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To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP
cc: Alan Roberson <aroberson@awwa.org>, Tom Curtis <tcurtis@awwa.org>
Subject: OMB Peer Review Comments

Attached are the comments of the American Water Works Association related to OMBs proposed bulletin on peer review and information Quality (68 FR 54023).

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American Water Works Association
The Authoritative Resource for Safe Drinking Water (SM)

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December 15, 2003

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
725 17th Street NW
New Executive Office Building
Washington, DC 20503

Re: Proposed Bulletin for Peer Review and Information Quality Guidelines

Dear Dr. Schwab:

The American Water Works Association (AWWA) appreciates the opportunity to comment on the Proposed Bulletin for peer review and information quality guidelines. The AWWA is an international, nonprofit, scientific and educational society dedicated to the improvement of drinking water quality and supply. Founded in 1881, the Association is the largest organization of water supply professionals in the world. Our 57,000-plus members represent the full spectrum of the drinking water community: treatment plant operators and managers, environmental advocates, scientists, academicians, and others who hold a genuine interest in water supply and public health. Our membership includes more than 4,700 utilities that supply roughly 80 percent of the nation's drinking water.

AWWA has always supported the use of the best information available to make smart regulatory decisions that will further public health protection. AWWA commends the Office of Information and Regulatory Affairs (OIRA) for its efforts to ensure that all of the federal agencies use the best information available in making regulatory decisions.

AWWA was a driving force in the 1996 SDWA Amendments. One of the cornerstones of those Amendments is the use of the "best available, peer-reviewed science" in the development of national drinking water regulations. AWWA supports the proposed Bulletin and its goal of improving the peer review process and the quality of data used in the regulatory development process.

The 1996 SDWA Amendments are the benchmark for both OMB and EPA for the quality and dissemination of the data underlying the regulatory development process. AWWA commends OMB for its incorporation of the cost-benefit assessment (CBA) language in the 1996 SDWA Amendments as the benchmark for information quality and dissemination standards for federal agencies to use in CBAs for their respective rulemakings. AWWA and its member utilities strove to include this specific language in the 1996 SDWA Amendments to ensure that the regulatory process was not hidden behind statistical "smoke and mirrors". EPA has made progress in meeting these information quality and dissemination requirements in its recent rulemakings.

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However, frustration is growing within the drinking water community with the slow progress in fully meeting some of those requirements. This frustration stems from EPA's lack of a comprehensive implementation plan to continually improve their CBAs and move closer to the goals underlying those requirements. Some of our CBA comments have been incorporated in recent EPA rulemakings, but many comments have not been addressed and/or the response has been superficial in some cases. Overall, while EPA's CBAs have improved in recent rulemakings, there is still significant room for improvement.

Hence, the concerns raised here are not only about how benefits and costs are estimated, but also about how they are compared to one another and interpreted in the standard setting context. Further, because the consumers who receive the benefits of drinking water standards are also the same group that will bear the costs, it is especially important that the CBAs clearly and accurately reflect the risk/cost tradeoffs that regulations will impose on them.

AWWA supports the proposed Bulletin and its supplemental information quality guidelines. AWWA does not believe that the proposal would unnecessarily burden participating scientists. However, AWWA recommends that the disclosure requirements for peer reviewers be limited to no more than ten years, rather than indefinitely, so as to not discourage participation. Additionally, AWWA supports allowing the agencies to retain significant discretion in formulating an appropriate peer review plan. The appropriate scientists, at least in the drinking water field, are relatively well known and the Agency should be able to find qualified peer reviewers. The selection process should remain with the Agency and not with a centralized body, as the latter approach would likely add significant inefficiencies.

The Office of Groundwater and Drinking Water (OGWDW) within the Environmental Protection Agency (EPA) is responsible for SDWA implementation. Generally, AWWA believes that OGWDW is improving both its peer review process and the quality of information used in its regulatory development process. However, we have the following serious concerns with the OGWDW regulatory development process. These examples highlight the need for the guidance currently proposed in the Bulletin:

- *Make the peer review process more consistent* - Some important regulatory documents go through a robust peer review process and some do not, and there doesn't appear to be any consistency on what type of documents are peer reviewed. For example, seven guidance manuals were developed in conjunction with the proposals for the Stage 2 Disinfection By-Products Rule (DBPR) and the Long-Term 2 Enhanced Surface Water Treatment Rule (LT2ESWTR) that were published in the *Federal Register* in August. Based on our review, it appears that adequate peer reviews were conducted for the Ultraviolet Light Guidance Manual and the Membrane Filtration Guidance Manual based on acknowledgements on the inside cover. However, it is not known if the peer reviews were conducted on rough drafts or the final proposed guidance manuals. Additionally, it appears that peer reviews were *not* conducted for the other five guidance manuals that have significant implications for the proposed regulation. Furthermore, it appears that peer reviews were not conducted for other significant regulatory information that includes the economic analyses, the occurrence analyses, the technology and cost document, or for several important health criteria

documents. All of these documents satisfy the “significant regulatory information” test and should be the subject of appropriate peer review.

- *Make the peer review process more transparent* – When peer reviewed appeared to occur for Stage 2 DBPR and LT2ESWTR documents, the Agency did not provide the method used to select the peer review panel. Nor did the Agency share with the public the resulting comments or how the comments were incorporated in the final documents. It is not clear whether the documents were subject to an internal Agency review, and again, who those reviewers were, what their comments were, and how the comments were incorporated. In support of the proposed OMB Bulletin, this documentation should be made available to the public in each rulemakings docket in a timely manner to inform the public comment period.
- *Definition of “Weight of evidence” needed* - This term is used throughout the proposed Stage 2 DBPR and LT2ESWTR without any clear definition. If you have three positive health effects studies and seven negative studies, do the three positive studies provide a “weight of evidence”? A clear and consistent definition should be used in rulemakings.
- *Clarify what constitutes peer review* - In some instances one person’s opinion has been the basis for acceptance or denial of a body of scientific evidence. Since such determination can significantly influence the rulemaking process, it would be more appropriate to reserve such decisions for a peer review group. We encourage OMB to clarify the meaning of what constitutes adequate and appropriate peer review to avoid the noted situation. More specifically the number of peer reviewers should, at a minimum, consist of at least three persons.

If you have any questions about these comments, please feel free to call me or Kevin Morley in our Washington Office.

Yours Sincerely,



Thomas W. Curtis
Deputy Executive Director

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