Dick Hanneman <dick@saltinstitute.org>
12/17/2003 01:42:50 PM

Record Type: Record

To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP

cc:
Subject: Peer Review

Margo,

Please accept my apologies. I thought this had gone on Monday and only learned today that it had not. I hope that our comments are still useful to you an your OIRA colleagues. I've attached the same document as an attachement.

Dick
<<TA7380-Peer Review.doc>>

- TA7380-Peer Review.doc

December 15, 2003 via e-mail: OMB_peer_review@omb.eop.gov

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

RE: Proposed Bulletin on Peer Review and Information Quality, *Federal Register*, September 15, 2003 at page 54023

Dear Dr. Schwab:

The Salt Institute congratulates OIRA for continuing its significant campaign to improve the quality of the data being used to support federal decision-making. This peer review "bulletin" is an important initiative and one that is connected integrally to the Data Quality Act. Peer review is no substitute for quality standards, but is a proven safeguard that encourages better science and appropriate to integrate into the DQA guidelines.

OIRA has asked for public input on several important questions. In response, we would make the following comments:

- The scope of the Bulletin is carefully crafted and appropriate. Arguments could be made that it be expanded, but it strikes a good balance of practicality without undue specificity. Each agency should be required to amend its DQA guidelines to incorporate these new peer review procedures.
- Government agency employees are often expert and would be appropriate peer reviewers. They should be treated identically to outside reviewers inasmuch as they should not be engaged as peer reviewers of research in their own agency (much as academicians do not serve as peer reviewers for research produced in their own departments). Any conflict of interest rules should apply equally to "inside" and "outside" reviewers. That said, anyone who is expert enough in the subject matter brings to their peer review all their unique perspective, experience and bias. Reviewers are not engaged in a consensus project; the peer review is to uncover flaws in method or reasoning or discover gaps in evidence that must be corrected to maintain scientific integrity.

- Qualified peer reviewers must be free of conflicts of interest. Bias is not the question here. Whether the peer reviewer receives some financial or other (career-enhancing) benefit is the test. Researchers who receive agency funding should be required to disclose that fact and some means devised to protect them against agency retaliation should their peer review not conform to their funding agency's preferred outcome. While the concept is well understood for employees of private, for-profit entities, there are equally strong, though often more subtly-expressed conflicts of interest for any non-governmental organization whether in the form of direct profit benefit or positioning a non-profit group to solicit funds in support of a particular outcome. All these relationships need to be fully disclosed and direct conflicts should disqualify such reviewers.
- We question that disclosure is burdensome. It certainly represents a sacrifice of a measure of personal privacy for the reviewer, but we believe this is a reasonable price for society to pay to ensure the integrity of the science undergirding important public policy decisions. We do believe, however, that safeguards are needed to protect against abusive use of the conflict-of-interest information in the disclosure statements and that this might include a five or ten year limit to the information required.
- Producing quality science may require agencies to pay for peer reviews. Government agencies build the cost of quality control into their contracts already in many ways including hiring an army of inspectors. If information is important enough to be the basis for policy, it is important enough to get it right. That said, many studies will have already undergone peer review for publication which may well meet the standards for the OMB peer review. Such publication peer review is not necessarily sufficient since its purpose is different and standards among publications vary widely. Publications use peer reviews to avoid the embarrassment of poor science, but often their primary overall objective is to publish fresh and exciting results, not objectively analyze a question. There will be some costs to review the adequacy of already-performed peer reviews, but those costs should be less than performing de novo peer reviews.
- Agencies should be charged with the responsibility to conduct the peer reviews. Thus, they should select the peer reviewers – subject to OMB guidelines under the Data Quality Act that ensure that the end result meets DQA standards. Agencies should, however, be required to submit for public comment the scope of the peer review charge, the peer review panel members and the peer review process. At this stage, the public should be invited to share with the peer reviewers any comments and perspectives that they feel important to call to the attention of those who will be conducting the review.

In addition to the above questions put forth by OIRA, we would offer several additional comments:

- The Bulletin clearly implies that the peer review requirements are part of the Data Quality Act. This should be made explicit. Peer review is part of ensuring the quality of the data used by federal agencies to make policy decisions and OMB should specifically assert its authority to enforce DQA standards through the peer review procedures. Thus, rather than a "bulletin," we believe this rulemaking should be a formal amendment to the DQA guidelines.

- The Bulletin should use consistent definitions with the DQA (e.g. “influential” information). Thus, we would suggest the language of “especially significant” be abandoned and “influential” substituted in its place with a notation that this term is already defined in DQA guidelines.
- Inclusion of proprietary information should not be a reason to deny the public access to the “sensitive” material. We would not object if information is not disclosed that is not used in the analysis, but would insist that standards of reproducibility demand full disclosure of data sufficient to document the findings and conclusions. In short, if confidentiality is paramount, the study cannot be used for public policy-making.
- Similarly, there are occasions when agencies propose rules that have been negotiated in legal challenges to its rules. While the court signs off on the consent order, there must be provision that all evidence used to sustain such orders meet the DQA and peer review guidelines. Thus, a court should not be in a position to “order” an agency to implement a consent decree that cannot withstand DQA scrutiny.

Thank you for this opportunity to provide our perspective. Congratulations to OIRA for its leadership in this important effort.

Sincerely,

Richard L. Hanneman
President

TA7380