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

THE DIRECTOR

M-05-03

December 16, 2004

MEMORANDUM FOR HEADS OF DEPARTMENTS AND AGENCIES

FROM: Joshua B. Bolten
Director

SUBJECT: Issuance of OMB's "Final Information Quality Bulletin for Peer Review"

OMB has today issued a bulletin applicable to all departments and agencies entitled "Final Information Quality Bulletin for Peer Review." This Bulletin establishes government-wide guidance aimed at enhancing the practice of peer review of government science documents. Peer review is an important procedure used by the scientific community to ensure that the quality of published information. Peer review can increase the quality and credibility of the scientific information generated across the federal government. This Bulletin is one aspect of a larger OMB effort to improve the quality of the scientific information upon which policy decisions are based.

The bulletin has benefited from extensive public and agency comments received on two prior draft versions, which were released by OMB in September 15, 2003 and April 28, 2004. The bulletin includes guidance to federal agencies on what information is subject to peer review, the selection of appropriate peer reviewers, opportunities for public participation, and related issues. The bulletin also defines a peer review planning process that will permit the public and scientific societies to contribute to agency dialogue about which scientific reports merit especially rigorous peer review.

If your staff has questions about this guidance, please contact Margo Schwab at (202) 395-5647 or mschwab@omb.eop.gov.

Attachments

OFFICE OF MANAGEMENT AND BUDGET

Final Information Quality Bulletin for Peer Review

INTRODUCTION

This Bulletin establishes that important scientific information shall be peer reviewed by qualified specialists before it is disseminated by the federal government. We published a proposed Bulletin on September 15, 2003. Based on public comments, we published a revised proposal for additional comment on April 28, 2004. We are now finalizing the April version, with minor revisions responsive to the public's comments.

The purpose of the Bulletin is to enhance the quality and credibility of the government's scientific information. We recognize that different types of peer review are appropriate for different types of information. Under this Bulletin, agencies are granted broad discretion to weigh the benefits and costs of using a particular peer review mechanism for a specific information product. The selection of an appropriate peer review mechanism for scientific information is left to the agency's discretion. Various types of information are exempted from the requirements of this Bulletin, including time-sensitive health and safety determinations, in order to ensure that peer review does not unduly delay the release of urgent findings.

This Bulletin also applies stricter minimum requirements for the peer review of highly influential scientific assessments, which are a subset of influential scientific information. A scientific assessment is an evaluation of a body of scientific or technical knowledge that typically synthesizes multiple factual inputs, data, models, assumptions, and/or applies best professional judgment to bridge uncertainties in the available information. To ensure that the Bulletin is not too costly or rigid, these requirements for more intensive peer review apply only to the more important scientific assessments disseminated by the federal government.

Even for these highly influential scientific assessments, the Bulletin leaves significant discretion to the agency formulating the peer review plan. In general, an agency conducting a peer review of a highly influential scientific assessment must ensure that the peer review process is transparent by making available to the public the written charge to the peer reviewers, the peer reviewers' names, the peer reviewers' report(s), and the agency's response to the peer reviewers' report(s). The agency selecting peer reviewers must ensure that the reviewers possess the necessary expertise. In addition, the agency must address reviewers' potential conflicts of interest (including those stemming from ties to regulated businesses and other stakeholders) and independence from the agency. This Bulletin requires agencies to adopt or adapt the committee selection policies employed by the National Academy of Sciences (NAS)[1] when selecting peer reviewers who are not government employees. Those that are government employees are subject to federal ethics requirements. The use of a transparent process, coupled with the selection of qualified and independent peer reviewers, should improve the quality of government science while promoting public confidence in the integrity of the government's scientific products.

PEER REVIEW

Peer review is one of the important procedures used to ensure that the quality of published information meets the standards of the scientific and technical community. It is a form of deliberation involving an exchange of judgments about the appropriateness of methods and the strength of the author's inferences.[2] Peer review involves the review of a draft product for quality by specialists in the field who were not involved in producing the draft.

The peer reviewer's report is an evaluation or critique that is used by the authors of the draft to improve the product. Peer review typically evaluates the clarity of hypotheses,

[1] 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.

the validity of the research design, the quality of data collection procedures, the robustness of the methods employed, the appropriateness of the methods for the hypotheses being tested, the extent to which the conclusions follow from the analysis, and the strengths and limitations of the overall product.

Peer review has diverse purposes. Editors of scientific journals use reviewer comments to help determine whether a draft scientific article is of sufficient quality, importance, and interest to a field of study to justify publication. Research funding organizations often use peer review to evaluate research proposals. In addition, some federal agencies make use of peer review to obtain evaluations of draft information that contains important scientific determinations.

Peer review should not be confused with public comment and other stakeholder processes. The selection of participants in a peer review is based on expertise, with due consideration of independence and conflict of interest. Furthermore, notice-and-comment procedures for agency rulemaking do not provide an adequate substitute for peer review, as some experts -- especially those most knowledgeable in a field -- may not file public comments with federal agencies.

The critique provided by a peer review often suggests ways to clarify assumptions, findings, and conclusions. For instance, peer reviews can filter out biases and identify oversights, omissions, and inconsistencies.[3] Peer review also may encourage authors to more fully acknowledge limitations and uncertainties. In some cases, reviewers might recommend major changes to the draft, such as refinement of hypotheses, reconsideration of research design, modifications of data collection or analysis methods, or alternative conclusions. However, peer review does not always lead to specific modifications in the draft product. In some cases, a draft is in excellent shape prior to being submitted for

[2] Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 75.
[3] William W. Lowrance, Modern Science and Human Values, Oxford University Press, New York, NY 1985: 85.

review. In others, the authors do not concur with changes suggested by one or more reviewers.

Peer review may take a variety of forms, depending upon the nature and importance of the product. For example, the reviewers may represent one scientific discipline or a variety of disciplines; the number of reviewers may range from a few to more than a dozen; the names of each reviewer may be disclosed publicly or may remain anonymous (e.g., to encourage candor); the reviewers may be blinded to the authors of the report or the names of the authors may be disclosed to the reviewers; the reviewers may prepare individual reports or a panel of reviewers may be constituted to produce a collaborative report; panels may do their work electronically or they may meet together in person to discuss and prepare their evaluations; and reviewers may be compensated for their work or they may donate their time as a contribution to science or public service.

For large, complex reports, different reviewers may be assigned to different chapters or topics. Such reports may be reviewed in stages, sometimes with confidential reviews that precede a public process of panel review. As part of government-sponsored peer review, there may be opportunity for written and/or oral public comments on the draft product.

The results of peer review are often only one of the criteria used to make decisions about journal publication, grant funding, and information dissemination. For instance, the editors of scientific journals (rather than the peer reviewers) make final decisions about a manuscript's appropriateness for publication based on a variety of considerations. In research-funding decisions, the reports of peer reviewers often play an important role, but the final decisions about funding are often made by accountable officials based on a variety of considerations. Similarly, when a government agency sponsors peer review of its own draft documents, the peer review reports are an important factor in information dissemination decisions but rarely are the sole consideration. Agencies are not expected to cede their discretion with regard to dissemination or use of information to peer reviewers; accountable agency officials must make the final decisions.

THE NEED FOR STRONGER PEER REVIEW POLICIES

There are a multiplicity of science advisory procedures used at federal agencies and across the wide variety of scientific products prepared by agencies.[4] In response to congressional inquiry, the U.S. General Accounting Office (now the Government Accountability Office) documented the variability in both the definition and implementation of peer review across agencies.[5] The Carnegie Commission on Science, Technology and Government[6] has highlighted the importance of "internal" scientific advice (within the agency) and "external" advice (through scientific advisory boards and other mechanisms).

A wide variety of authorities have argued that peer review practices at federal agencies need to be strengthened.[7] Some arguments focus on specific types of scientific products (e.g., assessments of health, safety and environmental hazards).[8] The Congressional/Presidential Commission on Risk Assessment and Risk Management suggests that "peer review of economic and social science information should have as high a priority as peer review of health, ecological, and engineering information."[9]

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[4] Sheila Jasanoff, The Fifth Branch: Science Advisors as Policy Makers, Harvard University Press, Boston, 1990.

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

[6] Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 90.

[7] National Academy of Sciences, Peer Review in the Department of Energy – Office of Science and Technology, Interim Report, National Academy Press, Washington, D.C., 1997; National Academy of Sciences, Peer Review in Environmental Technology Development: The Department of Energy – Office of Science and Technology, National Academy Press, Washington, D.C., 1998; National Academy of Sciences, Strengthening Science at the U.S. Environmental Protection Agency: Research-Management and Peer-Review Practices, National Academy Press, Washington, D.C. 2000; U.S. General Accounting Office, EPA's Science Advisory Board Panels: Improved Policies and Procedures Needed to Ensure Independence and Balance, GAO-01-536, Washington, D.C., 2001; U. S. Environmental Protection Agency, Office of Inspector General, Pilot Study: Science in Support of Rulemaking 2003-P-00003, Washington, D.C., 2002; Carnegie Commission on Science, Technology, and Government, In the National Interest: The Federal Government in the Reform of K-12 Math and Science Education, Carnegie Commission, New York, 1991; U.S. General Accounting Office, Endangered Species Program: Information on How Funds Are Allocated and What Activities are Emphasized, GAO-02-581, Washington, D.C. 2002.

[8] National Research Council, Science and Judgment in Risk Assessment, National Academy Press, Washington, D.C., 1994.

Some agencies have formal peer review policies, while others do not. Even agencies that have such policies do not always follow them prior to the release of important scientific products.

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 processes are appropriate. No formal interagency mechanism existed to foster cross-agency sharing of experiences with peer review practices and policies. Despite the importance of peer review for the credibility of agency scientific products, the public lacked a consistent way to determine when an important scientific information product is being developed by an agency, the type of peer review planned for that product, or whether there would be an opportunity to provide comments and data to the reviewers.

This Bulletin establishes minimum standards for when peer review is required for scientific information and the types of peer review that should be considered by agencies in different circumstances. It also establishes a transparent process for public disclosure of peer review planning, including a web-accessible description of the peer review plan that the agency has developed for each of its forthcoming influential scientific disseminations.

LEGAL AUTHORITY FOR THE BULLETIN

This Bulletin is issued under the Information Quality Act and OMB's general authorities to oversee the quality of agency information, analyses, and regulatory actions. In the Information Quality Act, Congress directed OMB to issue guidelines to "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility and integrity of information" disseminated by Federal agencies. Pub. L. No. 106-554, § 515(a). The Information Quality Act was developed as a supplement to the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., which requires OMB, among

[9] 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.

other things, to "develop and oversee the implementation of policies, principles, standards, and guidelines to . . . apply to Federal agency dissemination of public information." In addition, Executive Order 12866, 58 Fed. Reg. 51,735 (Oct. 4, 1993), establishes that OIRA is "the repository of expertise concerning regulatory issues," and it directs OMB to provide guidance to the agencies on regulatory planning. E.O. 12866, § 2(b). The Order also requires that "[e]ach agency shall base its decisions on the best reasonably obtainable scientific, technical, economic, or other information." E.O. 12866, § 1(b)(7). Finally, OMB has authority in certain circumstances to manage the agencies under the purview of the President's Constitutional authority to supervise the unitary Executive Branch. All of these authorities support this Bulletin.

THE REQUIREMENTS OF THIS BULLETIN

This Bulletin addresses peer review of scientific information disseminations that contain findings or conclusions that represent the official position of one or more agencies of the federal government.

Section I: Definitions

Section I provides definitions that are central to this Bulletin. Several terms are identical to or based on those used in OMB's government-wide information quality guidelines, 67 Fed. Reg. 8452 (Feb. 22, 2002), and the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq.

The term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA).

The term "agency" has the same meaning as in the Paperwork Reduction Act, 44 U.S.C. § 3502(1).

The term “Information Quality Act” means Section 515 of Public Law 106-554 (Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153-154 (2000)).

The term “dissemination” means agency initiated or sponsored distribution of information to the public. Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, the Government Performance and Results Act, or similar laws. This definition also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes. In the context of this Bulletin, the definition of “dissemination” modifies the definition in OMB’s government-wide information quality guidelines to address the need for peer review prior to official dissemination of the information product. Accordingly, under this Bulletin, “dissemination” also excludes information distributed for peer review in compliance with this Bulletin or shared confidentially with scientific colleagues, provided that the distributing agency includes an appropriate and clear disclaimer on the information, as explained more fully below. Finally, the Bulletin does not directly cover information supplied to the government by third parties (e.g., studies by private consultants, companies and private, non-profit organizations, or research institutions such as universities). However, if an agency plans to disseminate information supplied by a third party (e.g., using this information as the basis for an agency's factual determination that a particular behavior causes a disease), the requirements of the Bulletin apply, if the dissemination is "influential".

In cases where a draft report or other information is released by an agency solely for purposes of peer review, a question may arise as to whether the draft report constitutes an official "dissemination" under information-quality guidelines. Section I instructs agencies to make this clear by presenting the following disclaimer in the report:

> "THIS INFORMATION IS DISTRIBUTED SOLELY FOR THE PURPOSE OF PRE-DISSEMINATION PEER REVIEW UNDER APPLICABLE INFORMATION QUALITY GUIDELINES. IT HAS NOT BEEN FORMALLY DISSEMINATED BY [THE AGENCY]. IT DOES NOT REPRESENT AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY."

In cases where the information is highly relevant to specific policy or regulatory deliberations, this disclaimer shall appear on each page of a draft report. Agencies also shall discourage state, local, international and private organizations from using information in draft reports that are undergoing peer review. Draft influential scientific information presented at scientific meetings or shared confidentially with colleagues for scientific input prior to peer review shall include the disclaimer: "THE FINDINGS AND CONCLUSIONS IN THIS REPORT (PRESENTATION) HAVE NOT BEEN FORMALLY DISSEMINATED BY [THE AGENCY] AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY."

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. Accordingly, 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). For influential scientific information that does not have the imprimatur of the federal government, scientists employed by the federal government are required to include in their information product a clear disclaimer that "the findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the funding agency." A similar disclaimer is advised for non-government employees who publish government-funded research.

For the purposes of the peer review Bulletin, the term "scientific information" means factual inputs, data, models, analyses, technical information, or scientific assessments

related to such disciplines as the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks on a web page to information that others disseminate. This definition excludes opinions, where the agency's presentation makes clear that an individual's opinion, rather than a statement of fact or of the agency's findings and conclusions, is being offered.

The term "influential scientific information" means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. In the term "influential scientific information," the term "influential" should be interpreted consistently with OMB's government-wide information quality guidelines and the information quality guidelines of the agency. Information dissemination can have a significant economic impact even if it is not part of a rulemaking. For instance, the economic viability of a technology can be influenced by the government's characterization of its attributes. Alternatively, the federal government's assessment of risk can directly or indirectly influence the response actions of state and local agencies or international bodies.

One type of scientific information is a scientific assessment. For the purposes of this Bulletin, the term "scientific assessment" means 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; health, safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments. Such assessments often draw upon knowledge from multiple disciplines. Typically, the data and models used in 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 this Bulletin).

Section II: Peer Review of Influential Scientific Information

Section II requires each agency to subject "influential" scientific information to peer review prior to dissemination. For dissemination of influential scientific information, Section II provides agencies broad discretion in determining what type of peer review is appropriate and what procedures should be employed to select appropriate reviewers. Agencies are directed to chose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review.

The National Academy of Public Administration suggests that the intensity of peer review should be commensurate with the significance of the information being disseminated and the likely implications for policy decisions.[10] Furthermore, agencies need to consider tradeoffs between depth of peer review and timeliness.[11] More rigorous peer review is necessary for information that is based on novel methods or presents complex challenges for interpretation. Furthermore, the need for rigorous peer review is greater when the information contains precedent-setting methods or models, presents conclusions that are likely to change prevailing practices, or is likely to affect policy decisions that have a significant impact.

This tradeoff can be considered in a benefit-cost framework. The costs of peer review include both the direct costs of the peer review activity and those stemming from potential delay in government and private actions that can result from peer review. The benefits of peer review are equally clear: the insights offered by peer reviewers may lead

[10] National Academy of Public Administration, Setting Priorities, Getting Results: A New Direction for EPA, National Academy Press, Washington, D.C., 1995:23.
[11] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, 1997.

to policy with more benefits and/or fewer costs. In addition to contributing to strong science, peer review, if performed fairly and rigorously, can build consensus among stakeholders and reduce the temptation for courts and legislators to second-guess or overturn agency actions.[12] While it will not always be easy for agencies to quantify the benefits and costs of peer review, agencies are encouraged to approach peer review from a benefit-cost perspective.

Regardless of the peer review mechanism chosen, agencies should strive to ensure that their peer review practices are characterized by both scientific integrity and process integrity. "Scientific integrity," in the context of peer review, refers to such issues as "expertise and balance of the panel members; the identification of the scientific issues and clarity of the charge to the panel; the quality, focus and depth of the discussion of the issues by the panel; the rationale and supportability of the panel's findings; and the accuracy and clarity of the panel report." "Process integrity" includes such issues as "transparency and openness, avoidance of real or perceived conflicts of interest, a workable process for public comment and involvement," and adherence to defined procedures.[13]

When deciding what type of peer review mechanism is appropriate for a specific information product, agencies will need to consider at least the following issues: individual versus panel review; timing; scope of the review; selection of reviewers; disclosure and attribution; public participation; disposition of reviewer comments; and adequacy of prior peer review.

[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.
[13] ILSI Risk Sciences Institute, "Policies and Procedures: Model Peer Review Center of Excellence," 2002: 4. Available at http://rsi.ilsi.org/file/Policies&Procedures.pdf.

Individual versus Panel Review

Letter reviews by several experts generally will be more expeditious than convening a panel of experts. Individual letter reviews are more appropriate when a draft document covers only one discipline or when premature disclosure of a sensitive report to a public panel could cause harm to government or private interests. When time and resources warrant, panels are preferable, as they tend to be more deliberative than individual letter reviews and the reviewers can learn from each other. There are also multi-stage processes in which confidential letter reviews are conducted prior to release of a draft document for public notice and comment, followed by a formal panel review. These more rigorous and expensive processes are particularly valuable for highly complex, multidisciplinary, and more important documents, especially those that are novel or precedent-setting.

Timing of Peer Review

As a general rule, it is most useful to consult with peers early in the process of producing information. For example, in the context of risk assessments, it is valuable to have the choice of input data and the specification of the model reviewed by peers before the agency invests time and resources in implementing the model and interpreting the results. "Early" peer review occurs in time to "focus attention on data inadequacies in time for corrections.

When an information product is a critical component of rule-making, it is important to obtain peer review before the agency announces its regulatory options so that any technical corrections can be made before the agency becomes invested in a specific approach or the positions of interest groups have hardened. If review occurs too late, it is unlikely to contribute to the course of a rulemaking. Furthermore, investing in a more rigorous peer review early in the process “may provide net benefit by reducing the

prospect of challenges to a regulation that later may trigger time consuming and resource-draining litigation."[14]

Scope of the Review

The "charge" contains the instructions to the peer reviewers regarding the objective of the peer review and the specific advice sought. The importance of the information, which shapes the goal of the peer review, influences the charge. For instance, the goal of the review might be to determine the utility of a body of literature for drawing certain conclusions about the feasibility of a technology or the safety of a product. In this context, an agency might ask reviewers to determine the relevance of conclusions drawn in one context for other contexts (e.g., different exposure conditions or patient populations).

The charge to the reviewers should be determined in advance of the selection of the reviewers. In drafting the charge, it is important to remember the strengths and limitations of peer review. Peer review is most powerful when the charge is specific and steers the reviewers to specific technical questions while also directing reviewers to offer a broad evaluation of the overall product.

Uncertainty is inherent in science, and in many cases individual studies do not produce conclusive evidence. Thus, when an agency generates a scientific assessment, it is presenting its scientific judgment about the accumulated evidence rather than scientific fact.[15] Specialists attempt to reach a consensus by weighing the accumulated evidence. Peer reviewers can make an important contribution by distinguishing scientific facts from professional judgments. Furthermore, where appropriate, reviewers should be asked to provide advice on the reasonableness of judgments made from the scientific evidence.

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[14] Fred Anderson, Mary Ann Chirba Martin, E Donald Elliott, Cynthia Farina, Ernest Gellhorn, John D. Graham, C. Boyden Gray, Jeffrey Holmstead, Ronald M. Levin, Lars Noah, Katherine Rhyne, Jonathan Baert Wiener, "Regulatory Improvement Legislation: Risk Assessment, Cost-Benefit Analysis, and Judicial Review," Duke Environmental Law and Policy Forum, Fall 2000, vol. XI (1): 132.

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

However, 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.[16]

The charge should ask that peer reviewers ensure that scientific uncertainties are clearly identified and characterized. Since not all uncertainties have an equal effect on the conclusions drawn, reviewers should be asked to ensure that the potential implications of the uncertainties for the technical conclusions drawn are clear. In addition, peer reviewers might be asked to consider value-of-information analyses that identify whether more research is likely to decrease key uncertainties.[17] Value-of-information analysis was suggested for this purpose in the report of the Presidential/Congressional Commission on Risk Assessment and Risk Management.[18] A description of additional research that would appreciably influence the conclusions of the assessment can help an agency assess and target subsequent efforts.

Selection of Reviewers

Expertise. The most important factor in selecting reviewers is expertise: ensuring that the selected reviewer has the knowledge, experience, and skills necessary to perform the review. Agencies shall ensure that, in cases where the document being reviewed spans a variety of scientific disciplines or areas of technical expertise, reviewers who represent the necessary spectrum of knowledge are chosen. For instance, expertise in applied mathematics and statistics is essential in the review of models, thereby allowing an audit of calculations and claims of significance and robustness based on the numeric data.[19]

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[16] Ibid.
[17] 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.
[18] Presidential/Congressional Commission on Risk Assessment and Risk Management, Risk Commission Report, 1997, Volume 1: 39, Volume 2: 91.
[19] William W. Lowrance, Modern Science and Human Values, Oxford University Press, New York, NY 1985: 86.

For some reviews, evaluation of biological plausibility is as important as statistical modeling. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

Balance. While expertise is the primary consideration, reviewers should also be selected to represent a diversity of scientific perspectives relevant to the subject. On most controversial issues, there exists a range of respected scientific viewpoints regarding interpretation of the available literature. Inviting reviewers with competing views on the science may lead to a sharper, more focused peer review. Indeed, as a final layer of review, some organizations (e.g., the National Academy of Sciences) specifically recruit reviewers with strong opinions to test the scientific strength and balance of their reports. The NAS policy on committee composition and balance[20] highlights important considerations associated with perspective, bias, and objectivity.

Independence. In its narrowest sense, independence in a reviewer means that the reviewer was not involved in producing the draft document to be reviewed. However, for peer review of some documents, a broader view of independence is necessary to assure credibility of the process. Reviewers are generally not employed by the agency or office producing the document. As the National Academy of Sciences has stated, "external experts often can be more open, frank, and challenging to the status quo than internal reviewers, who may feel constrained by organizational concerns."[21] The Carnegie Commission on Science, Technology, and Government notes that "external science advisory boards serve a critically important function in providing regulatory agencies with expert advice on a range of issues."[22] However, the choice of reviewers requires a case-by-case analysis. Reviewers employed by other federal and state agencies may possess unique or indispensable expertise.

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[20] 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.

[21] National Research Council, Peer Review in Environmental Technology Development Programs: The Department of Energy's Office of Science and Technology, National Academy Press, Washington, D.C., 1998: 3.

[22] Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 90.

A related issue is whether government-funded scientists in universities and consulting firms have sufficient independence from the federal agencies that support their work to be appropriate peer reviewers for those agencies.[23] This concern can be mitigated in situations where the scientist initiates the hypothesis to be tested or the method to be developed, which effectively creates a buffer between the scientist and the agency. When an agency awards grants through a competitive process that includes peer review, the agency's potential to influence the scientist's research is limited. As such, when a scientist is awarded a government research grant through an investigator-initiated, peer-reviewed competition, there generally should be no question as to that scientist's ability to offer independent scientific advice to the agency on other projects. This contrasts, for example, to a situation in which a scientist has a consulting or contractual arrangement with the agency or office sponsoring a peer review. Likewise, when the agency and a researcher work together (e.g., through a cooperative agreement) to design or implement a study, there is less independence from the agency. Furthermore, if a scientist has repeatedly served as a reviewer for the same agency, some may question whether that scientist is sufficiently independent from the agency to be employed as a peer reviewer on agency-sponsored projects.

As the foregoing suggests, independence poses a complex set of questions that must be considered by agencies when peer reviewers are selected. In general, agencies shall make an effort to rotate peer review responsibilities across the available pool of qualified reviewers, recognizing that in some cases repeated service by the same reviewer is needed because of essential expertise.

Some agencies have built entire organizations to provide independent scientific advice while other agencies tend to employ ad hoc scientific panels on specific issues. Respect for the independence of reviewers may be enhanced if an agency collects names of potential reviewers (based on considerations of expertise and reputation for objectivity)

[23] Lars Noah, "Scientific 'Republicanism': Expert Peer Review and the Quest for Regulatory Deliberation, Emory Law Journal, Atlanta, Fall 2000:1066.

from the public, including scientific or professional societies. The Department of Energy's use of the American Society of Mechanical Engineers to identify potential peer reviewers from a variety of different scientific societies provides an example of how professional societies can assist in the development of an independent peer review panel.[24]

Conflict of Interest. The National Academy of Sciences defines "conflict of interest" as any financial or other interest that conflicts with the service of an individual on the review panel because it could impair the individual's objectivity or could create an unfair competitive advantage for a person or organization.[25] This standard provides a useful benchmark for agencies to consider in selecting peer reviewers. Agencies shall make a special effort to examine prospective reviewers' potential financial conflicts, including significant investments, consulting arrangements, employer affiliations and grants/contracts. Financial ties of potential reviewers to regulated entities (e.g., businesses), other stakeholders, and regulatory agencies shall be scrutinized when the information being reviewed is likely to be relevant to regulatory policy. The inquiry into potential conflicts goes beyond financial investments and business relationships and includes work as an expert witness, consulting arrangements, honoraria and sources of grants and contracts. To evaluate any real or perceived conflicts of interest with potential reviewers and questions regarding the independence of reviewers, agencies are referred to federal ethics requirements, applicable standards issued by the Office of Government Ethics, and the prevailing practices of the National Academy of Sciences. Specifically, peer reviewers who are federal employees (including special government employees) are subject to federal requirements governing conflicts of interest. See, e.g., 18 U.S.C. § 208; 5 C.F.R. Part 2635 (2004). With respect to reviewers who are not federal employees, agencies shall adopt or adapt the NAS policy for committee selection with respect to

[24] American Society for Mechanical Engineers, Assessment of Technologies Supported by the Office of Science and Technology, Department of Energy: Results of the Peer Review for Fiscal Year 2002, ASME Technical Publishing, Danvers, MA, 2003.

[25] 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.

evaluating conflicts of interest.[26] Both the NAS and the federal government recognize that under certain circumstances some conflict may be unavoidable in order to obtain the necessary expertise. See, e.g., 18 U.S.C. § 208(b)(3); 5 U.S.C. App. § 15 (governing NAS committees). To improve the transparency of the process, when an agency determines that it is necessary to use a reviewer with a real or perceived conflict of interest, the agency should consider publicly disclosing those conflicts. In such situations, the agency shall inform potential reviewers of such disclosure at the time they are recruited.

Disclosure and Attribution: Anonymous versus Identified

Peer reviewers must have a clear understanding of how their comments will be conveyed to the authors of the document and to the public. When peer review of government reports is considered, the case for transparency is stronger, particularly when the report addresses an issue with significant ramifications for the public and private sectors. The public may not have confidence in the peer review process when the names and affiliations of the peer reviewers are unknown. Without access to the comments of reviewers, the public is incapable of determining whether the government has seriously considered the comments of reviewers and made appropriate revisions. Disclosure of the slate of reviewers and the substance of their comments can strengthen public confidence in the peer review process. It is common at many journals and research funding agencies to disclose annually the slate of reviewers. Moreover, the National Academy of Sciences now discloses the names of its peer reviewers, without disclosing the substance of their comments. The science advisory committees to regulatory agencies typically disclose at least a summary of the comments of reviewers as well as their names and affiliations.

For agency-sponsored peer review conducted under Sections II and III, this Bulletin strikes a compromise by requiring disclosure of the identity of the reviewers, but not public attribution of specific comments to specific reviewers. The agency has considerable discretion in the implementation of this compromise (e.g., summarizing the

[26] Ibid.

views of reviewers as a group or disclosing individual reviewer comments without attribution). Whatever approach is employed, the agency must inform reviewers in advance of how it intends to address this issue. Information about a reviewer retrieved from a record filed by the reviewer's name or other identifier may be disclosed only as permitted by the conditions of disclosure enumerated in the Privacy Act, 5 U.S.C. § 552a as amended, and as interpreted in OMB implementing guidance, 40 Fed. Reg. 28,948 (July 9, 1975).

Public Participation

Public comments can be important in shaping expert deliberations. Agencies may decide that peer review should precede an opportunity for public comment to ensure that the public receives the most scientifically strong product (rather than one that may change substantially as a result of peer reviewer suggestions). However, there are situations in which public participation in peer review is an important aspect of obtaining a high-quality product through a credible process. Agencies, however, should avoid open-ended comment periods, which may delay completion of peer reviews and complicate the completion of the final work product.

Public participation can take a variety of forms, including opportunities to provide oral comments before a peer review panel or requests to provide written comments to the peer reviewers. Another option is for agencies to publish a “request for comment” or other notice in which they solicit public comment before a panel of peer reviewers performs its work.

Disposition of Reviewer Comments

A peer review is considered completed once the agency considers and addresses the reviewers’ comments. All reviewer comments should be given consideration and be incorporated where relevant and valid. For instance, in the context of risk assessments, the National Academy of Sciences recommends that peer review include a written

evaluation made available for public inspection.[27] In cases where there is a public panel, the agency should plan publication of the peer review report(s) and the agency's response to peer reviewer comments.

In addition, the credibility of the final scientific report is likely to be enhanced if the public understands how the agency addressed the specific concerns raised by the peer reviewers. Accordingly, agencies should consider preparing a written response to the peer review report explaining: the agency's agreement or disagreement, the actions the agency has undertaken or will undertake in response to the report, and (if applicable) the reasons the agency believes those actions satisfy any key concerns or recommendations in the report.

Adequacy of Prior Peer Review

In light of the broad range of information covered by Section II, agencies are directed to choose a peer review mechanism that is adequate, giving due consideration to the novelty and complexity of the science to be reviewed, the relevance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review.

Publication in a refereed scientific journal may mean that adequate peer review has been performed. However, the intensity of peer review is highly variable across journals. There will be cases in which an agency determines that a more rigorous or transparent review process is necessary. For instance, an agency may determine a particular journal review process did not address questions (e.g., the extent of uncertainty inherent in a finding) that the agency determines should be addressed before disseminating that information. As such, prior peer review and publication is not by itself sufficient grounds for determining that no further review is necessary.

[27] National Research Council, Risk Assessment in the Federal Government: Managing the Process, National Academy Press, Washington, D.C., 1983.

Section III: Peer Review of Highly Influential Scientific Assessments

Whereas Section II leaves most of the considerations regarding the form of the peer review to the agency's discretion, Section III requires a more rigorous form of peer review for highly influential scientific assessments. The requirements of Section II of this Bulletin apply to Section III, but Section III has some additional requirements, which are discussed below. In planning a peer review under Section III, agencies typically will have to devote greater resources and attention to the issues discussed in Section II, i.e., individual versus panel review; timing; scope of the review; selection of reviewers; disclosure and attribution; public participation; and disposition of reviewer comments.

A scientific assessment is considered "highly influential" if the agency or the OIRA Administrator determines that the dissemination could have a potential impact of more than $500 million in any one year on either the public or private sector or that the dissemination is novel, controversial, or precedent-setting, or has significant interagency interest. One of the ways information can exert economic impact is through the costs or benefits of a regulation based on the disseminated information. The qualitative aspect of this definition may be most useful in cases where it is difficult for an agency to predict the potential economic effect of dissemination. In the context of this Bulletin, it may be either the approach used in the assessment or the interpretation of the information itself that is novel or precedent-setting. Peer review can be valuable in establishing the bounds of the scientific debate when methods or interpretations are a source of controversy among interested parties. If information is covered by Section III, an agency is required to adhere to the peer review procedures specified in Section III.

Section III (2) clarifies that the principal findings, conclusions and recommendations in official reports of the National Academy of Sciences that fall under this Section are generally presumed not to require additional peer review. All other highly influential scientific assessments require a review that meets the requirements of Section III of this Bulletin.

With regard to the selection of reviewers, Section III(3)(a) emphasizes consideration of expertise and balance. As discussed in Section II, expertise refers to the required knowledge, experience and skills required to perform the review whereas balance refers to the need for diversity in scientific perspective and disciplines. We emphasize that the term "balance" here refers not to balancing of stakeholder or political interests but rather to a broad and diverse representation of respected perspectives and intellectual traditions within the scientific community, as discussed in the NAS policy on committee composition and balance.[28]

Section III(3)(b) instructs agencies to consider barring participation by scientists with a conflict of interest. The conflict of interest standards for Sections II and III of the Bulletin are identical. As discussed under Section II, those peer reviewers who are federal employees, including Special Government Employees, are subject to applicable statutory and regulatory standards for federal employees. For non-government employees, agencies shall adopt or adapt the NAS policy for committee member selection with respect to evaluating conflicts of interest.

Section III(3)(c) instructs agencies to ensure that reviewers are independent of the agency sponsoring the review. Scientists employed by the sponsoring agency are not permitted to serve as reviewers for highly influential scientific assessments. This does not preclude Special Government Employees, such as academics appointed to advisory committees, from serving as peer reviewers. The only exception to this ban would be the rare situation in which a scientist from a different agency of a Cabinet-level department than the agency that is disseminating the scientific assessment has expertise, experience and skills that are essential but cannot be obtained elsewhere. In evaluating the need for this exception, agencies shall use the NAS criteria for assessing the appropriateness of using employees of sponsors (e.g., the government scientist must not have had any part in the development or prior review of the scientific information and must not hold a position of managerial or policy responsibility).

[28] 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:

We also considered whether a reviewer can be independent of the agency if that reviewer receives a substantial amount of research funding from the agency sponsoring the review. Research grants that were awarded to the scientist based on investigator-initiated, competitive, peer-reviewed proposals do not generally raise issues of independence. However, significant consulting and contractual relationships with the agency may raise issues of independence or conflict, depending upon the situation.

Section III(3)(d) addresses concerns regarding repeated use of the same reviewer in multiple assessments. Such repeated use should be avoided unless a particular reviewer's expertise is essential. Agencies should rotate membership across the available pool of qualified reviewers. Similarly, when using standing panels of scientific advisors, it is suggested that the agency rotate membership among qualified scientists in order to obtain fresh perspectives and reinforce the reality and perception of independence from the agency.

Section III(4) requires agencies to provide reviewers with sufficient background information, including access to key studies, data and models, to perform their role as peer reviewers. In this respect, the peer review envisioned in Section III is more rigorous than some forms of journal peer review, where the reviewer is often not provided access to underlying data or models. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under federal information quality laws.

Section III(5) addresses opportunity for public participation in peer review, and provides that the agency shall, wherever possible, provide for public participation. In some cases, an assessment may be so sensitive that it is critical that the agency's assessment achieve a high level of quality before it is publicized. In those situations, a rigorous yet confidential peer review process may be appropriate, prior to public release of the assessment. If an agency decides to make a draft assessment publicly available at the

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http://www.nationalacademies.org/coi/index.html.

onset of a peer review process, the agency shall, whenever possible, provide a vehicle for the public to provide written comments, make an oral presentation before the peer reviewers, or both. When written public comments are received, the agency shall ensure that peer reviewers receive copies of comments that address significant scientific issues with ample time to consider them in their review. To avoid undue delay of agency activities, the agency shall specify time limits for public participation throughout the peer review process.

Section III(6) requires that agencies instruct reviewers to prepare a peer review report that describes the nature and scope of their review and their findings and conclusions. The report shall disclose the name of each peer reviewer and a brief description of his or her organizational affiliation, credentials and relevant experiences. The peer review report should either summarize the views of the group as a whole (including any dissenting views) or include a verbatim copy of the comments of the individual reviewers (with or without attribution of specific views to specific names). The agency shall also prepare a written response to the peer review report, indicating whether the agency agrees with the reviewers and what actions the agency has taken or plans to take to address the points made by reviewers. The agency is required to disseminate the peer review report and the agency's response to the report on the agency's website, including all the materials related to the peer review such as the charge statement, peer review report, and agency response to the review. If the scientific information is used to support a final rule then, where practicable, the peer review report shall be made available to the public with enough time for the public to consider the implications of the peer review report for the rule being considered.

Section III(7) authorizes but does not require an agency to commission an entity independent of the agency to select peer reviewers and/or manage the peer review process in accordance with this Bulletin. The entity may be a scientific or professional society, a firm specializing in peer review, or a non-profit organization with experience in peer review.

Section IV: Alternative Procedures

Peer review as described in this Bulletin is only one of many procedures that agencies can employ to ensure an appropriate degree of pre-dissemination quality of influential scientific information. For example, Congress has assigned the NAS a special role in advising the federal government on scientific and technical issues. The procedures of the NAS are generally quite rigorous, and thus agencies should presume that major findings, conclusions, and recommendations of NAS reports meet the performance standards of this Bulletin.

As an alternative to complying with Sections II and III of this Bulletin, an agency may instead (1) rely on scientific information produced by the National Academy of Sciences, (2) commission the National Academy of Sciences to peer review an agency draft scientific information product, or (3) employ an alternative procedure or set of procedures, specifically approved by the OIRA Administrator in consultation with the Office of Science and Technology Policy (OSTP), that ensures that the scientific information product meets applicable information-quality standards.

An example of an alternative procedure is to commission a respected third party other than the NAS (e.g., the Health Effects Institute or the National Commission on Radiation Protection and Measurement) to conduct an assessment or series of related assessments. Another example of an alternative set of procedures is the three-part process used by the National Institutes of Health (NIH) to generate scientific guidance. Under that process, a scientific proposal or white paper is generated by a working group composed of external, independent scientific experts; that paper is then forwarded to a separate external scientific council, which then makes recommendations to the agency. The agency, in turn, decides whether to adopt and/or modify the proposal. For large science agencies that have diverse research portfolios and do not have significant regulatory responsibilities, such as NIH, an acceptable alternative would be to allow scientists from one part of the agency (for example, an NIH institute) to participate in the review of documents prepared by another part of the agency, as long as the head of the agency

confirms in writing that each of the reviewers meets the NAS criteria relating to the appropriateness of using employees of sponsors (e.g., the government scientist must not have had any part in the development or prior review of the scientific information and must not hold a position of managerial or policy responsibility). The purpose of Section IV is to encourage these types of innovation in the methods used to ensure pre-dissemination quality control of influential scientific information.

The mere existence of a public comment process (e.g., notice-and-comment procedures under the Administrative Procedure Act) does not constitute adequate peer review or an "alternative process," because it does not assure that qualified, impartial specialists in relevant fields have performed a critical evaluation of the agency's draft product.[29]

Section V: Peer Review Planning

Section V requires agencies to begin a systematic process of peer review planning for influential scientific information (including highly influential scientific assessments) that the agency plans to disseminate in the foreseeable future. A key feature of this planning process is a web-accessible listing of forthcoming influential scientific disseminations (i.e., an agenda) that is regularly updated by the agency. By making these plans publicly available, agencies will be able to gauge the extent of public interest in the peer review process for influential scientific information, including highly influential scientific assessments. These web-accessible agendas can also be used by the public to monitor agency compliance with this Bulletin.

Each entry on the agenda shall include a preliminary title of the planned report, a short paragraph describing the subject and purpose of the planned report, and an agency contact person. The agency shall provide its prediction regarding whether the dissemination will be "influential scientific information" or a "highly influential scientific assessment," as the designation can influence the type of peer review to be undertaken.

[29] William W. Lowrance, Modern Science and Human Values, Oxford University Press, New York, NY 1985: 86.

The agency shall discuss the timing of the peer review, as well as the use of any deferrals. Agencies shall include entries in the agenda for influential scientific information, including highly influential scientific assessments, for which the Bulletin's requirements have been deferred or waived. If the agency, in consultation with the OIRA Administrator, has determined that it is appropriate to use a Section IV "alternative procedure" for a specific dissemination, a description of that alternative procedure shall be included in the agenda.

Furthermore, for each entry on the agenda, the agency shall describe the peer review plan. Each peer review plan shall include: (i) a paragraph including the title, subject and purpose of the planned report, as well as an agency contact to whom inquiries may be directed to learn the specifics of the plan; (ii) whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment; (iii) the timing of the review (including deferrals); (iv) whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be exercised); (v) whether there will be opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities will be provided; (vi) whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their review; (vii) the anticipated number of reviewers (3 or fewer; 4-10; or more than 10); (viii) a succinct description of the primary disciplines or expertise needed in the review; (ix) whether reviewers will be selected by the agency or by a designated outside organization; and (x) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers. The agency shall provide a link from the agenda to each document made public pursuant to this Bulletin. Agencies shall link their peer review agendas to the U.S. Government's official web portal: *firstgov* at http://www.FirstGov.gov

Agencies should update their peer review agendas at least every six months. However, in some cases -- particularly for highly influential scientific assessments and other particularly important information -- more frequent updates of existing entries on the agenda, or the addition of new entries to the agenda, may be warranted. When new

entries are added to the agenda of forthcoming reports and other information, the public should be provided with sufficient time to comment on the agency's peer review plan for that report or product. Agencies shall consider public comments on the peer review plan. Agencies are encouraged to offer a listserve or similar mechanism for members of the public who would like to be notified by email each time an agency's peer review agenda has been updated.

The peer review planning requirements of this Bulletin are designed to be implemented in phases. Specifically, the planning requirements of the Bulletin will go into effect for documents subject to Section III of the Bulletin (highly influential scientific assessments) six months after publication. However, the planning requirements for documents subject to Section II of the Bulletin do not go into effect until one year after publication. It is expected that agency experience with the planning requirements of the Bulletin for the smaller scope of documents encompassed in Section III will be used to inform implementation of these planning requirements for the larger scope of documents covered under Section II.

Section VI: Annual Report

Each agency shall prepare an annual report that summarizes key decisions made pursuant to this Bulletin. In particular, each agency should provide to OIRA the following: 1) the number of peer reviews conducted subject to the Bulletin (i.e., for influential scientific information and highly influential scientific assessments); 2) the number of times alternative procedures were invoked; 3) the number of times waivers or deferrals were invoked (and in the case of deferrals, the length of time elapsed between the deferral and the peer review); 4) any decision to appoint a reviewer pursuant to any exception to the applicable independence or conflict of interest standards of the Bulletin, including determinations by the Secretary or Deputy Secretary pursuant to Section III (3) (c); 5) the number of peer review panels that were conducted in public and the number that allowed public comment; 6) the number of public comments provided on the agency's peer

review plans; and 7) the number of peer reviewers that the agency used that were recommended by professional societies.

Section VII: Certification in the Administrative Record

If an agency relies on influential scientific information or a highly influential scientific assessment subject to the requirements of this Bulletin in support of a regulatory action, the agency shall include in the administrative record for that action a certification that explains how the agency has complied with the requirements of this Bulletin and the Information Quality Act. Relevant materials are to be placed in the administrative record.

Section VIII: Safeguards, Deferrals, and Waivers

Section VIII recognizes that individuals serving as peer reviewers have a privacy interest in information about themselves that the government maintains and retrieves by name or identifier from a system of records. To the extent information about a reviewer (name, credential, affiliation) will be disclosed along with his/her comments or analysis, the agency must comply with the requirements of the Privacy Act, 5 U.S.C. 552a, as amended, and OMB Circular A-130, Appendix I, 61 Fed. Reg. 6428 (February 20, 1996) to establish appropriate routine uses in a published System of Records Notice. Furthermore, the peer review must be conducted in a manner that respects confidential business information as well as intellectual property.

Section VIII also allows for a deferral or waiver of the requirements of the Bulletin where necessary. Specifically, the agency head may waive or defer some or all of the peer review requirements of Sections II or III of this Bulletin if there is a compelling rationale for waiver or deferral. Waivers will seldom be warranted under this provision because the Bulletin already provides significant safety valves, such as: the exemptions provided in Section IX, including the exemption for time-sensitive health and safety information;

the authorization for alternative procedures in Section IV; and the overall flexibility provided for peer reviews of influential scientific information under Section II. Nonetheless, we have included this waiver and deferral provision to ensure needed flexibility in unusual and compelling situations not otherwise covered by the exemptions to the Bulletin, such as situations where unavoidable legal deadlines prevent full compliance with the Bulletin before information is disseminated. Deadlines found in consent decrees agreed to by agencies after the Bulletin is issued will not ordinarily warrant waiver of the Bulletin's requirements because those deadlines should be negotiated to permit time for all required procedures, including peer review. In addition, when an agency is unavoidably up against a deadline, deferral of some or all requirements of the Bulletin (as opposed to outright waiver of all of them) is the most appropriate accommodation between the need to satisfy immovable deadlines and the need to undertake proper peer review. If the agency head defers any of the peer review requirements prior to dissemination, peer review should be conducted as soon as practicable thereafter.

Section IX: Exemptions

There are a variety of situations where agencies need not conduct peer review under this Bulletin. These include, for example, disseminations of sensitive information related to certain national security, foreign affairs, or negotiations involving international treaties and trade where compliance with this Bulletin would interfere with the need for secrecy or promptness.

This Bulletin does not cover official disseminations that arise in adjudications and permit proceedings, unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel (i.e., a major change in accepted practice) or likely to have precedent-setting influence on future adjudications or permit proceedings. This exclusion is intended to cover, among other things, licensing, approval and registration processes for specific product development activities as well as site-specific activities. The determination as to whether peer review

is practical and appropriate is left to the discretion of the agency. While this Bulletin is not broadly applicable to adjudications, agencies are encouraged to hold peer reviews of scientific assessments supporting adjudications to the same technical standards as peer reviews covered by the Bulletin, including transparency and disclosure of the data and models underlying the assessments. Protections apply to confidential business information.

The Bulletin does not cover time-sensitive health and safety disseminations, for example, a dissemination based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began. For this purpose, "health" includes public health, or plant or animal infectious diseases.

This Bulletin covers original data and formal analytic models used by agencies in Regulatory Impact Analyses (RIAs). However, the RIA documents themselves are already reviewed through an interagency review process under E.O. 12866 that involves application of the principles and methods defined in OMB Circular A-4. In that respect, RIAs are excluded from coverage by this Bulletin, although agencies are encouraged to have RIAs reviewed by peers within the government for adequacy and completeness.

The Bulletin does not cover accounting, budget, actuarial, and financial information including that which is generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures, or taxes.

Routine statistical information released by federal statistical agencies (e.g., periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends (e.g., unemployment and poverty rates) is excluded from this Bulletin.

The Bulletin does not cover information disseminated in connection with routine rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof.

If information is disseminated pursuant to an exemption to this Bulletin, subsequent disseminations are not automatically exempted. For example, if influential scientific information is first disseminated in the course of an exempt agency adjudication, but is later disseminated in the context of a non-exempt rulemaking, the subsequent dissemination will be subject to the requirements of this Bulletin even though the first dissemination was not.

Section X: OIRA and OSTP Responsibilities

OIRA, in consultation with OSTP, is responsible for overseeing agency implementation of this Bulletin. In order to foster learning about peer review practices across agencies, OIRA and OSTP shall form an interagency workgroup on peer review that meets regularly, discusses progress and challenges, and recommends improvements to peer review practices.

Section XI: Effective Date and Existing Law

The requirements of this Bulletin, with the exception of Section V, apply to information disseminated on or after six months after publication of this Bulletin. However, the Bulletin does not apply to information that is already being addressed by an agency-initiated peer review process (e.g., a draft is already being reviewed by a formal scientific advisory committee established by the agency). An existing peer review mechanism mandated by law should be implemented by the agency in a manner as consistent as possible with the practices and procedures outlined in this Bulletin. The requirements of Section V apply to "highly influential scientific assessments," as designated in Section III of the Bulletin, within six months of publication of the final Bulletin. The requirements in Section V apply to documents subject to Section II of the Bulletin one year after publication of the final Bulletin.

Section XII: Judicial Review

This Bulletin is intended to improve the internal management of the Executive Branch and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.

Bulletin for Peer Review

I. Definitions.

For purposes of this Bulletin --

1. the term "Administrator" means the Administrator of the Office of Information and Regulatory Affairs in the Office of Management and Budget (OIRA);

2. the term "agency" has the same meaning as in the Paperwork Reduction Act, 44 U.S.C. § 3502(1);

3. the term "dissemination" means agency initiated or sponsored distribution of information to the public (see 5 C.F.R. 1320.3(d) (definition of "Conduct or Sponsor")). Dissemination does not include distribution limited to government employees or agency contractors or grantees; intra- or inter-agency use or sharing of government information; or responses to requests for agency records under the Freedom of Information Act, the Privacy Act, the Federal Advisory Committee Act, the Government Performance and Results Act or similar law. This definition also excludes distribution limited to correspondence with individuals or persons, press releases, archival records, public filings, subpoenas and adjudicative processes. The term "dissemination" also excludes information distributed for peer review in compliance with this Bulletin, provided that the distributing agency includes a clear disclaimer on the information as follows: "THIS INFORMATION IS DISTRIBUTED SOLELY FOR THE PURPOSE OF PRE-DISSEMINATION PEER REVIEW UNDER APPLICABLE INFORMATION

QUALITY GUIDELINES. IT HAS NOT BEEN FORMALLY DISSEMINATED BY [THE AGENCY]. IT DOES NOT REPRESENT AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY." 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 does not represent the views of an agency. To qualify for this exemption, the information should display a clear disclaimer that "the findings and conclusions in this report are those of the author(s) and do not necessarily represent the views of the funding agency";

4. the term "Information Quality Act" means Section 515 of Public Law 106-554 (Pub. L. No. 106-554, § 515, 114 Stat. 2763, 2763A-153-154 (2000));

5. the term "scientific information" means factual inputs, data, models, analyses, technical information, or scientific assessments based on the behavioral and social sciences, public health and medical sciences, life and earth sciences, engineering, or physical sciences. This includes any communication or representation of knowledge such as facts or data, in any medium or form, including textual, numerical, graphic, cartographic, narrative, or audiovisual forms. This definition includes information that an agency disseminates from a web page, but does not include the provision of hyperlinks to information that others disseminate. This definition does not include opinions, where the agency's presentation makes clear that what is being offered is someone's opinion rather than fact or the agency's views;

6. the term "influential scientific information" means scientific information the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions; and

7. the term "scientific assessment" means 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; health,

safety, or ecological risk assessments; toxicological characterizations of substances; integrated assessment models; hazard determinations; or exposure assessments.

II. Peer Review of Influential Scientific Information.

1. In General: To the extent permitted by law, each agency shall conduct a peer review on all influential scientific information that the agency intends to disseminate. Peer reviewers shall be charged with reviewing scientific and technical matters, leaving policy determinations for the agency. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the federal laws governing information access and quality.

2. Adequacy of Prior Peer Review: For information subject to this section of the Bulletin, agencies need not have further peer review conducted on information that has already been subjected to adequate peer review. In determining whether prior peer review is adequate, agencies shall give due consideration to the novelty and complexity of the science to be reviewed, the importance of the information to decision making, the extent of prior peer reviews, and the expected benefits and costs of additional review. Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed.

3. Selection of Reviewers:

a. Expertise and Balance: Peer reviewers shall be selected based on expertise, experience and skills, including specialists from multiple disciplines, as necessary. The group of reviewers shall be sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

b. Conflicts: The agency – or the entity selecting the peer reviewers – shall (i) ensure that those reviewers serving as federal employees (including special government employees) comply with applicable federal ethics requirements; (ii) in selecting peer reviewers who are not government employees, adopt or adapt the National Academy of Sciences policy for committee selection with respect to evaluating the potential for

conflicts (e.g., those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income). For scientific information relevant to specific regulations, the agency shall examine a reviewer's financial ties to regulated entities (e.g., businesses), other stakeholders, and the agency.

c. Independence: Peer reviewers shall not have participated in development of the work product. Agencies are encouraged to rotate membership on standing panels across the pool of qualified reviewers. Research grants that were awarded to scientists based on investigator-initiated, competitive, peer-reviewed proposals generally do not raise issues as to independence or conflicts.

4. Choice of Peer Review Mechanism: The choice of a peer review mechanism (for example, letter reviews or ad hoc panels) for influential scientific information shall be based on the novelty and complexity of the information to be reviewed, the importance of the information to decision making, the extent of prior peer review, and the expected benefits and costs of review, as well as the factors regarding transparency described in II(5).

5. Transparency: The agency -- or entity managing the peer review -- shall instruct peer reviewers to prepare a report that describes the nature of their review and their findings and conclusions. The peer review report shall either (a) include a verbatim copy of each reviewer's comments (either with or without specific attributions) or (b) represent the views of the group as a whole, including any disparate and dissenting views. The agency shall disclose the names of the reviewers and their organizational affiliations in the report. Reviewers shall be notified in advance regarding the extent of disclosure and attribution planned by the agency. The agency shall disseminate the final peer review report on the agency's website along with all materials related to the peer review (any charge statement, the peer review report, and any agency response). The peer review report shall be discussed in the preamble to any related rulemaking and included in the administrative record for any related agency action.

6. Management of Peer Review Process and Reviewer Selection: The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin.

III. Additional Peer Review Requirements for Highly Influential Scientific Assessments.

1. Applicability: This section applies to influential scientific information that the agency or the Administrator determines to be a scientific assessment that:

(i) could have a potential impact of more than $500 million in any year, or

(ii) is novel, controversial, or precedent-setting or has significant interagency interest.

2. In General: To the extent permitted by law, each agency shall conduct peer reviews on all information subject to this Section. The peer reviews shall satisfy the requirements of Section II of this Bulletin, as well as the additional requirements found in this Section. Principal findings, conclusions and recommendations in official reports of the National Academy of Sciences that fall under this Section are generally presumed not to require additional peer review.

3. Selection of Reviewers:

a. Expertise and Balance: Peer reviewers shall be selected based on expertise, experience and skills, including specialists from multiple disciplines, as necessary. The group of reviewers shall be sufficiently broad and diverse to fairly represent the relevant scientific and technical perspectives and fields of knowledge. Agencies shall consider requesting that the public, including scientific and professional societies, nominate potential reviewers.

b. Conflicts: The agency – or the entity selecting the peer reviewers – shall (i) ensure that those reviewers serving as federal employees (including special government employees) comply with applicable federal ethics requirements; (ii) in selecting peer reviewers who are not government employees, adopt or adapt the National Academy of Sciences' policy for committee selection with respect to evaluating the potential for conflicts (e.g., those arising from investments; agency, employer, and business affiliations; grants, contracts and consulting income). For scientific assessments relevant

to specific regulations, a reviewer's financial ties to regulated entities (e.g., businesses), other stakeholders, and the agency shall be examined.

c. Independence: In addition to the requirements of Section II (3)(c), which shall apply to all reviews conducted under Section III, the agency -- or entity selecting the reviewers -- shall bar participation of scientists employed by the sponsoring agency unless the reviewer is employed only for the purpose of conducting the peer review (i.e., special government employees). The only exception to this bar would be the rare case where the agency determines, using the criteria developed by NAS for evaluating use of "employees of sponsors," that a premier government scientist is (a) not in a position of management or policy responsibility and (b) possesses essential expertise that cannot be obtained elsewhere. Furthermore, to be eligible for this exception, the scientist must be employed by a different agency of the Cabinet-level department than the agency that is disseminating the scientific information. The agency's determination shall be documented in writing and approved, on a non-delegable basis, by the Secretary or Deputy Secretary of the department prior to the scientist's appointment.

d. Rotation: Agencies shall avoid repeated use of the same reviewer on multiple assessments unless his or her participation is essential and cannot be obtained elsewhere.

4. Information Access: The agency -- or entity managing the peer review -- shall provide the reviewers with sufficient information -- including background information about key studies or models -- to enable them to understand the data, analytic procedures, and assumptions used to support the key findings or conclusions of the draft assessment.

5. Opportunity for Public Participation: Whenever feasible and appropriate, the agency shall make the draft scientific assessment available to the public for comment at the same time it is submitted for peer review (or during the peer review process) and sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public. When employing a public comment process as part of the peer review, the agency shall, whenever practical, provide peer reviewers with access to public comments that address significant scientific or technical issues. To ensure that public participation does not unduly delay agency activities, the agency shall clearly specify time limits for public participation throughout the peer review process.

6. Transparency: In addition to the requirements specified in II(5), which shall apply to all reviews conducted under Section III, the peer review report shall include the charge to the reviewers and a short paragraph on both the credentials and relevant experiences of each peer reviewer. The agency shall prepare a written response to the peer review report explaining (a) the agency's agreement or disagreement with the views expressed in the report, (b) the actions the agency has undertaken or will undertake in response to the report, and (c) the reasons the agency believes those actions satisfy the key concerns stated in the report (if applicable). The agency shall disseminate its response to the peer review report on the agency's website with the related material specified in Section II(5).

7. Management of Peer Review Process and Reviewer Selection: The agency may commission independent entities to manage the peer review process, including the selection of peer reviewers, in accordance with this Bulletin.

IV. Alternative Procedures.

As an alternative to complying with Sections II and III of this Bulletin, an agency may instead: (i) rely on the principal findings, conclusions and recommendations of a report produced by the National Academy of Sciences; (ii) commission the National Academy of Sciences to peer review an agency's draft scientific information; or (iii) employ an alternative scientific procedure or process, specifically approved by the Administrator in consultation with the Office of Science and Technology Policy (OSTP), that ensures the agency's scientific information satisfies applicable information quality standards. The alternative procedure(s) may be applied to a designated report or group of reports.

V. Peer Review Planning.

1. Peer Review Agenda: Each agency shall post on its website, and update at least every six months, an agenda of peer review plans. The agenda shall describe all planned and ongoing influential scientific information subject to this Bulletin. The agency shall provide a link from the agenda to each document that has been made public pursuant to

this Bulletin. Agencies are encouraged to offer a listserve or similar mechanism to alert interested members of the public when entries are added or updated.

2. Peer Review Plans: For each entry on the agenda the agency shall describe the peer review plan. Each peer review plan shall include: (i) a paragraph including the title, subject and purpose of the planned report, as well as an agency contact to whom inquiries may be directed to learn the specifics of the plan; (ii) whether the dissemination is likely to be influential scientific information or a highly influential scientific assessment; (iii) the timing of the review (including deferrals); (iv) whether the review will be conducted through a panel or individual letters (or whether an alternative procedure will be employed); (v) whether there will be opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities will be provided; (vi) whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their review; (vii) the anticipated number of reviewers (3 or fewer; 4-10; or more than 10); (viii) a succinct description of the primary disciplines or expertise needed in the review; (ix) whether reviewers will be selected by the agency or by a designated outside organization; and (x) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers.

3. Public Comment: Agencies shall establish a mechanism for allowing the public to comment on the adequacy of the peer review plans. Agencies shall consider public comments on peer review plans.

VI. Annual Reports.

Each agency shall provide to OIRA, by December 15 of each year, a summary of the peer reviews conducted by the agency during the fiscal year. The report should include the following: 1) the number of peer reviews conducted subject to the Bulletin (i.e., for influential scientific information and highly influential scientific assessments); 2) the number of times alternative procedures were invoked; 3) the number of times waivers or deferrals were invoked (and in the case of deferrals, the length of time elapsed between the deferral and the peer review); 4) any decision to appoint a reviewer pursuant to any exception to the applicable independence or conflict of interest standards of the Bulletin,

including determinations by the Secretary pursuant to Section III(3)(c); 5) the number of peer review panels that were conducted in public and the number that allowed public comment; 6) the number of public comments provided on the agency's peer review plans; and 7) the number of peer reviewers that the agency used that were recommended by professional societies.

VII. Certification in the Administrative Record.

If an agency relies on influential scientific information or a highly influential scientific assessment subject to this Bulletin to support a 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 applicable information quality guidelines. Relevant materials shall be placed in the administrative record.

VIII. Safeguards, Deferrals, and Waivers.

1. Privacy: To the extent information about a reviewer (name, credentials, affiliation) will be disclosed along with his/her comments or analysis, the agency shall comply with the requirements of the Privacy Act, 5 U.S.C. § 522a as amended, and OMB Circular A-130, Appendix I, 61 Fed. Reg. 6428 (February 20, 1996) to establish appropriate routine uses in a published System of Records Notice.

2. Confidentiality: Peer review shall be conducted in a manner that respects (i) confidential business information and (ii) intellectual property.

3. Deferral and Waiver: The agency head may waive or defer some or all of the peer review requirements of Sections II and III of this Bulletin where warranted by a compelling rationale. If the agency head defers the peer review requirements prior to dissemination, peer review shall be conducted as soon as practicable.

IX. Exemptions.

Agencies need not have peer review conducted on information that is:

1. related to certain national security, foreign affairs, or negotiations involving international trade or treaties where compliance with this Bulletin would interfere with the need for secrecy or promptness;

2. disseminated in the course of an individual agency adjudication or permit proceeding (including a registration, approval, licensing, site-specific determination), unless the agency determines that peer review is practical and appropriate and that the influential dissemination is scientifically or technically novel or likely to have precedent-setting influence on future adjudications and/or permit proceedings;

3. a health or safety dissemination where the agency determines that the dissemination is time-sensitive (e.g., findings based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began);

4. an agency regulatory impact analysis or regulatory flexibility analysis subject to interagency review under Executive Order 12866, except for underlying data and analytical models used;

5. routine statistical information released by federal statistical agencies (e.g., periodic demographic and economic statistics) and analyses of these data to compute standard indicators and trends (e.g., unemployment and poverty rates);

6. accounting, budget, actuarial, and financial information, including that which is generated or used by agencies that focus on interest rates, banking, currency, securities, commodities, futures, or taxes; or

7. information disseminated in connection with routine rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof.

X. Responsibilities of OIRA and OSTP.

OIRA, in consultation with OSTP, shall be responsible for overseeing implementation of this Bulletin. An interagency group, chaired by OSTP and OIRA, shall meet periodically to foster better understanding about peer review practices and to assess progress in implementing this Bulletin.

XI. Effective Date and Existing Law.

The requirements of this Bulletin, with the exception of those in Section V (Peer Review Planning), apply to information disseminated on or after six months following publication of this Bulletin, except that they do not apply to information for which an agency has already provided a draft report and an associated charge to peer reviewers. Any existing peer review mechanisms mandated by law shall be employed in a manner as consistent as possible with the practices and procedures laid out herein. The requirements in Section V apply to "highly influential scientific assessments," as designated in Section III of this Bulletin, within six months of publication of this Bulletin. The requirements in Section V apply to documents subject to Section II of this Bulletin one year after publication of this Bulletin.

XII. Judicial Review

This Bulletin is intended to improve the internal management of the executive branch, and is not intended to, and does not, create any right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its agencies or other entities, its officers or employees, or any other person.