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OMB's Response to Comments on the Revised Peer-Review Bulletin

On September 15, 2003, OMB published a draft Peer Review Bulletin designed to strengthen the technical quality of information prior to its dissemination by the federal government. To improve the draft Bulletin, OMB organized an explicit public comment process and encouraged federal agencies to sponsor a public workshop at the National Academy of Sciences (NAS).

OMB received 187 public comments during the comment period.¹ The NAS workshop (November 18, 2003 at the National Academies in Washington, D.C.) attracted several hundred participants, including leaders of the scientific community.² OMB also participated in outreach activities with major scientific organizations and societies that had expressed specific interest in the draft Bulletin. A formal interagency review of the draft Bulletin, resulting in detailed comments from numerous federal departments and agencies, was undertaken in collaboration with the White House Office of Science and Technology Policy.

In light of the substantial interest in the Bulletin, including a wide range of constructive criticisms of the initial draft, OMB decided to issue a revised draft for further comment. This revised draft was published in the *Federal Register* on April 28, 2004, and a second round of public comment was encouraged.

The revised draft stimulated a much smaller number of comments (56)³. A majority of the commenters, even those who oppose promulgation of OMB standards for peer review, noted that the revised draft was responsive to criticisms and significantly improved compared to the initial draft. However, commenters did offer additional criticisms, suggestions, and refinements for consideration by OMB.

The purpose of this document is to summarize the major comments received from the public and OMB's responses to these comments, and to highlight the differences between the final Bulletin and the revised draft published in April.

1. Some commenters expressed concern that the revised draft provides too much discretion to federal agencies, which may lead to uneven implementation of the Bulletin and inadequate peer reviews in certain situations. Others suggested that additional agency discretion should be considered.

¹ Public comments on the draft proposal for the Bulletin are available at:
http://www.whitehouse.gov/omb/inforeg/2003iq/iq_list.html

² The agenda and presentations from the workshop are available at
http://www7.nationalacademies.org/stl/STL_Peer_Review_Agenda.html. The transcript of the workshop is available at http://www7.nationalacademies.org/stl/Peer_Review_Transcript.pdf

³ Public comments on the revised draft proposal for the Bulletin are available at
<http://www.whitehouse.gov/omb/inforeg/infopoltech.html#iq>

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OMB recognizes that the revised draft provided substantial discretion to federal agencies. The final Bulletin retains a substantial degree of discretion for agencies. Agency discretion is necessary given the wide range of information covered by the Bulletin and varying amounts of agency resources (staff and time) that are required for different types of peer review. In the final Bulletin OMB has clarified the intent of its language concerning "adequacy of prior peer review" and the use of deferrals and waivers to address some reasonable concerns that the revised draft may have been perceived as too discretionary. On the other hand, OMB has reinforced its intent with respect to agency discretion in the context of time-sensitive health and safety information and adjudications, and has provided examples of existing procedures that would qualify as alternative procedures.

2. Some commenters argued that a public participation opportunity should be provided in all peer review processes, especially those that address the more important scientific assessments covered by Section III of the Bulletin. Other commenters continued to raise concerns that encouraging public participation in conjunction with the peer review process would lead to delay in important health and safety regulations.

The Bulletin encourages agencies to provide public participation opportunities for information covered by Section III. However, a strict mandate for public participation is avoided because there may be unusual cases where an agency must ensure that information is scientifically sound before it is made available to the public. In these unusual cases, confidential peer reviews without public participation may be advisable. On the other hand, commenters should be reminded that public participation is a key component of Section V of the Bulletin. This Section requires agencies to provide the public an opportunity to participate in peer review planning for all information covered by the Bulletin. However, OMB has added language to stress that agencies should avoid open-ended comment periods, which may delay completion of peer reviews and complicate the completion of the final work product. Commenters also are reminded of the exemption option for time-sensitive health and safety information.

3. Some commenters argued that information disseminated in the course of agency adjudications should be excluded completely from the Bulletin (rather than covering adjudications that are scientifically or technically novel or likely to have precedent-setting influence on future adjudications) while others argued that the revised Bulletin was too narrow in its coverage of such information.

OMB weighed these comments and decided to keep the coverage as proposed in April 2004, but to change the language to emphasize that it is the agency's responsibility to determine whether peer review is practical and appropriate within the context of a specific adjudication.

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4. Some commentators argued that a peer review process would not be credible to stakeholders and the public if a list of the names of peer reviewers (and their qualifications) was not made available to the public. Some went further and argued that the scientific comments of each reviewer should be disclosed with attribution. Others acknowledged that such transparency increases the credibility of the results of a peer review, but worried that agencies might find it difficult to attract scientists with sufficient qualifications without the guarantee of anonymity.

The preamble to the final Bulletin discusses the advantages and disadvantages of disclosing the names of peer reviewers and their comments. To ensure accountability in the process as well as credibility to the public, the final Bulletin requires that the names of peer reviewers used for both Section II and Section III information be disclosed to the public. However, the Bulletin does not require agencies to identify which scientific comments were made by each named reviewer. Agencies are provided discretion to preserve a degree of anonymity for each peer reviewer, which should encourage scientific participation and technical candor on the part of reviewers. We note that the National Academy of Sciences and the Environmental Protection Agency's Science Advisory Board have succeeded in attracting quality peer reviewers using this model for disclosure.

5. Some commentators expressed concern that desirable language in the original draft Bulletin -- language restricting the province of peer reviewers to science (as opposed to policy) -- had been deleted from the revised Bulletin. The concern is that peer reviewers might venture into policy questions that are the province of accountable public officials.

OMB did not intend a change in direction on this point. Thus, the final Bulletin has reinstated instructions that peer reviewers should be asked to provide commentary on scientific and technical questions, while reserving opinions regarding policy implications for policy makers.

6. Some commentators expressed concern that there is no enforcement mechanism in the Bulletin in the event that agencies do not comply with its requirements.

OMB believes that the Bulletin is a useful management tool for agency officials and OMB to employ as they take steps to increase the quality of scientific information prior to its dissemination. In this revised Bulletin, an "annual reporting requirement" has been added to allow OMB to further track how agencies are using the Bulletin, including provisions for waivers and exceptions. In addition, OMB expects the public will play a critical role in the process by monitoring agency activities under the Bulletin through the transparent peer review planning process required under the Section V. If the public and/or OMB are not satisfied with agency compliance under the Bulletin, they can raise these concerns with policy officials in the agency. To enhance the value of the peer review planning process, we have clarified that it will be necessary for an agency to designate at the time it plans a given peer review whether a particular dissemination should be designated as "influential scientific information" or "a highly influential

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scientific assessment.” Also, in view of the time it will take for agencies to appropriately implement transparent, web-accessible peer review planning processes, the final Bulletin extends the time at which the planning requirements of the Bulletin go into effect to six months after publication for highly influential scientific assessments. As in the revised proposal, agencies have from one year of publication of the Bulletin to implement the peer review planning requirements for “influential scientific information.”

7. Some commenters argued that the definition of “highly influential assessments” under Section III was too narrow, since few rules will pass the \$500 million impact test, and that the narrative criteria enumerated in the revised draft were demanding (i.e., information must involve precedent-setting, novel, and complex approaches, or significant interagency interest). Other commenters raised concerns that the \$500 million impact test, as written, might not cover public sector impacts.

OMB wishes to emphasize that the \$500 million test should not be directly compared to the \$100 million test in Presidential Executive Order (E.O.) 12866. While the E.O. test has been interpreted as an annual economic-impact test, the \$500 million test in the final Bulletin refers to any year of impact. Thus, influential scientific assessments that have more than a \$500 million impact in the first year (e.g., due to induced capital expenditures) will be covered by the Bulletin even if the annualized impact is less than \$500 million or even \$100 million. Because unexpected information can have large initial impacts that justify concern, the Bulletin’s economic-impact criteria were defined in terms of a threshold applicable to any specific year. More importantly, OMB believes that the economic test may be difficult to apply for many influential scientific assessments whose policy or economic impact is uncertain. For these assessments, the narrative criteria will prove to be more important, and these criteria have been broadened in the final Bulletin to include influential scientific assessments that are novel, controversial, or precedent-setting or have significant interagency interest. The “novel, controversial, or precedent-setting” language was suggested by some commenters, based on the language used in EPA’s Peer Review Handbook. Finally, OMB has clarified that the \$500 million impact test covers all impacts, regardless of sector.

8. Some commentators objected to language in the revised draft concerning reports from the National Academy of Sciences. These commenters saw no rationale for assuming that the substantive quality of NAS reports was always adequate and no reason to exempt NAS reports from the peer-review provisions of the Bulletin.

OMB is not aware of any systematic, substantive flaws in the scientific reports issued by the National Academy of Sciences. Nevertheless, the Bulletin does not provide a substantive information quality exemption for NAS information that agencies may choose to disseminate. NAS information relied upon by agencies of the federal government -- like all other information disseminated by the agency -- remains subject to the substantive quality standards defined in OMB’s government-wide information quality guidelines and the guidelines issued by the agencies under the Information Quality Act.

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What the Bulletin does is establish a general presumption that the peer review procedures used by the NAS are adequate to satisfy the objectives of the Bulletin. OMB has established this presumption because, over recent decades, NAS has developed a well-functioning and respected peer review process. While this general procedural presumption has been established in the Bulletin, the public is entitled to make a case to an agency that a specific NAS report has problems -- procedurally with regard to peer review or substantively -- that justify that the presumption be overridden in favor of additional review. OMB expects that it will be rare that an agency overrides this procedural presumption of adequate review.

9. Some commenters expressed concern that the desired exemption for time-sensitive health/safety information should not be restricted to medical data from clinical trials that were subject to adequate peer review prior to the start of the trial.

OMB agrees and has broadened the potential applicability of the exemption while retaining the usefulness of the specific clinical example.

10. Some commenters expressed concern that the language in Section III might preclude premier government scientists from serving on peer review panels, even when those scientists were not involved in development of the information to be reviewed.

For Section III assessments to be perceived as "independent" of the agency, OMB believes that peer reviewers should be selected from a pool of qualified reviewers that does not include employees of the department or agency that prepared the assessment. However, the final Bulletin now provides for a rare exception in a case where the expertise of a premier government scientist is essential and cannot be obtained elsewhere, the scientist did not participate in development of the information to be reviewed, and the scientist is employed in a different agency of the Cabinet-level department than the agency that prepared the assessment. Furthermore, within the context of the "Alternative Procedures" section, the final Bulletin suggests that large science agencies that have diverse research portfolios and do not have significant regulatory responsibilities, such as NIH, might design an alternative in which scientists from one part of the agency (for example, an NIH institute) are allowed to participate in peer reviews for another part of the agency, as long as the government scientist did not have any part in the development or prior review of the scientific information and does not hold a position of managerial or policy responsibility.

11. Some commenters raised concerns that the conflict standards were not stringent enough. Others raised concerns that the conflicts language was not inclusive of the breadth of possible conflicts.

OMB agrees that financial ties to all stakeholders should be examined. With respect to reviewers who are not federal employees, the final Bulletin now requires agencies to

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adopt or adapt the National Academy of Sciences policy for committee selection with respect to evaluating conflicts of interest. Government employees are always subject to federal ethics requirements, as stated in the revised Bulletin.

12. Some commenters expressed concern regarding the clarity and placement of our exemption for government funded scientists who publish information that does not represent the views of the agency.

OMB agrees that it is preferable to specify this policy in the “Definitions” section of the Bulletin rather than in the “Exemptions” section. For the purposes of this Bulletin, “dissemination” excludes research produced by government-funded scientists (e.g., those supported extramurally or intramurally by federal agencies or those working in state or local governments with federal support) if that information is not represented as the views of a department or agency (i.e., they are not official government disseminations). As in the revised proposal, an appropriate disclaimer is required for government scientists and is advised for non-government scientists.