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cc:
Subject: EEI Comments on Proposed Peer Review Guidance

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- EEI Comments on OMB Proposed Peer Review Guidelines.pdf



**EDISON ELECTRIC
INSTITUTE**

QUINLAN J. SHEA, III
Executive Director, Environment

December 15, 2003

Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10201
725 17th Street, NW
Washington, DC 20503

Re: Proposed Bulletin on Peer Review and Information Quality, 68 Federal Register
54023-54029 (September 15, 2003)

Dear Dr. Schwab:

The Edison Electric Institute (EEI) welcomes the opportunity to submit comments on the Office of Management and Budget's (OMB) *Proposed Bulletin on Peer Review and Information Quality* (Bulletin).

EEI is the association of the United States investor-owned electric utilities, combination gas & electric utilities, industry affiliates, and associates worldwide. Its U.S. members serve 90 percent of all customers served by the investor-owned segment of the industry. They generate approximately 73 percent of all the electricity generated by electric utilities in the country and service 70 percent of all ultimate customers in the nation.

The electric utility industry is affected by a broad scope of federal and state statutes and regulations, and is one of the most regulated industries in this country. In 2002 alone, EEI member companies spent more than \$6 billion on compliance with federal environmental regulations. There are many additional regulations our industry must comply with in the coming years on the federal, state, and local levels.

EEI and its members strongly support OMB's proposal to issue new guidance that appreciates the value of independent, objective, and meaningful peer review of the most important science disseminated by the federal government. We recognize the importance of the data quality program, particularly with respect to ensuring that objective, unbiased, and scientifically sound information is the foundation of federal regulations and policies designed to protect public health, safety, and the environment. We also recognize the importance of federal agencies using data of the highest quality possible in

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communicating and disseminating information to state and local authorities and the general public.

EEI offers the following comments on the proposed Bulletin for OMB's consideration:

Scope/Provisions of the Bulletin

Although many federal agencies already have some type of peer review programs in place, there is no consistency between agencies on the standards or procedures for the various peer review programs, and generally no consistency between different programs within the same agency. EEI is therefore supportive of providing agencies with minimum standards and specific criteria for all agencies to incorporate in peer review programs. These minimum criteria are necessary to improve the quality of rulemaking and information dissemination for all agencies.

As a minimum requirement, OMB must require external peer review for the influential risk information that is currently subject to the Safe Drinking Water Act (SDWA) objectivity criteria established in OMB's Information Quality Act (IQA) Guidelines. Those Guidelines recognize that risk information is especially important, uncertain and contentious, and for those reasons incorporated the SDWA criteria. For the same reasons, OMB should ensure that this kind of information is subject to Section 3 of the Bulletin.

OMB's Bulletin is a well-crafted step that moves peer review of regulatory science in the direction of being an essential part of the federal regulatory process. Nevertheless, we believe that the provisions should be expanded beyond the criterion of information that has a "clear and substantial impact on important public policies or important private sector decisions with a possible impact of more than \$100 million in any year." Federal agencies routinely issue work products that do not have a cost impact of \$100 million a year, but may have impacts and consequences that should be subject to additional scientific scrutiny. This may also serve to deter agencies from finding creative ways to assess the cost impacts of policies and programs so as not to exceed the \$100 million threshold.

EEI advocates using EPA's *Peer Review Handbook* as the basis for determining when agency work products should be peer reviewed, as it broadens the scope of what products and information should undergo external peer review. This approach also should be applied to all federal agencies with responsibilities in the public health, safety, and environment arenas.

The best time for peer review may be after a department or agency has received public comments subsequent to publication in the Federal Register of an Advanced Notice of

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Proposed Rulemaking (ANOPR). At that point, a department or agency has performed its preliminary technical and/or economic analysis of an upcoming rule, and interested stakeholders have had a formal opportunity to express their views on the ANOPR. The results of the peer review can then be incorporated into the analysis used for the Notice of Proposed Rulemaking (NOPR) and the Final Rule.

We recommend that OMB clarify terms that are used in both the Information Quality Guidelines and the proposed Bulletin. OMB should clarify whether “influential” and “significant” mean the same thing, and whether they were intended to cover the same (or different) types of information. In addition, to ensure consistency with the Information Quality Guidelines, OMB should eliminate the terms “significant regulatory information” and “especially significant regulatory information,” and substitute the term “influential.”

To avoid confusion and ensure that the Bulletin’s provisions are actively integrated by agencies, we recommend that all agencies be required to amend their respective Information Quality Guidelines to incorporate these new peer review procedures. Agency peer review programs that already meet or exceed the criteria outlined in the proposed Bulletin need not undergo significant revision.

Whether the Provisions in the Bulletin Would Discourage Participation

EEI does not believe that any of the requirements in the Bulletin would “unnecessarily burden” or “discourage” qualified scientists from serving on agency peer review panels. The Bulletin should direct agencies to emphasize that the peer review process is an important and necessary part of ensuring the efficacy and value of the science used to support the protective goals of the federal regulatory process. It should be made clear that peer review meetings must be conducted with appropriate professional courtesy and conduct, by both panelists and observers, and be focused on matters of substance. Qualified scientists must understand that they are chosen to serve as peer reviewers based on their qualifications and scientific expertise and advice, not because they may espouse a particular political point of view.

How Agencies Should Select Peer Reviewers

EEI believes that government agency employees should be able to serve on peer review panels; they are often experts in particular scientific disciplines and would be appropriate peer reviewers. EEI strongly supports OMB’s standard that “peer reviewers shall be selected primarily on the basis of necessary scientific and technical expertise.” To ensure that peer reviewers focus on scientific and technical issues, potential conflicts of interest and bias must be effectively managed before peer review panels are formed. EEI recommends that prospective reviewers be required to disclose any and all potential for

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conflicts of interest and bias. Guidelines should be established for peer review panel formation to ensure that sufficient—though not overly burdensome—financial and other information is available to peer review management staff responsible for establishing panels.

Additional Comments

OMB's IQA Guidelines do not set any standards for agency peer review. We recommend that OMB amend the Guidelines to explicitly provide supplementary guidance on this extremely important tool for assuring the objectivity of the most significant agency information. Also, it is critical that OMB closely monitor agencies' compliance with the finalized peer review Guidelines.

EI supports OMB's proposal to take a more active role in the IQA correction process, especially in commenting on draft agency responses to IQA petitions for corrections. OMB's involvement will help ensure the advancement of the Act's goal of improving the quality of information used and disseminated by the federal government.

Finally, OMB should require peer review of scientific/technical information that underlies "consent decrees" entered into by agencies to settle litigation. There are numerous examples historically where regulatory agencies have proposed rules that have been negotiated in whole or in part subsequent to legal challenges. Even though a court signs off on a consent order, there should be an explicit provision in the agency's IQA Guidelines that all information used to sustain such orders meet the requirements of an agency's guidelines and the Bulletin's peer review provisions. A court should not be put in a position to "order" an agency to implement a consent decree that cannot meet the intent of the IQA.

Conclusion

EI appreciates the opportunity to comment on this important public policy issue. Again, EI commends OMB, and particularly the Office of Information and Regulatory Affairs, for its efforts to make "smarter regulation" the norm at all federal regulatory agencies. Please contact me or Michael Rossler at 202/508-5516 (or at mrossler@eei.org) if you have any questions about these comments.

Sincerely,



Quinlan J. Shea, III