



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
WASHINGTON D.C. 20460

OFFICE OF THE ADMINISTRATOR
SCIENCE ADVISORY BOARD

March 4, 2011

MEMORANDUM

SUBJECT: Formation of Drinking Water Committee Augmented with Subject Experts to Review the Effectiveness of Partial Lead Service Line Replacements

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Exposure to lead through drinking water results primarily from the corrosion of lead pipes and plumbing materials. EPA's Office of Water (OW) promulgated the Lead and Copper Rule (LCR) to minimize the amount of lead in drinking water. The LCR requires public water systems that are not able to limit lead corrosion through treatment to replace service lines (pipes connecting buildings to water distribution mains) that are made from lead. Partial lead service line replacements are when the public water system replaces only their portion of the lead service line and the homeowner does not replace their portion. OW has requested the SAB to review and provide advice on recent studies examining the effectiveness of partial lead service line replacements in reducing exposure to lead in drinking water.

This memorandum addresses the set of determinations that were necessary for forming an augmented Drinking Water Committee (DWC) panel, referred to as the DWC Lead Review Panel, including:

- (A) The type of review body that will be used to conduct the review, and the nature of the review;
- (B) The list of candidates to be considered for the panel;

- (C) Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed;
- (D) How regulations concerning “appearance of a lack of impartiality,” pursuant to 5 C.F.R. § 2635.502, apply to members of the Panel; and
- (E) The selection of Panel members.

DETERMINATIONS:

- (A) The type of review body that will be used to conduct the review, and the nature of this review.

The DWC will be augmented with additional experts, and this augmented panel (referred to as the DWC Lead Review Panel) will review recent studies examining the effectiveness of partial lead service line replacements.

- (B) The list of candidates to be considered for the Panel.

The SAB Staff Office announced to the public through a *Federal Register* notice published on December 21, 2010 (75 FR 80050-80051) that it was soliciting nominations of recognized experts with demonstrated expertise and research in one or more of the following areas related to lead: environmental engineering, drinking water exposure assessment, epidemiology, statistics, and risk assessment.

The SAB Staff Office identified 12 experts to be considered to augment the DWC for this review. These candidates were identified through the public nomination process or by SAB staff, have relevant expertise, and are willing to serve on the Panel. On February 3, 2011, the SAB Staff Office posted a notice on the SAB Web site inviting public comments on the List of Candidates for the Panel, including biographical sketches, by February 24, 2011. Four public comments on the candidate list were submitted to the SAB Staff Office: Mr. Thomas Curtis, American Water Works Association (AWWA); Mr. Jeffrey Kempic, EPA; Dr. Nancy Love, University of Michigan; Dr. Lynn Roberts, Johns Hopkins University.

- (C) Financial conflict of interest considerations, including identification of parties who are potentially interested in or may be affected by the topic to be reviewed.

(a) Identification of parties who are potentially interested in or may be affected by the topic to be reviewed: The principal interested and affected parties for this topic are: (1) federal, state, and local government agencies, non-government organizations, water systems, and schools and childcare facilities that have their own water supplies; and (2) residents of homes with lead service lines.

(b) Conflict of interest considerations: For Financial Conflict of Interest (COI) issues, the basic 18 U.S.C. § 208 provision states that: “An employee is prohibited from participating *personally or substantially* in an official capacity in any *particular matter* in which he, to his

knowledge, or any person whose interests are imputed to him under this statute has a *financial interest*, if the particular matter will have a direct and predictable effect on that interest [emphasis added].” For a conflict of interest to be present, all elements in the above provision must be present. If an element is missing the issue does not involve a formal conflict of interest; however, the general provisions in the appearance of impartiality guidelines must still apply and need to be considered.

(i) Does the general charge to the Panel involve a particular matter? A “particular matter” refers to matters that “...will involve deliberation, decision, or action that is focused upon the interest of specific people, or a discrete and identifiable class of people.” It does not refer to “...consideration or adoption of broad policy options directed to the interests of a large and diverse group of people.” [5 C.F.R. § 2640.103(a)(1)] A particular matter of general applicability means a particular matter that is focused on the interests of a discrete and identifiable class of persons, but does not involve specific parties [5 C.F.R. § 2640.102(m)].

The activity of the DWC Lead Review Panel in addressing the charge for peer review of recent studies examining the effectiveness of partial lead service line replacements, will qualify as a *particular matter of general applicability* because the resulting advice will be part of a deliberation, and under certain circumstances the advice could involve the interests of a discrete and identifiable class of people but does not involve specific parties. That group of people constitutes those who are involved with private or public organizations facing regulatory decisions related to partial lead service line replacements.

(ii) Will there be personal and substantial participation on the part of the Panel members? Participating personally means direct participation in this review. Participating substantially refers to involvement that is of significance to the matter under consideration [5 C.F.R. § 2640.103(a)(2)]. For this review, the SAB Staff Office has determined that the *Panel members will be participating personally in the matter*. Panel members will be providing the Agency with advice and recommendations on the effectiveness of partial lead service line replacements, and such advice is expected to directly influence the Agency’s revision of the Lead and Copper Rule. *Therefore, participation in this review also will be substantial.*

(iii) Will there be a direct and predictable effect on a Panel member’s financial interest? A direct effect on a participant’s financial interest exists if “...a close causal link exists between any decision or action to be taken in the matter and any expected effect of the matter on the financial interest. ...A particular matter does not have a direct effect ...if the chain of causation is attenuated or is contingent upon the occurrence of events that are speculative or that are independent of, and unrelated to, the matter. A particular matter that has an effect on a financial interest only as a consequence of its effects on the general economy is not considered to have a direct effect.” [5 C.F.R. § 2640.103(a)(i)] A predictable effect exists if, “...there is an actual, as opposed to speculative, possibility that the matter will affect the financial interest.” [5 C.F.R. § 2640.103(a)(ii)]

Candidates for the Panel were evaluated against the requirements of 5 C.F.R. § 2640.101(a), using each candidate's confidential financial disclosure form (EPA Form 3110-48), to determine whether the work of the Panel will have a direct and predictable effect on his or her financial interests.

(D) How regulations concerning "appearance of a lack of impartiality," pursuant to 5 C.F.R. § 2635.502, apply to members of the Panel

The Code of Federal Regulations at 5 C.F.R. § 2635.502(a) states that: "Where an employee knows that a particular matter involving specific parties is likely to have a direct and predictable effect on the financial interest of a member of his household, or knows that a person with whom he has a covered relationship is or represents a party to such matter, and where the person determines that the circumstances would cause a reasonable person with knowledge of the relevant facts to question his impartiality in the matter, the employee should not participate in the matter unless he has informed the agency designee of the appearance problem and has received authorization from the agency designee." Further, § 2635.502(a)(2) states that, "An employee who is concerned that circumstances other than those specifically described in this section would raise a question regarding his impartiality should use the process described in this section to determine whether he should or should not participate in a particular matter."

Candidates for the Panel were evaluated against the 5 C.F.R. 2635(a)(2) general requirements for considering an appearance of a lack of impartiality. Information used in this evaluation has come from information provided by potential advisory committee members (including, but not limited to, EPA 3110-48 confidential financial disclosure forms) and public comment as well as their responses to the following supplemental questions (included on the EPA 3110-48 confidential financial disclosure form):

1. Do you know of any reason that you might be unable to provide impartial advice on the matter to come before the panel/committee/subcommittee or any reason that your impartiality in the matter might be questioned?
2. Have you had any previous involvement with the review document(s) under consideration including authorship, collaboration with the authors, or previous peer review functions? If so, please identify and describe that involvement.
3. Have you served on previous advisory panels, committees or subcommittees that have addressed the topic under consideration? If so, please identify those activities.
4. Have you made any public statements (written or oral) on the issue that would indicate to an observer that you have taken a position on the issue under consideration? If so, please identify those statements.

(E) The selection of Panel members

The SAB Staff Office Director makes the final decision about who serves on panels, based on all relevant information. This includes a review of the member's confidential financial

disclosure form (EPA Form 3110-48) and an evaluation of an appearance of a lack of impartiality, and application of criteria to ensure a balanced panel.

As a result of a review of all relevant information including each candidate's confidential financial disclosure form (EPA Form 3110-48), the responses to the four questions above, and public comments, the SAB Staff Office has determined that there are no conflicts of interest or appearances of a lack of impartiality for the members of this Panel.

For the SAB Staff Office, a balanced committee or panel is characterized by inclusion of candidates who possess the necessary domains of knowledge, the relevant scientific perspectives (which, among other factors, can be influenced by work history and affiliation), and the collective breadth of experience to adequately address the general charge. Specific criteria to be used in evaluating an individual committee member include: (a) scientific and/or technical expertise, knowledge, and experience (primary factors); (b) availability and willingness to serve; (c) absence of financial conflicts of interest; (d) absence of an appearance of a lack of impartiality; (e) skills working in committees, subcommittees and advisory panels; and, (f) for the committee as a whole, diversity of scientific expertise, and viewpoints.

On the basis of the above-specified criteria, the members of the DWC Lead Review Panel are as follows:

DWC Members

- Dr. Jeffrey Griffiths**, Tufts University (MA), Chair
- Dr. George Alexeeff**, California Environmental Protection Agency (CA)
- Dr. Mark Benjamin**, University of Washington (WA)
- Dr. Joel Ducoste**, North Carolina State University (NC)
- Dr. Susan Korrick**, Harvard University (MA)
- Dr. Desmond F. Lawler**, University of Texas (TX)
- Dr. Frank Loge**, University of California-Davis (CA)
- Dr. Nancy Love**, University of Michigan (MI)
- Dr. Stephen Randtke**, University of Kansas (KS)
- Dr. Lynn A. Roberts**, Johns Hopkins University (MD)
- Dr. Richard Sakaji**, East Bay Municipal Utility District (CA)
- Ms. Janice Skadsen**, CDM (MI)
- Dr. Marylynn Yates**, University of California-Riverside (CA)

Consultants

- Dr. Michael Kosnett**, University of Colorado Health Sciences Center (CO)
- Dr. Bruce Lanphear**, Simon Fraser University (Canada)
- Dr. Stephen Rothenberg**, National Institute of Public Health (Mexico)
- Dr. Virginia Weaver**, Johns Hopkins University (MD)
- Dr. Robert Wright**, Harvard School of Public Health (MA)

Concurred,

/SIGNED/

March 4, 2011

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EPA Science Advisory Board (1400R)

Date