference between the hacksaw and the pipe lathe ratios indicates that the difference between the two techniques is not significant. There probably is not a significant difference between the three cutting techniques in this study.

In a second study that examined pipe cutting techniques, Sandvig et al. (2008) examined the impact of a hacksaw versus pipe cutter (n = 5 for both techniques)[2] and concluded that the hacksaw resulted in a slightly higher mass of lead release following replacement. Their conclusion was not based on the first liter draw samples, but on the total mass of lead released from profile sampling.

If the questionable three cases are removed from Table 3.18 of Sandvig et al. (2008) (see footnote 2), the hacksaw still appears to release more lead following partial LSL replacement than the pipe cutter. Due to the small sample size and high degree of variability in the total mass of lead released, the difference between the two groups is likely not to be significant.

Cutting into an LSL is a very infrequent discrete physical event, compared to other events such as pressure transients. So while limited data suggests that the cutting techniques may have some impact on lead release following LSL replacement, the full range of these techniques should remain available to water utilities replacing LSLs.

Joining Techniques

Connecting two pieces of dissimilar material always creates heterogeneity. The issue of joining dissimilar pipe materials with a union that is made from the same material as one of the pipes, will be discussed in the section on galvanic cells and dielectric couplings (Issue 5). The use of Teflon® sleeves as described in Swertfeger et al. (2006) is discussed briefly below because it is not a union, but when used in combination with a union, functions more like a dielectric.

Swertfeger et al. (2006) examined the use of heat shrink Teflon® sleeves in their field study of full and partial LSL replacements. Six of the 21 study sites used Teflon® sleeves in partial service line replacement. These six sites represent the first field test of this technique which showed slightly lower lead release than PLSLR based on first draw samples. The results from their modified profile sampling to assess total lead release was not provided in the paper and could be a source of additional information.

The heat shrink Teflon® sleeve does not serve the same purpose as a coupling, i.e., joining two pieces of similar or dissimilar pipe materials together. The heat shrink tubing is only placed over one of the two pipes to be joined. A small amount of the tubing is allowed to extend out or hang over the cut edge. As heat is applied, the tubing shrinks in all dimensions to conform to the pipe, the overhanging material is not constrained by the pipe shrinks to cover the cut end and a portion of the internal pipe wall. This prevents the cut end of the pipe from coming into direct contact with the material it is being joined to.

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[2] There appears to be some question as to whether all the LSL replacements in Table 3.18 of Sandvig et al. (2009) were full or partial. Table 3.18 lists B5 (pipe cutter) and T9 (disc cutter) as being full LSL replacements, but Appendix F lists these as partial LSL replacements. There is a similar problem with case T7 (hacksaw), the case is listed as a full LSL replacement in Appendix F, but table 3.18 lists it as partial.

Benefits from this connecting technique for partial LSL replacement were inconclusive based on the variability in study results. As this was a new technique, the results could vary as a function of crew skills, since the sleeve must be applied in the field under less than "ideal" conditions. The authors recommend further testing and examination of the practicality of field application before accepting the technique as a best management practice. Given that this is a new technique the SAB believes their recommendation is warranted, however, the lack of conclusive evidence of benefit leads us to recommend against this technique without further study.

Flushing

In a service line replacement, the objective of flushing is to remove any materials that may have been introduced into the new service line while the service line was open and exposed to the surrounding environment (e.g., dirt, bacteria, etc.). The scouring action from the flushing can expose new pipe surface, if the materials bound to the surface are not securely attached. As the velocity of water traveling through the service line during this flushing activity is higher than would be encountered at any given fixture inside the home, the degree of scour and the ability to suspend and mobilize materials will be greater than under normal use periods. The high velocities when flushing service lines increases the possibility that new surfaces may be exposed to water for the first time and may need to be restabilized or passivated.

Boyd et al. (2006) examined the impact of flow on lead release in pipe loops composed of lead pipe removed from a utility system. The study examined both "low" and "high" flow conditions with both continuous and intermittent flow. The flow rates were lower than expected for normal water use. The study suggests that allowing water to continually flow through the service line will help to stabilize the service line and will eventually reduce lead release. The authors state that "the total lead concentrations eventually can be reduced below the AL and stabilized provided sufficient water is flushed through the pipe". The amount of water is dependent on the hydraulic flow patterns. For continuously flowing pipes, up to 850 gallons was required. For the intermittent flowing pipes, lead did not stabilize over the 2-week test period. This study was limited to one utility and therefore one set of water quality. Passivation of pipe surfaces is known to be a relatively slow process, the extended times observed in the studies needed to achieve concentrations below the lead action level could be an indication that passivation under optimal corrosion control conditions proceeds slowly.

Public education

In 2002, the EPA published the revised document "Lead in Drinking Water Regulation: Public Education Guidance." This document extensively addresses requirements and recommendations for utilities to implement to inform the public about the risks and potential mitigation measures regarding lead in drinking water if that utility's water samples exceed the lead action level. Additional public education requirements are addressed in other EPA publications (Lead and Copper Rule, 1991, Consumer Confidence Report Rule, 1998, SDWA Amendments, 1996 and Drinking Water Public Notification Rule, 2000). The CCR includes mandatory language for all utilities whether they exceed or comply with the lead and copper rule.

The public education guidance establishes requirements for content and delivery of public education materials, mandatory language, water testing services, procedures for establishing a task force and program implementation approaches. The guidance addresses lead service line replacement, but not specifically partial lead service line replacement. The document includes a recommendation for customers to flush the drinking water tap for 15-30 seconds before water use; or if a lead service line is present, flush for 1 minute. The recommendations on flushing may not adequately address the flushing needed for partial lead service line replacement based on the literature reviewed by the SAB (Boyd et. al, 2004). It is recommended that USEPA review the guidance in light of current information on partial lead service line impacts on water quality (and plumbing codes and green codes) to address the specific concerns over mitigation of lead spikes following replacement.

The guidance also includes other mitigation options to reduce lead, including:

- Have an electrician check your (customer) wiring to see if it is grounded to the water system. The guidance recommends checking to see if the customers' wiring can be grounded elsewhere.

- Purchase or lease a home treatment device. The guidance states that "these units are limited in that each unit treats only the water that flows from the faucet to which it's connected and that all devices require periodic maintenance and replacement." Reverse osmosis, distillation, and some activated carbon filters are listed as potential units for lead mitigation. The guidance further states that all units should be investigated for performance. Given the NSF International point-of-use device certification program, this recommendation should be modified to recommend purchase of an NSF certified device specifically certified for lead removal. Using a properly tested and certified point-of-use (POU) device that has been demonstrated to remove lead in the quantities potentially present is critical to the effectiveness of this mitigation approach. Even if the proper POU device is used, the consumer is responsible to see the device is properly installed, operated and maintained; failure to do so would likely lead to higher lead exposure. Utilities cannot assume liability for the implementation and operation of POU devices and therefore this potential mitigation approach should remain only as an option for customers to implement.

3.5. Issue 5 – Studies Examining Galvanic Corrosion

Galvanic corrosion is a possibility if copper pipe is joined directly with the remaining portion of the lead service line. Several studies examined the issue of galvanic corrosion (Boyd et al., 2010b; DeSantis et al., 2009; Deshommes et al., 2010; Rieber et al., 2006; Triantafyllidou et al., 2010). What conclusions can be drawn from these studies regarding the potential for elevated lead levels at the tap from galvanic corrosion? Please comment on the inclusion of a dielectric between the lead and copper pipes as a way to minimize spikes in drinking water lead levels after partial lead service line replacements. Please

comment on the inclusion of the dielectric as part of the standard operating procedures for partial lead service line replacements.

Charge Issue 5 focuses on galvanic corrosion, a process in which an electrical connection between different metals can accelerate the corrosion of the less noble metal. In responding to this issue, the Panel considers both the intentional, direct connection that can occur between a copper and a lead pipe during partial lead service line replacement, and also depositional corrosion, in which copper ions in solution can be deposited as metallic copper when they contact a less noble metal such as lead. When the copper is deposited in this way, a new copper/lead interface is created, and the conditions necessary for galvanic corrosion to proceed are established. Although the theory of depositional corrosion is well developed, insufficient data exist to fully assess its significance in systems with partial lead service lines. To the extent that depositional corrosion occurs, it can affect lead in two ways: lead is oxidized when the copper is first deposited, and the copper/lead electrical connection can subsequently serve as a site of galvanic corrosion.

Several studies have been conducted to identify and quantify the significance of galvanic corrosion when partial lead service line replacements are implemented. Parameters related to lead corrosion that have been measured in these studies include the profiles of electrical potential (Reiber and Dufresne, 2006; Boyd et al., 2010b) and current as a function of distance from the site of electrical contact, the magnitude of the galvanic current (Triantafyllidou and Edwards, 2010), and lead release into the water (Boyd et al., 2010b; Triantafyllidou and Edwards, 2010); in addition, precipitates that accumulate near the site of metal/metal contact have been characterized (DeSantis et al., 2009). The conclusions that have been drawn from the studies vary widely, in part because of the disparate procedures and metrics that have been used to assess the corrosion process, and in part because the process itself is complex and might proceed at vastly different rates in different systems. Despite some divergence of opinion as to the severity of the problem posed by galvanic corrosion, there seems to be widespread agreement that the electrical potentials and currents change when lead and copper are brought into electrical contact, and that the region over which these changes are substantial is confined to a few inches on either side of the contact point.

In several studies (e.g., Reiber and Dufresne, 2006), the parameters that were measured to assess the rate of galvanic corrosion changed substantially when the pipes were first joined, but the magnitude of these changes diminished significantly during a period of days to a few weeks thereafter. These observations, in combination with the limited spatial extent of the perturbation in electrical potential, have been used to support the contention that galvanic corrosion is unlikely to present a long-term problem, especially in systems where the water quality has been controlled to limit the lead corrosion rate. However, other studies have suggested that corrosion can continue at a significant rate for at least several months (Britton and Richards, 1981).

Part of the apparent discrepancy in the conclusions drawn in different studies is probably related to the different metrics employed. The studies that relied on lead release did not account for lead that was oxidized but not mobilized (i.e., that was converted to solids that remained at or near the site of corrosion). Also, the fact that galvanic corrosion occurs primarily over a small area in these systems does not imply that it is inconsequential, especially in light of the exceedingly small length and depth of pipe that must corrode to pose a potential risk to a consumer, if that lead exits the tap in a small volume of water. There is little doubt that lead can sometimes be released long after it corrodes, in response to physical or chemical changes in the system (e.g., stagnation, water hammer, and/or high water velocities - Deshommes et al., 2010; Boyd et al., 2004).

The studies that relied on measurements of galvanic current provide a direct indication of the rate at which metallic lead is converted to ionic lead, but not of the rate or likelihood that the corroded lead will be carried to the tap. If the water chemistry is well controlled (e.g., if a free chlorine residual is always present), this corroded lead might remain attached to the pipe almost indefinitely. The presence of large amounts of lead-containing solids near lead/copper joints decades after the galvanic connection was made (DeSantis et al., 2009) provides evidence that substantial corrosion can occur at such sites and that some portion of the corrosion products might remain in place for long periods, but it sheds no light on the question of how often, or in what doses, the lead is mobilized. In addition, even in systems where the normal conditions favor retention of corroded lead near the site of corrosion, changes in water quality due to stagnation, changes in treatment processes, blending of source waters, or other phenomena could mobilize the corrosion products.

Another source of the discrepancy is the complex interactions of the parameters that govern corrosion. For example, corrosion metrics have been reported to depend (in part) on the degree of passivation of the lead pipe (Reiber and Dufresne, 2006; Boyd et al., 2010b); the ratio of the cathode to the anode areas (i.e., the length ratio of the copper: lead pipe) (Reiber and Dufresne, 2006; Triantafyllidou and Edwards, 2010); the configuration of the galvanic contact (e.g., direct connection vs wired/jumpered connection) (Boyd et al., 2010b); and the chemistry of the water, including the concentration and identity of passivating agents or disinfectants present (Boyd et al., 2010b), the pH of the water (Boyd et al., 2010b), and the chloride:sulfate ratio (Edwards and Triantafyllidou, 2007; Triantafyllidou and Edwards, 2010). It has also been argued that the presence of microenvironments (Nguyen et al., 2010) that might result from localized corrosion, from biological activity, or from occasional periods of stagnation could affect corrosion. Such microenvironments might not be detected by measurements of the system properties at just a few locations that are more representative of the average system conditions. Studies in which water is continuously circulated could, therefore, potentially yield different results from those in which the water is allowed to stagnate (Triantafyllidou and Edwards, 2010).

The direct question that the panel was asked to address in Charge Issue #5 was: *What conclusions can be drawn from these studies regarding the potential for elevated lead levels at the tap from galvanic corrosion*? In attempting to answer this question, the Panel notes that galvanic corrosion has the potential to contribute to elevated lead levels at the tap by (1) increasing the rate of corrosion and/or (2) increasing the likelihood that corroded lead will be mobilized. The available evidence strongly supports the contention that galvanic corrosion increases the corrosion rate near the point of metal/metal contact shortly after the contact is made. It also supports the contention that galvanic corrosion can be significant for periods of at least several months thereafter. The time frame and magnitude of this increase are uncertain and probably differ among different systems, depending on the water quality and other local conditions. The Panel is not aware of evidence suggesting that lead that is oxidized galvanically is more or less likely to be mobilized than lead that is oxidized by other mechanisms. The Panel therefore concludes that galvanic corrosion associated with partial lead service line replacement does pose a risk of increased lead levels at the tap, and that this risk might persist for periods of at least several months, but that the risk is unlikely to be uniform on either a temporal or spatial basis and is therefore very difficult to quantify.

The panel was also asked to *comment on the inclusion of a dielectric between the lead and copper pipes as a way to minimize spikes in drinking water lead levels after partial lead service line replacements* and *on the inclusion of the dielectric as part of the standard operating procedures for partial lead service line replacements*.

Insertion of a dielectric breaks the electrical connection and thereby eliminates galvanic corrosion associated with the direct connection between copper and lead pipes, but it has no effect on depositional corrosion or the galvanic corrosion that can ensue at such a site. Because the relative magnitudes of galvanic corrosion at the pipe juncture and depositional corrosion have not been quantified, it is not possible to state with confidence how much galvanic corrosion will be reduced by insertion of a dielectric. However, there is no question that some reduction will be achieved.

The elevations(“spikes”) in drinking water lead levels that are commonly observed immediately after partial lead service line replacement could be caused by both mobilization of lead that was oxidized prior to the replacement and the relatively high rate of galvanic corrosion when the pipes are first joined. The insertion of a dielectric will eliminate the contribution of galvanic corrosion to these spikes. Because the relative importance of the two contributions is uncertain, the quantitative effect of inserting the dielectric cannot be predicted; it is likely that spikes in lead concentration would still be seen at the tap even if a dielectric were inserted, but the magnitude of those spikes might diminish dramatically in some cases. The general situation is largely the same in the longer term, except that the reasons for any spikes are less clear and predictable (e.g., they might occur because of a transient change in water quality, rather than the known physical disruption associated with a partial service line replacement). Under the circumstances, the panel believes that insertion of a dielectric is likely to have beneficial effects on lead concentrations at the tap, albeit of uncertain magnitude. Given the relatively low direct cost of inserting such a device, doing so would be an appropriate standard operating procedure in situations where the decision to implement a partial lead service line replacement has been made. The panel is aware that insertion of a dielectric might lead to other costs or have other consequences. For example, it would reduce the effectiveness of the water pipe as an electrical grounding device and would interfere with the use of electrical currents to thaw frozen water lines. These secondary phenomena have not been considered as part of this assessment.

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APPENDIX A – EPA CHARGE TO THE COMMITTEE

EPA published the Lead and Copper Rule (LCR) on June 7, 1991 to control lead and copper in drinking water at the consumers' taps. The LCR established a treatment technique to minimize lead and copper in drinking water (unlike most other rules that establish a Maximum Contaminant Level). When lead levels in drinking water exceed the action level of 15 µg/L, the LCR requires corrosion control treatment as the primary means of controlling lead in the drinking water. Public education for lead is also triggered by the initial lead action level exceedance. Lead service line replacement is an additional action required under the LCR when a system that has installed corrosion control treatment fails to meet the action level for lead. Under the 2000 LCR revisions, water systems are required to replace only the portion of the lead service line that it owns. When a water system replaces only a portion of the lead service line (the portion it owns), this is referred to as a partial lead service line replacement (PLSLR). Further regulatory background is presented in Attachment A.

<u>Overall Charge</u>

EPA is seeking SAB evaluation of current scientific data to determine whether partial lead service line replacements are effective in reducing lead drinking water levels. EPA has identified several studies for the SAB to consider for the evaluation, listed in Attachment B. The SAB may also consider other relevant studies for the evaluation.

<u>Specific Issues</u>

Issue 1 – Studies Examining Associations Between Elevated Blood Lead Levels and PLSLR

A recently published study by the Centers for Disease Control (Brown et al., 2011) examined an association between children's blood lead level, lead service lines, and water disinfection in Washington, DC using data from 1998 to 2006. How does this study inform the available information on the effectiveness of partial lead service line replacement in reducing drinking water exposure to lead?

Issue 2 – Studies Evaluating PLSLR with Tap Sampling Before and After Replacements

There are a number of studies that evaluated partial lead service line replacement with tap sampling conducted both before and after the replacement (Britton et al., 1981; Gittelman et al., 1992; Muylwyk et al., 2009; Sandvig et al., 2008; Swertfeger et al., 2006; USEPA 1991a; USEPA 1991b; Weston et al., 1990). These studies use a variety of sampling protocols and the timing of sampling after replacement differed between studies. What conclusions can be drawn from these studies regarding the effectiveness of partial lead service line replacement in light of the different sampling protocols and different timing of sampling? Please comment on the changes in lead concentrations in drinking water after partial lead service line replacements and the duration of those changes.

Issue 3 – Studies Comparing PLSLR with Full Lead Service Line Replacements

There are a number of studies that compared partial lead service line replacements with full lead service line replacements (HDR Engineering, 2009; Sandvig et al., 2008; Swertfeger et al., 2006). What conclusions can be drawn from these studies regarding the relative effectiveness of partial lead service line replacement versus full lead service line replacement in reducing drinking water lead levels in both the short-term and long-term?

Issue 4 – Studies Examining PSLR Techniques

Some studies have looked at other factors that can influence lead levels following a partial lead service line replacement, such as pipe cutting, flushing to clear the lines, and pipe joining techniques (Boyd et al., 2004; Kirmeyer et al., 2000; Sandvig et al., 2008; Wujek, 2004). What conclusions can be drawn from these studies regarding techniques that should be followed for partial lead service line replacements to reduce lead drinking water exposures? Please comment on whether a standard operating procedure can be developed to minimize spikes in drinking water lead levels after partial lead service line replacement.

Issue 5 – Studies Examining Galvanic Corrosion

Galvanic corrosion is a possibility if copper pipe is joined directly with the remaining portion of the lead service line. Several studies examined the issue of galvanic corrosion (Boyd et al., 2010; DeSantis et al., 2009; Deshommes et al., 2010; Rieber et al., 2006; Triantafyllidou et al., 2010). What conclusions can be drawn from these studies regarding the potential for elevated lead levels at the tap from galvanic corrosion? Please comment on the inclusion of a dielectric between the lead and copper pipes as a way to minimize spikes in drinking water lead levels after partial lead service line replacements. Please comment on the inclusion of the dielectric as part of the standard operating procedures for partial lead service line replacements.

ATTACHMENT A – Regulatory Background on the EPA Lead and Copper Rule

The LCR is a complicated rule because exposure to lead from drinking water results primarily from the corrosion of household plumbing materials and water service lines. EPA published the LCR on June 7, 1991 to control lead and copper in drinking water at the consumers' taps. The LCR established a treatment technique to minimize lead and copper in drinking water (unlike most other rules that establish an MCL). The LCR requires corrosion control treatment as the primary means of preventing lead and copper from contaminating drinking water. For systems serving 50,000 or fewer people, installation of corrosion control treatment is triggered when more than 10 percent of the samples from households with plumbing materials more likely to produce elevate levels of lead exceed an action level (15 µg/L for lead or 1300 µg/L for copper). Systems must treat drinking water to make it less corrosive to the materials it comes into contact with on its way to consumer's taps. Public education for lead is also triggered by the initial lead action level exceedance. Lead service line replacement is an additional action required under the LCR when a system that has installed corrosion control treatment fails to meet the action level for lead. Lead service line replacement is the issue on which we are seeking SAB input.

Water systems exceeding the action level for lead after installing corrosion control must replace annually at least 7 percent of the initial number of lead service lines in its distribution system. The LCR requires that a water system replace that portion of the lead service line that it owns. When there is split ownership, the water system typically owns to the edge of the property line. In these cases where the system does not own the entire lead service line, the system must notify the owner of the line that the system will replace the portion of the service line that it owns and offer to replace the owner's portion of the line. A system is not required to bear the cost of replacing the privately-owned portion of the line, nor is it required to replace the privately-owned portion where the owner chooses not to pay the cost of replacing the privately-owned portion of the line. A system can stop replacing lines if it can meet the lead action level for two consecutive 6-month monitoring periods.

There are three ways a lead service line can be considered replaced under the LCR. First, sites where all service line samples test at or below the lead action level of 0.015 mg/L can be considered replaced. Second, sites where the entire line is replaced – either the water system owns the entire line or the homeowner agreed to pay for the replacement of their portion of the line when the system was replacing its portion. Third, when the homeowner does not agree to pay to replace their portion of the lead service line, then the system will replace the portion under its ownership. This third type of replacement is referred to as a partial lead service line replacement. (It should be noted that systems that meet the lead action level also sometimes replace their portion of lead service lines that they encounter while doing routine maintenance or emergency repairs to the distribution system. These "voluntary" replacements are not subject to the requirements of the LCR and occur fairly frequently.)

Under the current version of the LCR, a utility only controls that portion of the service line which it owns[3]. EPA promulgated the current lead service line replacement requirements in 2000 as part of the LCR Minor Revisions Rule. In developing these requirements EPA considered the available studies evaluated partial lead service line replacement with tap sampling conducted both before and after the replacement. Based upon the available data EPA promulgated the current requirements for lead service line replacement.

Under the LCR, when the system does not own the entire lead service line, the system must notify the owner of the line that it will replace the line that it owns and offer to replace the owner's portion of the line. The system is not required to pay for the replacement of the privately-owned portion of the line nor is it required to replace that portion where the owner chooses not to pay for its replacement. The LCR does contain additional requirements when the owner does not agree to replace their portion of the line, resulting in partial lead service line replacement. The system must also do the following: At least 45 days prior to the partial lead service line replacement, notice must be provided to the residents of all building served by the line explaining that they may experience a temporary increase in lead levels in their drinking water, along with guidance on measures consumers can take to minimize their exposure to lead. In addition, the water system shall inform the residents served by the line that the system will, at the system's expense, collect a sample from each partially-replaced service line for analysis of lead content within 72 hours after the completion of the partial replacement of the service line. The system shall collect the sample and report the results to the owner and residents served by the line within three business days of receipt of results.

[3] When EPA promulgated the LCR in 1991, the Agency required water systems to replace the portion of the lead service line which the System controlled. The Agency's definition of control of lead service lines went beyond utility ownership alone to include a rebuttable presumption that the utility controls the water service line up to the wall of the building unless the utility does not own the line and neither has the authority to replace, repair or maintain the service line, nor has the authority to set standards for construction, maintenance, or repair of the line. This definition would have facilitated removal of full lead service lines. The Agency was sued, and the Court remanded this definition of control back to the Agency because EPA had not provided adequate opportunity for public comment on that aspect of the proposed rule. The Court did not rule on the substantive legal issues regarding EPA's authority to require utilities to take actions on private property. EPA revised the regulations in response to the remand.

ATTACHMENT B – Studies Identified by EPA

Studies identified by EPA for Issue 1:

Brown, M.J., et al., 2011. Association between children's blood lead levels, lead service lines, and water disinfection, Washington, DC 1998-2006. *Environmental Research,* 111(1):67-74.

Studies identified by EPA for Issue 2:

Britton, A. and Richards, W.N., 1981. Factors Influencing Plumbosolvency in Scotland. *Journal of the Institute for Water Engineers and Scientists*. Vol. 35, No. 5, pp. 349 - 364.

Gittelman, T.S. et al., 1992. Evaluation of Lead Corrosion Control Measures for a Multi-source Water Utility. *Proceedings of the 1992 AWWA Water Quality Technology Conference*. Toronto, Ontario, Canada. pp. 777 - 797.

Muylwyk, Q. et al., 2009. Lead Occurrence and the Impact of LSL Replacement in a Well Buffered Groundwater. *Proceedings of the 2009 AWWA Water Quality Technology Conference*. Seattle, WA.

Sandvig, A et al., 2008. Contribution of Service Line and Plumbing Fixtures to Lead and Copper Compliance Issues. Prepared for the American Water Works Research Foundation, Report 91229.

Swertfeger, J. et al., 2006. Water Quality Effects of Partial Lead Service Line Replacement. *Proceedings of the 2006 AWWA Annual Conference*. San Antonio, TX.

USEPA., 1991a. "Maximum Contaminant Level Goals and National Primary Drinking Water Regulations for Lead and Copper; Final Rule." Federal Register. Vol. 56, No. 110, p. 26505. June 7, 1991.

USEPA., 1991b. "Summary: Peach Orchard Monitoring, Lead Service Line Replacement Study." Prepared by Barbara Wysock. Office of Drinking Water Technical Support Division. April 1991.

Weston and EES, 1990. Lead Service Line Replacement: A Benefit-to-Cost Analysis. American Water Works Association, Denver, CO. p. 4-46.

Studies identified by EPA for Issue 3:

HDR Engineering, 2009. An Analysis of the Correlation between Lead Released from Galvanized Iron Piping and the Contents of Lead in Drinking Water. Prepared for the District of Columbia Water and Sewer Authority. September 2009.

Sandvig, A et al., 2008. Contribution of Service Line and Plumbing Fixtures to Lead and Copper Compliance Issues. Prepared for the American Water Works Research Foundation, Report 91229.

Swertfeger, J. et al., 2006. Water Quality Effects of Partial Lead Service Line Replacement. *Proceedings of the 2006 AWWA Annual Conference*. San Antonio, TX.

Studies identified by EPA for Issue 4:

Boyd, G. et al, 2004. Pb in Tap Water Following Simulated Partial Lead Pipe Replacements. *Journal of Environmental Engineering*. Vol. 130. Number 10. pp. 1188 – 1197.

Kirmeyer, G. et al, 2000. Lead Pipe Rehabilitation and Replacement Techniques. Prepared for the American Water Works Research Foundation, Report 90789.

Sandvig, A et al., 2008. Contribution of Service Line and Plumbing Fixtures to Lead and Copper Compliance Issues. Prepared for the American Water Works Research Foundation, Report 91229.

Wujek, J.J. 2004. Minimizing Peak Lead Concentrations after Partial Lead Service Line Replacements. Proceedings AWWA Water Quality Technology Conference. San Antonio, TX.

Studies identified by EPA for Issue 5:

Boyd, G., Reiber, S., and Korshin, G., 2010. Galvanic Couples: Effects of Changing Water Quality on Lead and Copper Release and Open-Circuit Potential Profiles. *Proceedings of the 2010 AWWA Water Quality Technology Conference*. Savannah, GA.

DeSantis, M. et al., 2009. Mineralogical Evidence of Galvanic Corrosion in Domestic Drinking Water Pipes. *Proceedings of the 2009 AWWA Water Quality Technology Conference*. Seattle, WA.

Deshommes, E. et al., 2010. Source and Occurrence of Particulate Lead in Tap Water. *Water Research.* pp. 3734 – 3744.

Reiber, S., and Dufresne, L., 2006. Effects of External Currents and Dissimiliar Metal Contact on Corrosion of Lead from Lead Service Lines. Prepared for USEPA Region III.

Triantafyllidou, S. and Edwards, M., 2010. Contribution of Galvanic Corrosion to Lead in Water After Partial Lead Service Line Replacements. Prepared for the Water Research Foundation, Report 4088b.

APPENDIX B - Rationale For a Reanalysis of Brown et al. (2011)

Table 3 of Brown et al. (2011) contains the key epidemiological information for assessing the effects of partial service line replacement on the blood lead of children < six years of age. The information provided in the paper is insufficient for evaluating the effects described for the following reasons.

1. The presented data did not adjust for potential confounders, such as alternative sources of lead exposure (measured in other parts of the paper by estimating the age of the residence), sex of subject, a variable indicating the switch from the older bronze fittings in the house to the "lead-free" fittings, adjusted for age instead of limited to children under 6, etc.

2. The analysis did not assess the comparison of partial replacement vs. lead service line not replaced in periods other than between 7/1/2004 – 12/31/2006. Including earlier periods would not only assess partial line replacement effects under different water treatment regimes, the earliest periods, before the lead in water problem was divulged to the public, would be freer of confounding due to people modifying their water use habits after partial line replacement.

3. The authors are unclear about the "logistic regression" they used in the analysis. Unqualified "logistic regression" is usually understood as a dichotomous outcome logistic regression. The outcome measure used in Table 3 is a three category ordered blood lead variable. The most powerful logistic statistical technique used for ordered categorical outcomes is some form of ordinal logistic regression, the specific type used depending on the data set and model satisfying certain assumptions. In the event that none of the ordinal logistic regression techniques can be used, multinomial logistic regression, ignoring the ordered nature of the categories, can be used. Multinomial logistic regression is essentially a time-saving way of performing multiple binary logistic regression.

4. The authors do not mention diagnosing their models, leaving open the question of complying with model assumptions regardless of the logistical regression technique used.

5. The authors do not present a trend analysis of the odds ratios for the three ordered categories of blood lead.

6. Since the original dependent variable was a continuous presumably log-normally distributed variable that was then categorized, sound statistical procedures suggest using a probit, rather than a logit, model if category blood lead must be used. Information criteria can be used to assess which model, logistic or probit, best fits the data.

7. The selection of any limited dependent variable analysis technique for these data is questionable since the original blood lead values were available. Ordinary least squares regression on blood lead values (or transformations of the same) provides the most powerful means of assessing the effect of partial lead service line replacement.

8. Selection of the highest venous blood lead value and the lowest capillary blood lead value for each subject has sound antecedents, as explained in the article. Nonetheless, a frequent error in taking capillary samples is to squeeze the puncture wound to aid in blood expression, a procedure that can lead to sample dilution from extracellular fluid. Capillary samples that were included in the lowest blood lead category could come from children with higher blood lead, especially if they were below the detection limit. Possible dilution in capillary samples could be examined in children with more than one capillary sample within a certain time interval. At the very least, capillary samples should be identified in the data set used for reanalysis by a dummy variable indicating capillary or venous origin.

9. All multiple samples, capillary or venous, that bracket the period of partial line replacement would allow powerful repeated measures analyses in the same children to provide an alternative assessment of the effects of partial line replacement. The before and after assessment in the same children would allow more confident attribution of causality to blood lead changes associated with partial line replacement.

Dr. Rothenberg proposes to reanalyze the Brown et al. (2011) data set with the aim of providing the missing information detailed above. A de-identified data set with all variables (except information giving subject identity) would allow this reanalysis and lead to a better understanding of the existing data. Since time is critical, if there will be delays in releasing this data set, the SAB should collaborate with an EPA statistician who would already have access to the data set to reanalyze the data.