UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGIONAL ADMINISTRATOR
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MEMORANDUM

SUBJECT: Region 5's Experience in Implementation of the Lead and Copper Rule

FROM: Robert A. Kaplan
Acting Regional Administrator

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TO: Michael H. Shapiro
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The purpose of this memorandum is to provide information to the Office of Water (OW) based on Region 5 experiences in implementing the Lead and Copper Rule (LCR or Rule) provisions of the Safe Drinking Water Act (SDWA). As stated in OW's Lead and Copper Rule Revisions White Paper (October 2016), addressing the contribution of legacy lead in residential plumbing involves complex technical issues and policy considerations. We provide this information in the hope that it will be of assistance to OW as it considers revisions to the LCR.

Region 5 has substantial experience in LCR implementation issues, given the abundance of lead-containing plumbing in older, industrialized cities in the upper Midwest. Region 5's experience with LCR implementation and drinking water lead levels in a number of communities including Flint, Mich.; East Chicago, Ind.; Chicago, Ill.; Galesburg, Ill.; Sebring, Ohio and other cities has given the Region an understanding of how the protections of the Rule work in actual practice.

The elevated levels of lead in drinking water in Flint in particular have provided extensive real-world information on key parts of LCR implementation. Flint is now one of the most sampled water systems in the nation. Michigan undertook a large-scale resident sampling effort in Flint resulting in the collection of tens of thousands of samples over a period of years. It has also been sampled extensively by EPA Region 5 and ORD scientists who conducted in-home testing themselves, using controlled and consistent techniques, with analysis by EPA labs. Further, Region 5 and ORD deployed pipe loops in the Flint Water Treatment Plant, which exposed actual Flint lead lines to various water conditions to study the type, quantity, and rate of lead released from the pipes. This wealth of analytical information derived from the sampling data before, during, and after the crisis provides unique insight into the operation of the Rule, and informs possible revisions. In addition, the EPA Flint Safe Drinking Water Task Force, a technical cross-agency group assigned to assess and make recommendations to the state of Michigan and the City of Flint (chaired by the Deputy Regional Administrator of Region 5), also generated significant insights into the implementation of the LCR, including its methodologies and underlying science.

The Region agrees that the LCR has helped to lower lead levels in the nation's drinking water -- and the median blood lead level in the nation's children -- since its promulgation in 1991. Nevertheless, our experience has made it clear that improvements to the Rule are needed to better protect public health. This is especially true with regard to young children, who are susceptible to the health impacts from even low levels of lead in drinking water – perhaps at levels less than the current Rule's Action Level (AL) of 15 ppb.[1]

There is a perception among states, cities, public utilities, elected representatives, and other decision-makers that appropriate implementation of the existing LCR will adequately protect the public from lead in drinking water. Based on lessons learned in the communities identified above about the actual levels of lead in drinking water, we do not believe that will always be the case. Proper implementation of and compliance with the LCR may not provide certainty that the public is protected from elevated levels of lead, particularly in communities with lead service lines (LSLs), and particularly with regard to susceptible populations such as young children. This is illustrated by recent examples from Region 5. In Flint and East Chicago, there were exposures to elevated lead levels, and the levels went undetected notwithstanding the implementation of or compliance with the LCR in those communities. Indeed, if the elevated lead levels in those communities had not been detected by sampling activities done wholly outside of the requirements of the LCR, it is possible that actions targeting those elevated levels would have been delayed (or may not have been taken).

Key LCR Implementation Issues: Region 5 has encountered several issues which tend to reduce the effectiveness of the current LCR. As stated previously, the Region believes that the timely provision of its observations may assist in any revisions to the LCR that are currently underway. We focus on the following issues, discussed below and summarized in Appendix A to this memorandum.

Issue 1. LCR Sampling Protocols.

In communities with LSLs, the LCR compliance sampling protocol may underestimate lead levels actually present in drinking water, which can lead to incorrect signals that Corrosion Control Treatment (CCT) is adequately addressing lead in drinking water. We have learned that the protections of the LCR depend in large part on the sampling protocols. If sampling anomalies bias a result low, the protections of the LCR may not be triggered in a timely manner – or at all. As set out below, OW issued guidance in 2016 after the Flint crisis that will help avoid a number of the issues. However, there are other fundamental issues that remain to be addressed.

The LCR compliance sampling protocol requires that:

- the water collected for lead testing from a residence must have been standing in the home's pipes for at least 6 hours;

[1]Some researchers have associated potential health impacts in young children with low levels of lead in water, see Simoni Triantafyllidou, Daniel Gallagher, and Marc Edwards, "Assessing risk with increasingly stringent public health goals: the case of water lead and blood lead in children," *Journal of Water and Health* 12, no. 1 (March 2014): 57-68, https://doi.org/10.2166/wh.2013.067.
EPA and the Centers for Disease Control and Prevention (CDC) agree that there is no known safe level of lead in a child's blood. See "Low Level Lead Exposure Harms Children: A Renewed Call for Primary Prevention," Advisory Committee on Childhood Lead Poisoning Prevention, Centers for Disease Control and Prevention, January 4, 2012, https://www.cdc.gov/nceh/lead/acclpp/final_document_030712.pdf.

- the water collected is "first draw" water (*i.e.,* the water that comes out of the faucet immediately upon opening the tap, without letting water go down the drain before filling the bottle);
- the amount of water collected is one-liter; and
- the residences sampled are those most likely to have a high risk of lead in the drinking water (*e.g.*, a home with a LSL or lead solder).

However, as we learned in Flint and have observed in other communities, a number of practices were being employed during water sampling that could minimize the amount of lead detected in the sampled water, including:

- running ("flushing") the water before the start of the minimum 6-hour standing time (since this pre-stagnation flushing can dilute the contribution of lead from a LSL, if present);

- removing and cleaning aerators prior to LCR sampling (cleaning aerators before sampling could remove particles that contain lead, thereby biasing results low compared to typical exposure for that sample site);

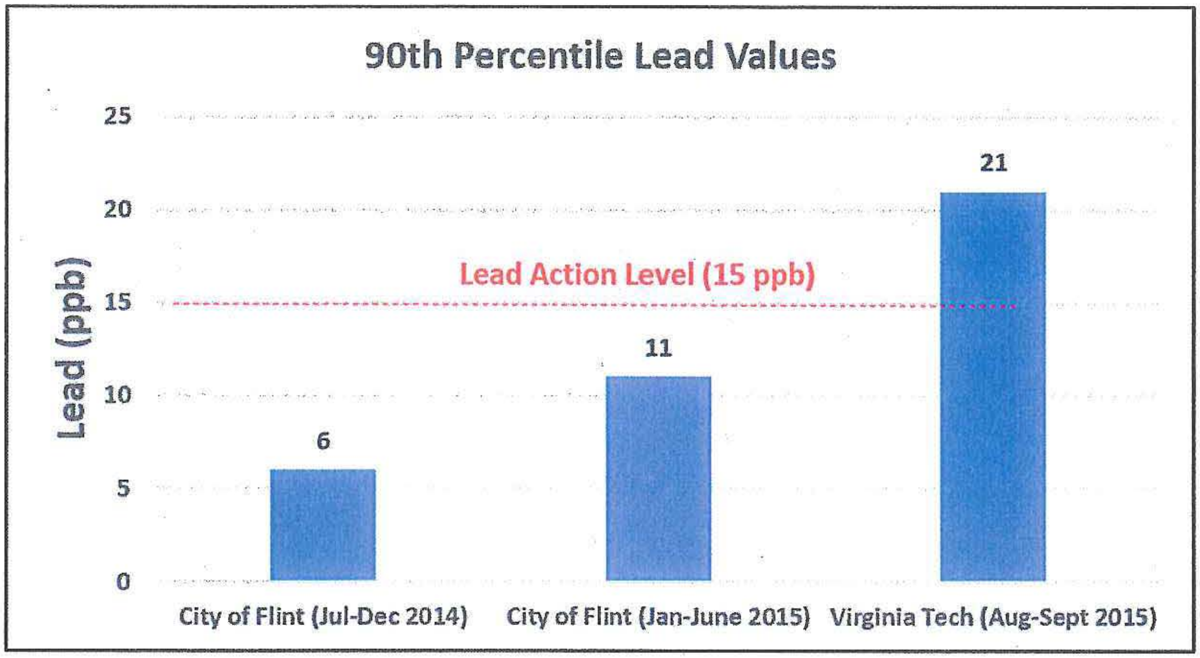
- collecting samples in narrow-mouth bottles (this tends to make samplers run the tap water at a lower flow rate which is less likely to dislodge particulate lead, if present); and

- failing to ensure that the homes sampled were high-risk for lead. (*e.g.*, homes with LSLs).

The City of Flint's sampling illustrates the point. In 2014-2015, two 6-month rounds of LCR sampling that Flint undertook resulted in 90th percentile values that were below the lead Action Level (AL) of 15 ppb. Notably, the sampling seemed to demonstrate that Flint remained below the lead AL, even in the absence of any CCT. The LCR sampling results for Flint were 6 ppb in January 2015 and, during the height of the crisis, 11 ppb in July 2015. Even as Flint's lead lines were stripped of protective coating from the corrosive Flint River water, the LCR did not reveal a need for action; indeed, the data tended to allay concerns rather than indicate that swift action was needed.

The nature and extent of the damage to Flint's pipes was first revealed by sampling conducted in Flint by Virginia Tech (VT) for approximately the same period. That "first draw" sampling indicated that Flint was actually exceeding the AL. See Figure 1, below.

Figure 1. 90th Percentile Lead Levels in City of Flint, 2014-2015



VT's sampling avoided three of the four commonly-used practices identified above (*i.e.*, pre-flushing, aerator cleaning, and low flow rates) that can lead to finding lower and non-representative levels of lead being detected. Consequently, the system-wide problem that was occurring in Flint was not detected in Flint until non-LCR investigative sampling was conducted by the VT researchers. (It should be noted that even the VT sampling did not target the highest risk sites, as required by the LCR; had it done so, the lead levels detected by VT would likely have been higher.)

To address some of the implementation issues with the LCR compliance protocol identified above, in February 2016, OW wrote its memo Clarification of Recommended Tap Sampling Procedures for Purposes of the Lead and Copper Rule. Specifically, the February 2016 memo provided the following advice to public water systems (PWSs):

a) Do not recommend removal and cleaning of aerators prior to LCR sampling (because it could remove particles that contain lead, and then bias results low compared to typical exposure for that sample site);

b) Do not ask samplers to run the water before the start of the minimum 6 hour standing time (since this pre-stagnation flushing can dilute the contribution of lead from an LSL, if present); and

c) Collect samples in wide mouth bottles to allow samplers to run the water at a higher flow rate (this more closely represents typical water use and is more likely to dislodge lead particles, if present).

A follow-up memo in October 2016 recommended PWSs update their distribution system materials evaluations as needed to maintain a robust pool of confirmed high-risk sites (e.g. homes with LSLs) available for LCR compliance sampling.

While the guidance from the two 2016 memos should improve the accuracy of sampling results, there are two fundamental issues with the LCR sampling protocol that are of greater concern to Region 5 than those covered by the memos: (1) first-draw sampling and (2) identification of Tier 1 sites.

"First Draw" Sampling. Historically, lead laterals were used to connect water mains from the street to residential interior plumbing. By only sampling the first liter of water from the tap, the LCR captures water already in interior plumbing, but not necessarily water that has been in contact with the lead lateral for an extended period of time. Based on our implementation experience in a number of communities, field sampling data show that for sites served by LSLs, first-draw sampling misses the highest levels of lead actually present in a home's drinking water ("peak lead") and, consequently, may underestimate lead levels. This is true even where the types of sampling issues discussed above have been addressed. Such underestimation of lead levels based on first-draw sampling may lead to the incorrect conclusion that CCT is adequately addressing lead in drinking water.

In 2011, Region 5 partnered with the Chicago Department of Water Management to conduct a study to evaluate the effectiveness of the regulatory water sampling protocol used by a PWS to monitor lead levels under the LCR.[2] The overall findings from the study were that:

1) the existing LCR sampling protocol can significantly underestimate lead release and lead levels in drinking water at sites with LSLs;

2) sites with disturbed LSLs had the highest lead levels;

3) sites with disturbed LSLs and low water use may have high lead levels for years; and

4) the time required to flush water containing lead from taps is in many cases greater than the time recommended by EPA and other sources for homes with LSLs.

Figure 2, below, shows the significant difference between the lower lead levels captured by first-draw sampling, and the significantly higher lead levels that are likely to be detected if a larger amount of water in a home's plumbing lines is sampled. Sequential sampling, which collects water from throughout a home's plumbing and can include water contained within the LSL itself, results in lead level data that is more reflective of the range of possible exposures in the drinking water line, and helps to pinpoint sources of lead. Figure 2 shows that on two different sampling occasions (as reflected by the blue and orange lines) the first-draw sample results taken in accordance with the LCR indicate a drinking water lead level of 3 ppb, considerably below the AL. However, using sequential sampling to collect a greater volume of water in the homes plumbing indicates that after the first few liters pass through the tap, the subsequent "sequential" samples collected reflect increasing lead levels, due to the fact that the water in the subsequent samples has been in closer proximity to or even contained within the LSL. As seen in Figure 2, lead levels begin to increase after collection of the fourth liter, and the fifth and several subsequent liters collected actually exceed the AL.

[2] Miguel A. Del Toral, Andrea Porter, and Michael R. Schock, "Detection and Evaluation of Elevated Lead Release from Service Lines: A Field Study," *Environmental Science & Technology* 47, (2013): 9300–9307, dx.doi.org/10.1021/es4003636.

Figure 2: Example Site from 2011 Chicago Sequential Sampling Study, EPA

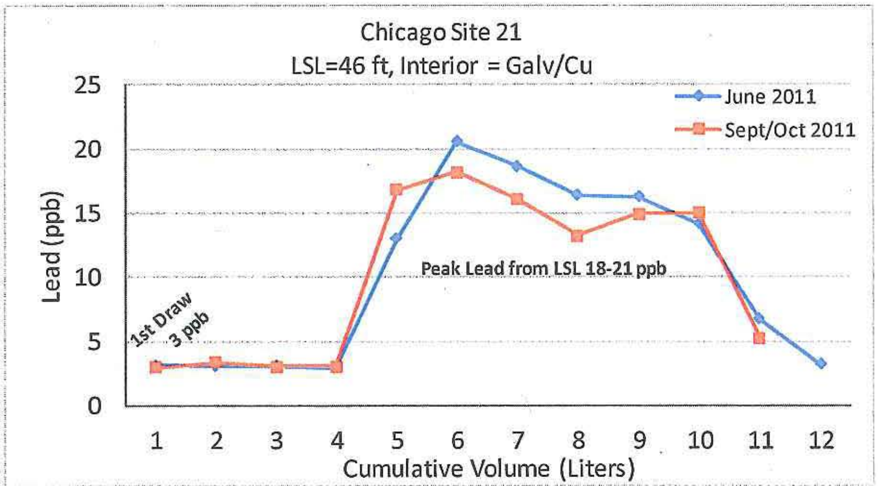


Figure 2:
Lead levels in first draw samples underestimate the high lead levels that can come from a LSL, even in a well-operated system adding orthophosphate for corrosion control (~0.5 mg/L as orthophosphate in blended phosphate) and without evidence of the LSL being disturbed.

This point is further made in Figure 3, below, which shows the difference between the first-draw results and sequential sampling results at 28 homes with LSLs. Of the homes sampled, fewer than 2% of the first draw-results were above the AL. Conversely, over 50% of the homes had peak levels above the AL in the samples collected from the plumbing further away from the tap.

Figure 3. First-Draw and Sequential Sampling at All LSL Sites in 2011 Chicago Study

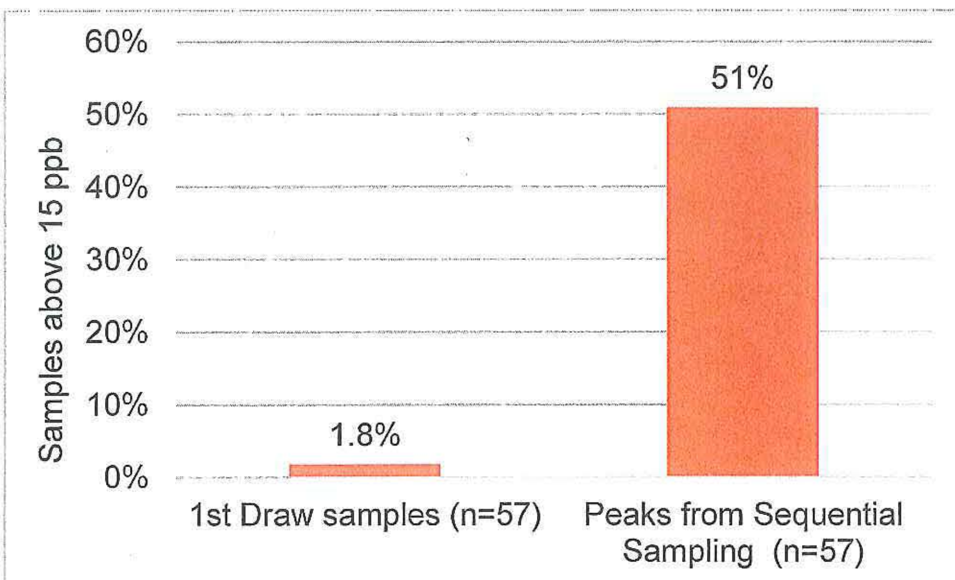


Figure 3: All sequential sampling profiles (28 LSL sites, most of which were sampled twice) from the Chicago study confirm the finding that lead levels in first draw samples underestimate the high lead levels that can come from a LSL. The one profile (1/57) with a first-liter sample above 15 ppb had an even higher peak lead level further from the tap.

Additional sampling efforts in other cities in Region 5 has made it clear that basing treatment on LCR-based compliance sampling can result in ineffective treatment being used by a PWS. The sequential sampling results from all of these cities show that a single sample may be inadequate for characterizing the lead concentrations present. In the 2011 Chicago study of LSL sites, our data analysis conducted using each of the single liter samples shows that at best, the use of the same liter sample (1st liter, 2nd liter, 3rd liter, etc.) at each of the sampling sites would result in missing the peak amount of lead present

77% of the time. Using the LCR first-draw sampling protocol missed the peak lead values 100% of the time at LSL sites.

Identification of Tier 1 Sites. Issues with the LCR sampling protocol are heightened by the fact that some communities may not be monitoring at the highest risk sites ("Tier 1 sites"), as required by the LCR. For systems with LSLs, the LCR requires that at least 50% of the samples must be from homes with LSLs or plumbing with lead solder. Many systems have limited record-keeping and therefore do not know which houses have LSLs. Consequently, the LCR sampling protocol is likely being implemented at lower-risk homes with no LSLs. This is important because the inclusion of homes without LSLs in the LCR sampling pool may skew the 90th percentile calculation downward, potentially masking a treatment problem. This is illustrated by the experience in replacing lead lines in Flint. In that program, using state-of-the-art methods to locate LSLs, approximately **19%** of suspected LSL sites that are excavated actually have no lead lines. That means that even using the best information and advanced techniques possible, 1 in 5 Flint homes that were thought to have lead lines actually do not. The inadvertent inclusion of houses without lead lines – especially in a relatively small sampling set -- could cause a community to report results below the lead AL. Deliberate inclusion of homes without lead lines is also a possibility. Given the uncertainties in identifying Tier 1 sites under the best of circumstances, such manipulation would present obvious challenges for enforcement.[3]

Similar to the results in Chicago, recent sampling in East Chicago, Indiana -- a medium-size system which is in compliance with the LCR and has been below the AL since 1993 -- demonstrates that even properly-conducted LCR compliance sampling may not uncover issues with inadequate CCT. See Figure 4, below. East Chicago installed blended phosphate-based CCT following a lead AL Exceedance (ALE) in 1993. Based on subsequent monitoring following the ALE, there was no requirement under the LCR to complete the installation of treatment. Like many older cities, East Chicago has a large percentage of LSLs. Sequential sampling conducted by EPA in 2016 showed low levels of orthophosphate in the East Chicago distribution system along with high lead levels in samples collected in a number of homes. In addition, sequential sampling at LSL sites showed peak lead levels were often significantly higher than the lead levels present in the first draw and also significantly higher than the City's LCR compliance sampling results. See Figure 5, below.

Figure 4: East Chicago Comparison Between First-Draw and Peak Sequential Sampling Results

[3] A search of the enforcement database in Region 5 shows that actions have been brought for a complete failure to report results, but not for failing to properly identify Tier 1 sites.

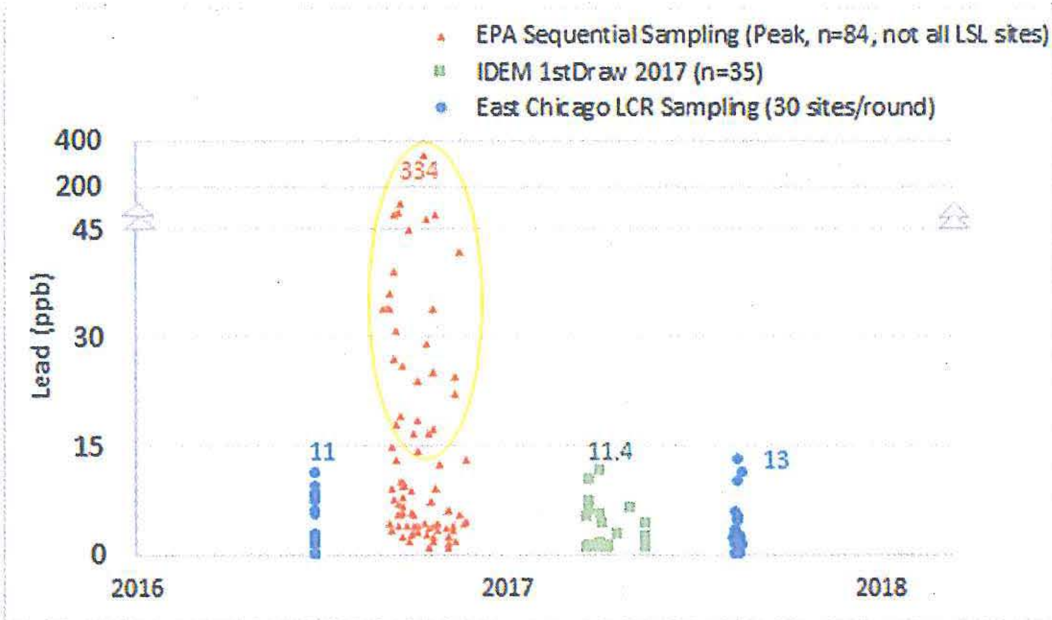


Figure 4: Comparison of first draw sampling results to peak sequential sampling results at homes in East Chicago illustrates the high lead levels that can be missed by first draw, first-liter sampling. All LCR compliance samples in East Chicago were below 15 ppb in 2016 and 2017 (90th Percentiles of 8.4 ppb and 5.6 ppb, respectively). 30% of the sequential sampling profiles peak values were above 15 ppb, and not all sites were known or suspected LSL sites. Only 15% of the sequential sampling profiles had lead levels above 15 ppb in the first liter equivalent (maximum 100 ppb). At LSL sites, the peak lead levels (up to 334 ppb in one case) were observed in the sequential sample(s) representative of the service lines.

Figure 5: East Chicago Sequential Sampling Site 3088

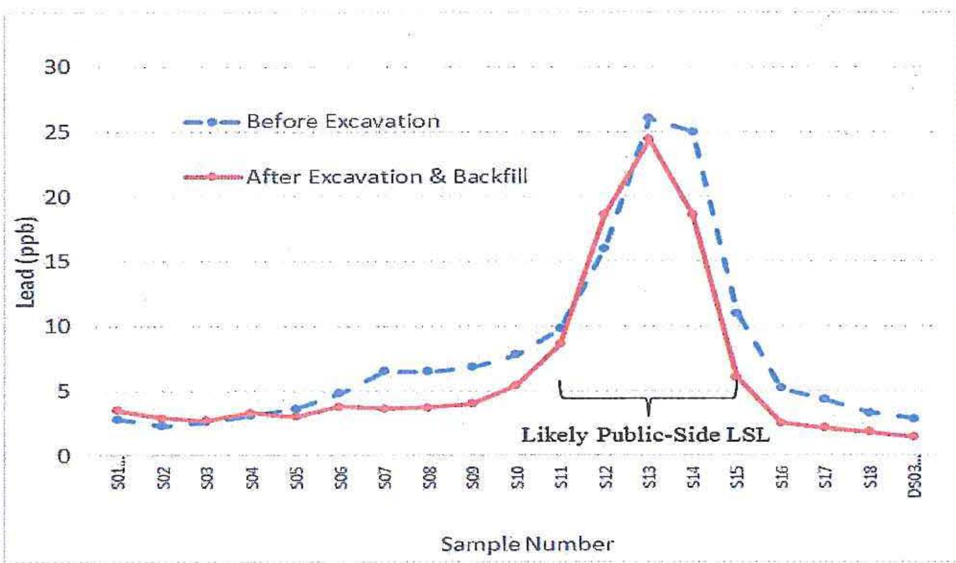


Figure 5: Sequential sampling at East Chicago Site 3088 illustrates that the very low levels present in the first liter, which would be collected for LCR compliance sampling, are not representative of the higher lead levels in water stagnating in the LSL.

Region 5 commends OW for the steps taken in 2016 to formalize the recommendations of the Flint Task Force. It is clear that the sampling protocol is a key factor in implementation of the LCR. The Rule's protections depend on a protocol that correctly and timely identifies potential issues with effective corrosion control treatment of drinking water.

Issue 2. Implementation of Treatment Controls for Lead in the LCR.

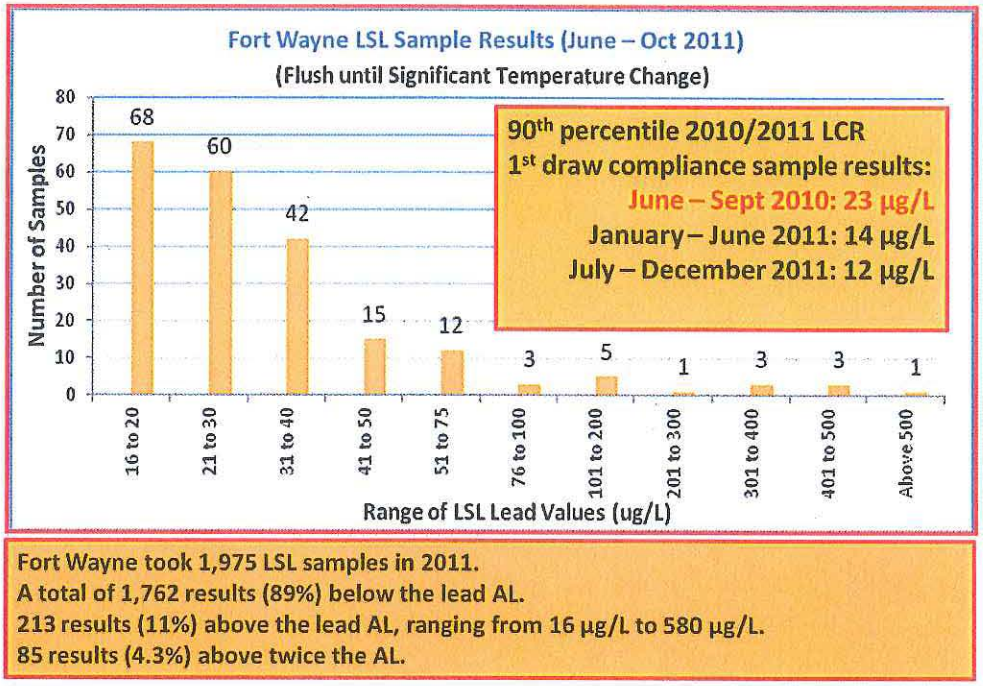
The compliance measures embodied in the LCR and relied on by states must be as effective as possible in preventing lead exposure. Under the LCR, systems are required to optimize CCT to minimize lead and copper levels at the tap.

The LCR requirements for ensuring that lead levels are minimized relies on the maintenance of optimal water quality parameters (OWQPs). The LCR assumes that once treatment is initiated, maintaining the specified OWQP values and ranges (*e.g.*, for pH, alkalinity and orthophosphate) designated in the LCR will result in continuous lead and copper level minimization at the tap. In Region 5's experience, including the examples set out below, there is often no correlation between meeting the OWQP limits and lead and copper levels at the tap.

OWQP requirements under the LCR vary depending on the population served by a water system. First, the LCR requires large systems to: 1) conduct corrosion control studies to achieve the minimization of lead levels at the taps; and 2) recommend OWQP values and ranges that are supposed to result in minimized lead and copper levels at the tap. Although the OWQPs that are specifically listed in the LCR (pH, alkalinity, orthophosphate, silicate, and calcium) can and do impact lead and copper levels, there are many other factors that can cause lead release. For many systems, controlling only the parameters specifically listed in the LCR may not result in minimization of lead levels at the tap.

This can be seen in a review of the data from Fort Wayne, Ind. which initially had a lead Action Level Exceedance (ALE) in 2010 but did not have an associated OWQP violation. Fort Wayne subsequently met the lead AL and was in compliance with their OWQPs for two consecutive 6-month rounds of monitoring in 2011, even as additional LSL sample results during the same two 6-month rounds were very high. See Figure 6, below. Conversely, Flint, Michigan had lead ALEs both with a OWQP violation, and without one.

Figure 6. High Lead Levels Observed in Fort Wayne



This experience is confirmed by a review of data in EPA's Safe Drinking Water Information System (SDWIS), which contains OWQP violation data and ALEs. Since 1991, in Region 5 there have been 100 OWQP violations at a total of 66 separate PWSs, as compared to 8,220 lead ALEs (at 4,621 separate PWSs) during the same time. Most OWQP violations did not have an associated lead or copper ALE, and most lead and copper ALEs did not have a corresponding OWQP violation. Stated simply, PWSs are virtually always "in compliance" with the OWQPs, regardless of lead levels at the tap.

After Region 5's evaluation of the relationship between compliance with OWQPs and actual lead levels in drinking water, Region 5 held a conference with states in the Region to discuss this issue. During the conference, a number of states explained that they do not have the necessary expertise in the area of corrosion control to question a drinking water system's OWQP recommendations. Moreover, the states indicated that, without having adequate technical knowledge on how to best set these ranges/minimum values, they are reluctant to set the OWQP ranges more tightly, the minimum values so high or maximum values so low that the systems incur violations. A subsequent national survey conducted by the Association of State Drinking Water Administrators (ASDWA) on the same topic revealed that this was a national issue (*i.e.,* states outside of Region 5 also experienced the same difficulty). Due to the uniqueness of water quality and other factors in each individual PWS, it is not possible to develop a universal set of OWQPs that can be monitored and controlled to minimize lead/copper at the tap.[4] For example, in Washington, D.C., it was a change from chlorine to chloramine disinfection that resulted in significant system-wide lead release. In Flint, the absence of corrosion control was exacerbated by high chloride levels in the water, making the water more corrosive. In Madison, Wisconsin, a study showed

[4] A recent study from 2017 further supports this claim through its finding that the use of blended phosphate for lead corrosion control does not result in a consistent protective barrier within the pipe. This suggests that water utilities need to conduct a demonstration study to determine the optimal chemical dosages, background water quality and treatment adjustments to minimize lead release. See Wasserstrom et al., "Scale Formation Under Blended Phosphate Treatment for a Utility with Lead Pipes," *Journal American Water Works Association* 109, no. 11 (November 2017): E464-E478, https://doi.org/10.5942/jawwa.2017.109.0121.

that iron and manganese served as a transport mechanism for lead which resulted in high lead levels within home plumbing even after LSLs were fully removed. These situations would not have been prevented by controlling the specified water quality parameters under the LCR.

The LCR has different requirements for water systems serving smaller populations. Specifically, small (serving 3,300 persons or less) and medium (serving 3,301 to 50,000 persons) systems that exceed the AL and are required by a state to conduct corrosion control studies frequently do not have the technical expertise or resources to do adequate studies. In Region 5, 98.4% (8,090 out of 8,220) of lead ALEs ever reported are from small and medium systems. Small and medium systems are not required to monitor/report water quality parameters unless they exceed the lead or copper AL. For context, of the 11,594 PWS in Region 5 that are subject to LCR, 10,815 (93%) of them are small and 648 (6%) are medium.

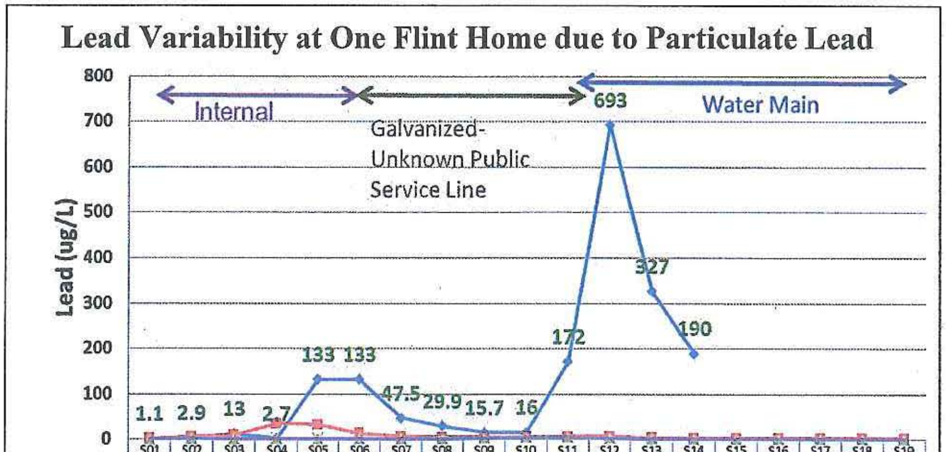
Because there are so few treatment technique (*i.e.*, OWQP) violations compared to the number of lead ALEs, the vast majority of LCR violations are monitoring violations or consumer notification violations, which do not have direct public health impacts.

In Sebring, Ohio (a medium-size system), pH/alkalinity adjustment was being used for corrosion control. Because it is a medium-size system, the system was not required to monitor or report pH values unless it exceeded an AL. After the system exceeded the lead AL, it was found that system pH was very low (*i.e.,* more corrosive) which caused the lead ALE. In other words, the low pH was discovered after the damage was already done because the system was not required to monitor or report pH levels to the state.

Issue 3. Releases of Particulate Lead.

Data indicate that lead contribution from residential plumbing does not occur at a predictable and stable rate. Observations in Flint, East Chicago, and many other communities make clear that there can be low levels of lead at a given residence on one day, and high lead at the same residence the next day or week or month. Sampling shows that lead-containing scale particles can be sporadically released from LSLs, other lead-containing plumbing, and/or associated galvanized iron pipe, especially when pipes are disturbed. See Figures 7 and 8, below.

Figure 7: Lead Variability at One Flint Home Due to Particulate Lead



	S01	S02	S03	S04	S05	S06	S07	S08	S09	S10	S11	S12	S13	S14	S15	S16	S17	S18	S19
2/16/2016	1.1	2.9	13	2.7	133	133	47.5	29.9	15.7	16	172	693	327	190					
7/21/2016	1.92	6.23	9.06	34.4	32.8	12.9	6.74	4.87	4.54	6.16	6.66	6.27	4.07	3.15	3.1	2.99	2.89	2.78	2.91
9/21/2016	1.33	2.67	1.48	1.57	1.64	1.66	2.03	2.66	4.22	6.89	5.58	3.63	2.03	1.9	1.79	1.79	1.72	1.67	1.92
11/10/2016	1.3	2.6	1.9	1.9	2	1.8	1.8	2.4	4	5.8	5.5	3.3	1.8	1.5	1.5	1.4	1.4	1.4	1.4

Figure 7: Sequential sampling demonstrates that lead-containing scale particles are sporadically released from LSLs, other lead-containing plumbing, and/or associated galvanized iron pipe, especially when pipes are disturbed.

Sporadic release is important because scale particulates can be high in lead. Scale analysis by EPA ORD and other researchers shows that corrosion control scale minerals contain 68.3% to 97.8% lead. By comparison, lead-based paint contains 0.5% lead. That means that drinking one barely visible lead-containing scale particle, released from plumbing materials, can result in the same lead exposure as eating a lead paint chip the size of a penny (310 µg lead, see photograph from Triantafyllidou *et al.* 2007 to right) with commensurate damage to the health of a child. Analysis of scale particles trapped in faucet aerators in Flint confirms the presence of scale particles containing large amounts of lead (maximum of 97,000,000 ppb, median 62,000 ppb, n=9) in drinking water.

Particles observed in aerators, including the one shown here, include scale minerals released from plumbing materials, which can contain high levels of lead.

Even with the best CCT possible in place, the centralized treatment used by a PWS may not prevent random and sporadic release of lead particles or high spikes in lead levels due to dislodged lead particulate caused by physical, chemical or hydraulic disturbances of a LSL and any associated galvanized iron pipes. These disturbances occur in systems across the country from work being performed by utilities. A PWS may not be aware of physical disturbances caused by work being performed by other entities such as transportation departments or gas, electric, cable and other utilities.

Figure 8: Significant Lead Can Be Released When LSLs are Disturbed

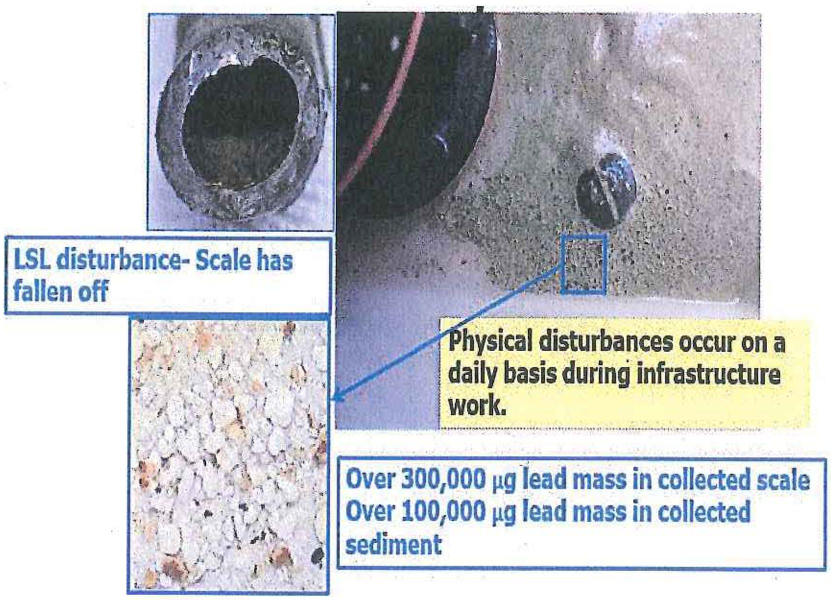


Figure 8: Scale and sediment containing over 400,000 μg lead were observed to be released during a partial LSL replacement at a Chicago home. This amount of lead is equivalent to a lead paint chip that covers a 36-inch TV screen (or 1,300 pennies). Other studies also reported high lead levels after physical disturbances of LSLs (Triantafyllidou and Edwards 2012; Lewis *et al.* 2017; Deshommes *et al.* 2017).

Potential revisions to the LCR, as well as interim measures to reduce exposures, should account for the fact that high levels of lead can be introduced into drinking water via particulate release.

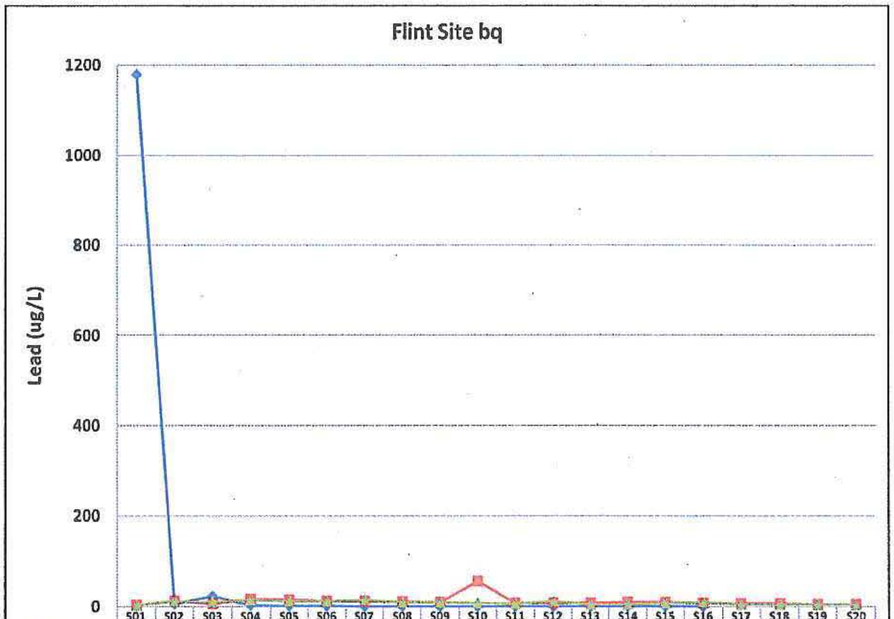
Issue 4: Detection of Elevated Levels of Lead.

Results above the 90^{Th} Percentile. The LCR's trigger for water system action is based on a calculated 90^{th} percentile value for lead (*i.e.,* 90% of the homes sampled must be at or below the lead AL of 15 ppb). The remaining 10% of homes may have elevated levels of lead in their drinking water, but do not factor into the LCR calculation. They might average out to 16 ppb (just above the action level) -- or they might be 1,000 or 4,000 ppb. There is no action required to be taken in response to the highest lead levels found, despite the risk of exposure to children consuming this water. In effect, the greatest exposure to and harm from the highest lead levels in the system is not visible in the LCR framework.

As noted, high sporadic lead levels are often the result of particulate lead. Such a particle may contain thousands to tens of thousands of ppb lead, which in extreme cases can result in acute lead exposure for a child in a single glass of water.[5] Because particulate lead release is unpredictable, sample results from the same tap in the same home can yield low lead on one day and high lead on another as illustrated in Figure 9 below. The majority of lead results at this home were low except when a lead particle was released into the water, spiking the lead level to 1180 ppb at the same kitchen tap that subsequently yielded very low results (2.69 ppb and 3.1 ppb). If the highest result is in the top 10% of sample results (i.e., is outside the 90^{th} percentile specified in the LCR), it has no regulatory consequence and can be ignored

[5] Kelsey J. Pieper, Min Tang, and Marc A. Edwards, "Flint Water Crisis Caused By Interrupted Corrosion Control: Investigating "Ground Zero" Home," *Environmental Science and Technology* 51, no. 4 (2017): 2007-2014, http://pubs.acs.org/doi/suppl/10.1021/acs.est.6b04034. (This study notes that a single sip of water from the home of a Flint resident sampled by Region 5 had a sufficient lead dose to increase the blood lead of her child from 0 to over 5 ug/dl CDC level of concern.)

Figure 9: Sporadic Lead Release in Flint



	S01	S02	S03	S04	S05	S06	S07	S08	S09	S10	S11	S12	S13	S14	S15	S16	S17	S18	S19	S20
2/16/2016	1180	6	23.6	2.7	2	1.2	0.77	0.6	0.56	0.51	0.47	0.6	0.44	0.41	0.45	0.37				
7/15/2016	2.69	11.1	6.51	15.6	14.5	11.3	11.4	10.4	9.37	56.2	6.93	7.61	7.76	8.2	9.14	7.42	6.51	5.4	4.26	4.1
9/21/2016	3.1	11	10	14	12	12	15	8.1	9.3	7.6	5.4	12	4	5	8	8.5	4.6	4	4.3	4.4

Figure 9: During initial testing at a home in Flint, the sample result for the first bottle was 1180 ppb. Subsequently, the sample results from the first bottle tested very low (2.69 ppb and 3.1 ppb).

The possibility of high sporadic lead levels should factor in risk communications, as well appropriate response action.[6] Knowledge of high sporadic lead results may provide valuable, actionable information to decision-makers. This is also true for residents, who may assume that results below the action level are a certification of safety.

<u>Sampling size</u>. While LCR consumer notification requirements inform the residents of the lead levels in the homes that were actually sampled for lead, there are likely many other homes in the system with levels that have not been sampled, and these residents are left unaware of the potential for high lead levels in their drinking water.

For example, Chicago has an estimated 1,201,732 housing units[7]. The LCR requires Chicago to sample <u>only 50 homes every 3 years</u>, meaning they are sampling only 0.004% of the residential units once every three years. Although the sites sampled under the LCR are intended to be 'highest-risk' single-family homes, it is still a small percentage of the dwelling units, especially given the variability of lead in drinking water and, as discussed above, an LCR compliance sampling protocol that can significantly underestimate the lead levels that are actually present for homes with LSLs.

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[6] For example, in Flint, the threat from such particles resulted in the "Flush for Flint" campaign in May 2016, an effort to run water at high volumes through the City for a month. See Matthew Dolan, "Flint Mayor, Governor Push Plan to Flush Pipes," *Detroit Free Press*, May 12, 2016, https://www.freep.com/story/news/local/michigan/flint-water-crisis/2016/05/12/flint-mayor-governor-push-flushing-plan-pipes/84276422/.

[7] "American Community Survey," U.S. Census Bureau, 2016 Data Release, https://www.census.gov/programs-surveys/acs/.

Figure 10: First Draw Sampling in Chicago

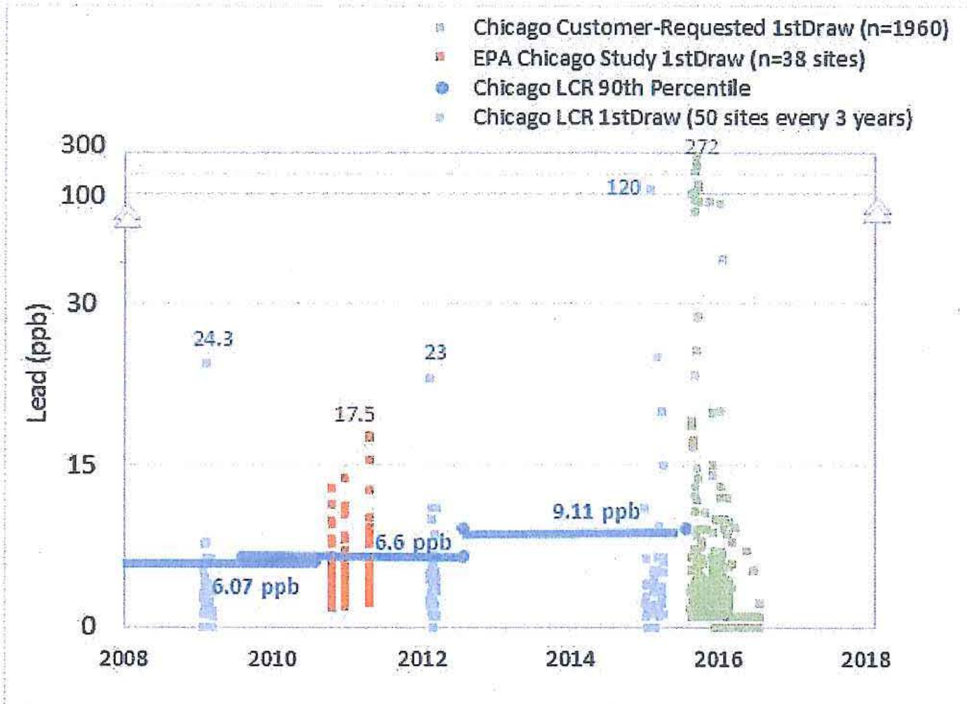


Figure 10: In a large community with LSLs, a large number of homes may have high lead without detection, as illustrated by first draw sampling in Chicago.

As shown in Figure 10, several sampled homes had lead levels above 15 ppb, and some sampled homes had lead levels above 100 ppb. Extending this dataset to the 314,317 single detached housing units in Chicago, there could be 4,600 homes with lead above 15 ppb, and 1,000 homes with lead above 100 ppb, that have never been sampled. Chicago's customer-requested sampling is open to all residents, so the dataset is likely biased low compared to LCR sampling by the inclusion of lower-risk sites like multi-family buildings (where stagnation is incomplete) and newer non-LSL homes.

In addition, for homes with LSLs, resident-requested sampling uses first-draw compliance sampling protocol and the results provided to residents can provide false assurance that the treatment is adequately controlling lead in water and that lead levels are lower than they actually are. This can result in residents failing to follow suggestions for mitigating lead exposure.

Issue 5. Health-based Limit for Lead.

The LCR lead AL is not a health-based number, but rather one that assists in evaluation of corrosion control. The construct of the 1991 LCR was for PWSs to take actions to control the corrosion from lead plumbing materials in their systems. The 90th percentile of 15 ppb using 1-liter, first-draw samples from these well-run systems was determined to be feasible for most of these systems to meet.

Over time, this lead AL of 15 ppb has been used by many as a default measure of safety. However, there is no evidence to support a conclusion that lead levels in drinking water near the 15 ppb are safe, especially for sensitive populations. In the absence of a risk-based limit, decision-makers and others have used the action level for purposes beyond its original intent. Region 5 understands that efforts are underway at OW and ORD to answer the difficult scientific questions involved in developing a health-based lead standard. Based on our implementation experience, we believe that effort is important for protection of public health.

As we saw in Flint and other communities, it has been a significant challenge for federal, state and local governments to advise residents whether drinking water is "safe" or "not safe" based on a lead action level that is not health-based. The AL does not relate to exposure or risk and is considerably above the Maximum Contaminant Level Goal of zero. Reconciling the Action Level of 15 ppb with the MCLG of zero has proven to be an especially difficult communications issue in Region 5 communities.

It is important to note that this is not only a problem of risk communication, but also of calibration of response. Without a health-based lead number, the LCR does not provide guidance on when actions (such as use of water filters or bottled water) need to be taken at an individual residence -- or on a system-wide basis – to protect public health. In Flint and other communities, the absence of a health-based number complicated the response, the ability to make recommendations for action, and our ability to answer critical questions:

- At exactly what point should the water system be considered unsafe?
- At what levels, or upon what combination of factors, may regulators state with a measure of confidence that the water quality has "returned to normal" or "safe" levels? For what populations?
- At what levels, and when, should residents be advised to use alternative sources of water and/or filters?
- After a comprehensive response with filters and bottled water, at what point should these measures be discontinued?

As OW considers revisions to the LCR, a crucial consideration is relating the lead AL (and recommended actions/controls) to levels that have a connection to public health. We found the absence of a health-based number to be an especially challenging problem that impacted every aspect of the crisis in Flint, including initial identification of the issue, appropriate and timely public notice, risk communications, emergency response, evidentiary basis for an enforcement response, intergovernmental relations and roles, remedy, restoration of public confidence, and criteria for discontinuance of alternate water/filters.

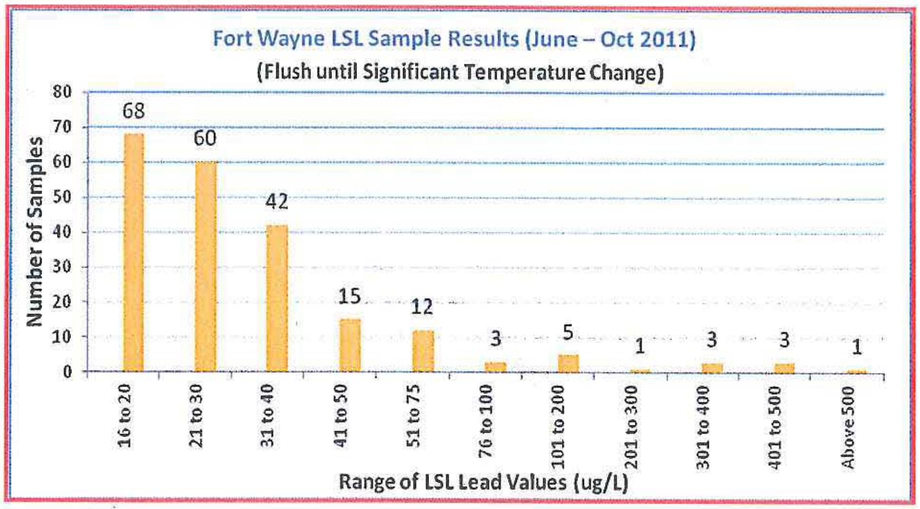
Issue 6. LCR Lead Service Line Replacement Provisions

Under the LCR, lead service line replacement (LSLR) is required when the treatment fails to keep lead levels below the lead AL. When triggered, the LCR requires 7% of the total inventory of LSLs in the system to be replaced per year for as long as the system exceeds the lead AL. Because many systems do not know where the LSLs are or how many LSLs they have, there can be a significant delay in the initiation of LSLR. In addition, the LCR allows systems to stop replacement entirely after two consecutive 6-month rounds of sampling with the 90th percentile values below the lead AL. Consequently, it is possible that no actual LSLR occurs before the system is again testing below the lead AL.

"Testing out." Another issue with LSLR is a provision in the LCR whereby: 1) systems are allowed to collect a sample intended to capture water that has resided within the LSL; and 2) if that sample result is at/below 15 ppb, the system can count that LSL as having been "replaced", even though nothing has physically been removed. This 'test-out' replacement counts toward the required 7% replacement requirement.

Region 5's experience in Fort Wayne, Ind. illustrates the point. There, the system was required to conduct replacement after an action level exceedance. Fort Wayne instead collected thousands of LSL samples using the 'significant temperature change' criterion and managed to meet the 7% replacement requirement without physically removing a single LSL.[8] See Figure 11, below. In the course of doing so, hundreds of sample results were above 15 ppb. However, there is no requirement for the system to replace any of the LSLs that test above 15 ppb, and these high sample results cannot be included in the 90th percentile calculation because they are not 1st draw samples (*i.e.,* compliance samples). The City was therefore legally able to exclude the high results and continue sampling until they found 7% that were under 15 ppb.

Figure 11. High Lead Levels in Fort Wayne



Even after the crisis in Flint, the water system could have opted not to replace any lead lines. After Flint had an ALE for the January through June 2016 compliance period, it had two subsequent LCR compliance monitoring rounds below the lead action level (July to December 2016 and January to June 2017), which meant that under the LCR the City was no longer required to replace 7% of its LSLs within the year after the lead ALE (by June 30, 2017). Flint has chosen to replace all of its LSLs– but was under no LCR obligation to do so even after the crisis. Flint could have relied on the two subsequent sampling rounds to avoid the requirement without replacing any LSLs.

Ownership issues/partial replacement. We have also found in Region 5 that ownership/control of LSLs is an impediment to replacement. In some cities, local ordinances give residents full legal "ownership" of their service lines. When this happens, even if a City triggers LCR's LSLR requirement, no service lines will be required to be replaced, since the City is only mandated to replace those lines it owns itself.

As an example, Galesburg, Ill. (a medium-size system) has a long history of exceeding the lead AL. Between 1992 and 2015, Galesburg collected lead samples under the LCR during 32 sampling periods. Of those 32 sampling events, Galesburg had 21 lead ALEs, including most recently in 2015 (90th percentile of 22 ppb). However, even when Galesburg triggered mandatory LSLR in 2000, Galesburg

[8] The applicable LSL sampling protocol in the LCR (*i.e.,* run water until there is a significant temperature change) is subjective and may not capture water that actually resides within the LSL due to the unique distances from the sample tap to the beginning of the LSL in every home.

was not required to replace any of its LSLs since the City does not own or control any of its LSLs. Galesburg recently has voluntarily chosen to replace lines that it does not own.

The LCR requires LSLR if a system exceeds the lead AL following CCT installation. However, the rule only requires replacement of the portion of the LSL owned by the utility, sometimes resulting in partial LSLR and physical disturbances to LSLs which results in higher lead levels in the water for an indeterminate amount of time. Instead of fixing the problem as intended, that solution might make it worse.[9]

When triggered into LSLR, a system that is removing only the public portion of the LSL (*i.e.,* partially replacing the LSL) must make an offer to the resident to replace the privately-owned portion at the owner's expense. However, if the system has not triggered LSLR under the LCR and the system is conducting routine activities such as water main replacement or repair, many are partially removing LSLs at the same time. While conducting these non-regulatory triggered partial LSLRs, there is no requirement in the LCR to offer to replace the customer portion or to provide any information on the increased lead levels that are a direct result of disturbing the LSL. As discussed above, the LCR does not address random particulate release or physical disturbances.

In Flint and other cities, Region 5 has also found substantial releases from galvanized iron pipes connected to LSLs. Such pipes themselves are not addressed by the LCR. Over the decades that the lead and galvanized iron pipes have been connected together, lead that was released from LSLs has adsorbed onto the corroded surfaces inside old galvanized iron pipes. The galvanized iron pipes are now effectively lead-lined pipes. These pipes are vulnerable to physical disturbances and changes in water corrosiveness towards iron. See Figure 12, below. When doing LSLR, old galvanized pipes are often not removed and continue to pose an elevated risk of high lead release.

[9] A recent study conducted in Montreal, Canada reinforces this finding, showing lead sample results from homes with LSLs at acute levels of lead (*i.e.,* tens of thousands ppb) and lead mass releases directly into the water in the tens and hundreds of thousands of micrograms from partial LSLRs. See Elise Deshommes et al., "Short- and Long-Term Lead Release after Partial Lead Service Line Replacements in a Metropolitan Water Distribution System," *Environmental Science & Technology* 51, no. 17 (2017): 9507-9515, http://dx.doi.org/10.1021/acs.est.7b01720.

Figure 12. Disturbed Galvanized Service Line Results from Flint

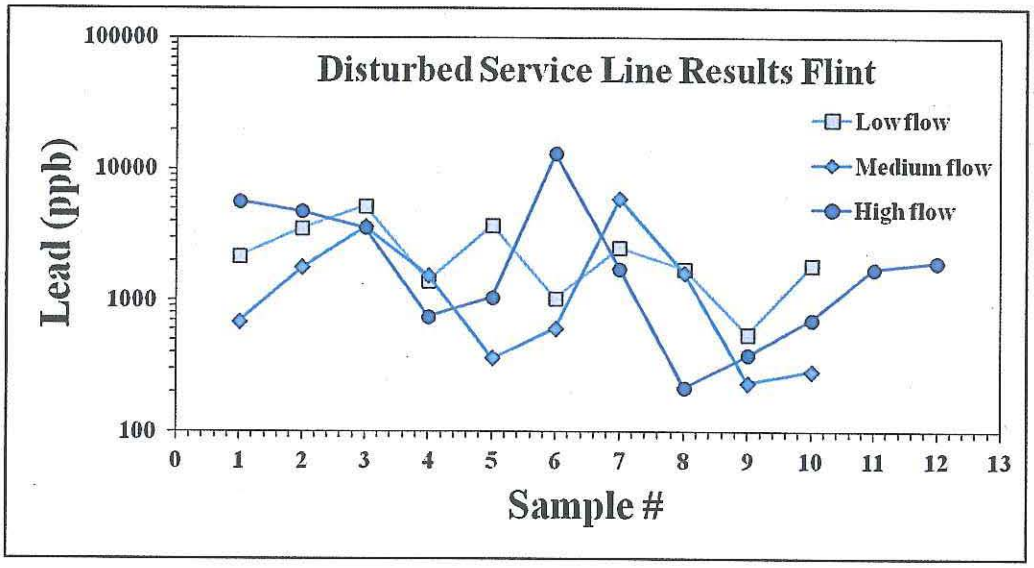


Figure 12: At one home in Flint sampled in 2015, very high lead levels were observed following physical disturbances to a galvanized iron section of the service line. The home had a short section of lead pipe connecting the galvanized iron section to the water main.

Towards Prevention

The response in Flint has proven the value of two important ways to protect public health: point of use filters and lead line replacement. Careful studies have demonstrated the value of both interventions.

Filters. EPA and the Agency for Toxic Substances and Disease Registry (ATSDR) conducted an evaluation of the use of point-of-use filters certified under NSF/ANSI 53 to remove lead.[10] The study showed these filters are an effective measure to prevent exposure to lead-contaminated water – even where the incoming lead is significantly higher than the NSF/ANSI 53 challenge standard level of 150 ppb. This was true even under extraordinarily high influent levels, up to more than 4,000 ppb. See Figure 13, below.

EPA collected samples of both filtered and unfiltered water from over 200 taps in Flint. Analysis showed that the maximum and average concentration of lead in the filtered water was exceptionally low. Approximately 80% of all results for filtered water were below the detection level for lead.

[10]"Flint, MI Filter Challenge Assessment," U.S. Environmental Protection Agency, June 22, 2016, https://www.epa.gov/sites/production/files/2016-06/documents/filter_challenge_assesment_field_report_-_epa_v5.pdf.

Figure 13. 2016 Water Filter Efficacy Study, EPA and CDC/ATSDR

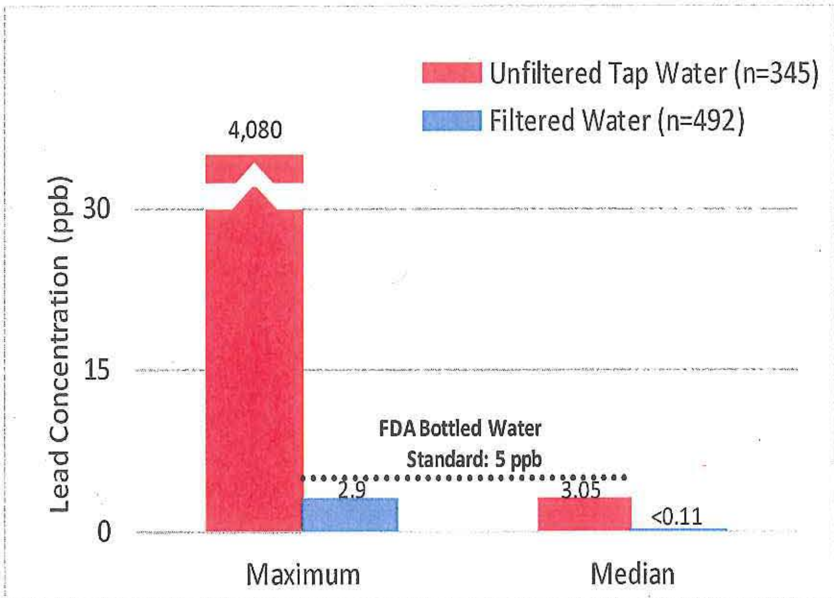


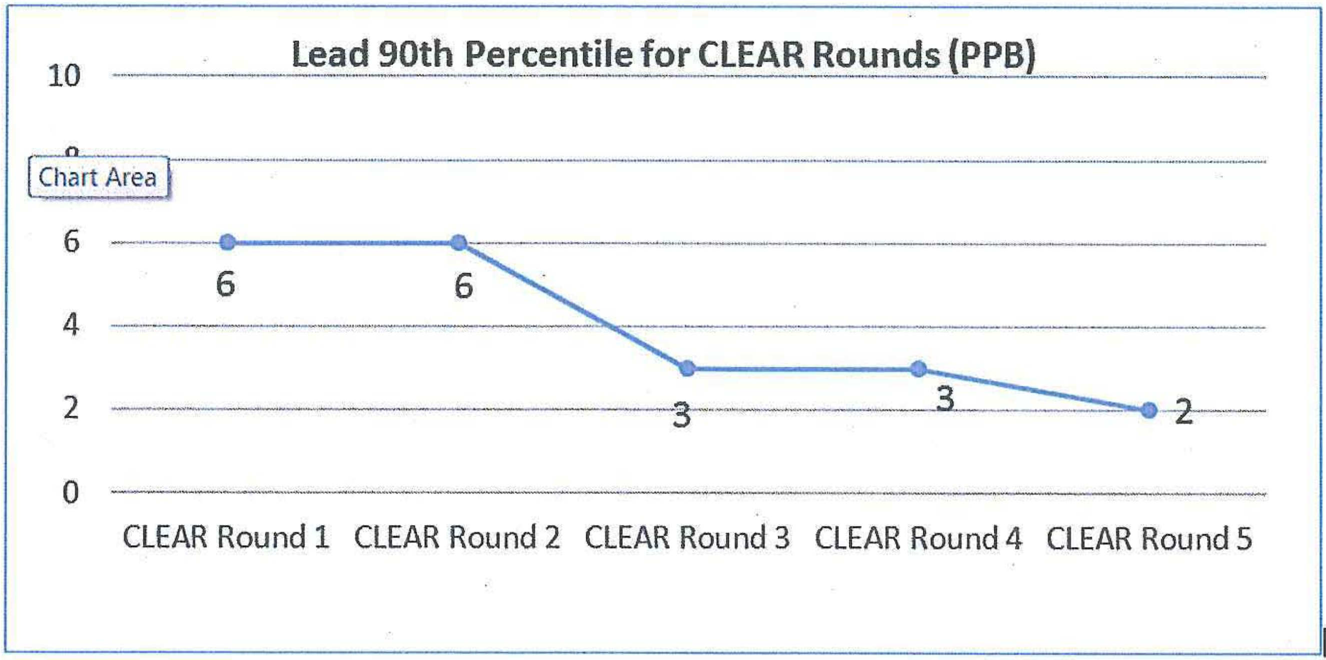
Figure 13: Results of Filtered Water Sampling. Lead levels in all but 6 filtered water samples (99%) were below American Academy of Pediatrics' recommendation of 1 ppb (AAP 2016), despite high lead levels in unfiltered water in Flint (21% of samples above 15 ppb and 4% of samples above the 150 ppb NSF/ANSI 53 challenge standard). All of filtered water samples were below the Food & Drug Administration (FDA) bottled water standard of 5 ppb.

ATSDR requested sampling at homes with sensitive populations, and homes tested previously with higher than 150 ppb. ATSDR and Centers for Disease Control (CDC) concluded based on the filter challenge results that "it is safe for residents of Flint to drink filtered tap water, including pregnant women, nursing and bottle-fed children, and children under six."

When properly used and maintained, filters are an effective and immediate response to elevated or uncertain levels of lead in drinking water. Based on our experience in Flint, Region 5 considers filters to be a valuable tool to protect public health.

Lead Line Replacement. In 2016, Flint embarked on an ambitious plan to replace every lead line in the City even though they were not required to do so. To date, the City has replaced over 6,000 lead lines. At the same time, MDEQ tested homes both before and after lead line removal at monthly intervals. The testing has proceeded through five rounds to date. The results show that removing lead lines is very effective at lowering lead levels in tap water.

Figure 14: MDEQ 90th Percentile Results Following LSL Replacement



As shown in Figure 14, of the 170 samples taken by MDEQ after replacement, 169 showed lead levels below the action level of 15 ppb. The 90th percentile five months after replacment was 2 ppb or less – 72% have sample results below the detection level for lead.[11]

The data from Flint show that replacing lead lines does not result in significant short term disturbances, and helps to reduce exposures to lead significantly. In several months, lead levels tend to fall to very low levels (or nondetect) after replacement. This is true even in homes that presumably have other sources of lead in interior plumbing (from lead solder, lead-containing fixtures, and residual lead from lead laterals). Complete lead line replacement is an effective intervention for homes with elevated lead levels. It is the most certain way in the long term to prevent exposures. While it is a lengthy and resource-intensive process, it is ultimately an infrastructure solution to a difficult legacy threat to human health.

Conclusion

As OW considers revisions to the LCR, Region 5's implementation experience may help to guide efforts to make the LCR more protective of public health. Region 5's experiences in many communities have demonstrated challenges related to the implementation of the current LCR. As we have seen, these challenges can result in public health impacts. We commend OW for its efforts to date based on recent lessons from Flint and other communities. We are hopeful that OW will consider both short-term mitigation strategies as well as longer-term approaches that will result in the prevention of exposures, especially for sensitive populations.

[11] "CLEAR Results and Data," Taking Action on Flint Water, State of Michigan, last modified December 4, 2017, http://www.michigan.gov/flintwater/0,6092,7-345-76292_76294_76297---,00.html.

Attachment: Summary Table of Region 5's Significant Concerns Regarding the LCR and Important Ways to Protect Public Health

	Concern	Summary (Plain English)	Region 5 Experience	Public Health
1	LCR compliance sampling techniques/ protocol needs improvement.	LCR sampling tends to underestimate lead and overestimate effectiveness of treatment. At sites with LSLs, the first liter does not include the lead from the LSL.	Graphs of sequential data show characteristic peaks of lead in the LSL that first-draw sampling misses (e.g., Chicago, IL). Data from Flint, MI and East Chicago, IN showed the need for better CCT regardless of LCR compliance data.	Consumers get false sense of exposure risk from first-draw compliance sampling if they have LSLs. Consumers may be unknowingly exposed to higher lead levels in water.
2	Exceeding the lead AL does not correlate to adjusting optimal water quality parameters.	LCR's treatment technique violations for OWQP may not prevent high lead levels. Small and medium systems have particular implementation challenges.	It is technically difficult to set ranges for all parameters that affect CCT. Fort Wayne, IN had a lead ALE but not a OWQP violation. Flint, MI had lead ALEs both with a OWQP violation, and without one. Sebring, OH CCT issues were discovered after damage was done.	PWSs do not get timely warning to adjust CCT to avoid high lead. Consumers get exposed to lead.
3	LCR does not capture important contributors, such as particulate lead release.	LCR may not protect consumers from unpredictable high lead exposure including when the LSLs are disturbed (construction work; water pressure changes, etc.)	Data from Flint, MI and Chicago, IL confirm release of lead particulates.	A particle of lead ingested by a child can cause lead poisoning.
4	LCR use of only 90 % of the data, taken from a subset of residences, does not reliably measure actual lead levels.	10% of compliance samples can be very high with no LCR consequences. Very few locations are tested for compliance; most consumers do not get their water tested.	Chicago, IL comparison of customer-requested samples to LCR compliance samples shows extreme variability in lead levels, with many samples above AL even when system is well-run and below AL for compliance.	Consumers do not get timely, or often any, information to protect themselves from elevated levels of lead in drinking water.
5	There is no health-based limit for lead.	The AL is often improperly relied upon by some as a health-based number, when it really was meant as a comparator to be used to evaluate corrosion control treatment.	In recent years, communication challenges have been raised by many cities and states because LCR compliance data is insufficient to categorize the risk to consumers from lead in water.	Public needs to know when water is acceptable to drink based on the level of lead, or if a water filter or bottled water should be used.

6	The LCR LSLR provisions should be made more effective to require replacement.	Systems can avoid LSLR by exploiting LCR shortcomings. LSLR does not get triggered or implemented often enough, so residents may be exposed to lead in the long-term.	Fort Wayne, IN triggered LSLR but was not obligated to replace any lead lines. Galesburg, IL avoided LSLR by not owning the lines. Flint data shows lead-seeded galvanized iron pipe can release high lead levels.	LSLR is supposed to be the last resort to protect people from lead in water when systems are unable to adequately control corrosion.
<u>Towards Prevention:</u>				
Suggested Measures		**Summary (Plain English)**	**Region 5 Experience**	**Public Health**
1	Using NSF/ANSI-Certified Point-of-Use Filters Can Be an Effective Measure	Studies show that appropriate filters, when properly used and maintained, are effective in removing lead from contaminated drinking water.	Based on the experience in Flint, filters are an effective and immediate response to elevated or uncertain levels of lead in drinking water, when properly used and maintained.	Filters are a valuable tool in protecting public health.
2	Complete LSL Replacement Can Be an Effective Measure	Lead levels tend to fall to very low levels in the several months following LSL replacement, and are an effective measure in reducing exposure.	The data from Flint since LSL replacement began in 2016 shows that replacing LSLs does not result in significant short-term disturbances, and helps reduce exposures to lead significantly.	LSL replacement is the most certain way in the long run to prevent exposure.