UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

EPA-SAB-20-xxx

The Honorable Andrew Wheeler
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, D.C. 20460

Subject: Science Advisory Board (SAB) Consideration of the Scientific and Technical Basis of EPA's Proposed Rule Titled National Primary Drinking Water Regulations: Proposed Lead and Copper Rule Revisions

Dear Administrator Wheeler:

As part of its statutory duties, the EPA Science Advisory Board (SAB) may provide advice and comments on the scientific and technical basis of certain planned EPA actions. The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other federal agency for formal review and comment, together with relevant scientific and technical information on which the proposed action is based. The SAB may then provide advice and comments on the adequacy of the scientific and technical basis of the proposed action. The SAB and SAB Drinking Water Committee met by teleconference on March 30, 2020 and elected to review the scientific and technical basis of the proposed rule titled *National Primary Drinking Water Regulations: Proposed Lead and Copper Rule Revisions* (Proposed Rule). Subsequent to the March 30th teleconference, a work group of chartered SAB and SAB Drinking Water Committee members was formed to carry out the review. Members of this work group then took the lead in SAB deliberations on this topic at a public teleconference held on [insert date]. The SAB's advice and comments on the Proposed Rule are provided in the enclosed report.

The Proposed Rule is intended to protect public health by reducing exposure to lead and copper in drinking water. The proposal includes procedures and requirements for lead tap sampling, corrosion control treatment, lead service line replacement, consumer awareness, and public education. The SAB provides comments and recommendations to strengthen the Proposed Rule. The SAB's major comments and recommendations are as follows:

- The Proposed Rule describes revisions to the current Lead and Copper Rule to improve tap sampling. These revisions include requirements for: (1) tiering of tap sample collection sites, (2) number of tap samples and frequency of sampling, and (3) sample collection methods. In general, the SAB finds that the proposed new sampling requirements will improve water sampling. However, the sampling objectives should be carefully considered and explicitly stated in the Proposed Rule. If the overall objective is to collect water that represents the highest possible lead levels to which a resident might be exposed, then the Proposed Rule should indicate how the sampling protocol will achieve this by obtaining representative samples from the lead service line, premise plumbing, or both. Careful attention needs to also be given to requirements for sample preservation, sample transport and storage, and analytical methods that will insure total lead and copper analyses to sub part-per-billion levels.

- The Proposed Rule includes revised requirements for corrosion control treatment (CCT) based on sampling results. The proposal establishes a new lead “trigger level” of 10 mg/L. At this trigger level, water system operators currently treating for corrosion would be required to re-optimize their existing treatment. Those that do not currently treat for corrosion would be required to conduct corrosion control studies. The SAB has reviewed the description of EPA’s CCT requirements and concludes that they are based on sound science. However, the focus in the Proposed Rule on lead service lines as the primary source of lead may overlook two secondary contributors to lead exposure through drinking water, the lead content of galvanized pipe used in premise plumbing and microbiologically influenced corrosion (MIC).

- The SAB is not in favor of introducing the new term “trigger level” for CCT because of the complexity of making lead management decisions regarding CCT (or service line replacement) around both trigger and action levels. This trigger level adds unnecessary complexity and is not adequate for protection of public health. The SAB finds that a more efficacious course of action could be to lower the lead action level to 10 μg/L and streamline the recommendations around CCT and/or lead service line replacement such that systems with a 90th percentile (P90) level >10 μg/L must follow the CCT installation or re-optimization guidelines.

- EPA’s benefit-cost analysis for the Proposed Rule focuses on quantifiable health risk reduction benefits associated with reduced levels of lead in water and the resultant impacts on childhood IQ. The EPA did not monetize benefits of reduced blood lead levels in adults, but estimates of blood levels in men and women were produced as part of the analysis and referenced in the context of cardiovascular effects, renal effects, reproductive and developmental effects, immunological effects, neurological effects, and cancer. EPA’s conclusion that the Proposed Rule is justified based on analysis of benefits and costs is valid. However, the SAB finds that the benefit-cost analysis appears to underestimate the benefits associated with reduced levels of lead in drinking water. Considerations and assumptions that have not been included in the benefit-cost analysis would likely support more aggressive efforts to replace service lines more quickly.

- The SAB commends the EPA for its quantitative analysis of children’s blood lead levels and IQ. The agency has applied current science in the analysis and has predicted blood lead levels (BLLs) and changes in IQ using currently available modeling techniques. However, the SAB recommends revision of the Proposed Rule to provide greater clarity and transparency regarding uncertainty in the findings.

- The Proposed Rule contains requirements for educating the public about: the hazards of lead in drinking water, the lead levels in their own water supplies, and the lead levels in water supplied to schools and childcare facilities. The SAB recommends revisions to strengthen some of the public education and risk communication requirements in the Proposed Rule and ensure that they are consistently interpreted, implemented, and enforced. In addition, the SAB recommends that the EPA develop a centralized portal to disseminate information on the Proposed Rule, training courses for states and utilities, and best practices to implement the Proposed Rule.

- In Section 4 of the enclosed report, the SAB has provided responses to specific questions submitted by the EPA.

The SAB appreciates the opportunity to provide the EPA with advice and comment on the Proposed Rule. We look forward to receiving the Agency’s response.

Sincerely,

Dr. Michael Honeycutt, Chair
Science Advisory Board

Enclosure

NOTICE

This report has been written as part of the activities of the EPA Science Advisory Board (SAB), a public advisory group providing extramural scientific information and advice to the Administrator and other officials of the Environmental Protection Agency. The SAB is structured to provide balanced, expert assessment of scientific matters related to problems facing the Agency. This report has not been reviewed for approval by the Agency and, hence, the contents of this report do not necessarily represent the views and policies of the Environmental Protection Agency, nor of other agencies in the Executive Branch of the Federal government, nor does mention of trade names of commercial products constitute a recommendation for use. Reports of the SAB are posted on the EPA Web site at http://www.epa.gov/sab.

U.S. Environmental Protection Agency
Science Advisory Board

CHAIR
Dr. Michael Honeycutt, Division Director, Toxicology Division, Texas Commission on Environmental Quality, Austin, TX

MEMBERS
Dr. Rodney Andrews, Director, Center for Applied Energy Research, University of Kentucky, Lexington, KY

Dr. Hugh A. Barton, Independent Consultant, Mystic, CT

Dr. Barbara Beck, Principal, Gradient Corp., Cambridge, MA

Dr. Deborah Hall Bennett, Professor, Environmental and Occupational Health Division, Department of Public Health Sciences, School of Medicine, University of California, Davis, Davis, CA

Dr. Frederick Bernthal, President Emeritus and Senior Advisor to the Board of Trustees, Universities Research Association, Washington, DC

Dr. Bob Blanz, Associate Director, Office of Water Quality, Division of Environmental Quality, Arkansas Department of Environmental Quality, North Little Rock, AR

Dr. Todd Brewer, Senior Manager, Grants, Education, and Utility Programs, American Water Works Association, Denver, CO

Dr. Joel G. Burken, Curator's Professor and Chair, Civil, Architectural, and Environmental Engineering, College of Engineering and Computing, Missouri University of Science and Technology, Rolla, MO

Dr. Janice E. Chambers, William L. Giles Distinguished Professor and Director, Center for Environmental Health Sciences, College of Veterinary Medicine, Mississippi State University, Mississippi State, MS

Dr. John R. Christy, Distinguished Professor of Atmospheric Science and Director of Earth System Science Center, University of Alabama in Huntsville, Huntsville, AL

Dr. Samuel Cohen, Professor, Pathology and Microbiology, University of Nebraska Medical Center, Omaha, NE

Dr. Louis Anthony (Tony) Cox, Jr., President, Cox Associates, Denver, CO

Dr. Alison C. Cullen, Interim Dean and Professor, Daniel J. Evans School of Public Policy and Governance, University of Washington, Seattle, WA

Dr. Otto C. Doering III, Emeritus Professor, Department of Agricultural Economics, Purdue University, W. Lafayette, IN

Dr. Susan P. Felter, Research Fellow, Global Product Stewardship, Procter & Gamble, Mason, OH

Dr. Joseph A. Gardella, SUNY Distinguished Professor of Chemistry, Department of Chemistry, College of Arts and Sciences, University at Buffalo, Buffalo, NY

Dr. John D. Graham, Dean, O'Neill School of Public and Environmental Affairs, Indiana University, Bloomington, IN

Dr. John Guckenheimer, Professor Emeritus and Interim Director, Center for Applied Mathematics, Cornell University, Ithaca, NY

Dr. Margaret MacDonell, Department Head, Argonne National Laboratory, Lemont, IL

Dr. Robert E. Mace, The Meadows Center for Water and the Environment, Texas State University, San Marcos, TX

Dr. Clyde F. Martin, Horn Professor of Mathematics, Emeritus, Department of Mathematics and Statistics, Texas Tech University, Crofton, MD

Dr. Sue Marty, Senior Toxicology Leader, Toxicology & Environmental Research, The Dow Chemical Company, Midland, MI

Mr. Robert W. Merritt, Independent Consultant, Houston, TX

Dr. Larry Monroe, Independent Consultant, Braselton, GA

Dr. Thomas F. Parkerton, Senior Environmental Scientist, Toxicology & Environmental Science Division, ExxonMobil Biomedical Science, Spring, TX

Dr. Robert Phalen, Professor, Air Pollution Health Effects Laboratory, Department of Medicine, University of California-Irvine, Irvine, CA

Dr. Kenneth M. Portier, Independent Consultant, Athens, GA

Dr. Robert Puls, Owner/Principal, Robert Puls Environmental Consulting, Bluffton, SC

Dr. Kenneth Ramos, Executive Director, Institute of Biosciences and Technology, Texas A&M University, Houston, TX

Dr. Tara L. Sabo-Attwood, Associate Professor and Chair, Department of Environmental and Global Health, College of Public Health and Health Professionals, University of Florida, Gainesville, FL

Dr. Mara Seeley, Unit Chief – Exposure Assessment, Environmental Toxicology Program, Bureau of Environmental Health, Massachusetts Department of Public Health, Boston, MA

Dr. Anne Smith, Managing Director, NERA Economic Consulting, Washington, DC

Dr. Richard Smith, Professor, Department of Statistics and Operations Research, University of North Carolina, Chapel Hill, NC

Dr. Jay Turner, Professor and Vice Dean for Education, Department of Energy, Environmental and Chemical Engineering, McKelvey School of Engineering, Washington University, St. Louis, MO

Dr. Brant Ulsh, Principal Health Physicist, M.H. Chew & Associates, Cincinnati, OH

Dr. Donald van der Vaart, Senior Fellow, John Locke Foundation, Raleigh, NC

Ms. Carrie Vollmer-Sanders, Director, Agriculture Engagement Strategy, Efroymson Conservation Center, The Nature Conservancy, Indianapolis, IN

Dr. Kimberly White, Senior Director, Chemical Products and Technology Division, American Chemistry Council, Washington, DC

Dr. Mark Wiesner, Professor, Department of Civil and Environmental Engineering, Director, Center for the Environmental Implications of NanoTechnology (CEINT), Pratt School of Engineering, Nicholas School of the Environment, Duke University, Durham, NC

Dr. Peter J. Wilcoxen, Laura J. and L. Douglas Meredith Professor for Teaching Excellence, Director, Center for Environmental Policy and Administration, The Maxwell School, Syracuse University, Syracuse, NY

Dr. Richard A. Williams, Retired Economist, U.S. Food and Drug Administration, Independent Consultant, McLean, VA

Dr. S. Stanley Young, Chief Executive Officer, CGStat, Raleigh, NC

Dr. Matthew Zwiernik, Professor, Department of Animal Science, Institute for Integrative Toxicology, Michigan State University, East Lansing, MI

SCIENCE ADVISORY BOARD STAFF

Dr. Thomas Armitage, Designated Federal Officer, U.S. Environmental Protection Agency, Washington, DC

U.S. Environmental Protection Agency
Science Advisory Board
Drinking Water Committee

CHAIR

Dr. Mark Wiesner, Professor, Department of Civil and Environmental Engineering, Director, Center for the Environmental Implications of NanoTechnology (CEINT), Pratt School of Engineering, Nicholas School of the Environment, Duke University, Durham, NC

MEMBERS

Dr. Craig Adams, Professor, Civil Engineering, Parks College of Engineering, Aviation and Technology, Saint Louis University, St. Louis, MO

Dr. Amy Childress, Professor and Director of Environmental Engineering, Sonny Astani Department of Civil & Environmental Engineering, University of Southern California, Los Angeles, CA

Dr. Baolin Deng, Professor, Department of Civil and Environmental Engineering, University of Missouri, Columbia, MO

Dr. James Englehardt, Professor, Civil, Architectural, and Environmental Engineering, College of Engineering, University of Miami, Coral Gables, FL

Dr. Raymond M. Hozalski, Professor, Civil Environmental, and Geo-Engineering, University of Minnesota, Minneapolis, MN

Dr. Mark W. LeChevallier, Principal, Dr. Water Consulting, LLC, Morrison, CO

Dr. Richard Sakaji, Independent Consultant, El Cerrito, CA

Dr. Craig Steinmaus, Public Health Medical Officer III, Office of Environmental Health Hazard Assessment, California Environmental Protection Agency, Oakland, CA

Dr June Weintraub, Manager of Water, Noise and Medical Cannabis Dispensary Permit Program, San Francisco Department of Public Health , San Francisco, CA, USA

Dr. Lloyd Wilson, Independent Consultant, Cropseyville, NY

Dr. Yuefeng Xie, Professor, Environmental Engineering, Pennsylvania State University, Middletown, PA

SCIENCE ADVISORY BOARD STAFF

Dr. Bryan Bloomer, Designated Federal Officer, U.S. Environmental Protection Agency, Washington, DC

TABLE OF CONTENTS

Acronyms and Abbreviations

AL	Action Level
ANSI	American National Standards Institute
BLL	Blood Lead Level
C:N:P	Carbon to Nitrogen to Phosphorus Ratio
CCT	Corrosion Control Treatment
CO_2	Carbon Dioxide
CWS	Community Water System
EA	Economic Analysis
ERDDAA	Environmental Research Demonstration Development Authorization Act
FRB	Federal Reserve Bank
GM	Geometric Mean
GSD	Geometric Standard Deviation
IQ	Intelligence Quotient
LCR	Lead and Copper Rule
LSL	Lead Service Line
LSLR	Lead Service Line Replacement
MCLG	Maximum Contaminant Level Goal
MIC	Microbiologically Influenced Corrosion
NSF	National Science Foundation
NPDES	National Pollution Discharge Elimination System
NTP	National Toxicology Program
NTNCWS	Non-Transient Non-Community Water System
PbO	Lead(II) oxide
PbO_2	Lead(IV) oxide
POU device	Point of Use Device
SDWIS	Safe Drinking Water Information System
WLL	Water Lead Level

1. EXECUTIVE SUMMARY

As part of its statutory duties, the EPA Science Advisory Board (SAB) may provide advice and comment on the scientific and technical basis of certain planned EPA actions. The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other federal agency for formal review and comment, together with relevant scientific and technical information on which the proposed action is based. The SAB may then provide advice and comments on the adequacy of the scientific and technical basis of the proposed action. The SAB and SAB Drinking Water Committee met by teleconference on March 30, 2020 and elected to review the scientific and technical basis of the proposed rule titled *National Primary Drinking Water Regulations: Proposed Lead and Copper Rule Revisions* (Proposed Rule). The Proposed Rule is intended to provide effective protection of public health by reducing exposure to lead and copper in drinking water. The proposal includes procedures and requirements for lead tap sampling, corrosion control treatment, lead service line replacement, consumer awareness, and public education. Subsequent to the March 30th SAB teleconference, a work group of chartered SAB and SAB Drinking Water Committee members was formed to review the Proposed Rule. Members of the work group then took the lead in SAB deliberations on this topic at a public teleconference held on [insert date]. The SAB's advice and comments on the Proposed Rule are provided in the enclosed report.

Water sampling

The Proposed Rule describes revisions to the current Lead and Copper Rule to improve tap sampling. These revisions include requirements for: (1) tiering of tap sample collection sites, (2) number of tap samples and frequency of sampling, and (3) sample collection methods. The EPA proposes to prioritize lead sampling at sites with lead service lines rather than sites with copper pipes with lead solder because the best available science indicates that lead service lines are at the highest risk of releasing elevated levels of lead. The SAB notes that lead service lines may not be the primary source of lead in drinking water in all homes; galvanized pipe may also be a source.

The Proposed Rule would: prohibit the inclusion of pre-stagnation flushing in all tap sampling protocols, prohibit the cleaning or removing of the faucet aerator in the tap sampling protocol, and require that tap samples be collected in bottles with a wide-mouth configuration. The SAB recommends that the sampling objectives be explicitly stated in Section G of the proposed rule, "Monitoring Requirements for Lead and Copper in Tap Water Sampling" (page 19). If the overall objective is to collect water that represents the highest possible lead levels to which the resident might be exposed, then it should be stated how the proposed sampling protocol will achieve this by obtaining representative samples from the lead service line, premise plumbing, or both. The SAB notes that modification of the sampling protocol to ensure that the sampled water comes from within the lead service connection requires knowledge of the diameter (or diameters if varying) of the piping to the faucet and an estimate of the length (or lengths if varying) of piping from the tap to the service connection.

The SAB finds that it could be much easier – and more representative of the public's exposure – to conduct random sampling (without any precondition for stagnation) of high-risk homes (e.g., those with lead service lines). This would indicate the true exposure (not a "worse case") for high-risk populations. Based on a more realistic sampling of exposure, an appropriate action level (e.g., 5 ug/L) could be set.

Water treatment

The EPA is proposing to revise requirements for corrosion control treatment (CCT) based on the tap sampling results. The EPA's proposal also establishes a new lead trigger level of 10 mg/L. At this trigger level, water system operators currently treating for corrosion would be required to re-optimize their existing treatments. Those that do not currently treat for corrosion would be required to conduct corrosion control studies.

The SAB notes that the Safe Drinking Water Act has effectively safeguarded and improved America's drinking water supply. The guiding principle of maintaining multiple barriers to prevent contaminants from entering the drinking water supply has served the goal of protecting public health and should remain unchanged. However, such a view has resulted in a regulatory structure that controls individual contaminants without consideration of unintended consequences or secondary impacts that could occur once the drinking water has left the treatment plant. Maintaining water quality within the distribution system and premise plumbing requires a delicate balance between chemistry and biology. The EPA should not leave solving these secondary issues up to the states and water systems as they arise. Doing so could lead to significant unintended consequences. The EPA should provide clear direction and, if none is available, provide variances that allow additional time for states and water systems to find solutions to compliance issues.

The Proposed Rule maintains the current lead Maximum Contaminant Level Goal (MCLG) of zero and action level (AL) of 15 ppb but requires a more comprehensive response at the action level and introduces a trigger level of 10 ppb. The trigger level is a new provision designed to compel water systems to take progressive, tailored actions to plan upgrades to aging infrastructure and reduce levels of lead in drinking water at levels approaching the action level. The SAB is not in favor of introducing the new term "trigger level" for CCT. Although the trigger level may possibly accelerate lead service line replacement, it adds unnecessary complexity resulting from having to make lead management decisions regarding CCT (or service line replacement) around both trigger and action levels. Moreover, neither the proposed trigger level nor the unchanged action level of 15μg/L can be considered to have a scientific basis given the compelling body of literature that has served as the basis for multiple public health organizations, including the U.S. Centers for Disease Control, to conclude that there is no safe level of lead exposure. The SAB finds that a more efficacious course of action could be to lower the lead action level to 10 μg/L and streamline the recommendations around CCT and/or lead service line replacement such that systems with a 90th percentile (P90) level >10 μg/L" must follow the CCT installation or re-optimization guidelines.

Benefit-cost analysis

The benefit-cost analysis for the Proposed Rule focuses on quantifiable health risk reduction benefits associated with reduced levels of lead in water and the resultant impacts on childhood IQ. The EPA did not monetize benefits in the reduction of blood lead levels in adults, but estimates of blood levels in men and women were produced as part of the analysis and referenced in the context of cardiovascular effects, renal effects, reproductive and developmental effects, immunological effects, neurological effects, and cancer. EPA's conclusion that the Proposed Rule is justified based on analysis of costs and benefits is valid. However, the SAB finds that the benefit-cost analysis appears to underestimate the benefits associated with reduced levels of lead in drinking water. Considerations and assumptions that have not been included in the analysis would likely support more aggressive efforts to replace service lines more quickly.

Analysis of children's blood lead levels and IQ

In developing the Proposed Rule, the EPA has estimated lead concentrations in tap water under different scenarios of lead service line (LSL) presence as well as different corrosion control treatment conditions. This information was used to model predicted blood lead levels, IQ decrements, and associated costs under different LSL and CCT conditions. Overall, the SAB commends the EPA for its quantitative analyses of children's blood lead levels and IQ. The agency has generally applied current science and predicted blood lead levels (BLLs) and changes to IQ using currently available modeling techniques. However, there are several parts of the Proposed Rule (VI (D), sections 1 and 2) where the discussion of the methodology should be clarified, especially with regard to choice of certain assumptions, and where more transparency in reporting uncertainty in the findings would improve the analysis.

Public education, notification, and risk communication

The Proposed Rule includes requirements for education of the public about: the hazards of lead in drinking water, the lead levels in their own water supplies, and the lead levels in water supplied to schools and childcare facilities. To effectively communicate risk, it is important to ensure that the appropriate level of the information is provided to the public. The also SAB notes that that EPA, or other agencies responsible for communicating with the public, should solicit information from experts in public communication so that the Agency's risk communication is understandable, convincing and well received. The SAB recommends that some of the public education and risk communication requirements in the Proposed Rule be revised to ensure that they are effective and consistently interpreted, implemented, and enforced.

With regard to the public education requirements described in Section F of the proposal: (1) The SAB finds that the level of information provided to the public on lead effects and the other factors would need be appropriate for someone with a relatively limited education. (2) The SAB finds that the requirements could leave residents of small community water systems (less than 10,000 persons) uninformed and vulnerable to lead effects, or responsible for paying for their own testing if they had an interest in knowing the lead levels in their drinking water. If the number of individuals served by small community water systems is substantial, this provision should be expanded include smaller water systems. (3) The SAB recommends that the EPA add more detail to assist water purveyors in complying with the requirements, and consider changing the outreach requirements to local health agencies, which may be more variable with respect to their knowledge of lead in drinking water.

With regard to public education and sampling requirements at schools and child care facilities: (1) The SAB questions whether sampling at schools and child care facilities sampling every 5 years sufficient. If it is known that the water supply, internal plumbing and fixtures are lead-free then sampling every five years is sufficient, otherwise more frequent sampling is needed. (2) The SAB recommends that the EPA consider establishing a clear procedure and standard verbiage for information flow to ensure that the highest percentage of families would understand the communication, including, as needed, in languages other than English. (3) The SAB finds that it makes sense to not duplicate sampling if the state or primacy agency has a suitable procedure in place. If the EPA-mandated sampling under the new rule is waived, there should be a mandate that the state or primacy agency provide information to parents consistent with what is required if EPA is responsible for obtaining the results. (4) The SAB recommends that the EPA provide a clear definition of childcare facility, which may include whether the facility is licensed and a minimum number of children enrolled. EPA should clarify whether private and/or home-based childcare facilities are subject to this rule.

SAB responses to specific questions from EPA

In Section 4 of the enclosed report, the SAB has provided responses to specific questions submitted by the EPA.

2. INTRODUCTION

As part of its statutory duties, the EPA Science Advisory Board (SAB) may provide advice and comment on the scientific and technical basis of certain planned EPA actions. The Environmental Research, Development, and Demonstration Authorization Act of 1978 (ERDDAA) requires the EPA to make available to the SAB proposed criteria documents, standards, limitations, or regulations provided to any other federal agency for formal review and comment, together with relevant scientific and technical information on which the proposed action is based. The SAB may then provide advice and comments on the scientific and technical basis of the proposed action.

The SAB and SAB Drinking Water Committee met by teleconference on March 30, 2020 and elected to review the scientific and technical basis of the proposed rule titled *National Primary Drinking Water Regulations: Proposed Lead and Copper Rule Revisions* (Proposed Rule). Subsequent to the March 30th teleconference, a work group of chartered SAB and SAB Drinking Water Committee members was formed to carry out the review. Members of this work group then took the lead in SAB deliberations on this topic at a public teleconference held on [insert date]. The SAB's advice and comments on the Proposed are provided in the enclosed report.

3. SAB ADVICE AND COMMENTS ON THE PROPOSED RULE

3.1. Water Sampling Requirements

The Proposed Rule describes revisions to the current Lead and Copper Rule (LCR) to improve tap sampling requirements in the areas of: (1) tiering of tap sample collection sites, (2) number of tap samples and frequency of sampling, and (3) sample collection methods.

3.1.1. Scientific and Technical Comments on the Water Sampling Requirements

The SAB provides the following scientific and technical comments on the water quality sampling requirements in the proposed rule

Tiering of tap sample collection sites

The EPA proposes to prioritize lead sampling at sites with lead service lines rather than sites with copper pipes with lead solder because the best available science indicates that lead service lines are at the highest risk of releasing elevated levels of lead. The SAB notes that lead service lines may not be the primary source of lead in drinking water in all homes; galvanized pipe may also be a source (Clark et al. 2015). While the work by Clark et al. is fairly recent, further historical examination of galvanized pipe manufacturing shows that the presence of lead in the zinc coating has been known for a long period of time since lead aided the galvanizing process. Research has shown the chemistry of lead in galvanized pipe in contact with disinfected drinking water to be fairly complex, but mechanisms for lead release from galvanized pipe have been identified. Additional research has shown that the lead scale in galvanized pipe can be a source of lead in drinking water (McFadden et al. 2011).

Number of tap samples and frequency of sampling

The EPA's proposed revisions to tap sampling frequency and locations are intended to ensure more frequent tap sampling is occurring at the most representative sites to identify elevated lead levels. However, the SAB notes that concerns about monitoring cycles in the proposed rule have been raised. In public comments submitted to the SAB, Earthjustice states that "Because of the established science on lead variability in drinking water and the risk to communities that prolonged monitoring periods pose, EPA should remove the rule's provisions that allow for reduced, three-year monitoring cycles. If EPA declines to fully eliminate triennial sampling cycles, EPA should significantly diminish the number of systems eligible for reduced three-year monitoring by imposing more stringent requirements for eligibility."

Sample collection methods

The Proposed Rule would prohibit the inclusion of pre-stagnation flushing in all tap sampling protocols, prohibit cleaning or removing of the faucet aerator in the tap sampling protocol, and require that tap samples be collected in bottles with a wide-mouth configuration. The SAB recommends that sampling objectives be explicitly stated in Section G of the proposal, "Monitoring Requirements for Lead and Copper in Tap Water Sampling" (page 19). If the overall objective is to collect water that represents the highest possible lead levels to which the resident might be exposed, then EPA should state how the proposed sampling protocol will achieve this by obtaining representative samples from the lead service line, premise plumbing, or both. EPA's recommendation that schools and child-care facilities conduct a two-step sampling procedure is informative to the public in differentiating lead in the outlets (e.g., faucet, fixtures, and water fountains) versus behind the wall (e.g., in the interior plumbing). Similarly, the public needs to understand the differences between premise plumbing and service lines – and the challenges with collecting representative samples of each. Although the discussion below focuses more on lead service lines, it should be noted that premise plumbing remains a significant source of lead exposure (Riblet 2019).

The SAB recognizes the challenges of collecting a sample from the lead service line – particularly as they are discussed in Section 2 of the Proposed Rule Lead Tap Sampling Requirements for Water Systems with Lead Service Lines" (page 49). EPA states that "first-draw samples of one-liter may not capture water that has sat in the lead service line, which may contain the highest lead in drinking water levels. When the 1991 Lead and Copper Rule was promulgated, the best available data obtained from first-draw one-liter samples. Recent studies have been conducted to identify which liter from the tap best captures the highest level of lead that could potentially be consumed by residents. The EPA has evaluated these studies and determined that a fifth liter tap sample may be a more conservative option than a first-draw sample because it would capture water from the lead service line, and sample results would theoretically result in more protective measures, even though it is unlikely that any given person consistently drinks water at the level of the fifth liter draw. Therefore, the EPA is considering a 'fifth-liter option.' To take a fifth liter tap sample, the person sampling, in accordance with all proposed tap sampling revisions, would fill a one-gallon container that would not be analyzed, then immediately collect a one-liter sample for lead in a separate bottle without turning off the tap. While technically this is not the fifth liter of water, the EPA will refer to this sample as the fifth liter." The SAB provides the following specific comments on the proposed sampling protocol.

- According to Cotruvo 2019: requiring a fifth-liter second-draw sample is arbitrary and not necessarily going to draw water from the service line in many homes because of the variation in distances from the tap to the service line. Modification of the sampling protocol to draw the second sample when a noticeable temperature change occurs in the flowing tap water is recommended.

- According to Lee et al. 1989 and Hozalski et al. 2005: modification of the sampling protocol to ensure that the sampled water comes from within the lead service connection requires knowledge of the diameter (or diameters if varying) of the piping to the faucet and an estimate of the length (or lengths if varying) of piping from the tap to the service connection. A calculation can then be made of the total volume of water in the piping. Then, the total water volume in the piping inside the home would be wasted, perhaps with a little extra, prior to collection of a water sample that represents the lead service line.

- According to Cartier et al. 2011, some countries (e.g., Canada and France) require that sampling be done by a trained technician. The study also recommends that flushing advisories be based on an estimation of plumbing volume and lead concentrations at the tap rather than on flushing duration.

- The SAB notes that, instead of having a trained technician collect tap samples from a residence, EPA could consider having a trained technician work with a resident to collect tap samples, recognizing this valuable opportunity for public education and outreach.

- Several studies (e.g., Baron 2001, Ng et al. 2018, and Riblet et al. 2019) have found random daytime sampling to provide mean values to accurately measure real exposure. In the case of measuring real exposure, rather than "worst case" exposure, which can't be predicted and is not representative of the customer exposure, a lower action level lower (e.g., 5 ug/L) could be set.

3.1.2. Recommendations to Improve the Scientific and Technical Basis of Water Sampling Requirements

In general, the SAB finds that the proposed changes to site selection tiering criteria, number and frequency of tap samples, and sample collection are a move in the right direction to improve public health protection. However, the SAB is concerned that 30 years of regulatory development have made the Lead and Copper Rule cumbersome; it could be that the best way to make the Lead and Copper Rule more implementable and effectively enforced is to develop a new rule and not revise the existing one. The SAB notes that, no matter which direction is taken, states must reaffirm their responsibilities and commit to greater oversight and compliance.

The SAB notes that the objectives of the Proposed Rule are not clear. It is not clear whether the Proposed Rule is intended to be a treatment technique rule for managing lead exposure through corrosion control (and if corrosion control fails, to then remove lead components) – or a lead exposure rule for protecting the public from exposure to high (>10 or >15 ug/L) concentrations of lead by targeting the worst-case condition for lead exposure. As the former, the purpose of the rule is to evaluate the effectiveness of the treatment technique (i.e., corrosion control). In trying to be the latter (a lead exposure rule), the rule must address the huge complexities of where, how, how much, when, and by whom to sample. As a result, the Proposed Rule loses touch with the original purpose.

For example, in Section G of the proposal, "Monitoring Requirements for Lead and Copper in Tap Water Sampling" (page 19) the EPA should explicitly state sampling objectives indicate and how the proposed sampling protocol will achieve the objectives. As previously discussed, modification of the sampling protocol to ensure that the sampled water comes from within the lead service connection requires knowledge of the diameter (or diameters if varying) of the piping to the faucet and an estimate of the length (or lengths if varying) of piping from the tap to the service connection.

It could be much easier – and more representative of the public's exposure – to conduct random sampling (without any precondition for stagnation) of high-risk homes (e.g., those with lead service lines). This would indicate the true exposure (not a "worst case") for high risk populations. Based on a more realistic sampling of exposure, an appropriate action level (e.g., 5 ug/L) could be set.

The Proposed Rule should consider not only control of corrosion but also control of particulate lead, which is not necessarily based on corrosion chemistry but is influenced by many other factors (e.g., erosion, vibration) that are unrelated to corrosion chemistry. The issue of particulate lead is not addressed by science – in its health effects, its control by corrosion chemicals, or how sampling would or would not target these particles. Very often, it is the particulate lead particles that drive the high measured values (whether these come from lead or galvanized pipes). Careful attention needs to also be given to sample preservation, sample transport and storage, and analytical methods that will insure total lead and copper analyses to sub part-per-billion levels.

3.2. Water Treatment

The EPA is proposing to revise requirements for corrosion control treatment (CCT) based on the tap sampling results. The EPA's proposal also establishes a new lead trigger level of 10 mg/L. At this trigger level, water systems that currently treat for corrosion would be required to re-optimize their existing treatment. Systems that do not currently treat for corrosion would be required to conduct a corrosion control study.

3.2.1. Scientific and Technical Comments on the Water Treatment Requirements

The SAB notes that the Safe Drinking Water Act has effectively safeguarded and improved America's drinking water supply. The guiding principle of maintaining multiple barriers to prevent contaminants from entering the drinking water supply has served the goal of protecting public health and should remain unchanged. However, such a view has resulted in a regulatory structure that controls individual contaminants without consideration of unintended consequences or secondary impacts that could occur once the drinking water has left the treatment plant. While the integrity of the distribution system excludes contaminants from entering drinking water as it moves from the treatment plant to the home tap, the Proposed Rule is attempting to control the release of lead from sources that are in direct contact with drinking water. The SAB notes that the use of orthophosphate as a corrosion inhibitor is based on sound science, but the failure to account for changes in water quality that occur in the distribution system could exacerbate lead release within individual households.

While the Proposed Rule takes into consideration the secondary impacts on wastewater treatment plants, the rule does not consider the potential for lead release resulting from chemical and microbiological changes in water quality that have taken place between treatment plant and the tap. There is no doubt that distribution system water quality is a complex issue, but changes in distribution system water quality and the impacts those changes can have on lead release from various materials are well documented.

Use of orthophosphate

The SAB has reviewed the description of EPA's CCT requirements and concludes that they are based on sound science. The SAB agrees with dismissing calcium hardness as an option as calcium scales are not likely to be important in reducing lead levels. The SAB also supports the specification that phosphate inhibitor must be orthophosphate. Research by Hozalski et al. (2005) and that of others (e.g., Holm and Schock, 1991) has shown that polyphosphate, as a metal chelator, is likely to result in much higher lead levels than when using orthophosphate alone.

A major issue regarding orthophosphate use is the potential impact on wastewater treatment plants and/or the environment. Phosphorous is often a limiting nutrient in inland waters such that increased addition of phosphorous can lead to eutrophication problems. The addition of phosphate to the water supply for lead corrosion control may place an undue burden on wastewater treatment facilities to install or improve phosphorous removal processes if NPDES permits specify a discharge limit on phosphorous. Even without a permitted phosphorous limit and associated impacts on wastewater treatment operations, the increased discharge of phosphorous into receiving waters due to phosphate dosing for corrosion control could have negative effects on receiving water quality. The SAB appreciates the time and effort taken by the EPA to provide an assessment of the economic and environmental impacts of phosphate use on wastewater treatment in the supplementary information included in the regulation package.

Changing Alkalinity and Use of Ortho-Phosphate as Corrosion Control Measures

The focus in the Proposed Rule on lead service lines as the primary source of lead may overlook two secondary contributors to lead exposure through drinking water: the lead content of galvanized pipe used in premise plumbing, and microbiologically influenced corrosion (MIC). Neither of these subjects seems to be included in the supplementary materials discussion of the Proposed Rule.

A study of blood lead levels conducted by Miranda et al (2007) found that a switch to chloramines resulted in elevated blood lead levels in a water system that was using chloramines and practicing corrosion control versus blood lead levels in a neighboring water system that continued to use free chlorine with no corrosion control. A partial reason for the Miranda et al. study results may be that the focus on the lead service lines in the Proposed Rule, overlooks galvanized pipe used in premise plumbing as a source of lead, not only as a repository for legacy lead from an LSR, but as a primary source. Work by Clark et al (2015) indicates that lead in galvanized pipe can be a significant source of lead. Historical examination of galvanized pipe manufacturing practices would find that manufacturers were aware of lead in the zinc coating because it aided the galvanizing process. In older homes galvanized pipe may constitute a significant portion or all of the premise plumbing.

The literature also contains research that suggests two possible means for lead to be released from galvanized pipe. One involves the conversion of PbO_2 to PbO in the presence of chloramines (Switzer et al 2006, Lin and Valentine 2008). PbO_2 is known to form in the presence of free chlorine, but when exposed to chloramine, the lead in PbO_2 is reduced from Pb(IV) to Pb(II), an oxide that does not bind to the surface of pipes as strongly as PbO_2. This chemistry is important because the reduction of Pb(IV) to Pb(II) occurs in the presence of monochloramine breakdown products during the transmission of drinking water from the treatment plant to the consumer's tap. The continual decay of chloramine increases the potential for lead release in homes that are at the far ends of the distribution system or in areas of high-water age.

High lead concentrations in first draw samples could be an indication that reduction of PbO_2 to PbO is occurring in premise plumbing. With a six hour stagnation period before sample collection there is additional time for chloramine to decay and the byproducts to react with Pb(IV) to convert it to Pb(II) with subsequent release in first draw sample. This comment does not preclude the presence of particulate lead in the premise plumbing from a lead service line, but provides a cautionary note that the current Tier classification system, which does not appear to include galvanized pipe, may be overlooking an important source of lead exposure that is not addressed in the Proposed Rule.

Chloramine decay may also be promoting lead release through another mechanism. The focus of the Proposed Rule appears to be on electrochemical corrosion, however, MIC is recognized as another means of inducing electrochemical corrosion on a "micro" scale. The microbial community living in films on the surfaces of equipment comes into contact with drinking water as it moves from the treatment plant to the tap. The drinking water bathes the films with the nutrients needed to grow. These biological films can produce localized changes in their environment that can also result in corrosion and the release of metals, such as lead. Borenstein (1994) refers to this as microbiologically influenced corrosion or MIC.

Although it was not available to the EPA while the revisions of the Lead and Copper Rule were underway, the nitrification review by Bradley et al (2020) distills several years of microbiology and distribution system research into a discussion on nitrification in premise plumbing. The role of nitrification in lead release is an important consideration because corrosion control techniques employ the addition of two key nutrients that can promote nitrification (bicarbonate alkalinity and phosphate). While the decay of chloramines provides nitrogen, using a corrosion control technique that increases the bicarbonate alkalinity provides an inorganic carbon source that is key to promoting nitrifier growth over heterotrophs.

The equations in Bradley et al (2020) are important because CO_2 and phosphate appear in them. Since the microbial community that nitrifies is comprised of chemolithoautotrophs (Yamanaka 2008) that utilize an inorganic source of carbon (bicarbonate), increasing alkalinity by altering the carbonate water chemistry will promote their growth over the normal heterotrophic fauna that typically inhabits the biofilms. Since microbial communities are in constant competition for resources, the addition of phosphate (typically a limiting nutrient in freshwater systems) will promote the wrong type of microbial growth, especially in water with low organic carbon, but with moderate to high bicarbonate alkalinity. Biologists use the carbon to nitrogen to phosphorous ratio (C:N:P) to determine which nutrient could be limiting growth. The addition of a limiting nutrient often results in favoring one group of microbes over another. Often organic carbon is the only source of carbon considered in this equation, because heterotrophic bacteria that utilize carbon as an energy source can out compete the slower growing nitrifiers. If the C:N:P ratio is unbalanced and nitrogen is no longer limiting growth, then either phosphate or carbon can limit growth. In low organic carbon water the carbon in the C:N:P ratio needs to be examined using inorganic carbon (like bicarbonate alkalinity) in place of organic carbon. If the organic carbon is low enough, i.e., the limiting nutrient, nitrifiers will have the opportunity to out compete the heterotrophs resulting in nitrification.

The nitrification equation in Bradley produces acid, which is produced within the biofilm and can result in localized conditions conducive to the release of lead. Note that homes that may have galvanized plumbing but never had a lead service line do not appear to be included in any of the Tier requirements to establish monitoring locations. This appears to leave homes with galvanized plumbing unmonitored for lead.

While one may argue that nitrification is seasonal (which is well documented), only occurring in warmer weather, this is also a time when drinking water would be in higher demand. Since lead exposure is more of an acute health risk, under the right water quality conditions, the confluence of warmer weather (leading to nitrification in premise plumbing) and higher demand for drinking water could result in greater lead exposure.

Point of use (POU) devices

The Proposed Rule requires the use of POU devices or water pitchers whose performance has been certified by ANSI for lead removal. If certification is conducted under NSF/ANSI Standard 53, it should be noted that certification takes place under specific and controlled water quality conditions. These conditions might not be sufficient to ensure that POU devices certified for lead removal would provide adequate protection in all cases.

Under NSF/ANSI Standard 53 the POU devices are challenged with a maximum concentration of 0.15 mg/L. The finished water must contain less than 0.010 mg/L under specific conditions of pH, hardness, and alkalinity. This means that a home with a lead concentration that exceeds 0.15 mg/L may not be adequately protected by a POU or a pitcher. In a recently released report issued by CDM-Smith (2019) for the City of Newark, New Jersey, there were cases of POU devices that failed to meet the 0.010 mg/L target. In this report, poor performance was attributed to lead levels at the tap that exceeded 0.15 mg/L. These failures occurred in less than 4% of the test sites, and may indicate that a POU device certified for lead removal may not provide adequate protection to the user.

3.2.2. Recommendations to Improve the Scientific and Technical Basis of Water Treatment Requirements

While a single regulation might target a specific contaminant, it is important to remember that drinking water quality can be altered significantly by factors encountered in the distribution system. Maintaining water quality within the distribution system and premise plumbing requires a delicate balance between chemistry and biology. The EPA should not leave secondary issues up to the states and water systems to solve as they arise. Doing so could lead to significant unintended consequences. The EPA needs to provide clear direction and, if none is available, provide variances that allow additional time for states and water systems to find solutions to compliance issues.

The SAB recommends that EPA consider modifying the requirement for use of POU devices so that the POU devices be certified to both lead and particulate removal. In Flint Michigan, Bosscher et al. (2019) reported that all POU units certified to NSF/ANSI Standards 53 and 42 (particulate removal) were capable of reducing lead levels to below the 0.010 mg/L trigger level. The Bosscher et al. study demonstrates that a POU device that meets NSF standards 53 and 42 may be needed to ensure lead levels can be reduced to below the trigger level. Failure to account for the limitations in certification testing and the failure to specify both lead and particulate removal can result in the use of POU devices that would not adequately protect the users.

3.3. Benefit-Cost Analysis

The benefit-cost analysis as presented with the Proposed Rule focuses on quantifiable health risk reduction benefits associated with reduced levels of lead in water and the resultant impacts on childhood IQ. Benefits in the reduction of lead to adults were not monetized, but estimates of blood levels to men and women were produced as part of the analysis and referenced in the context of cardiovascular effects, renal effects, reproductive and developmental effects, immunological effects, neurological effects, and cancer. Benefits from the reduction in co-occurring contaminants were also not considered. Quantifiable costs included in the analysis included those associated with sampling, corrosion control treatment, lead service line inventorying and replacement, point of use treatment, public education and outreach, implementation and administration.

The final conclusion that the Proposed Rule is justified based on analysis of costs and benefits is certainly valid. However, for the reasons discussed below, the current analysis would appear to under-estimate the benefits associated with reduced levels of lead in drinking water. Considerations and assumptions that do not appear to have been included in the analysis would likely support more aggressive efforts to replace service lines more quickly.

3.3.1. Scientific and Technical Comments on the Benefit Cost Analysis

Benefit-cost analyses were produced using discount rates of both 3% and 7%. Using the former rate, benefits were calculated to exceed costs, while the inverse was true using a discount rate of 7%, consistent with the EPA's policy, and based on guidance from the Office of Management and Budget (OMB). A time horizon of 35 years was assumed. It is not clear which, if either discount rate was used for arriving at the conclusion "… that the quantified and non-quantified benefits of the proposed Lead and Copper Rule revisions justify the costs." This conclusion is well-founded, particularly in light of the following considerations that may not have been included in the economic assessment (EA).

First, as stated in public testimony of Jason Schwartz, the Legal Director for the Institute for Policy Integrity, "…there are strong reasons to favor the calculations of costs and benefits based on a 3% or lower discount rate… A 3% or lower discount rate is likely more appropriate given both the special nature of the benefits (in particular the IQ-related income effects that will occur over the next 100 years to future generations of yet-to-be-born individuals) and … the special nature of the costs (which largely fall on publicly-owned water systems and households, both of which may have a different social rate of time preference and opportunity cost of capital [compared with private entities]." The use of the lower discount rate can also be supported based on the Federal Reserve Bank (FRB) discount rate. Approximately 66 years of data available on the web starting from 7/1/1954 yield a daily average FRB discount rate of 4.79% since 1954. Given that the EA described in the Proposed Rule covers a 35-year period, one might use data for only the previous 35 years prior to current time to estimate the FRB discount rate which is found to be 3.56% from 4/1/1985 to 3/31/2020. While there are additional costs for capital that may be incurred above the FRB discount rate, public utilities typically borrow at rates lower than private industries.

Second, there is an interplay between the calculated present value of costs and the rate of service line replacement which the proposed rule would reduce at a minimum from 3% per year to 7% per year, the values of these replacement rates being coincidentally the same numerical value as the discount rates applied. The EA presents costs for replacement under the Proposed Rule that are greater than those for the current rule. Because the new rule uses a minimum 3% replacement rate while the current rule uses a minimum value of 7%, the comparison of costs implies a different discount cost profile over time. In addition, for the case of the lead levels being less than the action level but greater than the trigger level, the new rule may oblige a replace rate to be determined by the States, the assumed value of which does not appear to be indicated. EPA should clarify the effect of replacement rate on the cost-benefit calculations, making the interplay between discount rate and replacement rate on the net present value explicit.

Third, the EPA assessment of benefits of the Proposed Rule in terms of avoided losses in intelligence quotient (IQ) in children includes a comparison of three different versions of the analysis of blood levels (BLLs) in children: the paper originally published by Lanphear et al. (2005), an EPA correction of one of their datasets (Kirrane and Patel, 2014, later confirmed in a published 2019 correction by Lanphear et al.), and an alternative analysis of the same data by Crump et al. (2013). The estimated betas (Exhibit 6-25, page 6-36) seem fairly similar but in the end the authors prefer the Crump analysis "to minimize issues with overestimating predicted IQ loss at the lowest levels of lead exposure (less than 1 µg/dL BLL), which is result of the use of the log-linear function." The most recent EPA review of lead notes "several epidemiologic studies found a supralinear concentration-response relationship," and by using the Crump linear value as opposed to the log-linear value in the Lanphear analysis, the evaluation potentially underestimates values at lower concentrations. Both the Crump and Lanphear analyses provide separate linear values for concurrent BLL<7.5 mg/dL that demonstrate a significantly steeper slope for lower concentrations. While EPA does note that the Agency used alternative values as a sensitivity analysis, it should also note this potential underestimate.

Although EPA's estimates for increased earnings per IQ point are overall consistent with estimates provided by Salkever (1995), they are about 10% lower than the Salkever estimates. The basis for the difference is not readily apparent without access to EPA's analysis. Further, a recent assessment by Salkever (2014) suggests that the 1995 estimates may actually underestimate the current effect of IQ on lifetime earnings, possibly by as much as approximately 20%, for example by not accounting for recent trends of increased skill differentials on earning potential and returns on education. Although Salkever (2014) does not provide updated estimates to quantify impact of IQ on earning potential, in the interest of transparency, the EPA should acknowledge that the increased earnings per IQ point estimates used in the Proposed Rule might be biased low.

Fourth, benefits associated with reduced lead exposure and associated reduction in hypertension/cardiovascular effects have been well documented (Chowhury et al. 2018) and should be monetized and included in the EA. Both the National Institute of Environmental Health Sciences National Toxicology Program (NTP) and the EPA have recently reviewed the literature looking at the relationship between lead exposure and cardiovascular outcomes. The NTP concludes that that "there is sufficient evidence that blood Pb levels <10 µg/dL in adults are associated with adverse effects on cardiovascular function" (NTP 2012). The EPA's Integrated Science Assessment for Lead (ISA) concluded that there was sufficient evidence for a causal relationship between adult lead levels and both hypertension and coronary heart disease (U.S. EPA 2013). Since the NTP and EPA conducted these evaluations, additional references have further strengthened this relationship (Chowdhurry et al. 2018; Lanphear et al. 2018). Therefore, the EPA should include the cardiovascular health endpoints in their assessment.

Fifth, estimates of benefits associated with either impacts on childhood IQ or cardiovascular effects rely on estimates of likely changes in tap water lead levels associated with changes to LSLs and CCTs. Public comments submitted to the SAB by Cynthia Giles, Former Assistant Administrator, EPA Office of Environment and Compliance Assurance, reference an EPA data audit report published in 2008, which found that 92% of the lead health-based violations were not reported by States to the EPA (U.S. EPA 2006). The EPA should explore the impacts of underreporting violations of the projected replacement rates on the quality of data on lead exposure in public drinking water systems, the implications for calculating lead exposure levels, and overall benefits and costs.

Sixth, the proposed lead trigger level of 10 µg/L and the action level of 15 µg/L cannot be justified on the basis of scientific evidence given that scientific consensus, as expressed by multiple public health organizations, including the U.S. Centers for Disease Control and Prevention, is that there is no safe level of lead exposure. A sensitivity analysis of Costs and Benefits as a function of lower regulated levels would therefore appear to be warranted.

3.3.2. Recommendations to Improve the Scientific and Technical Basis of the Benefit-Cost Analysis

The SAB provides the following recommendations to strengthen the benefit-cost analysis in the Proposed Rule.

- Given that the EA described in the Proposed Rule covers a 35-year period, one might use data for only the previous 35 years prior to current time to estimate the FRB discount rate which is found to be 3.56% from 4/1/1985 to 3/31/2020.

- The EPA should clarify the effect of lead service line replacement rate on the Cost Benefit calculations, making the interplay between discount rate and replacement rate on the net present value explicit.

- The EPA assessment of benefits of the Proposed Rule in terms of avoided losses in intelligence quotient (IQ) in children includes a comparison of three different versions of the analysis of blood levels in children. The EPA should note that the Agency's analysis potentially underestimates values at lower exposure levels.

- EPA should acknowledge that the estimates for increased earnings per IQ point used in Proposed Rule might be biased low.

- Benefits associated with reduced lead exposure and associated reduction in hypertension/cardiovascular effects have been well documented and should be monetized and included in the EA.

- EPA should explore the impacts of underreporting violations of the projected lead service line replacement rates on the quality of data on lead exposure in public drinking water systems, the implications for calculating lead exposure levels, and overall benefits and costs.

- The analysis of lead exposure levels was conducted by assembling a dataset from previous studies conducted in both the US and Canada. To compensate for the combination of datasets from different study designs (as well as, presumably, natural variations in lead levels from one place to another), the authors use a random effects model for their statistical analysis. While the use of a random effects model in this context is quite appropriate, the analysis should be clarified to address points discussed in 2.5.1 of this report.

- Multiple public health organizations, including the U.S. Centers for Disease Control and Prevention, have indicated that there is no safe level of lead exposure. Therefore, EPA should conduct a sensitivity analysis of Costs and Benefits as a function of lower regulated levels.

3.4. Trigger Level

The Proposed Rule maintains the current lead MCLG of zero and AL of 15 ppb but requires a more comprehensive response at the action level and introduces a trigger level of 10 ppb. The trigger level is a new provision designed to compel water systems to take progressive, tailored actions to plan upgrades to aging infrastructure and reduce levels of lead in drinking water at levels approaching the action level.

Systems above the lead trigger level of 10 ppb would be required to work with their states to set annual goals for replacing lead service lines. Water systems above 15 ppb would be required to fully replace a minimum of three percent of the number of known or potential lead service lines annually. The SAB finds that the requirements in the Proposed Rule for interrelated actions combined with transparency and outreach requirements will increase the current rate of lead service line replacements.

3.4.1. Scientific and Technical Comments on the Proposed Trigger Level

EPA's use of a "trigger level" of 10 μg/L for lead appears to be based on a desire to accelerate implementation of lead service line replacement (LSLR). Exceedance of the trigger level requires, in addition to corrosion control treatment, implementation of a *full* LSLR with annual replacement determined by the State. This requirement, plus the elimination of the "test-out" provisions of the current rule, and the requirement for full rather than partial LSLR, would appear to open the door for more rapid replacement of lead service lines in those states requiring annual replacement rates equal to or greater than the current 7% per year. Also, it may possibly accelerate LSLR even at the proposed 3% per year replacement that would be mandated by the federal government if the action level is exceeded. However, neither the proposed trigger level nor the unchanged action level of 15 μg/L can be considered to have a scientific basis given the compelling body of literature that has served as the basis for multiple public health organizations, including the U.S. Centers for Disease Control and Prevention, to conclude that there is no safe level of lead exposure.

EPA's stated objective is that water systems should initiate actions at lower levels than currently required to reduce lead in drinking water. However, the SAB notes that the Agency has not justified the need for both an action and a trigger level.

3.4.2. Recommendations to Concerning the Scientific and Technical Basis of the Trigger Level

The SAB is not in favor of introducing the new term "trigger level" because of the added complexity of having to make lead management decisions regarding CCT (or service line replacement) around both trigger and action levels. This adds unnecessary complexity and is not adequate for protection of public health.

The SAB finds that a more efficacious course of action could be to simply lower the lead action level to 10 μg/L and streamline the recommendations around CCT and/or lead service line replacement accordingly such that systems with 90^{th} percentile (P90) level >10 μg/L must follow the CCT installation or re-optimization guidelines. Lead can be easily detected to the ppt level. A 10 μg/L lead action level is reasonable and feasible, especially if guidelines established elsewhere around the globe are considered. For example, the World Health Organization and Australian government both have established a guideline value of 10 μg/L for lead and the maximum acceptable drinking water lead concentration in Canada was recently lowered from 10 to 5 μg/L (Health Canada, 2019). The SAB notes that The State of Michigan Department of Environment, Great Lakes and Energy (EGLE) has implemented a new lead and copper rule[1] which reduces the present action level of 15 ppb to 12 ppb in January 2025. If a step toward tighter regulation at lower exposures is to be taken, procedures and analysis of scientific studies should be accomplished to revise the action level to lower values, as done

[1] https://www.michigan.gov/egle/0,9429,7-135-3313_3675_3691-9677--,00.html

in Michigan. The SAB supports flexibility regarding how systems provide safe drinking water, as long as even persons served by community water systems (CWSs) or Non-transient non-community water systems (NTNCWSs) are adequately protected. As CCTs may be more challenging to implement for such systems, it is reasonable to allow other courses of action.

3.5. Analysis of Children's Blood Lead Levels and IQ

Overall, the SAB commends the EPA for its quantitative analyses of children's blood levels and IQ in the Lead and Copper Rule. The agency has generally applied current science and predicted blood lead levels and changes to IQ using currently available modeling techniques.

However, there are several parts of the proposal (specifically (VI)(D) Sections 1 and 2) where greater clarity on the methodology, especially as to choice of certain assumptions, and more transparency on uncertainty in the findings would improve the document. Due to time constraints and the request for "high level" comments, the SAB did not review the underlying economic analysis for the BLL and IQ decrement models. Specific comments are provided below.

3.5.1. Scientific and Technical Comments on the Analysis of Children's Blood Lead Levels and IQ

The SAB provides the following scientific and technical comments on the EPA's analysis of children's blood lead levels and IQ.

Calculations of water lead concentrations

- The EPA estimates lead concentrations in tap water under different scenarios of lead service line (LSL) presence, as well as different corrosion control treatment (CCT) conditions. These are, of course, simulated concentrations in drinking water and are of unknown relevance to how much lead in tap water typical children might actually consume due to family water use behavior, water consumption variability across children, as well as daily water consumption variability for an individual child. Thus, the predicted BLLs, IQ decrements, and associated costs under different LSL and CCT conditions cannot be correlated to what young children actually experience. This point should be made more explicit in the Proposed Rule.

- For POU water lead levels, the EPA assumes that everyone in households with LSLs is properly using POU control. To the extent that individuals do not necessarily replace POU technology as frequently as recommended, this assumption could overestimate water lead level reductions for the POU scenarios and hence overestimate BLL reductions.

- As previously discussed, the analysis for calculating water lead concentrations was conducted by assembling a dataset from previous studies conducted in both the U.S. and Canada. Canadian samples were included because the U.S. datasets do not cover a wide enough range of scenarios to analyze the proposed changes. To compensate for the combination of datasets from different study designs (as well as, presumably, natural variations in lead levels from one place to another), the EPA uses a random effects model for the statistical analysis, with random effects representing single "events" nested within "sites" within "cities." While the use of a random effects model in this context is quite appropriate, the SAB has questions about the details and provides the following comments:

- One confusing issue is EPA's use of the "profile liter" variable. The SAB interprets the discussion regarding this variable to mean that; when a tap is turned on, there is initially a lot of variation in lead levels as water from different parts of the system reach the faucet (Exhibit 6-3, page 6-6). Therefore, one needs to account for a time dependence in the resulting measurements. Rather than measuring time in minutes or seconds, it makes sense to measure it in liters of water flow. The variable "profile liter" is just a way of expressing that. The SAB finds that this point could be written more clearly in the proposal.

- Turning to more technical parts of the analysis, the authors model the "profile liter" effect through splines with three interior knots. They do not appear to have considered any alternative ways to model the profile liter effect (e.g., varying the number or positions of the knots). The SAB questions whether such alternatives would have any effects.

- In the random effects analysis it appears as though only the overall intercept has been modeled as random, whereas some of the coefficients of interest (in particular, those related to LSL or CCT) might also vary from one place to another. The SAB questions whether this was considered. It should be noted that the combined standard error of all three random components is 1.38, which is similar in magnitude to the claimed effects of LSL and CCT, so clearly, the inter-city or inter-site variation is important.

- Another issue related to the random effects is whether any attempt was made to relate the random effects to other site-specific or city-specific covariates, such as mean income in the surrounding neighborhoods. This could be relevant to addressing the "environmental justice" issue that was also raised in public discussion.

- The SAB's last comment about the statistics is that the authors proposed five models containing various interactions between the spline and LSL/CCT terms, and the "full model" seemed to perform best when assessed by various statistical measures (e.g., Akaike Information Criterion, Bayesian Information Criterion) yet the authors used the "reduced spline model" for their main analysis. The SAB suggests that the EPA elaborate on the reasons for this, and whether it in fact makes any difference to the end results.

Blood lead level calculations

- The EPA predicts "lifetime" (i.e., age 0 – 7 years) BLLs using the model by Zartarian et al., 2017. This model represents an important advancement in the use of the Integrated Exposure Uptake Biokinetic (IEUBK) Model by building up variability in BLLs based on differences in exposure variables. Instead of using the geometric standard deviation (GSD) of BLLs to predict the range in BLL across a population, along with the geometric mean (GM), the model "builds up" the variability through the use of probabilistic exposure inputs for exposure. As noted by Zartarian and coworkers, the GSD inferred by this analysis is less than the typical GSD in BLLs in the U.S., based on CDC's National Health and Nutrition Examination Survey. The reason for this difference is likely that, while exposure variability is included in the SHEDS IEUBK model, biological variability in the relationship between lead intake and BLL (e.g., due to variability in the ratio between lead in the red blood cell and plasma) is not. It is not clear how the analysis considered the biological variability component in BLL prediction. It would be helpful to clarify issue in the document and to discuss the impact of the GSD on the analyses.

- It is puzzling that the BLLs in Exhibit 6-14 do not show the expected decrease in BLLs between ages 1 - 2 through 6 - 7 years. The SAB would like to understand why the typical pattern of changes in BLLs with age in children is not observed in this table.

- The Zartarian et al. 2017 analysis presents an evaluation of contribution of lead in water to BLL in children 0 to 6 months versus 1 to < 2 years and 2 to < 6 years. As expected, based on childhood behavior as a function of age, the relative contribution of water versus food and soil/dust ingestion to BLL varies significantly with age. For example, based on Figure 4 in the Zartarian paper, the relative contribution of lead from tap water to BLL is several-fold greater at age 0 to 6 months than at 1 to < 6 years. This point is relevant to the EPA's choice of metric of lifetime BLL (versus concurrent BLL) for its benefit quantification, the importance of which is noted below. EPA should clarify its choice of lifetime BLL for its benefit analysis, considering differences in the contribution of water lead to BLL as a functions of children's ages.

- The SAB notes that that the LCR does not distinguish between particulate and "dissolved" or soluble lead. The LCR appears to assume that particulate lead enters the blood stream at the same rate as dissolved lead when it is ingested. The SAB questions whether this assumption has been proven.

Blood lead: IQ relationships

- In general, the SAB understands that, for purposes of quantifying benefits, the EPA relied on predicted geometric mean (GM) BLLs. However, it would be helpful for the EPA to also provide information relevant to the BLL distribution, e.g., % of population estimated to be above 5 µg/dL. This is especially relevant since, as discussed below in the context of the Crump et al. 2013 analysis[2], the evidence for an association between a concurrent BLL < 5 µg/dL or peak BLL < 7 µg/dL is uncertain due to limited data at lower BLLs.

- As previously discussed, the EPA compares three different versions of the analysis of BLL:IQ relationships in children: the paper originally published by Lanphear et al. (2005), an EPA correction of one of their datasets (Kirrane and Patel, 2014, later confirmed in a published 2019 correction by Lanphear et al.), and an alternative analysis of the same data by Crump et al. (2013). The estimated betas (Exhibit 6-25, page 6-36) seem fairly similar but in the end the authors prefer the Crump analysis because it is believed to have more faithfully represented the low-dose end of the curve. As previously discussed, while this seems a reasonable approach, EPA should describe whether this choice makes any difference in its estimates.

- The Crump et al (2013) analysis concluded that concurrent BLL provided the best descriptor of the exposure-response relationship between BLL and IQ. The use of concurrent BLL as the exposure metric in the benefits analysis would likely yield different results. The EPA should consider noting this point as a source of uncertainty in its analysis and the potential impact of a different metric for BLL.

[2] Used to predict the relationship between BLL and IQ decrements.

- The fact that the BLLs in the populations in the Crump analysis are in general higher than BLLs typical of U.S. populations today adds uncertainty to the BLL:IQ slope used in EPA's analysis. Nonetheless, the SAB notes that, even with the relatively small number of children with peak BLLs < 7.5 µg/dL in the pooled sample analyzed by Lanphear (2019 correction) and then Crump (2013), both groups of authors found a statistically significant steeper slope for concurrent BLLs and IQ. For all other types of measurements of lead (early life, lifetime, peak), the slopes were greater with lower concentrations, but none reached significance, potentially due to the small sample size. Budtz-Jorgensen et al. (2012) utilized this same pool of 7 cohorts with multiple statistical models, also finding a statistically significantly better fit with a piecewise linear model with a greater slope below 10 µg/dL than a linear model.

- The Crump et al. (2013) paper is based on studies conducted prior to 2005, and since that time, a number of studies have identified associations between BLLs below 5 µg/dL and IQ. Specifically, Jusko et al. (2008) enrolled 276 children born in Rochester, New York in 1994 and 1995 and took BLL measurements at 8 time-points until the children reached 6 years of age. At 6 years of age, 194 of these children were assessed for IQ. The children's peak BLL had a median value of 9.4 µg/dL with levels down to a 2.1µg/dL. Using a non-linear function, there was a relationship down to 2.1 µg/dL, indicating an association between BLLs lower than those evaluated by Crump et al. and IQ. Also, researchers were able to calculate the change in IQ between 5 and 10 µg/dL and IQ changes at higher concentrations, finding a greater change at the lower concentrations, i.e. between 5 and 10 µg/dL. Both these analyses provide evidence of greater slopes at lower BLLs. Min et al. (2009) enrolled a prospective study of 278 inner-city, primarily African American children born between 1994 and 1996, many with potential polydrug exposure, measuring lead exposure at age 4 and evaluating IQ at 4, 9, and 11 years of age. This study found a linear relationship down to the lower limit of the BLLs in their participants. Interestingly, the investigators found a steeper slope for individuals with levels below 7µg /dL, although the difference in slopes was not statistically significant.

- The prospective studies are supported by additional cross-sectional studies. Kordas et al. (2005) assessed 586 children in Torreon, Mexico for lead and a suite of 14 cognitive tests. Segmented regressions suggested a steeper slope at lower levels for all but two tests, with statistically significant results for 3 tests. Another recent cross sectional study looked at performance of 58,650 Chicago children born between 1994 and 1998 on 3rd grade on standardized tests in math and reading. Scores were influenced at levels below 5 µg/dL on both tests, and on the reading tests steeper failure rates were seen with lower blood levels and reached statistical significance (Evens *et al.* 2015). Thus, recent literature provides evidence that the slope between BLL and IQ may be steeper than that used by EPA in its own analysis, although the relative magnitude of the difference is unclear. The SAB recommends that the EPA discuss such literature in comparison to the work by Crump et al. (2013) and consider quantifying the modeled impact of BLL on IQ, using more recent literature.

3.5.2. Recommendations to Strengthen the Scientific and Technical Basis of the Analysis of Children's Blood Lead Levels and IQ

The SAB provides the following recommendations to strengthen the analysis of children's blood lead levels and IQ in the Proposed Rule.

- Predicted BLLs, IQ decrements, and associated costs under different LSL and CCT conditions cannot be correlated to what young children actually experience. This point should be more explicitly discussed.

- The discussion of the random effects model the in analysis should be clarified to address points discussed in Section 2.5.1 of this SAB report.

- It is not clear how the BLL analysis considered the biological variability component in BLL prediction. The SAB recommends that this issue be clarified in the document and that EPA discuss the impact of the GSD on its analyses.

- The EPA should explain why the typical pattern of changes in BLLs with age in children is not observed in Exhibit 6-14.

- EPA should clarify its choice of lifetime BLL for its benefit analysis, considering differences in the contribution of water lead to BLL as a function of children's ages.

- EPA should provide information about the BLL distribution, e.g., % of population estimated to be above 5 µg/dL.

- The Crump et al. (2013) analysis concluded that concurrent BLL provided the best descriptor of the exposure-response relationship between BLL and IQ. The use of concurrent BLL as the exposure metric in the benefits analysis would likely yield different results. The EPA should consider noting this point as a source of uncertainty in its analysis also consider discussing the potential impact of a different metric for BLL.

- As discussed above, recent literature provides evidence that the slope between BLL and IQ may be steeper than that used by EPA in its own analysis, although the relative magnitude of the difference is unclear. The SAB recommends that the EPA discuss such literature in comparison to the work by Crump et al. (2013) and consider quantifying the modeled impact of BLL on IQ, using more recent literature.

3.6. Public Education, Notification, and Risk Communication Provisions in the Proposed Rule

The Proposed Rule includes requirements for education of the public about the hazards of lead in drinking water, the lead levels in their own water supplies, and the lead levels in water supplied to schools and childcare facilities. Section F (Public Education) of the proposal describes the following requirements for water systems:

1. Within 60 days of the end of the monitoring program, the water system must inform consumers if the lead action level was exceeded, what the health effects of this exceedance might be, what the sources of lead in the subject drinking water are, why there are elevated levels of lead, actions that consumers could take to reduce their exposure to lead, and actions that the water system is taking to reduce lead in the water.

2. The water system must establish an inventory and must provide information to consumers within 30 days of establishment and must include information on financing to consumers should they decide to replace lead water lines on their property.

3. A community water system serving 10,000 or more persons must establish outreach activities on lead service line replacement by social media, by certified mail, by town hall meetings or community events, by direct contact or to organizations representing plumbers. The water system must have at least one activity in the year following its failure to meet the replacement goal, and two events per year if it fails to meet replacement goals for 2 years.

4. Consumers must be notified within 24 hours if tap water sample results exceed the action level of 15 µg/L.

5. The community water system must have annual outreach to state and local health agencies to ensure that health providers and caregivers hear the information on lead, respond appropriately, and participate in joint communication.

Section J (Public Education and Sampling at Schools and Child Care Facilities) of the proposal describes the following requirements:

1. The community water systems will provide information to schools and childcare facilities about the health risks of lead and the sources of lead in drinking water and will share with them the data accumulated from samples from these institutions that are taken at least every 5 years.

2. Prior to the sampling a list of schools and childcare facilities will be made, and 5 samples from the former and 2 samples from the latter will be taken. The results from these samples will be provided to the primacy agency and the local health department by 30 days after the sampling.

3. The school or the childcare facility would decide on communication of the results to the parents, and whether it would institute any follow-up remedial action.

4. The above sampling and reporting procedures could be waived if the state or the local agency has a testing policy that is at least as stringent as what is prescribed by EPA.

3.6.1. Scientific and Technical Comments on the Public Education, Notification, and Risk Communication Provisions

The SAB provides the following scientific and technical comments on the public education notification, and risk communication provisions of the Proposed Rule.

- The SAB notes that to effectively communicate risk, an appropriate level of the information must be provided to the public. The SAB finds that some of the public education and risk communication requirements in the Proposed Rule should be clarified and described in greater detail to ensure that they are effective and consistently interpreted, implemented, and enforced.

- The SAB notes that it is important for EPA or other agencies responsible for the communication to the public to solicit and use information from experts in public communication to ensure that risk communication understandable, convincing and well received.

3.6.2. Recommendations to Improve the Public Education and Risk Communication Provisions

The SAB provides the following recommendations to strengthen the requirements described in Section F (Public Education) of the Proposed Rule.

- The existing Lead and Copper Rule is one of the most complex rules administered by the EPA in that it encompasses many aspects in terms of monitoring, reporting and mitigation. The Proposed Rule with a new trigger level makes it even more complex. It is therefore critical that the EPA have effectively communication information to states, the utilities, and the public. States are primacy agencies to implement the rules, so all states will have to devote substantial amounts of resources to the education and communication activities. The SAB suggests that the EPA consider developing or contracting with one or more non-profit organizations to develop a centralized portal to provide a variety of information on the Lead and Copper Rule, training courses for states and utilities, and best practices to implement the Lead and Copper Rule. This is an economy of scale issue, so there is no need for each state to develop everything anew; instead states could adapt what the EPA has developed. It is also a way to enhance the effectiveness of the communication and to avoid miscommunications.

  In comments to the SAB, Dr. Cynthia Giles, former Assistant Administrator of the EPA Office of the Environmental and Compliance Assurance, indicates that there is much evidence showing "…that violation of the lead rule may be as much as ten times what EPA's data claims." The EPA has developed tools developed to allow direct data reporting, the Compliance Monitoring Data Portal and SDWIS Prime; if the EPA requires the states to use the data reporting systems, under- or mis-reporting issues could be addressed. The SAB notes that if this approach could be adopted, EPA would be able to communicate much more effectively with the public and alleviate some of the potential pressures for the utilities to address these issues.

- The SAB finds that there is insufficient information provided in the Proposed Rule about the level of information that should be provided to meet public education requirements. Considering the wide breadth of educational levels and scientific understanding within the general public, and because it is probably likely that some of the oldest water systems that are the most likely to leach lead are in areas housing people with relatively low socioeconomic status and educational levels, the level of information provided on lead effects and the other factors would need to be appropriate for someone with a relatively limited education, and perhaps a 4th grade reading level. This should be specified. In addition to providing material at the appropriate reading level, material should also be provided for non-English speaking residents who may also represent a significant proportion of residents in neighborhoods with elevated water lead levels.

- The SAB recommends that the "mandatory health effects statement" in the Proposed Rule be revised to clarify what is meant by "prenatal risks" and "similar risks": "Lead exposure among women who are pregnant increases prenatal risks. Lead exposure among women who later become pregnant has similar risks if lead stored in the mother's bones is released during pregnancy."

- The SAB notes that the public education requirements described in Section F could leave residents served by small community water systems (less than 10,000 persons) uninformed and vulnerable to lead effects, or responsible for paying for their own testing if they had an interest in knowing the lead levels in their drinking water. This could leave residents in highly rural areas at greater risk than people in more highly populated areas. It would be helpful for the EPA to provide an estimate of the number of individuals served by small community water systems, who would thus not be protected by the LCR. If this number is substantial, the requirements in the Proposed Rule should be expanded, to include smaller water systems.

- EPA should consider revising the requirement for notification of tap sample results within 24 hours, since U.S. mail delivery would not allow compliance with this requirement.

- The SAB notes that State health agencies are well-informed about sources of lead in drinking water; EPA should assist water purveyors in complying with the requirements of the Proposed Rule, and consider outreach to local health agencies, which may be more variable with respect to their knowledge of lead in drinking water.

The SAB provides the following recommendations to strengthen the requirements described in Section J (Public Education and Sampling at Schools and Child Care Facilities) of the Proposed Rule.

- The SAB questions whether sampling every 5 years sufficient. If it is known that the water supply, internal plumbing and fixtures are lead-free then sampling every five years is sufficient, otherwise more frequent sampling is needed. Frequency of sampling should be related to water lead levels (WLLs), LSLs, and facility plumbing and fixture age, with higher WLLs/presence of LSLs and/or older facilities requiring more frequent sampling.

- EPA should consider establishing a clear procedure and standard verbiage for information flow to ensure that the highest percentage of families would understand the communication, including, as needed, in languages other than English.

- It makes sense to not duplicate sampling if the state or primacy agency has a suitable procedure in place. If the EPA-mandated sampling under the new rule is waived, there should be a mandate that the state or primacy agency provide information to parents consistent with what is required if EPA is responsible for obtaining the results.

- EPA should provide a clear definition of childcare facility, which may include whether the facility is licensed and a minimum number of children enrolled. EPA should clarify whether private and/or home-based childcare facilities are subject to this rule.

4. SAB RESPONSES TO SPECIFIC EPA QUESTIONS

The EPA, states and communities would benefit from the SAB's scientific review of on the available non-disruptive technologies that can locate lead service lines. Such a review would enable EPA to improve guidance and would inform state and public water system's actions to implement LCR revisions.

Question: What conclusions can be drawn about the efficacy of statistical methods for predicting the presence of lead service lines regarding their sufficiency to support use in developing a lead service line inventory?

a. *What input variables are critical for the statistical modeling to produce good results? (Examples: known date for use of lead materials in water system, extensive knowledge of a water system's side of the inventory to help guide customer side models, and/or good documentation/record-keeping on utility side service line replacements)*

b. *If locations are predicted by statistical analysis as not likely to contain lead service lines what standard is sufficient, if any, to allow a water system to indicate in the inventory that no lead service line exist at these locations?*

What would seem to be needed is a rule that would take data from the various input variables suggested and used them to calculate the probability that a LSL exists (PLSL) in or near the specific location of interest.

It would be possible to construct a sampling exercise where (a) N locations are chosen at random, (b) all the relevant input variables at these locations are collected, (c) for these locations, it is determined definitively whether or not a LSL exists at that location. To make such a determination, it would be necessary to do "full trench excavation" to be definitive – this will limit the sample size N that it is cost-effective to use.

A variety of statistical methods may be used to estimate the PLSL based on the input variables. The basic technique is called logistic regression. This technique may be supplemented by many modern methods that use machine learning concepts, such as random forests, lasso regression or boosting. Essentially, all of these are analytic methods for determining the PLSL. Such rules may be validated by cross-validation and related techniques.

Once we have a rule for calculating the PLSL, the next thing would be to define a classifier – typically, we would classify a site as likely to contain an LSL if the PLSL is above some threshold (e.g. 30%). The threshold can be used to balance the type I and type II errors, where the type I error is the probability that we classify the site as containing an LSL when it does not, and the type II error is the other way round. For example, the question posed in question b. is one about limiting the type II error – it would be fairly typical to require that the type II error be less than 20% so that would determine the probability threshold for the PLSL.

To design such an experiment would require balancing the costs of conducting the analysis (which are minimized if N is small) against the type I and type II error probabilities (which will be smaller if N is large). It is common to conduct a power analysis (in effect, calculating the type II error associated with a given type I error probability, such as 0.05). Another statistical tool that is often used in this situation is a ROC analysis, which effectively balances the type I and type II error probabilities across a range of possible thresholds for the PLSL.

Question: EPA is aware of a number of methods, both intrusive and non-intrusive, that attempt to identify the location of lead service lines on a site-specific basis. These include visual inspection of the service line entering the home or meter box, inspection via a camera inserted in the curb box, potholing technologies, and full trench excavation. What conclusions can be drawn on which of these or other methods may most accurately determine the presence of a lead service line while also providing cost efficiency and minimization of the risk of a lead spike from potential LSL disturbance during identification?

If the sampling exercise suggested in response to question 1 were collected, it would be possible to expand the range of input variables to include those suggested here, such as inspection of the service line entering the home or inspection via a camera. This should improve the quality of the predicted PLSL.

Question: EPA is aware of science suggesting that galvanized service lines that are or were downstream of an LSL may have accumulated lead in interior scale deposits which may contribute to lead release. Where records do not exist, is it possible to determine whether a galvanized service line ever had an upstream LSL which is no longer in place?

The SAB finds that, based solely on the lead results from a first draw sample, it would not be possible to determine with absolute accuracy that the galvanized pipe had an upstream LSL. Attempting to infer the historical presence of a lead service line from water quality sampling might be possible, but only if the source of lead from the zinc coating on the galvanized pipe can be eliminated as the source of lead in the water sample. Work by Clark et al (2015) examine the lead, cadmium, and zinc ratio as being a means of identifying lead from the zinc coating, which could be used to infer that the result of exposure to an upstream LSL. However, the study also notes that the lead content in galvanized pipe can vary between non-detect and 2%. With such a variable lead content, using an average lead to cadmium to zinc ratio could lead to sites being misidentified as having had an upstream lead service line.

It is important to note that the article also identifies galvanized pipe as being a potential source of lead. This raises the question as to what the source or sources of lead in the interior scale of galvanized pipe might be and leads to the question as to whether or not galvanized pipe is being adequately addressed as a source of lead in the LCR revisions.

Question: How effective are social media platforms for providing information about lead in drinking water, the health effects of lead, sources of lead in water and action to reduce exposure?

Social media platforms are continually evolving, and EPA should consider whether they will endure in the rapidly changing landscape. If EPA retains reliance on social media, then specific parameters should be provided, such as a requirement to quantify whether an appreciable fraction of social media participants use it to obtain health information. If this is not an appreciable fraction, it is probably not useful and perhaps counterproductive to attempt this route. If EPA chooses to use this route, the information needs to come from a source trusted by the community being reached, either a well-known and well-informed individual or a trusted institution like state/local health departments or boards of health.

Question: What are the most effective modes and frequency of distribution of health information to ensure awareness without oversaturation?

EPA's requirements for modes and frequency of distribution of health information are generally sufficient. EPA should consider coordinating outreach efforts with pediatricians or family practitioners since the public generally considers these to be trusted sources.

Question: The EPA requests comment on whether the Agency should require water systems to distribute education materials to homes with unknown service line types to inform them of the potential for their line to be made of lead and the actions they can take to reduce their exposure to drinking water lead.

Positive and negative outcomes are possible from this action: the positive result could be increasing awareness of the public to the hazards of lead that would lead to more sampling and remediation, if needed. The negative result could be creating fear and confusion in the public regarding whether they or their children are being harmed, especially if they are in no position (financial or otherwise) to do any remediation. If predictions could be made as to whether the lines in question are likely to be lead lines, then providing the information to those who are more likely to have lead lines might be health-protective, and reminding people that flushing the water line prior to use is a simple and effective method of reducing lead levels.

Question: The EPA requests comment on the appropriateness of required outreach activities a water system would conduct if they do not meet the goal LSLR rate in response to a trigger level exceedance.

Increasing the number of outreach activities (if they are independent activities) from one to two per year is probably a realistic number; more might end up being ignored. However, if the outreach can be blended into other public forums, such as town hall meetings that are scheduled for other purposes, additional mention of the lead issues might reach more of the target audience. If this requirement is retained, EPA should include objective parameters by which to judge whether an outreach event "counts," such as minimum percent of the population in attendance at an event, number of languages into which material is translated, or number of impressions on a web page. EPA should also consider how this requirement would be enforced. For example, would water systems self-certify as part of their routine compliance reporting?

Question: The EPA also requests comments on other actions or additional outreach efforts water systems could take to meet their LSLR goal rate.

The outreach activities suggested by the EPA are considered sufficient.

Question: The EPA requests comment on the appropriateness, frequency, and content of required outreach to State and local health agencies and whether the requirement should apply only to a subset of the country's community water systems.

Evidence exists that state and local health agencies are well informed already about the hazards of lead exposure and the need to remediate water systems that are above the trigger or action levels; they only need occasional reminders. If community water systems are routinely doing a responsible job in sampling and replacing lead water lines, then they probably need minimal outreach. However, if community water systems are consistently not reaching their replacement goals, then more frequent outreach should be implemented until they come into compliance.

5. REFERENCES

Baron, J., 2001. Monitoring strategy for lead in drinking water at consumer's tap: Field experiments in France. *Water, Science, and Technology* 1(4):193-200.

Borenstein, S.W. 1994. *Microbiologically Influenced Corrosion Handbook.* Industrial Press, Inc. NY.

Bosscher, V., D.A. Lytle, M.R. Schock, A. Porter, and M. Del Toral. 2019. POU water filters effectively reduce lead in drinking water: a demonstration field study in Flint, Michigan. *Journal of Environmental Science and Health,* Part A 2019, 54(5):484–493. https://doi.org/10.1080/10934529.2019.1611141

Bradley, T.C., C.N. Haas, and C.M.Sales. 2020 Nitrification in premise plumbing: A review. *Water* 2020,12:830. https://www.mdpi.com/2073-4441/12/3/830

Budtz-Jorgensen, E, D. Bellinger, B. Lanphear, and P. Grandjean. 2013. An international pooled analysis for obtaining a benchmark dose for environmental lead exposure in children. *Risk Analysis* 33 (3):450-461.

C.D.M-Smith 2019 *City of Newark Point-of-Use Filter Study August – September 2019*. https://static1.squarespace.com/static/5ad5e03312b13f2c50381204/t/5dd70e112421805afa68ebd9/1574374964737/Newark+Point-of-Use+Filter+Study+-+Aug-Sept+2019+Final.pdf

Cartier, C., L. Laroche, E. Deshommes, S. Nour, G. Richard, M. Edwards, and M. Prévost. 2011. Investigating dissolved lead at the tap using various sampling protocols." *Journal of the American Water Works Association* 103(3):5-67.

Chowdhury, R., A. Ramond, L.M. O'Keeffe, S. Shahzad, S.K. Kunutsor, T. Muka, J.Gregson, P. Willeit, S. Warnakula, H. Khan, S. Chowdhury, R. Gobin, O.H. Franco and E. Di Angelantonio. 2018. Environmental toxic metal contaminants and risk of cardiovascular disease: systematic review and meta-analysis. *BMJ* 362:k3310, http://dx.doi.org/10.1136/bmj.k3310

Clark, B.N., S.V. Masters, and M.A. Edwards. 2015. Lead release to drinking water from galvanized steel pipe coatings. *Environmental Engineering Science* 32(8):713-721.

Cornwell, D.A.. R.A. Brown, and S.H. Via. 2016. National survey of lead service line occurrence. *Journal of the American Water Works Association* 108(4):68 (expanded summary). doi.org/10.5942/jawwa.2016.108.0086 pp.E182-E191.

Cotruvo, J.A. 2019. Lead reduction is a national success story. *Journal of the American Water Works Association* 111(4):73-75. https://doi.org/10.1002/awwa.1277.

Crump, K.S., C. Van Landingham, T.S. Bowers, D. Cahoy, and J.K. Chandalia. 2013. A statistical reevaluation of the data used in the Lanphear et al. (2005) pooled-analysis that related low levels of blood lead to intellectual deficits in children. *Critical Reviews in Toxicology* 43(9):785-799.

Evens, A., D. Hryhorczuk, B.P Lanphear, K.M. Rankin, D.A. Lewis, L. Forst, and D. Rosenberg. 2015. The impact of low-level lead toxicity on school performance among children in the Chicago Public Schools: A population-based retrospective cohort study. *Environmental Health* 14(1):21.

Geir Bjørklund, G., M. Dadar, S. Chirumbolo, and J. Aaseth, 2018. High content of lead is associated with the softness of drinking water and raised cardiovascular morbidity: A review. *Biological Trace Element Research* 186:384–394; https://doi.org/10.1007/s12011-018-1336-8

Health Canada. 2019. *Guidelines for Canadian Drinking Water Quality: Guideline Technical Document — Lead*. Water and Air Quality Bureau, Healthy Environments and Consumer Safety Branch, Health Canada, Ottawa, Ontario. (Catalogue No H144-13/11-2018E-PDF).

Holm, T.R. and Schock, M.R. 1991. Potential effects of polyphosphate products on lead solubility in plumbing systems. *Journal of the American Water Works Association* 83:7:76-82. https://doi.org/10.1002/j.1551-8833.1991.tb07182.x

Hozalski, R.M., E. Esbri-Amador, and C.F. Chen. 2005. Comparison of stannous chloride and phosphate for lead corrosion control. *Journal of the American Water Works Association* 97:3:89-103. https://doi.org/10.1002/j.1551-8833.2005.tb10847.x

Kordas, K., R.L. Canfield, P. Lopez, J.L. Rosado, G.G. Vargas, M.E. Cebrian, J.A. Rico, D. Ronquillo, and R.J. Stoltzfus 2006. Deficits in cognitive function and achievement in Mexican first-graders with low blood lead concentrations. *Environmental Research* 100:371-386.

Lanphear, B.P., R. Hornung, J. Khoury, K. Yolton, P. Baghurst, D.C. Bellinger, R.L. Canfield, K.N. Dietrich, R. Bornschein, T. Greene, S.J. Rothenberg, H.L. Needleman, L. Schnaas, G. Wasserman, J. Graziano, and R. Roberts. 2019. Erratum: Low-level environmental lead exposure and children's intellectual function: An international pooled analysis. *Environmental Health Perspectives* 127(9):99001.

Lanphear B.P., S. Rauch, P. Auinger, R.W. Allen, and R.W. Hornung. 2018. Low-level lead exposure and mortality in U.S. adults: a population-based cohort study. *Lancet Public Health* 2018;3:e177–84.

Lee, R.G., W.C. Becker, and D.W. Collins. 1989. Lead at the tap: Sources and control. *Journal of the American Water Works Association* 81:7:52-62. https://doi.org/10.1002/j.1551-8833.1989.tb03238.x

Lin, Y-P., and R.L. Valentine. 2008. Release of Pb(II) from monochloramine-mediated reduction of lead oxide (PbO2). *Environmental Science and Technology* 42(24):9137-9143 https://doi.org/10.1021/es801037n

McFadden, M., R. Giani, P. Kwan, and S.H. Rieber. 2011. Contributions to drinking water lead from galvanized iron corrosion scales. *Journal of the American Water Works Association* 103(4):76-89 · April 2011, DOI: 10.1002/j.1551-8833.2011.tb11437.x

Min, M.O., L.T. Singer, H.L. Kirchner, S. Minnes, E. Short, Z. Hussain, and S. Nelson. 2009. Cognitive development and low-level lead exposure in poly-drug exposed children. *Neurotoxicology and Teratology* 31(4):225-231.

Miranda, M.L., D. Kim, A.P. Hull, C.J. Paul, and M.A. Galeano. 2007. Changes in blood lead levels associated with use of chloramines in water treatment systems. *Environmental Health Perspectives* 115(2):221–225. doi:10.1289/ehp.9432

National Toxicology Program. 2012. *NTP Monograph on Health Effects of Low-Level Lead.* Office of Health Assessment and Translation, Division of the National Toxicology Program, National Institute of Environmental Health Sciences, National Institutes of Health. [Available at: https://ntp.niehs.nih.gov/ntp/ohat/lead/final/monographhealtheffectslowlevellead_newissn_508.pdf]

Ng, D., S. Liu, and Y. Lin. 2018, Lead as a legendary pollutant with emerging concern: Survey of lead in tap water in an old campus building using four sampling methods. *Science of the Total Environment* 636:1510-1516.

Riblet, C., E. Deshommes, L. Laroche, and M. Prevost. 2019. True exposure to lead at the tap: Insights from proportional sampling, regulated sampling, and water use monitoring. *Water Research* 156,327-336

Switzer, J. A., .V. Rajasekharan, S. Boonsalee, E.A. Kulp, and E.W. Bohannan. 2006. Evidence that monochloramine disinfectant could lead to elevated Pb levels in drinking water. *Environmental Science and Technology* 40(10):3384-3387. https://doi.org/10.1021/es052411r

U.S. EPA. 2006. *Drinking Water Data Reliability Analysis and Action Plan for State Reported Public Water System Data in the EPA Safe Drinking Water Information System/Federal Version* (SDWIS/FED). EPA 816-R-07-010

U.S. EPA. 2013. *Integrated Science Assessment (ISA) For Le*ad. EPA/600/R-10/075F. U.S. Environmental Protection Agency, Washington, D.C. [Available at: https://cfpub.epa.gov/ncea/isa/recordisplay.cfm?deid=255721]

Wang,Y., Y. Xie, and D.E. Giammar. 2019. *Lead(IV) Oxide Formation and Stability in Drinking Water Distribution Systems*. Water Research Foundation, Denver CO, REPORT #4211 2019.

Yamanaka, T. 2008. *Chemolithoautotrophic Bacteria*. Springer, Tokyo, Japan.

Zartarian, V. J. Xue, R. Tornero-Velez, and J. Brown. 2017. Children's lead exposure: A multimedia modeling analysis to guide public health decision-making. *Environmental Health Perspectives* 125 (9) :097009.