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## **Revised Information Quality Bulletin for Peer Review**

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The Office of Information and Regulatory Affairs (OIRA) of the Office of Management & Budget (OMB) issued a revised version of the proposed bulletin on Peer Review and Information Quality (Bulletin). The Bulletin is designed to provide guidance to Federal agencies on when and how to conduct peer reviews of information the agencies' disseminate to the public.

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## Office of Management and Budget Revised Information Quality Bulletin for Peer Review April 16, 2004

## **Summary**

The Office of Information and Regulatory Affairs (OIRA) of the Office of Management & Budget (OMB) issued a revised version of the proposed bulletin on Peer Review and Information Quality (Bulletin). The Bulletin is designed to provide guidance to Federal agencies on when and how to conduct peer reviews of information the agencies' disseminate to the public. The earlier September draft drew strong negative reactions from the Federal agencies and research community.

This new version of Bulletin requires peer review for influential scientific information to be disseminated by Federal agencies and serves as a supplement to the February 2002 OMB Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility and Integrity of Information Disseminated by Federal Agencies (Information Quality Act). The Information Quality guidelines encouraged but did not require peer review. This Bulletin gives the agencies discretion to chose the type of peer review mechanism to use in most cases based on the novelty, complexity or precedent-setting nature of the methods or models used in the information. OIRA outlines seven issues to be considered in deciding the type of review mechanism. Recognizing the need for timeliness and a weighing of benefits and costs, agencies are urged to examine: individual versus panel reviews; timing, scope; selection of reviewers, disclosure; public participation and the disposition or reporting of reviewers' comments.

OIRA requires a more rigorous review mechanism for highly influential scientific assessments, defined as a subset or type of scientific information. The requirements tied to this more rigorous review are in addition to the areas to be considered for scientific information. Because scientific assessments are linked more directly to regulatory actions with a potential effect of more than \$500 million in any year and/or may have a broader interagency interest, OIRA requires the review panel to be "sufficiently broad and diverse" from a scientific perspective. Any financial ties between reviewers and the regulated industry or the agency must be examined. To ensure independence, agency employees are barred from serving on the peer panel and additional questions must be asked of potential panelist to evaluate their independence. Panel reports must be made available on the agency's web site along with the agency's response to the report.

The proposed Bulletin includes a list of types of information exempt from these guidelines and provides the agency head with the ability to waive or defer a peer review for compelling reasons. The proposed exemptions allow eight categories of information including information related to national security and the public's health and safety to be disseminated without prior peer review.

## **Observations on the Bulletin**

OIRA clearly considered the concerns of the agencies and the public including COGR and the other university associations and scientific organizations in crafting this revision. In its December 2003 letter, COGR questioned the Bulletin's vague description of the scope of review, the overly prescriptive nature of the required peer review process including the selection of peer reviewers, and the cumbersome processes for public participation and reporting. We believed the earlier version of the Bulletin as written virtually guaranteed a weakening of the quality of the reviews, delays in implementing regulations and increases in the cost of peer reviews conducted by the federal agencies.

The new draft Bulletin proposes guidelines for the review of influential scientific information rather than the ill-defined focus on "significant regulatory information" that COGR questioned in the earlier version. It states that information already peer reviewed as in the case for publication in a journal does not have to be re-reviewed if the agency determines the prior peer review to have been adequate. The decision on the adequacy of prior reviews as well as the choice of the mechanism to be use for non-reviewed influential scientific information is to be grounded in the nature of the science itself – its novelty and complexity. The benefit and cost implications of the review must be weighed as well. Review panelists' conflicts of interest are to be reviewed and managed using processes similar to the Federal ethics requirements or the policies used by the National Academy of Science. To make the whole peer review process more transparent. a summary or copy of reviewers' comments, with their names and affiliations, must be made available to the public. These revisions address key questions COGR raised in its comment. These revisions include reasonable definitions of troubling terminology – influential and adequate – and ground decision-making in the nature of the science.

A more rigorous and stringent set of requirements, including the selection of reviewers, are reserved for highly influential scientific assessments. Clearly linked with regulatory activity, the peer review requirements are tied to the scientific assessment to be reviewed – the same standard used for the more general scientific information. One of the most contentious issues with the earlier version was the exclusion of scientists who have received funds from the agency but may have critical expertise or attempting to balance biases. The new version of the Bulletin supports convening panels with the greatest expertise that reflect the breadth and diversity of scientific perspectives. The Bulletin states clearly that grants awarded to scientists based on investigator-initiated, competitive, peer-reviewed proposals, generally don't raises questions of conflicts or independence. Again, the approach for selecting and vetting potential reviewers used by the National Academy is offered as a model. COGR's concern about excluding the best scientists on the basis research funding has been fully addressed.

COGR had expressed serious concerns about the earlier version's requirement to link panelists with specific comments. We believed this type of attribution would weaken the goal of providing frank assessments on the quality of science and are pleased to see this requirement eliminated in this version. This draft of the Bulletin requires the preparation of a peer review report either as a summary of individual views or a single report from

the panel with the names, affiliations, and a brief professional biographical sketch included in a public posting of the report along with the agency's response to the review panels report.

In response to broad community concerns over the agencies' inability to act in a timely manner in response to public health or security threats by placing the authority to waive the peer review requirements with the OIRA administrator, the new Bulletin gives the agency director the waiver authority and goes a step further by exemption eight categories of information from the Bulletin's requirements. These exemptions include information related to: national security; time-sensitive medical, health or safety issues' routine Federal statistical information like unemployment rates; financial information focused on questions like interest rates; and some other classes of information generated by agencies, and in some case their scientists, in the conduct of their business.

Finally, the OIRA will require the agencies to post a report of planned peer reviews - a list updated at least every six months to notify the public of planned and ongoing influential scientific information disseminations and how the peer review will be conducted for hat information.

COGR is not planning a formal response to this version of the Information Quality Bulletin for Peer Review. Universities interested in commenting should submit comments to OIRA by May 16, 2004. For instructions, please see the OMB website at: <a href="http://www.whitehouse.gov/omb/inforeg/infopoltech.html">http://www.whitehouse.gov/omb/inforeg/infopoltech.html</a>