

Summary of Public and Agency Comments on Proposed Bulletin on Information Quality and Peer Review, Including Responses by OMB

Date: April 15, 2004

Office of Information and Regulatory Affairs, US Office of Management and Budget

INTRODUCTION

On September 15, 2003, the US Office of Management and Budget (OMB) released for public comment an originally proposed Bulletin on Peer Review. A Bulletin is an official document issued by OMB to provide guidance to federal agencies on a specific matter. Bulletins are not laws or binding regulations; they are a tool used by OMB to foster effective and consistent management throughout the federal government. The purpose of this particular Bulletin is to promote the appropriate and transparent use of peer review, with the goal of enhancing the technical quality and credibility of information disseminated by federal agencies.

In order to improve the draft Bulletin, OMB established a 90-day comment period, which ended December 15, 2003. OMB and OSTP encouraged public discussion of the originally proposed Bulletin at an open workshop held at the National Academy of Sciences on November 18, 2003. Federal agencies were given additional time, until January 16, 2004, to provide comments, thereby allowing agencies to benefit from the public comment process in the development of their responses. In total we received 187 public comments; these are available on OMB's web site.

The purpose of this document is to provide a summary of the important public and agency comments and our responses to these comments. In so doing, we have sought to capture the major themes contained in both the public and agency submissions. This document is being released in conjunction with the revised OMB Bulletin on Peer Review, which was made available to the public on April 15, 2004.

The comments on the originally proposed Bulletin spanned the spectrum from highly favorable to blanket requests that the draft be withdrawn and reconsidered. Other comments suggested one or more specific modifications to the originally proposed Bulletin. The suggestions of some commenters (e.g., expand the applicability of the Bulletin) were sometimes in conflict with the suggestions of other commenters (e.g., narrow the applicability of the originally proposed Bulletin). In the revised Bulletin, we have sought to achieve a balance among the broad spectrum of perspectives that were expressed.

THE NEED FOR THE BULLETIN

Many commenters suggested that we should better articulate the need for the Bulletin. The purpose of this particular Bulletin is to promote the appropriate use of peer review in order to enhance the technical quality and credibility of information disseminated by federal agencies. This may be best understood by referring to more than a decade of debate¹ and scholarship² on the proper roles of peer review in a regulatory context, as well as the wide variety of authorities who have argued that peer review practices at various federal agencies need to be strengthened.³ Other arguments have focused on specific types of scientific products (e.g., assessments of health, safety and environmental hazards).⁴ Indeed, the Congressional/Presidential Commission on Risk Assessment and Risk Management suggests that peer review of social science

¹ Lars Noah, "Scientific 'Republicanism': Expert Peer Review and the Quest for Regulatory Deliberation, Emory Law Journal, Atlanta, Fall 2000:1066; Testimony of Bruce Alberts, PhD., President, National Academy of Sciences, February 24, 1998, Hearing on S. 981, before Senate Committee on Governmental Affairs

² Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving

information should have as high a priority as peer review of health, ecological, and engineering information.⁵

Some agencies have formal peer review policies and have made improvements to some of their scientific advisory mechanisms, but other federal agencies have no formal peer review policies. Even agencies that have such policies do not always follow them prior to the release of important scientific products that espouse an agency position.

Prior to the development of this Bulletin, there were no government-wide standards concerning when peer review is required and, if required, what type of peer review process is appropriate. The Executive Branch also lacked of a transparent process for determining the type of peer review that is appropriate for a particular agency report. No formal interagency mechanism exists to foster cross-agency sharing of experiences with peer review practices and policies.

THE SCOPE OF THE BULLETIN

Several commenters suggested limiting the coverage of the originally proposed Bulletin whereas others suggested broadening it. Arguments for a variety of additional inclusions and exclusions were presented. Arguments presented for and against each suggestion were carefully considered.

We received comments indicating that the originally proposed Bulletin's focus on "regulatory" information was ambiguous. The commenters indicated that it would be difficult to determine in advance whether an information product might reasonably be expected to be used in support of a regulatory action in the future. In response to these comments, the revised Bulletin no longer focuses specifically on the potential regulatory impact of the information disseminated. Rather, the re-proposal limits coverage to "influential" scientific information. As defined in OMB's Information Quality Guidelines, "influential" means that "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on

⁵ Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, Volume 2, Risk Assessment and Risk Management in Regulatory Decision-Making, 1997: 103.

important public policies or important private decisions.” Each agency has defined “influential” in its Information Quality Guidelines in a manner that is appropriate for its information products.

We agree with the extensive comment that the scope of Section III of the originally proposed Bulletin, which describes the characteristics of peer review for the most important types of information, should be narrowed. We also agree that the terminology used to describe this category of information (especially significant) could be confusing in light of terminology used in Executive Order 12866. In response, Section III has been narrowed to cover only “scientific assessments” (as opposed to all influential information) that either have a \$500 million annual impact (rather than a \$100 million annual impact) or involve novel, complex, or precedent setting approaches or generate significant interagency interest. A “scientific assessment” is an evaluation of a body of scientific or technical knowledge which typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. These assessments include, but are not limited to, state-of-science reports, technology assessments, weight-of-evidence analyses, meta-analyses, risk assessments, toxicological profiles of substances, integrated assessment models, hazard determinations, exposure assessments, or health, ecological, or safety assessments. Typically, much of the data and models used in these scientific assessments have already been subject to some form of peer review (e.g., refereed journal peer review or peer review under Section II of the Bulletin).

Furthermore, we agree with a variety of agency comments that there are difficulties associated with including Regulatory Impact Analyses (RIAs) within the scope of the Bulletin. The revised Bulletin makes it clear that although the models and data underlying RIAs are covered, the actual RIA is not. The RIA is subject to Circular A-4, which defines good regulatory analysis and standardizes the way benefits and costs of federal regulatory actions are measured and recorded. Furthermore, we encourage peer review of RIAs by government analysts in addition to the review conducted by OIRA during the E.O. 12866 process.

Although the originally proposed Bulletin was not intended to cover government-sponsored research conducted and communicated (e.g., published) as the work of individual scientists (as

opposed to the sponsoring agency), several of the commenters assumed such coverage. We have clarified in the re-proposal that the Bulletin covers only official “disseminations” of the US government. It does not cover information products released by government-funded scientists (for example, those supported extramurally or intramurally by agencies such as (but not limited to) NSF and NIH or those working in state or local governments on federal support) if those information products are not represented as the views of the agency or department supporting the research. An information product is not covered by the Bulletin unless it represents an official view of one or more departments or agencies of the federal government. In order to reduce ambiguity in this area, we advise government-funded scientists to include a statement with their disseminated work indicating that “the views in this report are those of the author(s) and do not necessarily represent the views of the funding agency” in cases where the imprimatur of the federal government is not intended.

In response to the concern raised by several commenters, time-sensitive medical, public health, and safety disseminations or disseminations based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began are exempt from the coverage of the revised Bulletin.

Several comments also suggested that we exempt reports generated by the National Academy of Sciences (NAS) from the coverage of the Bulletin. Congress assigned the NAS a special role in advising the federal government on scientific and technical issues. We have specified in the revised Bulletin that the peer-review procedures of the NAS are generally quite rigorous and thus agencies should presume that major findings from NAS reports have been adequately peer reviewed.

In response to the many comments about the “waiver” for emergencies, we have specified that the responsibility for determining the need for a waiver from the peer review requirements of the Bulletin rests squarely with the agencies. Specifically, the agency head may waive or defer some or all of the peer review requirements of the revised Bulletin where warranted by a compelling rationale.

THE NEED FOR AGENCY DISCRETION TO CHOOSE PEER REVIEW PROCEDURES

Some commenters argued that the originally proposed Bulletin was too prescriptive, particularly in its description of the peer review requirements that would apply to “especially significant regulatory information.” They argued that agencies needed considerable discretion to tailor peer review procedures to individual reports based on a variety of considerations.

We agree that agencies need discretion to fashion appropriate peer review activities based on the nature, complexity and policy significance of a report. The need for such agency discretion was highlighted in GAO’s 1999 report on peer review practices.⁶ The revised Bulletin provides agencies greater flexibility in several ways. First, while peer review of all “influential” scientific information is required, agencies are provided wide discretion in determining the intensity of peer review that is appropriate for specific documents. For example, the agencies are provided discretion about when public comment procedures should accompany peer review and when a panel of reviewers should deliberate in public (as opposed to letter reviews by individual scientists). The revised Bulletin also provides agency discretion in determining when the comments of specific reviewers should be disclosed with attribution and when the comments of reviewers should be summarized without attribution.

Second, agencies are permitted to propose and use alternative scientific procedures -- other than the peer-review procedures specified in the Bulletin -- if they demonstrate that these alternative scientific procedures will satisfy the information quality goals in OMB’s government-wide guidelines and agency guidelines issued under the Information Quality Act of 2000.

⁶ U.S. General Accounting Office, Federal Research: Peer Review Practices at Federal Agencies Vary, GAO/RCED-99-99, Washington, D.C., 1999

SELECTION OF REVIEWERS

We agree with the many comments that emphasized that the most important factor in selecting reviewers is expertise: making sure the selected reviewer has the knowledge, experience, and skills necessary to perform the requested review. We have incorporated the suggestion that agencies seek nominations for peer reviewers from the public, including relevant scientific and professional societies.

Other comments highlighted the need to consider diversity in scientific viewpoint and discipline. Specifically, there exists a range of legitimate viewpoints regarding scientific interpretation of the available literature on most scientifically uncertain issues. As such, the revised Bulletin underscores the importance of selecting reviewers to represent a diversity of scientific perspectives relevant to the report's subject.

Several commenters raised concerns about both the appropriateness and the implications of limiting the participation of academic scientists who receive grant support from federal agencies. We considered whether a reviewer is independent of the agency if that reviewer receives a substantial amount of research funding from the agency sponsoring the review. The revised Bulletin clarifies that research grants that were awarded to the scientist based on investigator-initiated, peer-reviewed competitions do not generally raise issues of independence. However, consulting or contractual relationships with the agency may raise issues of independence or conflict, depending upon the situation. Repeated use of the same reviewer in multiple assessments may raise issues of independence, unless the reviewer's expertise is unique or the reviewer is serving on a standing panel for a fixed term.

Others commented that we did not clearly distinguish the terms expertise, independence, balance, and conflict-of-interest. In the revised Bulletin, we provide separate discussions of expertise, balance, independence, and conflict of interest. With respect to conflict-of-interest, we emphasize that agencies should ensure that any federal employees serving as reviewers comply with all applicable federal ethics requirements. With respect to reviewers who are not federal employees, agencies should adopt or adapt the prevailing practices of the NAS regarding

committee composition, real or perceived conflicts, balance⁷ and/or the applicable ethics requirements that have been developed by the U.S. government, including the standards of the Office of Government Ethics.⁸ Furthermore, we stress that financial ties of potential reviewers to regulated entities and regulatory agencies should be scrutinized when influential information is likely to be relevant to specific regulatory policies.

IDENTITY OF REVIEWERS

We received many comments suggesting that disclosing names of reviewers and their comments would be detrimental to both the candor of the review and agencies' ability to recruit reviewers. The revised Bulletin describes the trade-off between transparency and disclosure, encouraging agencies to weigh the need for each during its peer review planning.

PUBLIC PARTICIPATION

Many commenters raised concerns about the appropriate degree of public participation in the peer review process. Some of the comments addressed logistical considerations, such as the timing of public comment and difficulties associated with implementing a public comment period, while others focused on the delay that such a public comment period would add to the rule-making process. Some commenters raised concerns that public comment would not add substantially to the process, as many public comments do not address scientific or technical issues. Others suggested that public comment might undermine the integrity of the peer review process.

The revised Bulletin leaves this matter to agency discretion for peer reviewers conducted under Section II of this Bulletin and reminds agencies that conducting peer review before information is disseminated can prevent delay if the information is later used in support of rule making.

⁷ National Academy of Sciences, "Policy and Procedures on Committee Composition and Balance and Conflicts of Interest for Committees Used in the development of Reports," May 2003, available at <http://www.nationalacademies.org/coi/index.html>.

⁸ United States Office of Government Ethics, "Standards of Ethical Conduct for Employees of the Executive Branch," Washington, D.C., 2002, available at: http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/reference/rfsoc_02.pdf

Although we considered imposing a public comment and/or oral hearing requirement as part of Section III, we determined that these forms of public participation in scientific assessment may not be appropriate for all assessments. Public comment is not always feasible and can lead to unnecessary delay if it is conducted too late in the process. In addition, some assessments may be so sensitive that it is critical that the agency complete its quality assurance process before the assessment is publicized. In those situations, a rigorous yet confidential peer review process may be appropriate, prior to public release of the report. If an agency decides to make a draft assessment publicly available at the onset of a peer review process, the agency should, whenever possible, provide a vehicle for the public to provide written comments and/or to make an oral presentation before the peer reviewers. When written public comments are received, the agency should ensure that peer reviewers receive copies of comments that address significant scientific issues with ample time to consider them.

Other commenters requested a mechanism for the public to request the use of a modified peer review plan. We agree that the public should be able to comment on the agency's plan for peer review. We have expanded our discussion of peer review planning and clarified that the roster of forthcoming studies is the vehicle through which the public can track and comment on an agency's peer review plans. Specifically, agencies are required to inform the public as to their peer review plans for all upcoming documents subject to this Bulletin. The roster must be posted on the agency's web site, and the web site must include a mechanism for submission of comments from the public. Agencies must post their plans for peer review with ample time both for the public to comment and for the agency to consider those comments before implementing the peer review plan.

LITIGATION AGAINST AGENCIES

Some public and agency commenters raised concerns that the originally proposed Bulletin suggested new avenues for litigation against agencies. In response to this concern, we have clarified that the Bulletin is intended to improve the internal management of the Executive Branch, and is not intended to create any new right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its departments, agencies, or other

entities, its officers or employees, or any other person. Similarly, this Bulletin does not abridge any existing rights of action.

UNCERTAINTY IN SCIENCE

Some reviewers pointed out that our discussion of uncertainty and scientific judgment might not provide appropriate guidance, as science is by nature an uncertain process. In the revised preamble we emphasize that uncertainty is inherent in science, and in many cases individual studies do not produce conclusive evidence. Rather, what is being reviewed in the case of scientific assessments is a scientific judgment rather than “scientific fact.”⁹ Specialists attempt to reach a consensus by weighing the accumulated evidence. As such, it is important that peer reviewers be asked to ensure that scientific uncertainties are clearly identified and characterized.

Several commenters suggested that it was inappropriate to request that peer reviewers recommend research to address uncertainties. In the revised Bulletin we clarify the goal of such a request. Specifically, since not all uncertainties will have an equal effect on the conclusions drawn, it is important to understand the potential implications of the uncertainties for the technical conclusions drawn. Within this context, peer reviewers can make an important contribution by distinguishing scientific facts from professional judgments. Reviewers might be asked to provide advice on reasonable judgments that can be made from the scientific evidence, but the charge should make clear that the reviewers are not to provide advice on the policy (e.g., the amount of uncertainty that is acceptable or the amount of precaution that should be embedded in an analysis). Such considerations are the purview of the government. In addition, peer reviewers might consider value-of-information analyses to identify whether more research is likely to decrease key uncertainties.¹⁰ Value-of-information analysis was suggested for this purpose by the Presidential/Congressional Commission on Risk Assessment and Risk

⁹ Mark R. Powell, Science at EPA: Information in the Regulatory Process, Resources for the Future, Washington, D.C., 1999: 139.

¹⁰ Granger Morgan and Max Henrion, “The Value of Knowing How Little You Know,” Uncertainty: A Guide to Dealing with Uncertainty in Quantitative Risk and Policy Analysis, Cambridge University Press, 1990:307.

Management.¹¹ A description of additional research that would appreciably influence the conclusions of the assessment might help an agency target any additional research resources.

OIRA OVERSIGHT ROLE

Some commenters expressed concern that the Bulletin would remove agency discretion to warn the public regarding health emergencies. As noted above, agencies will make the critical decisions as to whether to release any information that is time sensitive through either a specific exemption or a waiver. Similarly, the Bulletin was not intended to provide OIRA with veto authority on the release of any study. Rather, OIRA's role will be to ensure implementation of agencies' peer review plans and work with agencies to ensure that studies have the appropriate level of review before dissemination. The oversight of peer review planning in the Bulletin provides an opportunity to ensure that the reviews planned by federal agencies are based on the most rigorous standards of peer review, appropriate to the level of importance of the information being generated.

COSTS AND BENEFITS OF PEER REVIEW

Some commenters requested an estimate of the costs and benefits of peer review. Many of these commenters expressed concerns that imposing a peer review requirement would lead to delays in regulatory decisions, while others suggested peer review can accelerate the regulatory process by reducing controversy and reanalysis. Other commenters highlighted specific situations in which early peer review improved (or could have improved) the value of the information that was used in a regulatory setting.

In the revised Bulletin, we make it clear that when agencies consider the type of peer review mechanism that is appropriate, they should consider the costs and benefits of peer review. Even when costs and benefits cannot be fully quantified, the tradeoff can be analyzed from a benefit-

¹¹ Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, 1997, Volume 1: 39, Volume 2: 91.

cost perspective. For example, some scholars ¹² have suggested that the insights offered by peer reviewers may lead to policy with more benefits, fewer costs, or more certainty that the policy will withstand legal challenge and legislative opposition.

The obvious costs of peer review are the direct costs of the peer review activity. According to agency estimates, these figures are approximately (1) \$5,000 for several individual letter reviews, (2) \$50,000 for a panel review involving 10 reviewers and a public meeting, and (3) \$1,000,000 or more for an in-depth review by a formal committee of the National Academy of Sciences. In addition, delay in government decision-making that can result from peer review. While individual letter reviews can be accomplished in two to ten weeks, a panel review involving a public meeting may consume three to nine months. A formal NAS Committee may require two years or more (NAS has developed new committee methods that permit prompter, lower cost reports). Certainly, even a lengthy peer review would not necessarily delay an agency action if the review is conducted on a parallel track with other work of the agency on that action. Indeed, it is our hope that the peer review planning mechanism described in Section V of the revised Bulletin will improve the coordination and timing for producing scientific information products and accordingly will minimize unwarranted delay. If a policy or regulation is delayed and the peer review does not lead to changes in the policy or regulation, then the benefits (and costs) of that policy or regulation could be delayed (unless an interim policy is enacted).

For example, a regulatory proposal with a 30-year time horizon that is expected to reap \$2 billion per year in benefits at a cost of only \$1 billion per year may face a 30 percent chance of judicial or legislative reversal. Even if it is assumed that this proposal would be delayed to consider the results of a two year NAS study that costs \$1 million and does not lead to changes in the proposal, the public will lose \$1 billion per year for two years compared to acting immediately (ignoring the relatively small monetary cost of the NAS study). Even under these circumstances, the two year NAS study may be worthwhile. The NAS study may reduce the probability that the policy is reversed or may lead to creative policy innovations that increase benefits and/or reduce costs. Table 1 presents study outcomes that make the two-year NAS

¹² Mark R. Powell, *Science at EPA: Information in the Regulatory Process*, Resources for the Future, Washington, D.C., 1999: 148, 176; Sheila Jasanoff, *The Fifth Branch: Science Advisors as Policy Makers*, Harvard University Press, Boston, 1990: 242.

worthwhile, even if immediate adoption of the policy is expected to have net benefits of \$1 billion per year for 30 years. This example is hypothetical, but agencies can use the analytic framework provide in Table 1 when considering real-world dilemmas involving potentially costly and time-consuming reviews.

Table 1: Benefit – Cost Analysis of NAS Peer Review for a Hypothetical Regulation: Study outcomes that would make a two year delay worthwhile*		
	3 Percent Discount Rate	7 Percent Discount Rate
If the NAS study increased the probability of avoiding reversal of the rule by this percent, the NAS study would be worth the two year delay.	4.3%	10.1%
If the NAS study increased net benefits of the rule by this amount per year, the NAS study would be worth the two year delay.	\$60.9 million	\$144.9 million
*This analysis assumes that annual net benefits are realized at the end of the year, and that the study itself did not have any direct costs but would delay decision-making for two years. If the \$1 million costs were added to the costs of delay, the probabilities and net benefits presented here would increase slightly.		

ESTIMATED COST OF THE BULLETIN

Several commenters requested we provide an estimate of the cost associated with the proposed Bulletin. We assessed the annual burden imposed by the revised Bulletin by estimating: (1) the number of disseminations that might be affected and (2) the extent of the burden per document, including the ancillary burden of peer review planning in Section V of the Bulletin.

First, based on the number of rules that OIRA reviews annually and agency definitions of “influential” under their Information Quality Guidelines, we estimate that there will be around 125 influential scientific documents. In addition, we conservatively assume for the purposes of this discussion that there could be ten times as many influential scientific documents unrelated to rulemaking (e.g., scientific guidance documents) that might be covered. It is likely, however, that some of these documents will be eliminated from coverage by the Bulletin under the various

exemptions or because they have already been adequately peer reviewed. We estimate that a subset of about one or two dozen of these influential scientific disseminations might be categorized as “highly influential scientific assessments” in a given year.

Second, assuming for the sake of this analysis that none of these documents already receive peer review, the cost per document would need to include: (1) recruitment of qualified reviewers; (2) preparation of these peer reviews, including peer review planning as per Section V of the revised Bulletin; and (3) documentation and disclosure of these peer reviews and, where appropriate, inclusion of these reviews in the administrative record. For the many documents that may be reviewed through high-quality individual letter reviews, the agency-estimated cost is around \$5,000 per document. For the “highly influential scientific assessments,” an average peer review cost of \$50,000 per document is estimated. These costs are likely large overestimates of the incremental costs of the Bulletin because many agencies already engage in peer review practices.