UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

September 28, 2011

EPA-SAB-11-015

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 (PLSLR). EPA's Office of Water sought SAB evaluation of current scientific data to determine whether PLSLR is effective in reducing drinking water lead levels. EPA identified several studies for the SAB to consider, and the SAB reviewed additional studies for their evaluation.

The SAB was asked to evaluate the current scientific data regarding the effectiveness of PLSLR centered around five issues: associations between PLSLR and blood lead levels in children; lead tap water sampling data before and after PLSLR; comparisons between partial and full 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").

The SAB finds that the quantity and quality of the available data are inadequate to fully determine the effectiveness of PLSLR in reducing drinking water lead concentrations. The small number of studies available have major limitations (small number of samples, limited follow-up sampling, lack of information about the sampling data, limited comparability between studies, etc.) for fully evaluating PLSLR efficacy. Nevertheless, despite these limitations, the SAB concludes that PLSLRs have not been shown to reliably reduce drinking water lead levels in the short term, ranging from days to months, and potentially even longer. Additionally, PLSLR is frequently associated with short-term elevated drinking water lead levels for some period of time after replacement, suggesting the potential for harm, rather than benefit during that time period. Available data suggest that the elevated tap water lead levels tend to then gradually stabilize over time following PLSLR, sometimes at levels below and sometimes at levels similar to those observed prior to PLSLR. The SAB response to the EPA's charge is detailed in the report. The major SAB comments and findings are provided below.

- The SAB evaluated a study from the Centers for Disease Control and Prevention (CDC) that examined associations between childhood blood lead levels (BLLs) and PLSLR. BLLs are used as biomarkers for lead exposure. The results suggest that there is a potential for harm (i.e. higher BLLs) resulting from PLSLR, and provide no evidence of a demonstrable benefit from PLSLR on reductions in childhood BLLs in the short term (e.g., within approximately one year). The available scientific evidence regarding BLLs and PLSLRs, while limited to this study, does not support the use of PLSLR as an effective or safe measure to reduce short-term Pb exposure of those served by lead service lines. The long term (e.g., over a period of years) relationship between PLSLRs and childhood BLLs cannot be determined from this publication.

- The SAB evaluated several studies of tap water lead levels both before and after PLSLR. The weight of evidence indicates that PLSLR often causes tap water lead levels to increase significantly for a period of days to weeks, or even several months. There are insufficient data to reliably predict whether the tap water lead level will significantly increase following a PLSLR in a given home or distribution system, the extent to which it will increase, or how long the increase will persist.

- In studies of full LSLR and PLSLR, the evaluation periods have been too short to fully assess differential reductions in drinking water lead levels. With this caveat, full LSLR appears generally effective in reliably achieving long-term reductions in drinking water lead levels, unlike PLSLR. Both full LSLR and PLSLR generally result in elevated lead levels for a variable period of time after replacement. The limited evidence available suggests that the duration and magnitude of the elevations may be greater with PLSLR than full LSLR.

- Studies examining PLSLR techniques (e.g., cutting techniques, flushing) did not provide definitive information on the impact that these techniques could have on 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. Line flushing appears to provide some benefit, but the time to realize the benefit (flushing for up to several weeks) precludes any likely practical implementation of this technique. The SAB finds that the development of a Standard Operating Procedure for PLSLR is premature.

- Galvanic corrosion associated with PLSLR poses a risk of increased lead levels in tap water 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 with currently available data. Insertion of a lead-free dielectric eliminates galvanic corrosion at the new pipe junction by breaking the electrical circuit between the new and old pipes, but it has no effect on depositional corrosion. The SAB concludes that insertion of a dielectric will likely reduce lead levels in tap water, but it cannot confidently estimate the magnitude of the reductions because the contribution of galvanic corrosion and depositional corrosion to drinking water lead levels has not been quantified.

In summary, the SAB found the available information is broadly suggestive that PLSLR may pose a risk to the population, due to the short-term elevations in drinking water lead concentrations. In answering the five charge questions, the larger picture which emerged is the lack of data available to fully evaluate the effectiveness of PLSLR, which limited the SAB's ability to offer stronger conclusions and recommendations.

The SAB appreciates the opportunity to provide EPA with advice and looks forward to the Agency's response.

Sincerely,

/Signed/	***/Signed/***
Dr. Deborah L. Swackhamer Chair EPA Science Advisory Board	Dr. Jeffrey K. Griffiths Chair SAB Drinking Water Committee

Enclosures

NOTICE

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Mr. Aaron Yeow, Designated Federal Officer, U.S. Environmental Protection Agency, Science Advisory Board (1400R), 1200 Pennsylvania Avenue, NW, Washington, DC, Phone: 202-564-2050, Fax: 202-565-2098, (yeow.aaron@epa.gov)

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Dr. Angela Nugent, Designated Federal Officer, U.S. Environmental Protection Agency, Science Advisory Board (1400R), 1200 Pennsylvania Avenue, NW, Washington, DC, Phone: 202-564-2218, Fax: 202-565-2098, (nugent.angela@epa.gov)

ACRONYMS AND **ABBREVIATIONS**

AL	Action Level
BLL	Blood Lead Level
EPA	United States Environmental Protection Agency
CDC	Centers for Disease Control and Prevention
LCR	EPA’s Lead and Copper Rule
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 drinking water lead (Pb) levels. The charge to the SAB was centered around five issues. They were: associations between PLSLR and blood lead levels (BLLs) in children; water sampling data at the tap before and after PLSLR; comparisons between partial and full lead service line replacements (LSLRs); PLSLR techniques; and the impact of galvanic corrosion. The SAB DWC Lead Panel held a public meeting on March 30-31, 2011, and a follow-up teleconference on May 16, 2011, to deliberate on the charge. This report was subsequently reviewed and approved by the Chartered SAB on July 19, 2011. This Executive Summary highlights the SAB’s major findings and conclusions.

The number of studies to examine the ability of PLSLR to reduce lead exposure is small and those studies have major limitations (small number of samples, limited follow-up sampling, lack of information about the sampling data, limited comparability between studies, etc.). Overall the SAB finds that, based on the current scientific data, PLSLRs have not been shown to reliably reduce drinking water lead levels in the short term, ranging from days to months, and potentially even longer. Additionally, PLSLR is frequently associated with short-term elevated drinking water lead levels for some period of time after replacement, suggesting the potential for harm, rather than benefit during that time period. Available data suggest that the elevated tap water lead levels tend to then gradually stabilize over time following PLSLR, sometimes at levels below and sometimes at levels similar to those observed prior to PLSLR.

Issue 1 - Associations Between PLSLR and Blood Lead Levels in Children

The current scientific literature was reviewed, and Brown et al. (2011) is the only study found that directly examines the relationship between childhood blood lead levels (BLLs) and PLSLRs. BLLs are used as biomarkers for lead exposure. The results of Brown et al. (2011) provide no evidence of demonstrable benefits from PLSLR on reductions in childhood BLLs in the short term (e.g., within approximately one year). In fact, the results provide suggestive evidence of the potential for harm (i.e., higher BLLs) related to PLSLR, among children living in households at which a PLSLR was performed. This finding is scientifically consistent with the observation that drinking water Pb levels often increase after PLSLR (see Issue 2).

Design limitations in Brown et al. (2011) preclude reliance on this single study as the basis for final conclusions about the relation of BLLs with PLSLR. These limitations 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 the measurement of BLLs; not accounting for the duration of residence in housing; possible ascertainment bias in the detection of elevated BLLs; potential for measurement error in the assignment of BLLs; low statistical power due to the limited number of children with elevated BLLs in the subanalyses; limited BLL data for formula-fed infants under one year of age who are at greatest risk; and limited ability to generalize the findings to other populations, communities, and water systems. In addition, the long-term relationship (over a period of years) between PLSLR and childhood BLLs cannot be determined from Brown et al. (2011). The SAB has several recommendations to address these limitations, such as a reanalysis of Brown et al. (2011) using expanded data resources and improved methods as outlined in Appendix B.

Issue 2 - Water Sampling Data at the Tap Before and After PLSLR

The weight of evidence indicates that PLSLR often causes tap water Pb levels to significantly increase for a period of days to weeks, or even several months. Available data suggest that tap water Pb levels tend to gradually stabilize over time following PLSLR, sometimes at levels below or above those observed prior to PLSLR. There are insufficient data to reliably predict whether the tap water Pb level will significantly increase following a PLSLR in a given home or distribution system, the extent to which it will increase, or how long the increase will persist.

The magnitude and duration of elevated tap water Pb levels following PLSLR may be influenced by the extent of disturbance of the lead service line (LSL), as well as any countermeasures taken to offset such effects (as discussed under Issue 4); the quantity and characteristics of the deposits in the LSL and downstream plumbing materials; the chemistry of the local water supply, including treatment to control corrosion; biological activity; localized corrosion; and other factors. Reasons for the increase in a given setting are generally not known.

Issue 3 - Comparisons Between Full and Partial Lead Service Line Replacements

Several studies that compared partial and full LSLRs were evaluated. The SAB finds that in these studies, the time periods of evaluation of Pb concentrations following partial and full LSLR have been inadequate to fully evaluate the effectiveness of reducing drinking water Pb levels. Nevertheless, for the time periods reported in the studies, the SAB concludes that in water distribution systems optimized for corrosion control, full LSLRs have been shown to be a generally effective method of reducing drinking water Pb levels. However, PLSLRs have not been shown to be reliably effective in reducing drinking water Pb levels, at least in the time frames of the reported studies. Both full LSLRs and PLSLRs generally result in elevated Pb levels for a variable period of time after replacement, but the limited evidence available suggests that the duration and magnitude of the elevations may be greater with PLSLR than full LSLR.

Issue 4 - PLSLR techniques

Several studies were evaluated that examined the impact that PLSLR techniques can have on Pb release. These included different cutting techniques, different joining techniques, the effectiveness of flushing, and public education. The SAB concludes that the studies do not provide definitive information on the impact that PLSLR techniques can have on Pb 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 a heat shrink Teflon sleeve as a joining technique, but the results are inconclusive, and the technology is still very new and has not been extensively evaluated. Line flushing appears to provide some benefit, but the time to realize the benefit (flushing up to several weeks) precludes any likely practical implementation of this technique.

Part of the PLSLR technique involves public notification and education. Informing the public about the risk of Pb exposure is a critical component of a PLSLR program. While the agency has published guidance (last revised in 2008), it does not specifically address PLSLR. The SAB recommends that EPA review and update the 2008 guidance in light of PLSLR and mitigation of Pb spikes following PLSLR. The SAB concludes that public education should complement engineering practices and should not be relied on as a replacement for engineering practices.

Given the lack of definitive studies on the effectiveness of different procedures and approaches to PLSLR, development of standard operating procedures to mitigate the impacts on tap water Pb levels from PLSLR is premature.

Issue 5 - Galvanic Corrosion

Several studies have been conducted to identify and quantify the significance of galvanic corrosion when PLSLRs 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 Pb 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 Pb 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 SAB is not aware of evidence suggesting that Pb that is oxidized galvanically is more or less likely to be mobilized than Pb that is oxidized by other mechanisms. The SAB therefore concludes that galvanic corrosion associated with PLSLR does pose a risk of increased Pb levels in tap water, 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 Pb 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 SAB concludes that insertion of a lead-free dielectric is likely to have beneficial effects on Pb concentrations in tap water, albeit of uncertain magnitude, but the SAB did not evaluate other factors or consequences associated with this practice. Given the relatively low direct cost of inserting such a device, the SAB has concluded that doing so would be appropriate in situations where the decision to implement a PLSLR has been made, provided that other issues (e.g., electrical grounding requirements, durability, and pipe-thawing practices) are adequately addressed.

2. INTRODUCTION

Human exposure to lead (Pb) has been shown to cause adverse health effects on the neurodevelopment of children, including deficits in IQ and altered behavior, as well as hypertension and cardiovascular disease in adults. Lead 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 that has been leached from materials present in water distribution systems, including Pb in service lines and household fixtures. There are a number of factors associated with Pb leaching into water, including water quality, the types of chemicals used in water disinfection, water temperature, and pH. The Pb content of solder, fixture constituents, scale deposits, and the service lines themselves are also important factors.

EPA's Office of Water (OW) regulates drinking water Pb levels through the 1991 Lead and Copper Rule (LCR) by establishing a treatment technique to minimize Pb levels in tap water. The LCR established an action level (AL) for Pb in drinking water, above which, water systems are required to install corrosion control treatment. It should be noted that the AL is not a health-based level and that EPA's health-based maximum contaminant level goal (MCLG) for lead is zero. If the AL is still not met after installing corrosion control treatment, LSLR is required. Under the 2000 LCR revisions, a water system is required to replace only the portion of the lead service line (LSL) that it owns (a water system is also required to offer replacement of the lead service that they do not own, at cost, to the owner). Replacement of only a portion of the LSL is referred to as a partial lead service line replacement (PLSLR).

EPA's OW requested that the Science Advisory Board (SAB) evaluate the current scientific data to determine the effectiveness of PLSLR in reducing drinking water Pb 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 SAB, presented in Appendix A, is centered around five issues: associations between PLSLR and blood lead levels (BLLs) in children, tap water sampling data before and after PLSLR, comparisons between full and partial LSLRs, PLSLR techniques, and the impact of galvanic corrosion. EPA identified several studies pertaining to each of the issues for the SAB to consider in their evaluation, but the SAB 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 and a follow-up teleconference on May 16, 2011 to deliberate on the charge. The Chartered SAB approved the report on July 19, 2011. The response to the charge is detailed in this 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?

Summary and Conclusions from Brown et al. (2011)

The SAB did not identify any other peer reviewed literature in addition to Brown et al. (2011) that explicitly addresses the relationship between BLLs and PLSLRs.

Brown et al. (2011) used administrative data from the Washington, D.C. Childhood Lead Poisoning Prevention Program (CLPPP) to characterize BLLs among children less than 6 years of age 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 an LSL, had a PLSLR performed, or had a non-Pb pipe delivery system prior to the BLL measurement. By matching CLPPP and WASA address data, the relationship between childhood BLLs and household water characteristics was assessed for 63,854 children. The study found that children with higher BLLs were more likely to have an LSL; this relationship was stronger during the time period of November 2000 through June 2004 when chloramine was being used as the water disinfectant (Brown et al., 2011, Table 2). Key to Issue 1, was the finding that, in a subset of 3,651 children with BLLs measured between 2004 to 2006, residing in a household which had a PLSLR performed, as compared to a household with an LSL not replaced, resulted in an odds ratio of 1.1 (95% CI: 0.8, 1.3, p=0.67[1]) of having a BLL between 5-9 µg/dL and an odds ratio of 1.4 (95% CI: 0.9, 2.1, p=0.18[1]) of having a BLL $\geq$10 µg/dL compared to having a BLL < 5 µg/dL (Brown et al., 2011, right half of Table 3). The mean time between PLSLR and BLL measurement was approximately 10-11 months.

Thus, Brown et al. (2011) provides no evidence of a benefit to PLSLR as measured by childhood BLLs, compared to having an LSL not replaced, in the short term (e.g., within approximately one year). In fact, the study's results provide suggestive evidence of the potential for harm (i.e., greater Pb exposure as evidenced by higher BLLs) related to PLSLR. This finding is consistent with the observation that drinking water Pb levels often increase after PLSLR (see Issue 2).

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[1] p-values were not reported in Brown et al., 2011 but were calculated from the frequency data presented in the right half of Table 3 using a two-sided Fisher's exact test.

Limitations and Caveats to the Interpretation of Brown et al. (2011)

There are a number of design limitations in Brown et al. (2011) that preclude reliance on this single study as the basis for final conclusions about the relationship between BLLs and PLSLRs. These include the following:

1. Perhaps the 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 living in homes where a PLSLR was performed compared to those living in homes 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, Pb content of household plumbing fixtures, 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 relationship between BLLs and PLSLRs. Not accounting for such confounders could have biased the findings. For example, if households living in home where a PLSLR was performed filtered their drinking water in response to the PLSLR, the observed relationship between BLLs and PLSLRs would underestimate the true risk to BLLs. This factor may have been particularly important 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 intact LSL. 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 residences where PLSLRs were performed may have sustained higher chronic Pb exposure prior to the replacement, and this in turn may have influenced the comparison of BLLs between households with PLSLRs and households with intact LSLs.

3. The study neither accounted for the timing of PLSLR relative to measurement of BLLs nor the duration of residence in housing with an LSL, though the timing between PLSLR and BLL measures was available in the study’s administrative data. In the latter case, the authors reported that BLLs were measured, on average, 10-11 months after a PLSLR, a lag which may have attenuated any associations. Lack of accounting for such factors could result in exposure misclassification. Such misclassification, if non-differential, would attenuate associations. If the misclassification was differential, it would bias findings, with the direction of bias dependent upon how such factors were distributed between children living in homes where a PLSLR was performed compared to those living in homes with an intact LSL.
4. There was possible ascertainment bias in the detection of elevated BLLs. For example, the implementation of a PLSLR at a household may have increased parental awareness regarding the hazards of childhood Pb exposure, and may have motivated a higher rate of BLL screening in children already subject to other risk factors for elevated BLLs.

5. There was potential for measurement error in assignment of BLLs. Although many children had more than one BLL measurement, analyses were restricted to one BLL 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 BLL.

6. The PLSLR sub-analyses were based on a modest number of children with elevated BLLs. Specifically, among children who lived in housing with a PLSLR, 598 had BLLs < 5 µg/dL, 105 had BLLs = 5-9 µg/dL, but only 27 had BLLs ≥ 10 µg/dL. In addition, due to the very unequal distribution of subjects in the two water service line groups (PLSLR vs. intact LSL), and the use of categorical BLL outcome logistic analysis with low *a posteriori* probability of BLLs exceeding 10 µg/dL, the power of the analysis to detect a difference in the BLLs 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 odds ratio of 1.36 (calculated from the frequency data in the right hand side of Table 3 in Brown et al., 2011).

7. A significant limitation from the perspective of public health protection is that the CLPPP data had relatively little (13%) BLL data for infants less than 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 repeated BLLs – including child and early infant levels as well as data on drinking water Pb levels and consumption patterns – before and after PLSLR could provide valuable information regarding the relationship between BLLs and PLSLRs over time. However, the most cost-effective and expeditious way of addressing the need for robust data relevant to Issue 1 would likely be 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 BLLs using a tobit regression for censored outcomes would increase the power to detect significant increases in BLLs associated with PLSLRs, should they exist. In addition, fully utilizing available data (e.g., age of housing, time between PLSLR and BLL testing, multiple BLL measurements) would improve a reanalysis of the data. A subset of the data used in Brown et al. (2011) was reviewed as part of this response to Issue 1 and recommendations for further EPA analyses of these data were made as described in detail by Panel member, Dr. Stephen Rothenberg (see Appendix B).

Public Health Considerations

The short-term and long-term consequences of PLSLR on BLLs may differ. For example, children's BLLs may increase substantially in the first few months following a PLSLR due to short term elevations in drinking water Pb concentration, a possibility not specifically investigated by Brown et al. (2011). However, short-term elevations in BLLs, particularly in children for whom Pb is a well-established and potent neurodevelopmental toxicant, can have long-term adverse health impacts.

To demonstrate the role of water Pb elevations on childhood BLLs, the SAB used EPA's Integrated Exposure Uptake and Biokinetic Model (IEUBK) (USEPA, 2009) to estimate BLLs for infants (ages 0-12 months) resulting from a moderate range of water Pb concentrations (Table 1). The IEUBK model has been extensively reviewed, tested, and validated and is used throughout EPA to predict childhood BLLs from lead exposure. These BLL 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 BLLs 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 BLLs in excess of 10 µg/dL (Table 1).

Table 1: Predicted Infant Blood Lead Levels by Tap Water Lead Concentrations and Water Intake for Formula-fed Infants

Predicted geometric mean blood lead (Pb) (µg/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

* Predictions from EPA's Integrated Exposure Uptake Biokinetic (IEUBK) model (USEPA, 2009) with absorption fraction (bioavailability) = 50% and input parameters for all other sources of Pb set to zero.

Summary and Conclusions

The task for Issue 1 was to assess the evidence in the available medical literature, including the study by Brown et al. (2011), regarding the effectiveness of PLSLR in reducing drinking water exposure to Pb. There is well-documented and substantial population morbidity associated with even low-level Pb 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). The relationship between Pb exposure and BLL is well established. Thus, the effectiveness of a technology or process, such as PLSLR, to reduce or eliminate Pb exposure should be possible to gauge by examining BLL, a biological marker of Pb exposure, when other Pb exposures are held constant or are accounted for.

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

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

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 (summarized in Appendix C) clearly indicates that PLSLRs often cause tap water Pb levels to increase significantly for a period of days to weeks, or even several months. After this period the water Pb levels stabilize, sometimes at levels below and sometimes at similar levels as those observed prior to PLSLR. It appears that the latter tends to be the case when the tap water Pb levels are initially close to or below the AL. In some cases, variations in tap water Pb levels have been observed many months after a PLSLR, but the SAB found no evidence that such variations were caused by PSLSRs; and it is reasonable to assume they are attributable to other factors. Long-term data are sparse, so it is not possible to reliably predict whether the tap water Pb level will significantly increase following a PLSLR in a given home or distribution system, the extent to which it will increase, or how long the increase will persist. It is nonetheless clear that tap water Pb levels of significant concern may persist until the remaining portion of the LSL and any Pb-contaminated piping within the home are replaced. Furthermore, the Pb concentrations to which consumers of unfiltered tap water are actually exposed to following PLSLR may be significantly higher or lower than the concentrations found using the sampling protocols specified in the LCR or other common sampling protocols that can potentially undersample or oversample particulate Pb (see Appendix D).

The magnitude and duration of elevated tap water Pb levels following PLSLR may be influenced by the extent of disturbance of the LSL, as well as any countermeasures taken to offset such effects (as discussed under Issue 4); the quantity and characteristics of the deposits in the LSL and downstream plumbing materials; the chemistry of the local water supply, including treatment to control corrosion; biological activity; localized corrosion; and other factors. Unfortunately, studies documenting elevated tap water Pb levels following PLSLR have generally not studied the mechanisms involved, so the reason for the increase in a given setting is generally not known. Some investigators have speculated that particulate Pb is released into the water when Pb-contaminated encrustations are physically or hydraulically disturbed. There is a substantial amount of evidence that such disturbances can and do occur and that they result in release of particulate Pb (e.g., HDR, 2009; Deshommes et al., 2010; McFadden et al., 2011). Some investigators speculate that galvanic corrosion (a process in which an electrical connection between different metals can accelerate the corrosion of the less noble metal) may occur when the new line is connected and that Pb levels decline as the new material is gradually passivated; this possibility is discussed further in the response to Issue 5.

A critical consideration in evaluating the effectiveness of PLSLR is the extent to which it actually reduces human exposure to Pb. 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. PLSLR obviously eliminates a portion of the potential for exposure, since the Pb removed from the system is no longer available as a source of exposure; and in certain situations PLSLR would be expected to significantly reduce actual long-term exposure to Pb. For example, this could be the case where most of the Pb in tap water is dissolved, the LSL is the predominant and proximate source of Pb, and a significant fraction of the water actually consumed first sits in the utility-owned portion of the line long enough for the Pb concentration to significantly increase.

However, the weight of evidence is that PLSLR often causes short-term increases in tap water Pb levels and is unlikely to reduce actual exposure in proportion to the fraction of the LSL removed. In many situations, PLSLR is likely to result in little or no reduction in actual exposure, e.g., where the proximate source of most of the Pb actually consumed is household plumbing materials (Pb-bearing faucets, fittings, and soldered joints) or Pb-contaminated encrustations in the customer-owned portions of the system, especially those capable of releasing Pb-bearing particles into the water. The following paragraphs elaborate on several of these points.

If Pb in drinking water were associated only with LSLs and faucet fixtures, and if consumers flushed the faucet before taking a drink of water, it might be reasonable to assume that potential Pb exposure would be reduced roughly in proportion to the fraction of the LSL removed, with actual exposure depending on use patterns and other factors. However, Pb can accumulate in interior plumbing downstream from an LSL, especially in galvanized pipes (Sandvig et al., 2008; HDR, 2009; and McFadden et al., 2011). This phenomenon, referred to as "seeding" by some investigators (e.g., Sandvig et al., 2008), occurs when dissolved and particulate Pb are released from an LSL and captured downstream by various mechanisms. These mechanisms include: adsorption of dissolved Pb onto scale deposits and corrosion products; incorporation of dissolved Pb into scales by precipitation and co-precipitation; and deposition of Pb-bearing particles onto surfaces, especially the very irregular and rather porous surfaces typically associated with iron rust (which develops in galvanized pipe after the protective zinc layer dissolves away). Thus, the entire plumbing system, not just the LSL, may be a significant source of Pb; and Pb-contaminated encrustations may contain enough Pb to pose a significant health hazard for many years after the LSL has been partially or fully replaced.

Since 1991, a number of studies have documented the importance of particulate Pb in tap water (e.g., McNeill and Edwards, 2004; Triantafyllidou and Edwards, 2007; HDR, 2009; Deshommes et al., 2010). It is now widely recognized that a large fraction of the Pb in a given water sample may be present in particulate form, and that particulate Pb can be sporadically released into the water from LSLs or from Pb-contaminated household plumbing downstream from an LSL. Such releases can result from 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 "water hammer" (the banging of a pipe caused by a sudden increase or decrease in flow rate).

Although the concentration of dissolved Pb (including soluble complexes) in tap water can exceed the AL, Pb is relatively insoluble in tap water. Dissolved Pb concentrations exceeding 100 μg/L are generally not expected to be found in systems with optimized corrosion control. Particulate Pb concentrations, however, can be much greater. For example, McNeill and Edwards (2004) found 508 μg/L of particulate Pb in a first-draw sample collected by a surveyed water utility, and they found over 2,000 μg/L of Pb (mostly particulate) in two samples collected during a pipe loop study. HDR (2009) reported finding 2,172 μg/L of Pb in a sample influenced by "water hammer," but the dissolved Pb concentration was below the AL. Britton and Richards (1980) reported a Pb concentration of over 4 mg/L in a first draw sample collected one week after a PLSLR, and most of the Pb in this sample was presumably particulate given the solubility of Pb in tap water. The potential for the tap water Pb concentration to be this high, in even a single sample, in a household served or previously served by an LSL, merits careful consideration in future exposure assessments. The bioavailability of Pb is expected to vary with particle size and composition, and this also merits further evaluation.

Even in cases where particulate Pb does not pose a problem, PLSLRs may result in little or no benefit if much of the water consumed is initially stagnant for an extended period of time in the customer-owned portion of the LSL, in Pb-contaminated household piping, or in Pb-bearing fixtures. Consumers who fail to flush their lines before drawing a glass of water may be exposed to relatively high concentrations of dissolved Pb. Those who flush their lines using a change in water temperature as an indication that the water is coming from the main may be exposed to high Pb levels if the customer-owned portion of the LSL is significantly colder than room temperature.

An important consideration in evaluating the effectiveness of PLSLR is the extent to which the short-term increases in exposure following PLSLR are offset by the long-term reductions in exposure anticipated following PLSLR. 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 Pb levels (USEPA, 1991a). The SAB concludes this premise should be thoroughly re-evaluated, based on current information, for the following reasons:

1. The health risks associated with even relatively short-term exposures could be substantial depending on the magnitude and duration of elevated Pb levels, water intake, and individual susceptibility.

2. Tap water Pb 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.

3. Recent data published after 1991 demonstrate that young children are vulnerable to Pb at exposure levels lower than were previously recognized.
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4. The tap water Pb levels to which consumers are actually exposed following PLSLR may be higher than those determined using current sampling protocols, which tend to undersample particulate Pb (Appendix D), and consumers can be exposed to Pb not only by drinking Pb-contaminated tap water but also by ingesting food cooked with tap water or beverages or infant formula prepared using tap water.

5. Sporadic release of particulate Pb into tap water from Pb-contaminated interior plumbing materials can result in extremely high tap water Pb levels, reducing the anticipated effectiveness of PLSLR.

If the health risks associated with short-term increases in tap water Pb levels following PLSLR are significant, it may be possible to achieve significant risk reduction by modifying the LSLR requirements in the LCR. Options for reducing exposure include using point-of-use treatment capable of removing both dissolved and particulate Pb, public education, full LSLR, and replacement of any plumbing materials encrusted with Pb-bearing deposits. As discussed in the response to Issue 3, full LSLRs are generally more effective than PLSLRs in reducing tap water Pb levels, but full LSLRs can also result in short-term increases in tap water Pb levels that merit further evaluation and perhaps improved mitigation measures. Full LSLRs are currently recommended, but few home owners choose this option due to its cost. Options for increasing participation in full LSLR programs include public education as well as economic inducements such as subsidies, loan programs, and mandatory notification of prospective home buyers that the home contains a LSL.

Several public commenters, as well as several Panel members, noted that most PLSLRs are done by utilities for reasons other than compliance with the LCR. Some utilities voluntarily replace more LSLs than required under the LCR; but most replacements are done in the normal course of utility operations such as repairing leaks and replacing mains, sometimes in emergency situations. In most cases, such replacements are partial because the majority of home owners choose not to replace the privately owned portion of the line. The SAB's consensus is that these voluntary PLSLRs pose short-term exposure risks (and potential long-term health risks) similar to those associated with mandatory PLSLRs, since they are expected to result in similar short-term increases in tap water Pb levels; and they may pose even greater exposure risks if the risks are not as well managed, e.g., by notifying consumers, flushing the lines, etc. Most voluntary replacements involve LSLs that either must be disturbed (e.g., to permit installation of a new main) or that are disturbed before being recognized as LSLs, so disturbance of the lines and the resulting short-term increases in tap water Pb levels are unavoidable. Thus, voluntary PLSLRs may represent an opportunity for significant risk reduction if properly managed. Options for risk reduction include public education, encouraging full replacements, recommending point-of-use treatment while Pb levels remain elevated, using bottled water, and recommending or requiring certain management practices such as line flushing. Some utilities already employ some of these practices.

Accurate assessment of the effectiveness of PLSLR in reducing exposure to Pb depends, in part, on the accurate determination of tap water Pb concentrations, which in turn, depends on collection of representative samples. The sampling protocols specified in the LCR were designed to determine Pb only in: (1) first-draw samples of standing water (to assess the effectiveness of optimized corrosion control and the potential for exposure to Pb in the first glass of drinking water drawn without flushing the tap); and (2) water left standing in the customer-owned portion of LSL. These and other common sampling methods may fail to produce samples containing representative concentrations of particulate Pb (Appendix D). Therefore, results obtained using these methods may result in significant underestimation of exposure to Pb in tap water or overestimation when using methods designed to dislodge particulate Pb. There appears to be no simple solution to this problem, but the limitations of current sampling protocols should be carefully considered in future revisions to the LCR, in evaluating studies of Pb in tap water, and in assessing the potential impacts of tap water Pb levels on human health.

Summary

The weight of evidence indicates that PLSLR often causes tap water Pb levels to significantly increase for a period of days to weeks, or even several months. Available data suggest that tap water Pb levels tend to gradually stabilize over time following PLSLR, sometimes at levels below those observed prior to PLSLR, and sometimes at levels similar to those observed prior to PLSLR. There are insufficient data to reliably predict whether the tap water Pb level will significantly increase following a PLSLR in a given home or distribution system, the extent to which it will increase, or how long the increase will persist.

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 studies cited in the charge that provided direct or indirect comparisons between partial and full LSLRs were reviewed. HDR Engineering (2009) compared Pb concentrations after partial or full LSLR in households with galvanized premise plumbing. Pb concentrations in tap water were not substantially lower in the homes with full LSLRs. The LSLs were believed to have 'seeded' the galvanized premise plumbing with Pb prior to the LSLR, and the Pb released from the 'seeded' premise plumbing was believed to account for much of the load observed in tap water after the (partial or full) replacement of the service line.

In Sandvig et al. (2008), corrosion control was identified as the most effective method, and a necessary first step, to achieve LCR compliance. The report recognized, however, that LSLR was inevitable on a site-by-site basis when routine maintenance required replacement of parts of the distribution system. For homes with LSLs, those lines were found to contribute 50 to 75% of the Pb mass in household tap water, premise plumbing was found to contribute an additional 20 to 35% of the Pb mass (likely from 'seeding' from LSLs), and faucets were found to contribute 1 to 3% of the Pb mass. PLSLR did not reduce Pb levels in the first liter collected during sampling, and resulted in only minimal improvement in total mass measured in household tap water over the entire duration of sampling. Full LSLR reduced the total mass of Pb measured in tap water during sequential sampling as well as in the first liter collected. It was also found that the effectiveness of full LSLR relative to PLSLR in reducing tap water Pb levels is highly site specific. Both partial and full LSLR generally result in elevated Pb concentrations for site-specific durations after replacement.

In the study performed by Swertfeger et al. (2006), 21 houses were sampled: (a) five houses with a full LSLR; (b) five houses with a PLSLR; (c) six houses with a PLSLR with Teflon® shrink wrap tubing around the cut section at the property line; and (d) five control sites where no work was performed on the LSL. Corrosion control measures were implemented in the distribution system at roughly the same time as partial and full LSLR, confounding any comparison of Pb levels in the tap water immediately after the LSLR. However, comparing Pb levels in tap water one year after replacement are deemed credible as a basis for comparing the effectiveness of partial versus full LSLR. At that time, all five households with a full LSLR, but only three of the five homes with a PLSLR, had Pb levels less than 5 μg/L; the other two households with a PLSLR had Pb levels close to the LCR AL of 15 μg/L.

The studies by Britton et al. (1981), Gittelman et al. (1992), Muylwyk et al. (2009), USEPA (1991a, 1991b), and Weston et al. (1990) were also considered. The study by Wujek (2004) was not considered relevant to this issue because the disinfectant was changed from chloramine to free chlorine between the pre- and post-PLSLR sampling, making it impossible to draw any valid, causal relationship between the line replacement and Pb concentrations measured in the tap water. In all the studies conducted to date (with the exception of the one-year sample followup in the 2006 Swertfeger et al. study), the time period of evaluation of Pb concentrations following partial and full LSLRs has been inadequate to fully evaluate their relative long-term effectiveness. Nevertheless, based on review of the above mentioned studies, the SAB concludes (Pb levels are in reference to total Pb, inclusive of both dissolved and particulate Pb):

- In water distribution systems optimized for corrosion control, full LSLR has been shown to be a generally effective method in achieving long-term reductions in drinking water Pb levels. However, full LSLR often results in elevated and inconsistent Pb levels (frequently above the LCR AL) for a variable period of time after replacement.

- PLSLR has not been shown to be reliably effective in reducing drinking water Pb levels, at least in the time frames of the reported studies. Pb levels are typically elevated for a variable period of time after replacement, as is the case for full LSLR. The limited evidence available suggests that the duration and magnitude of the elevations may be greater with PLSLR than full LSLR.

- Following full LSLR, in households with non-leaded household plumbing, elevated Pb levels in drinking water largely originate from release of Pb that has been deposited onto non-Pb premise plumbing. The problem is apparently more acute in households with galvanized plumbing.

- Management of Pb consumption by residents following partial or full LSLR would benefit from more aggressive occupant education. In the judgment of theSAB, occupant education has been inadequate and has therefore not been nearly as protective of the public health as is possible. Occupant education should reflect (in layman's terms) the knowledge gained from the studies cited in this report about the lengthy period of elevated Pb levels in both first-flush and profile samples of tap water. Specific suggestions could be given about flushing the lines and monitoring Pb levels over a period of months.

- The contribution of Pb mass measured in household tap water during profile sampling is greatest from the LSLs, followed by premise piping, and then faucets. The contribution from water meters is negligible. For this reason, the strategy for reducing drinking water Pb levels should be done in that same order, that is, (1) full LSLR; (2) removal of Pb precipitate and Pb-contaminated deposits in premise plumbing; (3) replacement of Pb-bearing faucets. Removal of Pb from premise plumbing after full LSLR may involve, but is not limited to, aggressive flushing strategies; in cases in which the deposits are heavily encrusted with Pb, simple water flushing might be inadequate.

Summary

Several studies that compared partial and full LSLRs were evaluated. The SAB finds that in these studies, the time periods of evaluation of Pb concentrations following partial and full LSLR have been inadequate to fully evaluate the effectiveness of reducing drinking water Pb levels. Nevertheless, for the time periods reported in the studies, the SAB concludes that in water distribution systems optimized for corrosion control, full LSLRs have been shown to be a generally effective method of reducing drinking water Pb levels. However, PLSLRs have not been shown to be reliably effective in reducing drinking water Pb levels, at least in the time frames of the reported studies. Both full LSLRs and PLSLRs generally result in elevated Pb levels for a variable period of time after replacement, but the limited evidence available suggests that the duration and magnitude of the elevations may be greater with PLSLR than full LSLR.

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.*

LSLR is one of two “treatment techniques” identified by EPA that can be used to achieve compliance with the 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 LSLR 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 LSL. 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. Not all involve physical contact with the service line, yet all are critical to the success of a LSL replacement program and are necessary for reducing Pb exposure. Therefore, water pressure and flow changes, cutting techniques, joining techniques, flushing, and public education were considered in the discussion on PLSLR techniques[2].

The studies supplied with the issue statement provide limited insight on the impact that PLSLR techniques can have on Pb release. Based on the limited research available, the SAB can find no clear evidence that the techniques used for PLSLR are responsible for the elevated Pb levels observed in tap water following PLSLR.

Water Pressure Changes and Flow which Affect Pb Release

Since water is under pressure, it must be shut off 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 at the service connection is a quick and efficient way to isolate the worksite in preparation for a PLSLR with minimal service disruption. Shutting the water off to the home for a PLSLR is a one-time event that is not as frequent as the local mechanical actions of turning a faucet on or off.

Boyd et al. (2006) used LSLs recovered from a water distribution system in pipe loops to examine how the intermittent operation of faucets might affect Pb release following a PLSLR. The different loops were operated with intermittent flow (one with slow opening and closing movements and one with rapid movements) to simulate the opening and closing of a faucet. These loops showed continual releases of Pb for over two weeks after startup. The study data provide some insight on how normal pressure transients under household flow conditions could impact Pb release after a PLSLR. The flow rates used in the study were atypical of both high and low flow faucets typically provided by home faucets, but the results did demonstrate that the on/off operation of faucets could produce elevated Pb releases in the LSLs. Having the researchers provide their raw data for further analysis would be a potential means of gathering more information that could be used to evaluate the role of pressure and flow transients in Pb exposure within the home.

In similar tests with galvanically coupled (Pb-Cu) pipes exposed to flow twice per day, Cartier et al. (2011) found that lead was released in spikes of up to a few hundred micrograms per liter for at least six months after the pipes were connected, when high water flow rates (32 L/min) were used. The spikes were less frequent and less severe at medium flow rates (8 L/min), and were virtually non-existent at low flow rates (1.3 L/min). These results emphasize the importance of specifying the flow rate when

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[2] Information on locating and identifying LSLs is provided in Appendix E. Replacement and rehabilitation techniques are also discussed in Appendix E. At present, these techniques are not thought to affect lead release from PLSLR.

sampling for Pb concentrations in drinking water and demonstrate that an incorrect conclusion could be drawn about the potential human exposure to lead if sampling is conducted at lower flow rates than are commonly used when consumers open their taps.

In summary, Pb release appears to be affected by water flow and pressure changes associated with faucet use under experimental conditions. No clear conclusions can be drawn regarding how pressure changes or flow could be managed or optimized so as to minimize Pb exposure after PLSLR.

Cutting Techniques

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

Two studies (Sandvig et al., 2008 and Wujek, 2004) examined the methods used to cut into the existing service line in an attempt to determine their impact on Pb release following a PLSLR. The available techniques that were examined were using a hacksaw, pipe cutter, and pipe lathe. The Sandvig et al. (2008) study examined the use of a hacksaw and disc cutter on PLSLR. Five PLSLR cases were conducted with a hacksaw which resulted in an increase in the mass release of Pb following PLSLR in three of the five cases. Using a disc cutter in three PLSLRs resulted in only one case showing an increase in the mass of Pb level released following PLSLR. However, due to the limited sample size and high degree of variability in the total Pb mass released, the difference between the two groups is not likely to be statistically significant. The Wujek study conducted Pb profiles before and after PLSLR and was used to demonstrate the effectiveness of PLSLR. However, this study has been criticized because data were collected during a transition in disinfection which could have affected the measured water Pb levels. The Wujek finding that Pb levels decreased after PLSLR could in fact be in part or whole due to changes in water treatment, rather than the replacement of Pb-releasing service lines.

In summary, given the variable circumstances, the small sample size, and the fact that the other variables associated with PLSLR, such as flushing, were not adequately controlled, the SAB concluded that they could not determine if any one cutting technique provided any benefit over another.

Joining Techniques

Connecting two dissimilar metals creates a potential for galvanic corrosion, an issue addressed in Issue 5. Swertfeger et al. (2006) investigated the use of Teflon® sleeves to connect the two pipe ends in a PLSLR. When used in combination with a union, the sleeve serves as a dielectric. Swertfeger et al. (2006) found that Pb concentrations in first-draw samples after PLSLR were slightly lower when the pipes were joined by heat shrink Teflon® sleeves compared to when the pipes were directly joined. The results for total Pb release (including water collected after the first-draw sample) were not provided and could be a source of additional information. Given that this is a new technique that has not been extensively evaluated, the SAB does not believe that there is sufficient evidence to assess its potential benefits.

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.) or that were released from the interior pipe walls when the pipe was disturbed (corrosion products and biofilms). Following service line replacement, the line will be flushed at the point of connection and/or at the household faucet. Flushing at the point of connection is likely to be more vigorous than flushing via household faucets because the latter restrict water flow to a greater extent than the larger diameter connection pipes. The scouring of the inside of the pipe caused by flushing can expose new pipe surface when materials next to or bound to the surface are caught or entrained by the passing water. These newly exposed pipe surfaces may then undergo restabilization or passivation. Restabilizing pipe surfaces is known to be a relatively slow process. The elevated water Pb levels observed after PLSLR which only declined after an extended period could be an indication that optimal corrosion control conditions may not be optimal for passivation.

As noted previously, Boyd et al. (2006) examined the impact of flow on Pb release in pipe loops composed of Pb pipe removed from a water 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, but the study suggests that allowing water to continually flow through the service line will stabilize the service line resulting in reduced Pb 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”. For the pipes studied under intermittent flow conditions, Pb continued to be released from the line over the 2-week test period. This study was limited to one utility.

Sandvig et al. (2008) recommended that a rigorous flushing regime of up to 60 minutes might help to reduce particulate Pb following PLSLR. At Seattle Public Utilities, it was found that 63 days of intermittent flushing at 1 L/min for 3 hours per day was required before the Pb levels stabilized below the AL following a physical disturbance to the water meters. DC Water found that flushing immediately after LSLR was effective at reducing tap water Pb levels and they recommended 60 minutes of flushing after PLSLR. However, the study did not include longer term follow-up to examine reoccurrence of Pb over time. Greater Cincinnati Water Works examined Pb in plumbing components at one tap for 2 years. They found that Pb decreased but was still present based on sampling after a variety of flushing times.

In summary, line flushing appears to provide some benefit, but the magnitude of the water flow, and the duration of time, required to realize this benefit is not well understood. The time to realize the benefit (up to several weeks of flushing in the reviewed studies) likely precludes any practical implementation of this technique.

Public education

In 2008, EPA published a revised public education guidance document. This document extensively addresses public notification and education regarding mitigation measures should the water Pb AL be exceeded. Additional public education requirements are addressed in other EPA publications (USEPA, 1991a, 1998, 2010; and the Safe Drinking Water Act Amendments of 1996). The LCR includes mandatory language for all utilities whether they meet or exceed the action levels specified in the LCR. Thus, public education is a method with the potential for mitigating Pb exposure from tap water.

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 LSLR, but not specifically PLSLR. The document includes a recommendation for customers to "Run water for 15-30 seconds to flush Pb from interior plumbing [or insert a different flushing time if your system has representative data indicating a different flushing time would better reduce Pb exposure in your community and if the State Primacy Agency approves the wording] or until it becomes cold or reaches a steady temperature before using it for drinking or cooking, if it hasn't been used for several hours. [It is likely that systems with lead service lines will need to collect data to determine the appropriate flushing time for lead service lines.]" While this guidance provides for broad consideration for establishing utility-specific flushing times, the guidance may not adequately address the flushing needed for reducing the risk from PLSLRs. The SAB recommends that USEPA review the 2008 guidance in light of current information on PLSLR impacts on water quality in order to address the specific concerns regarding mitigation of lead spikes following replacement. EPA should also review sampling and flushing protocols to ensure they accurately reflect maximum flow rates from faucets that are certified to meet the plumbing "green" codes.

The guidance also includes other mitigation options to reduce lead, including the purchase of bottled water or a point-of-use treatment device: "You may want to consider purchasing bottled water or a water filter. Read the package to be sure the filter is approved to reduce lead or contact NSF International at 800-NSF-8010 or www.nsf.org for information on performance standards for water filters. Be sure to maintain and replace a filter device in accordance with the manufacturer's instructions to protect water quality." Even if a proper point-of-use treatment device is used, the consumer is responsible to see the device is properly installed, operated, and maintained; failure to do so would likely result in higher Pb exposure.

The SAB concludes that public education cannot be expected to provide public health protection if the formulated advice is not well grounded in science. If the fundamental tenets of Pb release are not well understood, it could result in an unsuspecting public being unintentionally exposed to elevated Pb levels. In addition, public education should complement engineering practices rather than be viewed as a sole means to solving a water quality issue.

The SAB found no information to suggest that PLSLR undertaken voluntarily in the course of maintenance or repair operations differ from PLSLR undertaken to ensure compliance with the LCR in their capacity to cause elevations in the lead content of water at the tap. However, the lack of mandatory water lead testing and homeowner education associated with voluntarily PLSLR suggests that in practice, voluntary replacement might be associated with greater exposure of the public to lead.

Conclusion

The SAB reviewed studies of techniques which could mitigate exposure to lead in drinking water after PLSLR. In general, only scanty information is available. There is some evidence that flushing may be beneficial, however studies regarding the magnitude and duration of the flushing process are lacking. Public education has the potential to provide some benefit as well, and there may be an opportunity for enhancing the mitigation of Pb exposure if voluntary PLSLR also triggered public education.

Given the lack of definitive studies on the effectiveness of different procedures and approaches to PLSLR, recommendations regarding standard operating procedures to mitigate the impacts on lead exposure relating to PLSLR cannot be made at this time.

Several Panel members also suggested that one method that would reduce drinking water lead exposure (due to the short-term drinking water lead level elevations) would be to refrain from conducting PLSLRs. However, other Panel members indicated that this might not be practical due to the fact that most PLSLRs are "voluntary" and are performed in the normal course of utility operations such as repairing leaks, replacing mains, and sometimes in emergency situations.

The SAB recommended that EPA note that the following set of studies could inform this issue:

- Cutting techniques: Future studies could be conducted under carefully controlled conditions to ensure the elements that comprise PLSLR (e.g., cutting and flushing) can be isolated and evaluated for their individual effectiveness on the mitigation of Pb exposure after PLSLR and LSLR.

- Flushing: The relationship of flushing on Pb release under different water quality conditions and water use patterns could be studied under carefully crafted protocols that isolate the impacts of flushing from the other components of PLSLR.

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.

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 SAB considered both the intentional, direct connection that can occur between a copper and a Pb pipe during PLSLR, 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 Pb. When the copper is deposited in this way, a new copper/Pb 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 LSLs. To the extent that depositional corrosion occurs, it can affect Pb in two ways: Pb is oxidized when the copper is first deposited, and the copper/Pb 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 PLSLRs are implemented. Parameters related to Pb 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 Pb 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 Pb 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 invoked 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 Pb corrosion rate. However, one other study has 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 Pb release did not account for Pb 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 Pb exits the tap in a small volume of water. There is little doubt that Pb 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 Pb is converted to ionic Pb, but not of the rate or likelihood that the corroded Pb 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 Pb might remain attached to the pipe almost indefinitely. The presence of large amounts of Pb-containing solids near Pb/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 Pb is mobilized. In addition, even in systems where the normal conditions favor retention of corroded Pb 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 Pb 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 pipe to Pb 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 to 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 asked in Issue 5 was: *What conclusions can be drawn from these studies regarding the potential for elevated lead levels at the tap from galvanic corrosion*? The SAB notes that galvanic corrosion has the potential to contribute to elevated Pb levels in tap water by (1) increasing the rate of corrosion and/or (2) increasing the likelihood that corroded Pb 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 SAB is not aware of evidence suggesting that Pb that is oxidized galvanically is more or less likely to be mobilized than Pb that is oxidized by other mechanisms. The SAB therefore concludes that galvanic corrosion associated with partial lead service line replacement does pose a risk of increased Pb levels in tap water, 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 SAB 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 Pb pipes, but it has no effect on depositional corrosion or the galvanic corrosion that can ensue at such a site. As noted earlier, one approach for inserting a dielectric is to use heat-shrink Teflon® to join the two pipe ends. Because the relative magnitudes of galvanic corrosion at the pipe juncture vs. that induced by 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 short-term elevations ("spikes") in drinking water Pb levels that are commonly observed immediately after PLSLR 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 Pb concentration would still be seen in tap water even if a dielectric were inserted, but the magnitude of those spikes might diminish 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 PLSLR). Under the circumstances, the SAB concludes that insertion of a lead-free dielectric is likely to have beneficial effects on Pb concentrations in tap water, albeit of uncertain magnitude. Given the relatively low direct cost of inserting such a device, the SAB has concluded that doing so would be appropriate in situations where the decision to implement a

PLSLR has been made, provided that other issues (e.g., electrical grounding requirements, durability, and pipe-thawing practices) are adequately addressed. The SAB is aware that insertion of a dielectric might result in 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 and other secondary phenomena have not been considered as part of this assessment.

Summary

The available evidence strongly supports the contention that galvanic corrosion increases the corrosion rate of the Pb pipe near the point of metal/metal contact shortly after the contact is made. The SAB concludes that galvanic corrosion associated with PLSLR does pose a risk of increased Pb levels in tap water, 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 Pb pipe junction, but it has no effect on depositional corrosion or the galvanic corrosion that can subsequently ensue at the site of depositional corrosion. The SAB concludes that insertion of a lead-free dielectric is likely to have beneficial effects on Pb concentrations in tap water, albeit of uncertain magnitude, but the SAB did not evaluate other factors or consequences associated with this practice.

3.6. Conclusion

The number of studies to examine the ability of PLSLR to reduce lead exposure is small and those studies have major limitations (small number of samples, limited follow-up sampling, lack of information about the sampling data, limited comparability between studies, etc.). Overall the SAB finds that, based on the current scientific data, PLSLRs have not been shown to reliably reduce drinking water lead levels in the short term, ranging from days to months, and potentially even longer. Additionally, PLSLR is frequently associated with short-term elevated drinking water lead levels for some period of time after replacement, suggesting the potential for harm, rather than benefit during that time period. Available data suggest that the elevated tap water lead levels tend to then gradually stabilize over time following PLSLR at levels both above and below those observed prior to PLSLR.

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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 1.

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, listed in Attachment 2. The SAB may also consider other relevant studies for the evaluation.

Specific Issues

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.

APPENDIX A (cont'd)

Attachment 1 – 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

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[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

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.

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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.

APPENDIX A (cont'd)

Attachment 2 – 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. Presented at the 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 Dissimilar 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 and Recommendations for a Reanalysis of Brown et al. (2011)

Rationale for Reanalysis

Table 3 of Brown et al. (2011) contains key epidemiological information for assessing the effects of partial lead service line replacement on the blood lead of children less than six years of age. For the following reasons, a reanalysis of the data presented in this paper might offer expanded insight into the influence of PLSLR on childhood BLLs:

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. Tobit regression on left-censored 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.

Recommendations for Reanalysis

The Centers for Disease Control and Prevention (CDC) had provided EPA's Office of Water (OW) with a dataset which was shared with theSAB, hereafter referred to as "the data set." This data set is the most recent version of the data set used by Brown et al. (2011) to analyze the effect of partial lead service line replacement (PLSLR) on blood lead concentrations of children in the Washington, DC metropolitan water district. Though there are many issues that can be addressed using this longitudinal data set, here the focus will be on improving the analysis of Brown et al. published as the right side of their Table 3.

The original analysis focused on the difference in blood lead of children under age 6 among those living in residences with lead service lines after PLSLR and those not experiencing PLSLR during the period of 07/01/2004 – 12/31/2006, when chloramine (combined with orthophosphate) was used as the water disinfectant. Brown et al. used blood lead grouped into three categories of outcome, < 5 µg/dL, 5-9 µg/dL, ≥ 10 µg/dL . Most blood lead was reported as whole number µg/dL, though some were reported as decimal number µg/dL. The assumption made here is that the middle blood lead category included children with blood lead up to 9.9 µg/dL. In addition, a fractional blood lead value (1.4 µg/dL) was used as the censoring value of the lowest blood lead measurements, below the detection limit of the analytical procedure for blood lead.

Brown et al. reported the results of a simple polytomous logistic regression, using blood lead category as the outcome and having or not a PLSLR before the blood lead measurement in children living in residences with a lead service line. They reported their results as odds ratios, though the recommended interpretation of coefficients of polytomous logistic regression is relative risk ratio.

The motive behind characterizing blood lead in three categories appeared to be the current CDC recommendation, dating from 1991, that the action limit for children be 10 µg/dL and a more recent amendment of 5 µg/dL for pregnant women. Most active researchers consider these action limits currently baseless, as all research with blood lead in children shows no lower threshold for lead effect.

The analysis by Brown et al. did not take into account the interval between PLSLR and the blood lead measurement used in the analysis. It also did not take into account the limited data on age of housing, a proxy for other lead exposure sources in the children's residence, though it should be noted that this would reduce the number of subjects available for analysis. The data set reviewed as part of this SAB charge did not list subject sex, though this variable was available to Brown et al., given their descriptive analysis divided by sex. Inclusion of sex in any subsequent analysis would serve to further reduce unexplained variance in blood lead outcome.

Since there is little current reason to adopt the CDC action limits for children (and pregnant women) blood lead, the major recommendation for reanalysis of the PLSLR data is to use as much of the blood lead data as possible in its original format instead of categorizing the variable. Due to the left-hand censoring of the original blood lead variable to account for the measurement detection limit, the most powerful statistical tool for analyzing these data, ordinary least squares (OLS) regression, is not recommended for analysis. Application of OLS regression to censored data will distort both coefficients and standard errors.

Recommendation 1

Tobit regression is specifically designed to analyze censored outcome data. It gives less biased coefficients and more efficient standard errors than OLS applied to the same data. It is available in most major statistical packages, including SAS, Stata, and SPSS. It is more powerful than polychotomous logistic regression and will return any blood lead differences between PLSLR and non-PLSLR groups, instead of just differences in category of blood lead**.**

Some of the outcome data within the specified date interval includes multiple measurements of blood lead on the same subjects. Brown et al. used a selection algorithm to pick the single blood lead measurement used in their analysis of PLSLR effect: if the blood sample was drawn by venous blood sample, they selected the highest blood lead available in the multiple blood lead series for that subject; if the blood sample was by finger-stick and thus capillary, they selected the lowest blood lead available for that subject; in the case of unknown method of blood draw, they defaulted to the capillary blood selection criterion. The algorithm was applied to several hundred subjects with multiple blood lead measurements.

Though there is sufficient information in the literature to support such an algorithm to reduce artifact, especially for capillary samples, a result of using the algorithm was to not always select the blood lead sample nearest to the PLSLR event. The mean interval between PLSLR and blood sample was over 300 days with a range extending to two years. The selection algorithm was responsible for lengthening the time interval between PLSLR and blood lead draw, since the first available blood lead measurement for each subject was not always used.

Recommendation 2

Tobit regression should be used on data generated by using the Brown et al. selection algorithm for multiple blood lead samples in the same subjects. An alternative tobit analysis should be used selecting the first available blood lead measurement after PLSLR (or in the case of the non-PLSLR group, the first available blood lead measurement within the specified time period). Dummy variables indicating sample type (venous, capillary, and unknown) should be included in the tobit regression. If gender is available in the data set it should also be included in the tobit regression.

If PLSLR produces an increase in water lead downstream of the replacement and that increase decreases in time after replacement, as the admittedly flawed available data seems to indicate, then the time between the PLSLR and drawing the blood sample will influence the lead concentration of the blood sample.

Lead solubility in water is influenced by water temperature. Though measurements of water sample temperature are not available in the data set, the date of the blood sample and the date of the PLSLR are available. Since water temperature varies according to season, these dates can be used as proxies for water temperature.

Recommendation 3

Include the interval between PLSLR replacement and blood draw as a continuous variable in the tobit regression. Include the date of blood draw as a cyclic (sum of sine and cosine terms, assuming a 12 month periodicity) indicator of water temperature.

Age is an important determinant of blood lead in children. The dependency of blood lead on age often follows a non-linear pattern, rising from birth to 1-2 years, then decreasing.

Recommendation 4

Include a second-order polynomial term for subject age in the tobit regression.

Comparing two independent groups, though a standard in experimental design, depends on being able to control for group differences that not are not the focus of the research to avoid detecting spurious relationships. Repeated measures designs are one of the best means to assure that subject-specific characteristics are either maintained or measured and thus controlled for during the course of the research. A subset of subjects has blood lead measurements both before and after PLSLR during the time period considered. Please consider that blood lead measurements may be biased toward higher values in children with multiple blood lead measures, since elevated blood lead is often an indication for making multiple measurements. Thus, this analysis should be considered supplemental to the group comparison analyses considered above. Change in blood lead will be the important outcome in such analyses, not absolute blood lead.

Recommendation 5

Use a mixed model, repeated measures analysis on only the subjects with before and after PLSLR blood lead measures. The analysis will be with unbalanced panels, as each subject will have a varying number of pre and/or post-PLSLR blood lead measures. Though Stata has a random effects tobit model available, it does not have a mixed tobit model in the current version 11. SAS may have a mixed model tobit available. To our knowledge, only LIMDEP (Econometric Software) has an unbalanced mixed model tobit design available.

Model coefficients and standard errors are interpretable only to the degree to which model assumptions are met. A case in point is the form of the outcome variable. Skewed outcome variables often result in residual heteroscedasticity, a violation of a model assumption. Often there are remedies for non-compliance with model assumptions as simple as variable transformation.

Recommendation 6

All models should be thoroughly diagnosed for compliance with model assumptions. Alternative forms of the outcome variable, blood lead, should be tested for assumption compliance. Each tobit model should be tested with blood lead in original format and natural log transformed blood lead to determine the best fitting characterization. Continuous independent variables in various transformations should also be considered to better determine the functional form of the fit. Heteroscedasticity-robust standard errors should be calculated where variable transformation cannot resolve issues of heteroscedasticity of model residuals. Boot-strap standard errors may also be calculated and compared to the standard errors calculated according to other formulations. Care should be taken to avoid multiple collinearity.

The data set used for analysis could be expanded if it is found that the Washington, DC water supply has continued to use chloramine with orthophosphate beyond the 12/31/2006 cutoff date applied in the Brown et al. analyses.

Recommendation 7

Consider using data collected after 12/31/2006 to expand the analyzed data set to improve power.

APPENDIX C - Reported Tap Water Lead Levels Following PLSLR

Table C-1: Summary of Relevant Findings

Study	Summary of Relevant Findings
Britton and Richards, 1990	First-draw (FD) and random daytime (RDT) samples were collected on 10 days prior to a single PLSLR, 5 to 16 days after the PLSLR, then 2 and 4 mos. later. Prior to PLSLR only 1 sample (out of 20) had >0.1 mg Pb/L. On days 5 – 16, 3 of 10 FD samples and 3 of 10 RDT samples had >0.5 mg Pb/L, with a maximum of >4 mg Pb/L in the day-8 FD sample. On days 56 – 63, all FD and RDT samples (6 each) had <0.1 mg Pb/L; however, on days 64 – 69, all samples (4 of each type) had 0.1 – 0.25 mg Pb/L (perhaps for reasons unrelated to PLSLR, such as a change in water quality or temperature). After 4 mos., all FD and RDT samples (10 each) had <0.1 mg Pb/L, and the avg. Pb level was about 20 – 25% lower than pre-PLSLR; but the lower Pb levels may have been due in part to the long-term effects of optimized corrosion control treatment (OCCT) implemented shortly before pre-PLSLR sample collection.
Commons, 2011	FD and “run until cold” samples (6 h stagnation) were collected before and 12-h, 3.d, 2-wks, and 4-mos after PLSLR at 8 sites. Profile samples were also collected before and 4 mos after PLSLR. After 12 h, Pb was higher in FD samples at 6 of 8 sites, but the increase was <5 µg/L at 2 sites. After 2 wks, Pb levels were more variable than before PLSLR but similar on average. After 4 mos, sequential sampling showed an average reduction of 62% in Pb delivered to the tap (range = 36 – 79%). The data are further examined, collectively, in Table C-2. Pb levels in the first-draw samples were significantly elevated (nearly four-fold, on average) after 12 hours; but at 3 days and 2 weeks, they were not significantly different from pre-PLSLR levels; and after 4 mos they were lower. The results for the run-until-cold samples were similar; the Pb levels were slightly higher, on average, at 3 days and 2 weeks, but the averages were below the AL and the “error bars” overlapped with those of the pre-PLSLR samples. Temperature data were not presented. The Pb levels after 4 mos may have been lower due to a lower water temperature. Temperatures of FD samples collected inside the home after 6 hours stagnation should be similar year round, but the customer-owned LSLs may have been colder.
Gittelman et al., 1992	Data from 21 LSLR sites are summarized (unclear if partial or full LSLRs; presumably FD samples; sample timing not described; study presumably done prior to OCCT). Pb increased slightly after LSLR, with 90th percentile ~14 ppb and maximum ~17 ppb.
HDR, 2009 (same study reported by McFadden et al., 2011, who showed only summary data)	Profile samples were collected before LSLR, after PLSLR, and then again after FLSLR at 4 sites, 3 with galvanized plumbing and 1 with mixed materials. At site G1, Pb levels were increased in some samples 1 d, 2 wks and 4 wks after PLSLR; at 8 wks, Pb was elevated only in the FD sample and avg. Pb was ~40% lower the pre-PLSLR. After FLSLR, Pb was <AL in all samples from 1 d on, and more than 50% lower than the pre-LSLR. Results were similar at site G3, but following FLSLR, Pb levels were

	elevated on day 1 and in the 8-wk FD sample (18 ppb). At site G2, post-PLSLR Pb levels were elevated in the interior-plumbing portions of all profiles (1-d and 2, 4, and 8-wk), but lower in the new Cu line; similar results were obtained following FLSLR. At site M1, Pb levels were higher 1 d and 2 wks after PLSLR, but 4 and 8 wks later Pb was <AL in all samples and ~33% lower on avg. than pre-PLSLR. After FLSLR, Pb was <AL, except the FD and 2nd-draw samples on day 2 (~19 & 22 ppb, resp.), and >50% lower on avg. than pre-LSLR.
Muylwyk et al., 2009	Compliance and profile samples (30-min stagnation) were collected at 3 sites in Guelph, Ontario (PLSLRs, with a full LSLR completed at one site on day 7). At site 1, Pb was > 20 ppb in all pre-LSLR samples. After PLSLR, Pb levels were variable for 3 days, but < 20 ppb in all samples and <10 ppb in all compliance samples (Ontario standard). After full LSLR (day 7), Pb was <10 ppb in all samples (1 d and 1, 2, 3, and 7 wks later), and 91% lower after 2 months. At site 3, Pb was ~21–24 ppb in all pre-LSLR samples. After PLSLR, Pb was lower in most samples, but elevated (20 to 45 ppb) in some samples during the first 7 days (and in one compliance sample taken 3 months later). Pb was 43% lower after 9 months; but Pb levels were > 10 ppb in all compliance samples during the following year. At site 5, Pb was 45–160 ppb in the pre-LSLR samples and 60 ppb in the pre-PLSLR compliance sample, but <45 ppb in all post-PLSLR samples except one. Pb levels in were variable over the next year and remained > 10 ppb in compliance samples until the 6 mo and 1 yr samples were collected.
Sandvig et al., 2008	Case studies and field studies were done at several utilities. Case study results included: 1) at DCWASA, Pb levels > 1,000 ppb were observed following PLSLR; 2) at Louisville Water Co., elevated Pb levels were found while flushing immediately after PLSLR, but could be reduced to <AL by forward flushing for 15 minutes; and FD samples after PLSLR were all < 6 ppb at four locations, with one exception; 3) at Madison Water Utility, total Pb was erratic for several years after FLSLR, which was attributable to Pb associated with Fe & Mn scales; and 4) at Cincinnati, a 1991 study found high Pb levels immediately after PLSLR (about 300 ppb in one sample, according to DeMarco, 2004), but lower levels 9 months later. FD and profile samples (after 6 hrs stagnation) were collected in cooperation with 4 utilities for 14 FLSLRs, 2 PLSLRs, and 1 PLSLR where the customer's line was copper. In Boston, particulate Pb was elevated (up to 800 ppb) at 3 of 4 sites immediately after FLSLR. For the PLSLRs: in DC, Pb in the FD samples increased from 3.7 to 7.5 ppb after 2 months, but Pb was <AL and the total mass of Pb in the profile samples was 15 μg lower; and, in Toronto, Pb in the FD samples dropped from 18.8 to 16.0 after 2 months, but was still >10 ppb, the provincial standard. Many sites registered high Pb for up to 3 days following both partial and full LSLRs; but by 1 to 2 months after partial or full LSLR, all sequential samples at the tap were either lower than

	before or essentially the same. They concluded that "elevated lead levels may occur in standing samples in the short term (up to 3 days), and may in some cases persist for longer periods of time, particularly if only a portion of the lead service line is removed"; and a "rigorous flushing regime (up to 60 minutes) may help…"
Swertfeger et al., 2006	Samples were collected before, one wk after, and at one mo intervals after 5 FLSLRs, 5 PLSLRs, 6 PLSLRs with the freshly cut end protected by Teflon, and 5 control sites. Samples were FD after at least 6 h stagnation, then after a 3-min flush and a 10-min flush. Tap flow rates not reported. The pH of the distributed water was increased from 8.5 to 8.8 before 1-wk samples at all sites and the 1-mo samples at the FLSLR sites were collected, causing Pb levels to decrease at the control sites. Overall, PLSLR sites had Pb levels similar to those at the control sites. Only FLSLR resulted in a significant Pb reduction, short (first week) or long term, at all sites tested. Elevated Pb levels were observed for a week to a month at 4 of 11 PLSLR sites. After 1 mo, Pb averaged 11.5 μg/L for the controls and 10 μg/L for the PLSLRs. The authors concluded that PLSLR may not necessarily be effective in reducing water lead levels compared with performing no replacement.
USEPA, 1991b (Internal EPA report by Wysock)	Morning FD and service line samples (based on wasting an estimated volume of water) were collected 4 times before and 3 times after PLSLRs at 15 sites (8 with no internal LSLs). Softeners in 14 of 15 homes were to have been bypassed, but all may not have been bypassed. Results before and after did not differ at the 95% confidence level for either FD or LSL samples; but all sites had Pb levels <AL prior to PLSLR, so replacement would not have been required under the LCR.
Weston and EES, 1990 (cited as AWWA, 1990 in Table 11 in the LCR, USEPA, 1991a)	At 9 sites in Newport News, samples were collected at the water meter (not the tap) before, immediately after, and 2 wks after (presumably partial) LSLRs. Pb levels were elevated, up to 106 ppb, at 8 of 9 sites immediately after LSLR, but all lower 1 to 2 weeks later.
Data Provided by Public Commenters	
Commenter	Summary of Relevant Results
Steve Reiber, March 30, 2011	In one graph (p. 7 of his presentation), Mr. Reiber presented data from DC Water showing average post-PLSLR Pb levels in FD and run-to-cold samples over time, e.g., within 3 days (n = 229), 4 to 7 days (n =105), etc. The total number of samples represented in 511. The data clearly show that, on average, post-PLSLR Pb levels were sharply elevated within the first 3 days (average = 381 ppb in FD samples) and from days 4 to 7 (average = 81 ppb in FD samples); but the average Pb levels in both FD and run-to-cold samples were <15 ppb for all time periods between 1 wk and 1 mo, and <10 ppb between 1 and 2 mos. Post-PLSLR Pb levels, on average, clearly dropped dramatically after 1 wk; however, the spread of the data (standard deviation and maximum values) was not shown, so the magnitude and duration of elevated Pb levels at individual sites are not evident. A second graph (p. 8) shows profile samples collected at one home after PLSLR. Pb levels were high in a galvanized section of pipe 1 d after

	PLSLR, but only slightly elevated at 2 and 4 weeks (one sample > 15 ppb in each case), and low (all < 15 ppb) at 8 weeks.
Ralph Scott, May 10, 2011	Mr. Scott provided DC Water data on post-PLSLR Pb levels, but noted that some sample dates may be in error and that homeowners were instructed to run all their home plumbing fixtures at a high rate for several minutes prior to collecting samples. He stated that the average FD level was 200 ppb and the average 2nd draw (run-to-cold) level was 43 ppb; but it is not clear which data set these average were derived from. The data in Table D2 (324 samples collected at various times after PLSLRs) show a median Pb level of 9 ppb in FD samples; but the 90th percentile was 70 ppb, 30 samples had Pb > 0.1 mg/L and 9 had Pb > 1.0 mg/L. So, although FD Pb levels were, on average, <AL, they can be much higher in some samples. Since the sampling dates are in question, it is not clear whether the high levels occurred immediately after PLSLR or later on, nor can possible seasonal effects be reliably ascertained. If the FD samples were collected after an appropriate (e.g., 6 h) stagnation period, the results are not comparable with those of FD samples in other studies. Until these issues are addressed and resolved, it is not possible to draw many reliable conclusions from these data. Mr. Scott also provided copies of LCR compliance reports obtained from DC Water. The report for Jan – June 2006 shows 90th percentile Pb at 10 ppb in FD and 12 ppb in 2nd-draw samples (82% full lead lines; 18% partial). The July – December 2006 report shows 90th percentile Pb at 12 ppb in FD (76% full lead lines; 24% partial). The data were presumably collected using the sampling procedures specified by the LCR; but the results for full and partial LSLRs are not broken down separately, so it is not clear whether the results for the PLSLR samples were lower than those for no replacement. In any event, since the 90th percentile values were below the AL, no LSLRs were required.
Thomas W. Curtis, May 12, 2011	Mr. Curtis provided data summaries (Tables C-3 and C-4) obtained from DC Water. Table C-4 summarizes data for FD and 2nd-draw (run to cold) samples after no replacement, PLSLR, and FLSLR during periods of stable OCCT. Pb levels 1 – 3 yrs after PLSLR were similar to those for no replacement (2006 – 2007), but were clearly much higher than those found 2 yrs after full LSLR (March 2008 special study). Based on the 2009 – 2010 data, Pb levels 2 – 4 yrs after PLSLR were significantly lower than in the "no replacement" samples, and the 90th percentile values were 4.2 and 3.6 ppb in the FD and 2nd-draw samples, resp. Table 2 summarizes data for 1st and 2nd draw samples 5 – 8 mos post-LSLR (18 full, 7 partial). Pb levels were low (median and average values all < 2.3 µg/L) and similar for both full and partial LSLR. The accompanying text indicates that only one sample exceeded 10 ppb (11.5 in a 2nd draw post-PLSLR sample). Collectively, these data suggest that PLSLR, after an extended period of time, on average, does little or no harm and perhaps some good.

Additional References

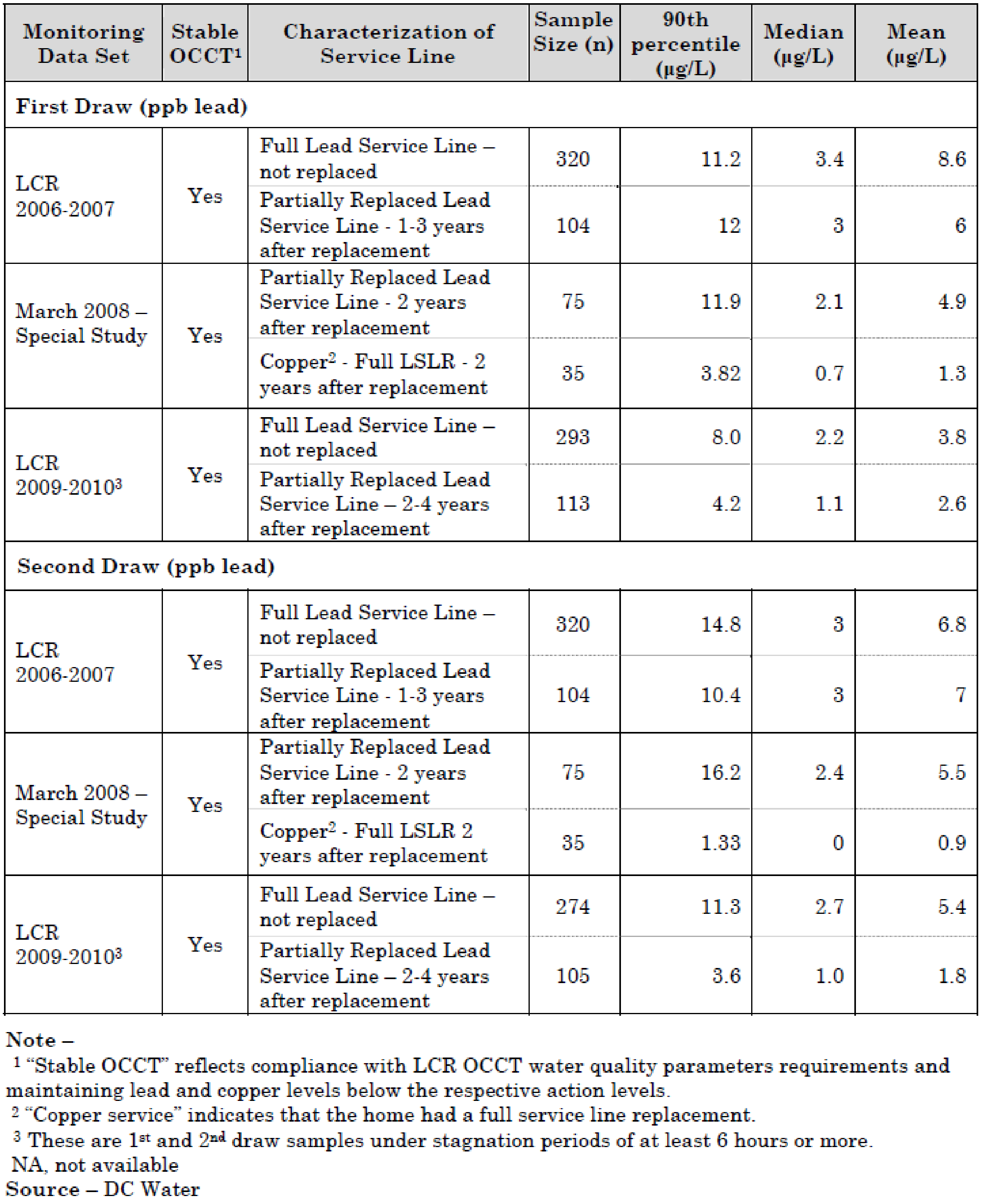
Commons, C., 2011. Effect of Partial Lead Service Line Replacement on Total Lead at the Tap. Unpublished report describing a study by the Rhode Island Department of Health, submitted to the Panel during the comment period.

Demarco, J., 2004. Case Study #1: Greater Cincinnati Water Works Partial Lead Service Line Replacement. USEPA Workshop on Lead Service Line Replacement. October 26-27, Atlanta, Ga.

Table C-2: Further analysis of the combined results of Commons (2011) for 8 PLSLRs

Time	Sample Type	Avg. Pb (mg/L)	Std. Dev. (mg/L)	n > AL (out of 8)
Pre-PLSLR	First Draw	0.016	0.010	4
12 hours	First Draw	0.061	0.055	6
3 days	First Draw	0.019	0.019	2
2 weeks	First Draw	0.014	0.007	4
4 months	First Draw	0.007	0.004	0
Pre-PLSLR	Run until cold	0.009	0.004	1
12 hours	Run until cold	0.031	0.029	4
3 days	Run until cold	0.012	0.007	2
2 weeks	Run until cold	0.011	0.007	3
4 months	Run until cold	0.003	0.002	0

Table C-3: Observed Lead Levels After LSLR



Monitoring Data Set	Stable OCCT[1]	Characterization of Service Line	Sample Size (n)	90th percentile (µg/L)	Median (µg/L)	Mean (µg/L)
First Draw (ppb lead)						
LCR 2006-2007	Yes	Full Lead Service Line – not replaced	320	11.2	3.4	8.6
		Partially Replaced Lead Service Line - 1-3 years after replacement	104	12	3	6
March 2008 – Special Study	Yes	Partially Replaced Lead Service Line - 2 years after replacement	75	11.9	2.1	4.9
		Copper[2] - Full LSLR - 2 years after replacement	35	3.82	0.7	1.3
LCR 2009-2010[3]	Yes	Full Lead Service Line – not replaced	293	8.0	2.2	3.8
		Partially Replaced Lead Service Line – 2-4 years after replacement	113	4.2	1.1	2.6
Second Draw (ppb lead)						
LCR 2006-2007	Yes	Full Lead Service Line – not replaced	320	14.8	3	6.8
		Partially Replaced Lead Service Line - 1-3 years after replacement	104	10.4	3	7
March 2008 – Special Study	Yes	Partially Replaced Lead Service Line - 2 years after replacement	75	16.2	2.4	5.5
		Copper[2] - Full LSLR 2 years after replacement	35	1.33	0	0.9
LCR 2009-2010[3]	Yes	Full Lead Service Line – not replaced	274	11.3	2.7	5.4
		Partially Replaced Lead Service Line – 2-4 years after replacement	105	3.6	1.0	1.8

Note –

[1] "Stable OCCT" reflects compliance with LCR OCCT water quality parameters requirements and maintaining lead and copper levels below the respective action levels.

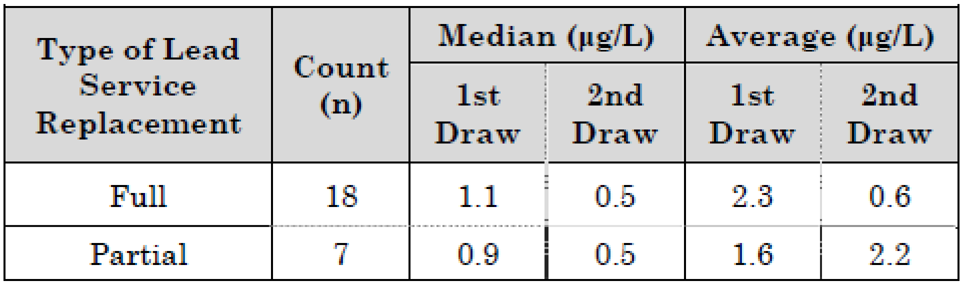
[2] "Copper service" indicates that the home had a full service line replacement.

[3] These are 1st and 2nd draw samples under stagnation periods of at least 6 hours or more.

NA, not available

Source – DC Water

Table C-4: Lead Levels Observed 5 – 8 months After LSLR



Type of Lead Service Replacement	Count (n)	Median (µg/L)		Average (µg/L)	
		1st Draw	2nd Draw	1st Draw	2nd Draw
Full	18	1.1	0.5	2.3	0.6
Partial	7	0.9	0.5	1.6	2.2

Source – DC Water

APPENDIX D - Sampling Methods for Lead in Tap Water

This appendix identifies methods for collecting samples for the determination of Pb in tap water, summarizes their purposes, and describes some of their strengths and weaknesses. The purposes of this discussion are: 1) to serve as a source of information for readers who may be unfamiliar with one or more of the methods described, 2) to support statements made in the main body of the report regarding the tendency of sampling methods to undersample or oversample particulate Pb, and 3) to help the reader understand why Pb levels in samples collected using a particular method are not necessarily a good measure of the Pb levels to which consumers of drinking water are actually exposed. The SAB did not intend to prepare an exhaustive list of all methods in use, to exhaustively review and evaluate available methods, or to recommend particular methods for future use.

Tap-water samples for Pb 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 the faucet and lines and fittings under the sink. This is useful in assessing water corrosivity and the effectiveness of a utility’s optimized corrosion control program, and also in determining the Pb levels to which consumers may be exposed if they take a drink of water, after it has stood for 6 hours in the faucet, before flushing the water from the tap. First-draw samples are not filtered, so they may contain particulate Pb; but particulate Pb initially present in the water, prior to stagnation, may settle out in the water lines during the stagnation period and may therefore be significantly undersampled when the sample is collected. First-draw samples often have Pb levels grossly different from those in subsequent samples collected sequentially, as documented in numerous studies, some of which are cited in Table C-1. This is especially true in samples collected in homes having full or partial LSLs, or in homes having interior plumbing materials heavily encrusted with Pb-bearing deposits (HDR, 2006; McFadden et al., 2011). In such cases, both dissolved and particulate Pb levels can be much higher than those in the first-draw sample.

2) **LSL sampling –** required by 40 CFR 141.86(b)3 for determining Pb 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 Pb) 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 collecting 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 nicely complements first-draw sampling by attempting to obtain a sample from the LSL itself. However, all three sampling options are problematic in that the Pb levels measured may be considerably lower than those to which the consumer is actually exposed when drinking water left standing in the LSL. Water collected using the first sampling option may not be from the LSL, because pipe volume between the LSL and the tap could be miscalculated as a result of mathematical or measuring errors, or because the volume of the pipe occupied by scale and corrosion products was not taken into account. A

sample drawn directly from the LSL will be a standing water sample, so particulate Pb could potentially be grossly undersampled due to settling. Particulate Pb could also be oversampled or undersampled depending on flushing of the line (flow rate and duration) prior to the stagnation period, since aggressive flushing can increase particulate Pb levels (by dislodging them from the pipe surfaces) or flush them out the system. If the third option is employed, a significant change in temperature could indicate the presence of relatively Pb-free water from the main rather than water from the LSL; and difficulty sensing a temperature change, as may occur in the summer months when surface water temperatures are often close to room temperature, may result in collection of a sample from a random location.

3) **Profile sampling –** used to examine the Pb 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 Pb 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; but Pb levels are known to vary with flow rate (e.g., Britton and Richards, 1990; HDR, 2009; Deshommes et al, 2010; McFadden et al, 2011). Using a low flow rate minimizes erosion and resuspension of particulate Pb, so this method can potentially result in gross underestimation of particulate Pb. Another disadvantage of this protocol is that a large number of samples must be collected and analyzed, increasing monitoring costs.

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 Pb 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 certain ways from those actually consumed. For example, if samples are not collected early in the morning for fear of waking the residents, a representative number of first-draw (standing water) samples may not be included and the results for dissolved Pb may therefore be biased on the low side; or, if the samples are collected without flushing and the consumer normally flushes the tap first, the results may be biased high.

5) **Others protocols –** used by researchers for specific purposes. Examples include high velocity, particle stimulation, and water hammer simulation sampling protocols designed to stimulate release of particulate lead (e.g., HDR, 2009; Deshommes et al, 2010). When using these protocols the Pb levels in the samples may exceed those to which consumers are normally exposed but they may represent worst-case conditions reasonably well.

The sampling protocols currently specified in the LCR have significant limitations, as do other protocols. The SAB recognizes that these protocols were adopted for pragmatic reasons. However, the SAB also recognizes that the results obtained using these methods are widely perceived as being useful for estimating the tap-water Pb levels to which humans are exposed when in fact they may result in significant underestimation or overestimation of actual exposure. Exposure assessments are complicated not only by the limitations of sampling methods but also by the fact that, in a given home, little or no information is typically available regarding consumer behavior, e.g., how long the tap is run before taking a drink, how fast the water is run when flushing, how rapidly the tap is turned on and off, whether the water is filtered, how much water is actually consumed, whether the water is used for cooking, etc. The limitations of current sampling protocols and their usefulness in producing data suitable for exposure assessments should be carefully considered in future revisions to the LCR, in evaluating the results of studies of Pb in tap water, and in assessing the impacts of tap-water Pb levels on human health.

APPENDIX E - Techniques for Locating, Identifying, Replacing, and Rehabilitating Lead Service Lines

Although seemingly a simple matter, the replacement of any water service line, regardless of the material of composition, is not a simple one-step task. While the response to Issue 4 highlights those techniques used in PLSLR that the SAB finds to have the greatest potential for releasing lead following a PLSLR, the list of techniques discussed is not complete. This appendix describes additional techniques that are used to locate lead service lines, identify/confirm the composition of the service line material, then replace or rehabilitate the line. The SAB finds that these techniques do not contribute to the elevated Pb levels observed following a PLSLR. Their inclusion in this appendix is offered as verification that the techniques were considered during the deliberations.

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. Although some techniques used for locating service lines are minimally invasive (some of the direct methods used to identify the service line material require physical access and direct contact with the service line) there is no evidence to suggest that these methods contribute to lead release following PLSLR. The SAB found no evidence that these methods contribute to the elevated lead levels following PLSLR.

Using indirect methods for locating and identifying LSLs requires an extensive database that accurately characterizes home age, plumbing materials, and renovation history. In general, the indirect methods have been demonstrated to be less accurate than direct methods leading to the misidentification and subsequent misclassification of LSLs[1]. The SAB is confident that indirect LSL locating techniques do not contribute to lead release following PLSLR.

Replacement and Rehabilitation Techniques

According to Kirmeyer et al. (2000) the techniques used to access or rehabilitate LSLs include: open trench, pipe bursting, pipe pulling (moling), lining an existing LSL, or coating an existing LSL. Unlike the open trench, which exposes the service line, replacing an LSL by pipe bursting or pipe pulling (moling) on a new or existing route involves minimal trenching. In pipe bursting, 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 (moling) along the same route following parallel to the existing line.

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. Although these techniques have been employed by some utilities in the UK and the Netherlands, practical and regulatory concerns have thus far limited their use in the U.S.

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[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%.

Although the Kirmeyer et al. (2000) study provided an excellent summary of techniques that could be used for a PLSLR, the study did not include a water quality evaluation of these rehabilitation techniques, hence the SAB was unable to evaluate the impact that the techniques might have on lead release.

Generally, the SAB finds that, unless the PLSLR 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 LSLR.