



EXECUTIVE OFFICE OF THE PRESIDENT  
OFFICE OF MANAGEMENT AND BUDGET  
WASHINGTON, D.C. 20503

FOR IMMEDIATE RELEASE  
August 29, 2003

2003-34

**OMB PROPOSES DRAFT PEER REVIEW STANDARDS FOR REGULATORY SCIENCE**

Washington D.C.—The Office of Management and Budget's (OMB) Office of Information and Regulatory Affairs (OIRA) proposed today a standardized process by which all significant regulatory-science documents will be subjected to peer review by qualified specialists in appropriate technical disciplines. Although some federal agencies already practice peer review, there are no minimum, government-wide standards for peer review.

"Peer review is an effective way to further engage the scientific community in the regulatory process. A more uniform peer review policy promises to make regulatory science more competent and credible, thereby advancing the Administration's "smart-regulation" agenda. The goal is fewer lawsuits and a more consistent regulatory environment, which is good for consumers and businesses." said Dr. John D. Graham, OIRA Administrator.

As described in the proposed Bulletin, each federal agency will report annually to OIRA on the significant regulatory science documents the agency anticipates issuing in the coming year. The roster of studies, including scientific, engineering and economic analyses, will include a short statement of the agency's peer review plan for each study. OIRA, in collaboration with the Office of Science and Technology Policy, will consult with agencies on the adequacy of these plans.

For the most significant regulatory information, the draft Bulletin:

- establishes uniform government-wide standards for the peer review,
- focuses on the role of public participation in peer review activities, the content of peer review reports, and the agency's responsibilities to respond to the comments of peer reviewers,
- and requires disclosure of a peer review panel.

In order to conserve scarce agency resources, the proposed Bulletin authorizes agencies to tailor the intensity of the peer review to the importance of the document. If information has already been subject to adequate peer review (e.g., by a respected scientific journal), the Bulletin permits agencies to use that peer review to satisfy the requirements of the Bulletin.

The OIRA proposal comes in the form of a draft "Bulletin" that was released today. The Bulletin will be modified, as appropriate, based on public comment and interagency review. OIRA currently intends that the final Bulletin will take effect next February.

###

## **OFFICE OF MANAGEMENT AND BUDGET**

### **Peer Review and Information Quality**

**AGENCY:** Office of Management and Budget, Executive Office of the President

**ACTION:** Proposed Bulletin under Executive Order 12866 and supplemental information quality guidelines

**SUMMARY:** As part of an ongoing effort to improve the quality, objectivity, utility, and integrity of information disseminated by the federal government to the public, the Office of Management and Budget (OMB), in coordination with the Office of Science and Technology Policy (OSTP), proposes to issue new guidance to realize the benefits of meaningful peer review of the most important science disseminated by the federal government regarding regulatory topics.

**AUTHORITY:** Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554; H.R. 5658); 44 U.S.C. §§ 3504(d)(1), 3506(a)(1)(B); Executive Order No. 12866, as amended.

**DATES:** Interested parties should submit comments to the Office of Information and Regulatory Affairs (OIRA), Office of Management and Budget, at the address shown below on or before October 28, 2003.

**ADDRESSES:** Due to potential delays in OMB's receipt and processing of mail, respondents are strongly encouraged to submit comments electronically to ensure timely receipt. We cannot guarantee that comments mailed will be received before the comment closing date. Electronic comments may be submitted to: [OMB\\_peer\\_review@omb.eop.gov](mailto:OMB_peer_review@omb.eop.gov). Please put the full body of your comments in the text of the electronic message and as an attachment. Please include your name, title, organization, postal address, telephone number, and e-mail address in the text of the message. Comments may also be submitted via facsimile to (202) 395-7245. Comments may be mailed to 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.

**FOR FURTHER INFORMATION CONTACT:** 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 (tel. (202) 395-3093).

### **SUPPLEMENTARY INFORMATION:**

A "peer review," as used in this document for scientific and technical information relevant to regulatory policies, is a scientifically rigorous review and critique of a study's methods, results, and findings by others in the field with requisite training and expertise.

Independent, objective peer review has long been regarded as a critical element in ensuring the reliability of scientific analyses. For decades, the American academic and scientific communities have withheld acknowledgement of scientific studies that have not been subject to rigorous independent peer review. Peer review “has been an essential part of the American science scene and one of the reasons why American science has done so well.” Columbia University Provost Jonathon R. Cole (quoted in Abate, Tom, “What’s the Verdict on Peer Review?” 21st Century, volume 1 (No. 1), Spring 1995, Columbia University); *see also* GAO Report, Peer Review Practices at Federal Science Agencies Vary, at 1 (March 1999) (“To help ensure the quality and integrity of the research, U.S. science has traditionally relied on independent reviews by peers.”).

Independent peer review is especially important for information that is relevant to regulatory policies. Agencies often develop or fund the science that underlies their regulations, and then oversee the peer review of those studies. Unless the peer review is conducted with genuine independence and objectivity, this can create at least the appearance of a conflict-of-interest. For example, it might be thought that scientists employed or funded by an agency could feel pressured to support what they perceive to be the agency’s regulatory position, first in developing the science, and then in peer reviewing it. Scientists with a financial interest in the subject matter of a study (*e.g.*, ties to a regulated business) face a similar issue. Given that genuinely independent and objective peer review can provide a vital second opinion on the science that underlies federal regulation, the peer review of such information should be carried out under proper and clearly-articulated procedures.

Scientists and government officials have recognized the importance of peer review in regulatory processes:

- **Joint Presidential/Congressional Commission on Risk Assessment and Risk Management:** “Peer review of economic and social science information should have as high a priority as peer review of health, ecological, and engineering information.” Risk Assessment and Risk Management in Regulatory Decision-Making, vol. 2, at 103 (1997).
- **The National Academies’ National Research Council:** “[B]enefit-cost analysis should be subject to systematic, consistent, formal peer review.” Valuing Health Risks, Costs, and Benefits for Environmental Decision Making, at 207 (1990).
- **Congress’ General Accounting Office:** “Peer review is critical for improving the quality of scientific and technical products . . . .” GAO Testimony Before the House Subcommittee on Energy and Environment, Committee on Science, at 8 (Mar. 11, 1997).
- **Sally Katzen, Former Administrator of OIRA:** Scientific inferences “should pass muster under peer review by those in the same discipline, who should have an opportunity for such review to ensure that the

underlying work was done competently and that any assumptions made are reasonable.” Testimony Before the Environment, Energy, and Natural Resources Subcommittee of the House Committee on Government Operations (Feb. 1, 1994).

In addition, many bipartisan legislative proposals have supported independent, external peer review. *See, e.g.*, S. 343, the “Comprehensive Regulatory Reform Act of 1995;” S. 1001, the “Regulatory Procedures Reform Act of 1995;” S. 291, the “Regulatory Reform Act of 1995;” H.R. 1022, the “Risk Assessment and Cost-Benefit Act of 1995.” In 1999, for instance, a bipartisan coalition (including Senators Frist and Daschle, among many others) proposed to require agencies to conduct genuinely independent and transparent peer reviews of their most important risk assessments and cost-benefit analyses. *See* S. 746, the “Regulatory Improvement Act of 1999.”<sup>1</sup>

Existing agency peer review mechanisms have not always been sufficient to ensure the reliability of regulatory information disseminated or relied upon by federal agencies. While most agencies have policies that require or encourage peer review, they do not always conduct peer review according to their own policies – even for major rulemakings. Indeed, an agency Inspector General recently found that although one agency had issued extensive agency peer review policies and mandates, “[t]he critical science supporting the [agency’s] rules was *often not independently peer reviewed*. Consequently, the quality of some science remains unknown.” EPA OIG, Science to Support Rulemaking, at ii (Nov. 15, 2002) (emphasis supplied).

Even when agencies do conduct timely peer reviews, such reviews are sometimes undertaken by people who are not independent of the agencies, or are not perceived to be independent. Simply put, the agency proposing or supporting a regulation or study may not always be the best entity to commission or supervise its own peer review. Nonetheless, some agencies sometimes use their own employees to do peer reviews – a practice forbidden by other agencies’ peer review manuals. *See, e.g.*, Agency for Toxic Substances & Disease Registry Peer Review Policy (Mar. 1, 1996) (peer review is “by outside (not ATSDR) expert scientists”); DOJ, Office of Juvenile Justice & Delinquency Prevention, Peer Review Guideline at 1 (“Peer review is . . . by experts from outside the Department”). As the National Academies’ National Research Council has explained:

External experts often can be more open, frank, and challenging to the status quo than internal reviewers, who may feel constrained by organizational concerns. Evaluation by external reviewers thus can enhance the credibility of the peer review process by avoiding both the reality and the appearance of conflict of interest.

Peer Review in Environmental Technology Development Programs: The Department of Energy’s Office of Science and Technology 3 (1998) (“NRC Report”).

---

<sup>1</sup> This legislative proposal was sponsored by a bipartisan coalition of 21 Senators, including Senators Levin, Thompson, Daschle, Frist, Moynihan, Voinovich, Stevens, Rockefeller, Abraham, Breaux, Roth, Robb, Cochran, Lincoln, and Enzi.

The American Geophysical Union has likewise recognized that “real or perceived conflicts of interest” include the review of papers “from those in the same institution.” AGU, Guidelines to Publication of Geophysical Research (Oct. 2000). Congress did the same in the Superfund legislation by providing that reviewers should not have “institutional ties with any person involved in the conduct of the study or research under review.” 42 U.S.C. § 9604(i)(13).

When an agency does initiate a program to select outside peer reviewers for regulatory science, it sometimes selects the same reviewers for all or nearly all of its peer reviews on a particular topic. While this may be appropriate in limited circumstances, more often it could lead an observer to conclude that the agency continually selected the peer reviewers because of its comfort with them. This hardly satisfies the purposes and principles underlying independent peer review. Thus, the National Academies’ National Research Council has stressed that even “standing panels should have rotating membership terms to ensure that fresh perspectives are regularly replenished.” NRC, Scientific Research in Education 138.

It is also important to understand the relationship of the peer reviewers with the agency, including their funding history. A peer reviewer who is financially dependent on the agency, or at least hopes to profit financially from other dealings with the agency, may not always be completely independent, or appear truly independent. One agency’s Inspector General has encouraged the agency to do a better job of “consistently inquir[ing] whether peer review candidates have any financial relationship with [the agency].” EPA OIG Report No. 1999-P-217, at 10 (1999). Medical journals have similarly recognized the possibility that the receipt of significant funding from an interested entity can lead to bias, or the perception of bias, on the part of a reviewer. *See* “Financial Associations of Authors,” *New England Journal of Medicine*, vol. 346, 1901-02 (2002); Philip Campbell, “Declaration of Financial Interests,” *Nature*, vol. 412, 751 (2001). But while some federal agencies are becoming more sensitive to peer reviewers’ financial ties to *private* interests, most have not been as focused on reviewers’ ties to the agency itself. *See, e.g.*, Food & Drug Administration Guidance on Conflict of Interest for Advisory Committee Members, Consultants & Experts (Feb. 2000); National Institutes of Health Center for Scientific Review, Review Procedures for Scientific Review Group Meetings (Oct. 24, 2002).

In addition to selecting independent and qualified peer reviewers for regulatory science, it is also essential to grant the peer reviewers access to sufficient information and to provide them with an appropriately broad mandate. In the past, some agencies have sought peer review of only narrow questions regarding a particular study or issue. While the scope of peer reviewers’ responsibilities will necessarily vary by context, peer reviewers must generally be able to render a meaningful review of the work as a whole. As one agency’s peer review handbook explains, a good charge to the peer reviewers is ordinarily one that both “focuses the review by presenting specific questions and concerns” the agency is aware of, and also “invites general comments on the entire work

product” so as to ensure that the peer review is not hemmed in by inappropriately narrow questions. EPA Science Policy Council, Peer Review Handbook, § 3.2.1 (2d ed. 2000).

Even when an agency solicits a comprehensive and independent peer review of regulatory science, the results are not always available for public scrutiny or comment. While a non-transparent peer review may be better than no peer review at all, public scrutiny of at least a summary of the peer reviewers’ analyses and conclusions helps to ensure that the peer review process is meaningful and that the agency has fairly considered the peer reviewers’ conclusions. Simply put, openness enhances the credibility of the peer review of regulatory science.

For these reasons, the Fish and Wildlife Service and the National Oceanic and Atmospheric Administration have required that peer reviewers’ reports and opinions be included in the administrative record for the regulatory action at issue. *See* Endangered & Threatened Wildlife and Plants: Notice of Interagency Cooperative Policy for Peer Review in Endangered Species Act Activities, 59 Fed. Reg. 34,270 (July 1, 1994). The Agency for Toxic Substances and Disease Registry further requires that final research reports “consider all peer review comments,” and that the “reasons for not adopting any peer reviewer’s comment should be documented.” Agency for Toxic Substances & Disease Registry Peer Review Policy at 5.

While the peer review policies described above promote independent and transparent peer review, experience has shown that they are not always followed by all of the federal agencies, and that actual practice has not always lived up to the ideals underlying the various agencies’ manuals. In the National Science and Technology Policy, Organization, and Priorities Act of 1976 (Public Law 94-282), Congress called on OSTP to serve as a source of scientific and technological analysis and judgment for the President with respect to major policies, plans, and programs of the Federal Government. Pursuant to the 1976 Act, OSTP has evaluated the scale, quality, and effectiveness of the federal effort in science and technology, and has led interagency efforts to develop and to implement sound science and technology policies.

The President and the Congress have also granted OMB the authority and responsibility to address agency peer review practices. Executive Order 12866, issued in 1993 by President Clinton, specifies in § 1(b)(7) that “[e]ach agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, or other information concerning the need for, and consequences of, the intended regulation.” The Executive Order further requires OMB to provide guidance to the agencies regarding regulatory planning. *See id.* § 2(b).

Similarly, the Paperwork Reduction Act requires the Director of OMB to “develop and oversee the implementation of policies, principles, standards, and guidelines to . . . apply to Federal agency dissemination of public information,” and specifies that agencies are “responsible for . . . complying with the . . . policies established by the Director.” 44 U.S.C. §§ 3504(d)(1), 3506(a)(1)(B). In the Information Quality Act, Congress further specified that OMB’s guidelines should “provide policy

and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies.” P.L. 106-554, § 515(a).

### **Proposed Guidance**

OMB’s current information quality guidance encourages but does not require peer reviews, and identifies general criteria that agencies should consider when they conduct such reviews. *See* Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8,452, 8,454-55, 8,459-60 (Feb. 22, 2002). To best serve the President’s policy of improving our federal regulatory system and the quality and integrity of information disseminated by the federal agencies, OMB, in coordination with OSTP, now proposes to ensure that agencies conduct peer reviews of the most important scientific and technical information relevant to regulatory policies that they disseminate to the public, and that the peer reviews are reliable, independent, and transparent. This notice seeks comment on the following proposed guidance, which would take the form of an OMB Bulletin, would supplement (but not replace) OMB’s information quality guidelines pursuant to the Information Quality Act, P.L. 106-554, § 515(b), and would also serve as guidance pursuant to the Paperwork Reduction Act, 44 U.S.C. § 3504(d), and Executive Order 12866. OIRA will consult with OSTP in implementing this Bulletin as it relates to the peer review process.

Many agencies already have extensive peer review requirements. This guidance would supplement those requirements for the peer review of “significant regulatory information,” which is scientific or technical information that (i) qualifies as “influential” under OMB’s information quality guidelines and (ii) is relevant to regulatory policies. This category does not include most routine statistical and financial information, such as that distributed by the Census Bureau, the Bureau of Labor Statistics and the Federal Reserve. Nor does it include science that is not directed toward regulatory issues, such as most of the scientific research conducted by the National Institutes of Health and the National Science Foundation. It is also limited to the peer review of studies to be disseminated, as opposed to applications for grants. In order to avoid duplication of effort, we have also exempted information that has already been adequately peer-reviewed from the peer review requirements of this Bulletin. Finally, OMB has excluded some categories of information, such as national security information, and some types of proceedings, such as individual adjudications and permit applications, from the scope of this Bulletin. The Bulletin also recognizes that waivers of these requirements may be required in some circumstances, such as when court-imposed deadlines or other exigencies make full compliance with this Bulletin impractical.

This Bulletin requires peer review of the category of “significant regulatory information” described above. It also articulates specific requirements for the peer review of “significant regulatory information” that the agency intends to disseminate in support of a major regulatory action, that could have 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, or that the Administrator of OIRA determines to be of significant interagency interest or relevant to an Administration policy priority. Such an impact can occur whether or not a federal rulemaking is envisioned or considered likely to occur, in part because information might influence local, state, regional, or international decisions. For this category of especially important information, whose reliability is paramount, agencies must take care to select external peer reviewers who possess the requisite experience and independence from the agency. The agencies must also provide the peer reviewers with sufficient information and an appropriately broad charge. The agency must then publicly respond to the peer reviewers' written report, and make other appropriate disclosures.

In addition to setting forth basic peer review procedures, this guidance also elaborates on the reporting requirements of Executive Order 12866 and the Information Quality Act. Pursuant to these authorities, agencies already provide OMB with information regarding upcoming regulatory initiatives and information quality issues. In doing so, each agency should make sure to identify: studies that will be subject to the peer review requirements of this Bulletin; the agency's plan for conducting the peer review; and correction requests filed by members of the public regarding the quality of information disseminated by the agency. These reporting requirements will permit the public, OMB, and OSTP to monitor agency compliance throughout the peer review process.

Finally, this Bulletin provides that each agency that receives a non-frivolous administrative correction request challenging the agency's compliance with the Information Quality Act must promptly post the request on its Internet website or forward a copy to OIRA and, if requested, consult with OIRA regarding the request. This consulting requirement will assist OMB in discharging its responsibility under the Information Quality Act to monitor the quality of information disseminated to the public. Together with the peer review and reporting requirements discussed above, it should also give the public reasonable assurance that the most important regulatory science disseminated by the federal government comes with indicia of reliability.

### **Additional Requests for Comment**

OMB seeks comments from all interested parties on all aspects of this proposed Bulletin and guidelines. In particular, OMB seeks comment on the scope of this Bulletin. As explained above, this proposal covers significant regulatory information, with some exceptions. It may be that the overall scope of this Bulletin should be reduced or enlarged, or that fewer or more exceptions should be made.

OMB also seeks comment on whether some provisions of this proposal should be strengthened, modified, or removed. While the bipartisan legislative proposal discussed above required all peer reviewers to be independent of the agency, this proposal leaves open the possibility that agency employees could serve on peer review panels in certain circumstances. This proposal also identifies circumstances that raise questions about the independence of peer reviewers (e.g., agency employees and agency-supported research



projects), but it does not flatly preclude the selection of peer reviewers who raise some of those concerns. Members of the public are welcome to comment on whether these provisions strike the appropriate balance between safeguarding the fact and appearance of impartiality, on the one hand, and ensuring that qualified peer reviewers will not be precluded from service based on unnecessarily stringent conflict-of-interest requirements, on the other. OMB is especially concerned about the government's need to recruit the best qualified scientists to serve as peer reviewers.

For this reason, OMB also seeks comment on whether any of the provisions of this proposal would unnecessarily burden participating scientists or discourage qualified scientists from participating in agency peer reviews. Specifically, OMB seeks comment on whether peer reviewers' disclosure requirements should be limited to a specific number of years, perhaps to activities occurring during the previous five or ten years, instead of extending back indefinitely. More generally, OMB seeks suggestions regarding how agencies can encourage peer-review participation by qualified scientists.

In addition, OMB seeks comment on whether agencies should be permitted to select their own peer reviewers for regulatory information. Although some observers may favor a system whereby a centralized body would appoint peer reviewers or supervise the details of the peer review process, OMB is not proposing such a system. Within the broad confines of this guidance, the agencies would retain significant discretion in formulating a peer review plan appropriate to each study. It is, however, arguable that an entity outside of the agency should select the peer reviewers and perhaps even supervise the peer review process. The latter approach might lend the appearance of greater integrity to the peer review process, but could be unduly inefficient and raise other concerns.

Finally, OMB seeks comment from the affected agencies on the expected benefits and burdens of this proposed Bulletin. OMB believes that most agencies usually submit the types of studies covered by this Bulletin to at least some peer review. As a result, while this Bulletin should improve the quality of peer reviews, it may not impose substantial costs and burdens on the agencies that they are not already incurring. OMB seeks comment on this and all other aspects of this proposed Bulletin.

## **PROPOSED OMB BULLETIN AND SUPPLEMENTAL INFORMATION QUALITY GUIDELINES:**

**Section 1. Definitions.** For purposes of this Bulletin and guidance:

“Administrator” means the Administrator of the Office of Information and Regulatory Affairs.

“Agency” has the meaning ascribed to it in the Paperwork Reduction Act, 44 U.S.C. § 3502(1).

“Dissemination” has the meaning ascribed to it in OMB’s Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies, 67 Fed. Reg. 8,452, 8,460 (Feb. 22, 2002) (“OMB’s Information-Quality Guidelines”).

“The Information Quality Act” means Section 515 of the Treasury and General Government Appropriations Act for Fiscal Year 2001 (P.L. 106-554; H.R. 5658).

“Major regulatory action” means the type of significant regulatory action that is defined in Section 1(f)(1) of Executive Order 12866 and is not exempt from the requirements of that Order.

“Regulatory information” means any scientific or technical study that is relevant to regulatory policy. Information is relevant to regulatory policy if it might be used by local, state, regional, federal and/or international regulatory bodies.

“Significant regulatory information” means regulatory information that satisfies the “influential” test in OMB’s Information-Quality Guidelines.

“Study” refers broadly to any research report, data, finding, or other analysis.

## **Section 2. Peer Review of Significant Regulatory Information**

To the extent permitted by law, agencies shall have an appropriate and scientifically-rigorous peer review conducted on all significant regulatory information that the agency intends to disseminate. Agencies need not, however, have peer review conducted on studies that have already been subjected to adequate independent peer review. For purposes of this Bulletin, peer review undertaken by a scientific journal may generally be presumed to be adequate. This presumption is rebuttable based on a persuasive showing in a particular instance. In addition, agencies need not have peer review conducted on significant regulatory information that relates to national defense or foreign affairs, or that is disseminated in the course of an individual agency adjudication or proceeding on a permit application.

During the planning of a peer review for significant regulatory information, the agency should select an appropriate peer review mechanism based on the novelty and complexity of the science to be reviewed, the benefit and cost implications, and any controversy regarding the science. Depending on these factors, appropriate peer review mechanisms for significant regulatory information can range from review by qualified specialists within an agency (if they reside in a separate agency program) to formal review by an independent body of experts outside the agency. The experts may be selected by the agency or an outside group.

## **Section 3. Additional Peer Review Requirements for Especially Significant Regulatory Information**

If significant regulatory information is subject to the peer review requirements of Section 2 of this Bulletin and (i) the agency intends to disseminate the information in support of a major regulatory action, (ii) the dissemination of the information could otherwise have 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, or (iii) the Administrator determines that the information is of significant interagency interest or is relevant to an Administration policy priority, then, to the extent permitted by law, the agency shall have a formal, independent, external peer review conducted on the information. The peer review shall proceed in accordance with the following guidance:

**Selection of Peer Reviewers:** Peer reviewers shall be selected primarily on the basis of necessary scientific and technical expertise. When multiple disciplines are required, the selected reviewers should include as broad a range of expertise as is necessary. When selecting reviewers from the pool of qualified external experts, the agency sponsoring the review shall strive to appoint experts who, in addition to possessing the necessary scientific and technical expertise, are independent of the agency, do not possess real or perceived conflicts of interest, and are capable of approaching the subject matter in an open-minded and unbiased manner. Factors relevant to whether an individual satisfies these criteria include whether the individual: (i) has any financial interests in the matter at issue; (ii) has, in recent years, advocated a position on the *specific* matter at issue; (iii) is currently receiving or seeking substantial funding from the agency through a contract or research grant (either directly or indirectly through another entity, such as a university); or (iv) has conducted multiple peer reviews for the same agency in recent years, or has conducted a peer review for the same agency on the same *specific* matter in recent years. If it is necessary to select a reviewer who is or appears to be biased in order to obtain a panel with appropriate expertise, the agency shall ensure that another reviewer with a contrary bias is appointed to balance the panel.

**Charge to Peer Reviewers:** The agency shall provide to peer reviewers an explicit, written charge statement describing the purpose and scope of the review. The charge shall be appropriately broad and specific to facilitate a probing, meaningful critique of the agency's work product. Peer reviewers shall be asked to review scientific and technical matters, leaving policy determinations for the agency. This must be clearly stated and adhered to during the peer review process so the review is based solely on the science being evaluated. In addition, the agency shall be careful not to divulge internal deliberative information to the peer reviewers. The charge should generally frame specific questions about information quality, assumptions, hypotheses, methods, analytic results, and conclusions in the agency's work product. It should ask reviewers to apply the standards of OMB's Information-Quality Guidelines and the agency's own information quality guidelines. Where reviewers are expected to identify scientific uncertainties, they should generally be asked to suggest ways to reduce or eliminate those uncertainties.

**Information Access:** The agency shall provide peer reviewers sufficient information to enable them to understand the data, methods, analytic results, and conclusions of the material to be peer reviewed, with due regard for the agency's interest in protecting its deliberative processes. Reviewers shall be informed of the reproducibility and other quality guidelines issued by OMB and federal agencies under the Information Quality Act. If the document is a formal regulatory analysis, reviewers should be briefed on the content of OMB's guidelines for regulatory analysis. If aspects of the agency's work are likely to be controversial, reviewers should be provided relevant background information on those potential sources of controversy.

**Opportunity for Public Comment:** The agency shall provide an opportunity for other interested agencies and persons to submit comments. The agency shall ensure that such comments are provided to the peer reviewers with ample time for consideration before the peer reviewers conclude their review and prepare their report.

**Peer Review Reports:** The agency shall direct peer reviewers of the regulatory information—individually or often as a group—to issue a final report detailing the nature of their review and their findings and conclusions. The peer review report shall also disclose the names, organizational affiliations, and qualifications of all peer reviewers, as well as any current or previous involvement by a peer reviewer with the agency or issue under peer review consideration. If there is a group report, any partial or complete dissenting statements should be included with the group's final report. The agency shall also provide a written response to the peer review report(s) explaining: the agency's agreement or disagreement with the report(s), including any recommendations expressed therein; the basis for that agreement or disagreement; any actions the agency has undertaken or proposed to undertake in response to the report(s); and (if applicable) the reasons the agency believes those actions satisfy any concerns or recommendations expressed by the report(s). The agency shall disseminate the final peer review report(s) and the agency's written statement of response in the same manner that it disseminates the work product that was reviewed. All of these written materials should be included in the administrative record for any related rulemakings.

**Consultation with OIRA and OSTP:** Agencies shall consult with OIRA and OSTP concerning the sufficiency of their planned peer review policies. Upon request, an agency should discuss with OIRA how the agency plans to review a specific document covered by the Bulletin and whether such a plan is sufficient. This consultation is understood to serve as one of the pre-dissemination quality procedures envisioned by the Information Quality Act.

**Certification in Administrative Record:** If an agency relies on significant regulatory information subject to the requirements of this section in support of a major regulatory action, it shall include in the administrative record for that action a certification explaining how the agency has complied with the requirements of

this Bulletin and the Information Quality Act with respect to the significant regulatory information at issue.

#### **Section 4. Peer Review Procedures**

##### **a. Federal Advisory Committee Act**

When considering selection of an outside panel of peer reviewers for regulatory information subject to the requirements of this Bulletin, an agency should assess the treatment of such a panel under the Federal Advisory Committee Act, and may retain a firm to oversee the peer review process with instructions to comply with principles consistent with those set forth in this Bulletin. *See Byrd v. EPA*, 174 F.3d 239 (D.C. Cir. 1999) (holding that peer review panels selected and supervised by outside consultants are not governed by the Federal Advisory Committee Act, 5 U.S.C.S. App. II §§ 1-15). Although such a firm can be engaged to oversee multiple peer review processes for an agency, the agency shall ensure that the firm itself possesses independence (and the appearance of independence) from the agency.

##### **b. Agency Guidelines**

Based on this supplement to OMB's information quality guidelines, each agency shall supplement or amend its own information quality guidelines to incorporate the requirements of Sections 2 and 3 herein on a prospective basis, except that an agency need not amend its guidelines if there is no reasonable likelihood that the agency will disseminate information covered by the requirements of Sections 2 and/or 3 of this Bulletin. In addition to incorporating these requirements, agencies should have specific guidelines as to what entanglements with agencies or affected businesses are so significant as to preclude an individual's participation as a peer reviewer, irrespective of other factors. Agency guidance should also address the following additional aspects of the peer review process, as well as any other matters they wish to address: the protection of confidential business information; any other needs for confidentiality in the peer review process (including any privacy interests of peer reviewers); and any types of information regarding the peer reviewers that should be publicly disclosed in addition to the information identified in Section 3 of this Bulletin (potentially including prior service as an expert witness, sources of personal or institutional funding, and/or other matters that might suggest a possible conflict of interest or appearance of a conflict of interest).

##### **c. Waiver**

The Administrator may waive some or all of the peer review requirements of Sections 2 and/or 3 of this Bulletin if an agency makes a compelling case that waiver is necessitated for specific information by an emergency, imminent health hazard, homeland security threat, or some other compelling rationale. As appropriate, the Administrator shall consult with the Director of OSTP before deciding whether to grant a waiver.

## **Section 5. Interagency Work Group on Peer Review Policies**

The Administrator will periodically convene a meeting of an interagency group of peer review specialists and program managers, including the OSTP Associate Director for Science. The group may make recommendations regarding best peer review practices and may recommend other steps to expedite and improve agency processes.

## **Section 6. Reports on Agency Peer Reviews**

Each agency shall provide to OIRA at least once each year:

- a summary description of any existing, ongoing, or contemplated scientific or technical studies that might (in whole or in part) constitute or support significant regulatory information the agency intends to disseminate within the next year; and
- the agency's plan for conducting a peer review of such studies under the requirements of this Bulletin, including the identification of an agency contact to whom inquiries may be directed to learn the specifics of the plan.

In order to minimize the paperwork involved, agencies should include this information in one of the periodic reports they submit to OMB under Executive Order 12866 or the Information Quality Act.

**Section 7. Correction Requests under the Information Quality Act.** The Information Quality Act requires OMB to issue guidance concerning administrative mechanisms by which members of the public may seek to obtain correction of information maintained and disseminated by an agency. *See* P.L. 106-554, § 515(b)(2)(B). OMB must also monitor the agencies' handling of such correction requests. *See id.*(C).

In order to improve OMB's ability to assess the quality of information disseminated to the public and the adequacy of agencies' request-handling processes, an agency shall, within seven days of receipt, provide OIRA with a copy of each non-frivolous information quality correction request. If an agency posts such a request on its Internet website within seven days of receipt, it need not provide a copy to OIRA.

Upon request by OIRA, each agency shall provide a copy of its draft response to any such information quality correction request or appeal at least seven days prior to its intended issuance, and consult with OIRA to ensure the response is consistent with the Information Quality Act, OMB's government-wide Information Quality Guidelines, and the agency's own information quality guidelines. The agency shall not issue its response until OIRA has concluded consultation with the agency. OIRA may consult with OSTP as appropriate if a request alleges deficiencies in the peer review process.

## **Section 8. Interagency Comment**

Interagency comment can assist in identifying questions or weaknesses in scientific and technical analyses. As part of its consideration of peer reviews, information quality correction requests, or major regulatory actions, OIRA may exercise its authority to request comment from other agencies. OIRA may make such comment public, or direct that it be included in the Administrative Record for any related rulemakings. Interagency comment may be conducted in addition to peer review, or may comprise the peer review required by Sections 2 and/or 3 of this Bulletin if it is conducted in accordance with the requirements of this Bulletin.

## **Section 9. Effective Date and Existing Law**

The requirements of this Bulletin apply to information disseminated on or after January 1, 2004. The requirements are not intended to displace other peer review mechanisms already created by law. Any such mechanisms should be employed in a manner as consistent as possible with the practices and procedures laid out herein. Agencies may consult with OIRA regarding the relationship of this Bulletin with preexisting law.