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OFFICE OF MANAGEMENT AND BUDGET
Revised Information Quality Bulletin for Peer Review

INTRODUCTION

On September 15, 2003, OIRA published a draft Peer Review Bulletin for public comment. We received 187 comments during the public comment period, participated in a public workshop at the National Academy of Sciences (NAS), and undertook an interagency review process. This process led to a substantially revised Bulletin, which incorporates many of the diverse perspectives and suggestions voiced during the comment period.

As almost all commenters recognized, peer review is an important way to enhance the quality of information. When done in an open, rigorous manner, independent peer review improves both the quality of scientific information and the public's confidence in the integrity of science.

Under this Bulletin, agencies must undertake a peer review of influential scientific information before they disseminate the information to the public. Different types of peer review are appropriate for different types of information products, and agencies are granted under this Bulletin appropriate discretion to weigh the benefits and costs of using a particular peer review mechanism for a particular information product. This Bulletin leaves the selection of a peer review mechanism for influential scientific information to the agency's discretion. Based on public and agency comments, we also exempted various types of information products from the requirements of this Bulletin, including time-sensitive medical, health, and safety determinations, in order to ensure that peer review does not unduly delay the release of time-sensitive findings.

This Bulletin also imposes 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 which typically synthesizes multiple factual inputs, data, models, assumptions, and/or

applies best professional judgment to bridge uncertainties in the available information. Although the proposed Bulletin imposed heightened peer review requirements on a broader array of information products, we agree with some commenters that, in order to ensure that the Bulletin is not too costly or rigid, more intensive peer review should be restricted to the more important information disseminated by the federal government.

Even for this category of highly influential scientific assessments, the revised Bulletin leaves broad 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 a written charge to the peer reviewers, the peer reviewers' report, and the agency's response to the peer reviewers' report. 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 independence from the agency. In response to comments, this revised Bulletin encourages agencies to consider using the panel selection criteria employed by the NAS. The use of a transparent process, coupled with the selection of objective 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 in science to ensure that the quality of published information meets the standards of the scientific 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.¹ Peer review occurs when a draft product is reviewed for quality by specialists who were not involved in producing the draft.

¹ Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 75.

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, the validity of the research design, the quality of the 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 products that contain 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, independence, and the absence of conflict of interest. Furthermore, notice-and-comment procedures for agency rulemaking do not provide an adequate substitute for peer review, as disinterested experts -- especially those most knowledgeable in a field -- often do 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.² 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

² William W. Lowrance, Modern Science and Human Values, Oxford University Press, New York, NY 1985: 85.

prior to being submitted for 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 blinded, confidential reviews that precede a public process of panel review. As part of 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 are rarely 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 agencies³. In response to congressional inquiry, the U.S. General Accounting Office documented the variability in both the definition and implementation of peer review across agencies.⁴ The Carnegie Commission on Science, Technology and Government⁵ 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.⁶ Other arguments focus on specific types of scientific products (e.g., assessments of health, safety and environmental hazards).⁷ Indeed, the Congressional/Presidential Commission on Risk Assessment and Risk Management

³ Sheila Jasanoff, The Fifth Branch: Science Advisors as Policy Makers, Harvard University Press, Boston, 1990.

⁴ U.S. General Accounting Office, Federal Research: Peer Review Practices at Federal Agencies Vary, GAO/RCED-99-99, Washington, D.C., 1999.

⁵ Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 90.

⁶ 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.

⁷ National Research Council, Science and Judgment in Risk Assessment, National Academy Press, Washington, D.C., 1994.

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.”⁸

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 lacks 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 will 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 the establishment of an agenda that describes the peer review process that the agency has chosen for each of its forthcoming influential scientific information products.

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

⁸ 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.

quality, objectivity, utility and integrity of information” disseminated by Federal agencies. Pub. L. 106-554, § 515(a). The Information Quality Act was crafted as an amendment to the Paperwork Reduction Act, 44 U.S.C. § 3501 et seq., which requires OMB, among 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. 51735 (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 general authority to manage the agencies under the purview of the President’s Constitutional authority to oversee the unitary Executive Branch. See, e.g., the Budget and Accounting Procedures Act of 1950, as amended, 31 U.S.C. § 1111; Reorganization Plan No. 2 of 1970, 84 Stat. 2085; Executive Order 11541, 35 Fed. Reg. 10737 (July 1, 1970); Executive Order 12866. 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 Departments or 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. The term “agency” includes all agencies subject to the Paperwork Reduction Act, see 44 U.S.C. § 3502(1).

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

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 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. Finally, “dissemination” also excludes information distributed for peer review in compliance with this Bulletin, provided that the distributing agency includes an appropriate and clear disclaimer on the information, as explained more fully below.

In the context of this Bulletin, the definition of “dissemination” also goes beyond 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. In cases where a draft report or other information is released by an agency for purposes of peer review, a question may arise as to whether the draft report constitutes an official “dissemination” under information-quality guidelines. Normally, draft reports undergoing peer review are not intended as disseminations -- because they are not yet final -- and thus 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] AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY.”

This disclaimer should appear on each page of a draft report in cases where the information is highly relevant to specific policy or regulatory deliberations. Agencies also should discourage state, local, international and private organizations from using

information in draft reports that are undergoing peer review. Draft influential scientific information being presented at scientific meetings prior to peer review must include the disclaimer: “THE VIEWS IN THIS REPORT (PRESENTATION) ARE THOSE OF THE AUTHOR(S) AND DO NOT NECESSARILY REPRESENT THE VIEWS OF THE FUNDING AGENCY.”

For the purposes of the peer review Bulletin, the term “scientific information” means factual inputs, data, models, analyses, 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 views, is being offered.

The term “influential scientific information” means the scientific information the dissemination of which the agency reasonably can determine will have or does have a clear and substantial impact on important public policies or private sector decisions. In OMB’s government-wide information quality guidelines, the term “influential information” is used in the context of “influential scientific, financial, or statistical information.” However, this Bulletin only covers “influential scientific information.”

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, risk assessments, toxicological profiles of substances, integrated assessment models, hazard determinations, exposure assessments, or health,

ecological, or safety assessments. The assessment will often draw upon knowledge from multiple disciplines.

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.

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.⁹ Furthermore, agencies need to consider tradeoffs between depth of peer review and timeliness.¹⁰ 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 are the direct costs of the peer review activity, and the 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 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

⁹ National Academy of Public Administration, *Setting Priorities, Getting Results: A New Direction for EPA*, National Academy Press, Washington, D.C., 1995:23.

¹⁰ Presidential/Congressional Commission on Risk Assessment and Risk Management, *Risk Commission Report*, 1997.

reduce the temptation for courts and legislators to second-guess agency actions.¹¹ While it will not always be easy for agencies to quantify the benefits and costs of peer review, we encourage agencies 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, and 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,” as well as adhering to defined procedures.¹²

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; the scope of the review; the selection of reviewers; disclosure; public participation; and disposition of reviewer comments. These issues are relevant to any peer review under this Bulletin.

Individual versus Panel Review

Letter reviews by several experts generally will be more expeditious than convening a panel of a dozen or more experts. Individual letters 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.

¹¹ 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.

¹² 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>.

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 appropriate 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 an information product. 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."¹³

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. For instance, use of peer review is more often regarded as "generally successful" when it occurs "early" in the agency's deliberative process. 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

¹³ Testimony of Bruce Alberts, PhD., President, National Academy of Sciences, February 24, 1998, Hearing on S. 981, before Senate Committee on Governmental Affairs.

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.

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. Rather, what is being reviewed in the case of scientific assessments is a scientific judgment rather than “scientific fact.”¹⁵ Specialists attempt to reach a consensus by weighing the accumulated evidence. As such, it is important that peer reviewers be asked to ensure that scientific uncertainties are clearly identified and characterized. Furthermore, since not all uncertainties will have an equal effect on the conclusions drawn, reviewers can be asked to ensure that the potential implications of the uncertainties for the technical conclusions drawn are clear. Within this context, peer reviewers can make an important contribution by distinguishing scientific facts from professional judgments. Reviewers might be asked to provide advice on reasonable judgments that can be made from the scientific evidence, but the charge should make clear that the reviewers are not to provide advice on the policy (e.g., the amount of

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

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 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 reports 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 might help an agency target any additional research resources available for this problem.

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. 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 should be 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 For some reviews, evaluation of biological plausibility is as important as statistical modeling.

Balance. 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

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.

National Academy of Sciences) specifically recruit reviewers with strong opinions to test the scientific strength and balance of their reports.

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 often 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.”²⁰ 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.”²¹ However, the choice of reviewers requires a case-by-case analysis. In some instances, reviewers employed by other federal and state agencies may be sufficiently independent.

A related issue raised by some commentators 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.²² This concern can be mitigated in situations where the scientist determines the hypothesis to be tested or the method to be developed, which effectively creates a buffer between the scientist and the agency. Similarly, 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

²⁰ 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.

²¹ Carnegie Commission on Science, Technology, and Government, Risk and the Environment: Improving Regulatory Decision Making, Carnegie Commission, New York, 1993: 90.

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 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 issues pose a complex set of questions which much be considered by agencies when peer reviewers are selected. In general, agencies should 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 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.²³

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

²² Lars Noah, "Scientific 'Republicanism': Expert Peer Review and the Quest for Regulatory Deliberation," Emory Law Journal, Atlanta, Fall 2000:1066.

²³ American Society for Mechanical Engineers, Assessment of Technologies Supported by the Office of Science and Technology, Department of Engineering: Results of the Peer Review for Fiscal Year 2002, ASME Technical Publishing, Danvers, MA, 2002.

competitive advantage for a person or organization.²⁴ This standard provides a useful benchmark for agencies to consider in selecting peer reviewers. Agencies should 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 and regulatory agencies should 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 prevent any real or perceived conflicts of interest with potential reviewers and questions regarding the independence of reviewers, we refer agencies 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. With respect to reviewers who are not federal employees, agencies should adopt or adapt the prevailing practices of the NAS regarding committee composition, conflicts, and balance²⁵ and/or the applicable ethics requirements that have been developed by the U.S. government, including the standards of the Office of Government Ethics.²⁶ Both NAS and the federal government recognize that under certain circumstances some conflict may be unavoidable in order to obtain the necessary expertise. See, for example, 18 U.S.C. § 208(b)(3).

²⁴ National Academy of Science, "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>.

²⁵ Ibid.

Disclosure Policies: Anonymous versus Identified Reviewers

In choosing the appropriate peer review mechanism, agencies must balance the need for confidentiality of reviews with the need for transparency. In a journal review, the most common practice is to keep the names and affiliations of the reviewers confidential. This confidentiality is designed to encourage reviewers to be candid in their evaluations of the draft product under review. Such confidentiality may also encourage participation by qualified scientists. However, in the context of peer review of government products, such confidentiality may not always add to the credibility of the review process. Where the issue under review is likely to have large public or private sector impacts, the agency may decide that more transparency is in the public interest. In such cases, disclosure of the slate of reviewer names and their qualifications can strengthen public confidence in the peer review process. It may be feasible to disclose information about reviewers without disclosing their specific opinions. The degree of public disclosure of information about reviewers should balance the need for transparency with the need to protect the privacy of scientists.

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.

²⁶ United States Office of Government Ethics, “Standards of Ethical Conduct for Employees of the Executive Branch,” Washington, D.C., 2002. Available at: http://www.usoge.gov/pages/forms_pubs_otherdocs/fpo_files/reference/rfsoc_02.pdf

Public participation can take a variety of forms, including opportunities to provide oral comments before a peer review or requests to provide written comment 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 reasonable consideration and be incorporated where relevant and valid. As part of the peer review planning process, agencies should determine whether they will consider reviewer comments confidential or make them available to the public once the reviewed document is disseminated. 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 Reviewers should be informed about how their comments will be disseminated, whether they will be disclosed with attribution, or whether they will be summarized without attribution. In cases where there is a public panel, the agency should plan publication of both the peer review report(s) and the Agency’s response to peer reviewer comments.

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. In addition, Section III has some specific 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

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

Section II, i.e., individual versus panel review; timing; the scope of the review; the selection of reviewers; disclosure; public participation; and disposition of reviewer comments.

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, risk assessments, toxicological profiles of substances, integrated assessment models, hazard determinations, exposure assessments, or health, ecological, or safety assessments. 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).

A scientific assessment is considered "highly influential" if the agency or the OIRA Administrator determines that the dissemination could have a clear and substantial impact on important public policies (including regulatory actions) or private sector decisions with a potential effect of more than \$500 million in any one year or that the dissemination involves precedent setting, novel and complex approaches, or 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. If information is covered by Section III, an agency is required to adhere to the peer-review procedures specified in Section III.

With regard to the selection of reviewers, Section III(2)(a) emphasizes consideration of expertise and balance. 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.

Section III(2)(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 should adopt or adapt the applicable ethical standards used by the federal government and/or the NAS.

Section III(2)(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 information. This does not preclude Special Government Employees, such as academics appointed to advisory committees, from serving as peer reviewers. Agencies (or their contractors) should seek and consider potential reviewers who have been nominated based on their expertise and objectivity by the public, including scientific and professional societies. We considered whether a reviewer is independent of the agency if that reviewer receives a substantial amount of research funding from the agency sponsoring the review. 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. Repeated use of the same reviewer in multiple assessments may raise issues of independence unless the particular reviewer's expertise is essential. Agencies can generally avoid the effect of use of the same reviewer by rotating membership across the available pool of qualified reviewers. Similarly, when using standing panels of scientific advisors, we suggest rotating membership among qualified scientists in order to obtain fresh perspectives and reinforce the reality and perception of independence from the agency. Section III(3)(c) also requires agencies to consider the

prevailing selection practices used by the National Academy of Sciences, since they were designed to ensure independence from sponsors in the federal government.

Section III(3) 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 should be informed of applicable access, objectivity, reproducibility and other quality standards under federal information quality laws.

Section III(4) addresses opportunity for public participation in peer review, and provides that the agency should, 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 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 should ensure that peer reviewers receive copies of comments that address significant scientific issues with ample time to consider them in their review.

Section III(5) 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 should disclose the name of each peer reviewer and a brief description of their organizational affiliation, credentials and relevant experiences. When the agency uses a panel, the peer review report should either summarize the views of the group as a whole (including any dissenting views) or summarize the views of individual reviewers (with or without attribution of specific views to specific names). The agency must 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 web site, including all the materials related to the peer review such as charge statement, peer review report, and agency response to the review.

Section III(6) 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 section. 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. 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 OSTP, that ensures that the scientific information product meets applicable information-quality standards. For example, an agency might choose 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. The purpose of Section IV is to encourage innovation in the methods used to ensure pre-dissemination quality control of influential scientific information.

Section V: Peer Review Planning

Section V requires agencies to begin a systematic process of peer review planning for influential scientific information and highly influential scientific assessments that the agency plans to disseminate in the foreseeable future. A key feature of planning is a web site listing of forthcoming influential scientific disseminations that is regularly updated by the agency, at least every six months. Each entry on the list of forthcoming disseminations should 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. In addition, the agency should briefly describe its peer review plan, including the anticipated number of reviewers (3 or less; 4-10; more than 10), whether they shall work as individuals or a panel, and a succinct description of the primary disciplines or types of skills, expertise and experience needed in the review.

In addition, each peer review plan shall include the following: (1) whether reviewers will be selected by the agency or by a designated outside organization; (2) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers; (3) 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; and (4) whether or not the agency will provide peer reviewers copies of significant and relevant public comments prior to doing their work.

The peer review agenda will allow agencies to gauge the extent of public interest in the peer review process for influential scientific information. The agenda can also be used by the public to monitor agency compliance with this Bulletin. The Bulletin requires agencies to update their peer review agenda at least every six months. However, in some cases -- particularly for highly influential scientific assessments and other particularly important information products -- 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 products, 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 some form of listserv 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) four months after publication. However, the planning requirements do not go into effect for documents subject to Section II of the Bulletin 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: Certification in the Administrative Record.

If an agency relies on influential scientific information 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 this Bulletin and the Information Quality Act. Relevant materials are to be placed in the administrative record.

Section VII: Safeguards and Waivers

Section VII establishes basic procedures to protect privacy and confidentiality concerns, and to allow for waiver of the requirements of the Bulletin where necessary. First, peer review must be conducted in a manner that respects privacy interests, confidential business information, and intellectual property. Second, 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. If the agency head

waives the peer review requirements prior to dissemination, peer review should be conducted as soon as practicable thereafter.

Section VIII: 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 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.

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. Since the Bulletin covers only official "disseminations" of the U.S. government, it does not cover information products released 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 those information products are not represented as the views of the agency or Department supporting the research. In cases where the imprimatur of the federal government is not intended, government-funded scientists are advised to include a statement with their disseminated work indicating that "the views in this report are those of the author(s) and do not necessarily represent the views of the funding agency".

This Bulletin does not cover official disseminations that arise in adjudications and permit proceedings, unless the agency determines that the influential dissemination is scientifically or technically novel (i.e., a major change in accepted practice) and 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 products and development activities, as well as site-specific disseminations such as those made under Superfund or the National Environmental Policy Act (NEPA). The Bulletin also 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 a Department or agency plans to disseminate information supplied by a third party (i.e., using this information to support decisions, thereby adopting this information as an official dissemination), the requirements of the Bulletin apply, assuming the dissemination is "influential".

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

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 EO 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. One model for such a review prior to submission to OIRA is offered by the Interagency Economic Peer Review (IEPR). The IEPR comprises agency economists engaged in benefit-cost analysis from across the federal government.

The Bulletin does not cover accounting, budget, 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 the analysis 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 rules that materially alter entitlements, grants, user fees, or loan programs or the rights and obligations of recipients thereof, other than influential scientific information disseminated in connection with non-routine rules in this category.

In general, the Bulletin does not impose new peer-review requirements on information that has already been adequately peer reviewed. Under the terms of the Bulletin, agencies should exercise discretion in determining when a draft information product has already been adequately peer reviewed. The mere existence of a public comment process (*e.g.*, notice-and-comment procedures under the Administrative Procedures Act) does not constitute adequate peer review, because it does not assure that qualified, impartial specialists in relevant fields have performed a critical evaluation of the agency's draft product.²⁸ For both Sections II and III of this Bulletin, principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed. Publication in a refereed scientific journal may mean that adequate peer review has been performed. However, because the intensity of journal review is highly variable, there may 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 all of the questions that the agency should address before publishing a report. In addition, because science primarily advances through further research in which new data challenges prior theories, prior peer review and publication is not by itself sufficient grounds for determining that no further review is necessary.

Congress has assigned the NAS a special role in advising the federal government on scientific and technical issues. The peer-review procedures of the NAS are generally quite rigorous, and thus agencies should presume that major findings from NAS reports have been adequately peer reviewed.

²⁸ William W. Lowrance, Modern Science and Human Values, Oxford University Press, New York, NY 1985: 86.

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 IX: OIRA and OSTP Responsibilities

OIRA, in consultation with OSTP, is responsible for overseeing agency implementation of the requirements 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 under the Bulletin.

Section X: Effective Date and Existing Law

The requirements of this Bulletin, with the exception of Section V, apply to information disseminated on or after four months after publication of this Bulletin. However, the Bulletin does not apply to information products that are 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. As noted above, the requirements in Section V apply to “highly influential scientific assessments,” as designated in Section III of the Bulletin, within four 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 XI: Judicial Review

This Bulletin is intended to improve the internal management of the executive branch and is not intended to create any new right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person. Nor does this Bulletin abridge any existing rights of action. Consistent with current law, materials generated during the peer review process may be considered by courts adjudicating existing rights of action.

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;

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(d) (definition of “Conduct or Sponsor”)). Dissemination does not include distribution limited to government employees or agency contracts 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 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] AND SHOULD NOT BE CONSTRUED TO REPRESENT ANY AGENCY DETERMINATION OR POLICY”;

4. the term “influential scientific information” means scientific information the dissemination of which the agency reasonably can determine that dissemination of which will have or does have a clear and substantial impact on important public policies or private sector decisions;

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

6. 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, risk assessments, toxicological profiles of substances, integrated assessment models, hazard determinations, exposure assessments, or health, ecological, or safety assessments, and

7. the term “scientific information” means factual inputs, data, models, analyses, or scientific assessments related to 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.

II. Peer Review of Influential Scientific Information.

1. In General: To the extent permitted by law, each agency shall have a peer review conducted on all influential scientific information that the agency intends to disseminate. Agencies need not, however, have peer review conducted on information that has already been subjected to adequate peer review.

2. Adequacy of Peer Review: To be considered “adequate” for purposes of the preceding paragraph, a peer review need not comply with all of the requirements of this Bulletin. An agency may deem a prior peer review adequate if it determines that the peer review was sufficiently rigorous in light of the novelty and complexity of the science to be reviewed and the benefit and cost implications. For both Sections II and III of this Bulletin, principal findings, conclusions and recommendations in official reports of the National Academy of Sciences are generally presumed to have been adequately peer reviewed.

3. Choice of Peer Review Mechanism: When planning a peer review for influential scientific information, the agency shall select an appropriate peer review mechanism based on the novelty and complexity of the science to be reviewed and the benefit and cost implications. Depending on these factors, appropriate peer review mechanisms can range from review by qualified specialists within the federal government to formal review by an independent body of experts outside the government. Peer reviewers shall be selected on the basis of necessary technical or scientific expertise, and should not have participated in development of the work product.

4. Conflicts: In order to properly handle participation by scientists with a conflict of interest, the agency – or the entity selecting the peer reviewers – shall (i) ensure that those reviewers serving as federal employees (including special government employees as defined in 18 U.S.C. 202(a)) comply with applicable federal ethics requirements (ii) apply or adapt the federal ethics requirements for reviewers who are not federal

employees; and (iii) consider the conflict of interest policy used by the National Academy of Sciences, including principles regarding potential financial conflicts arising from factors such as a reviewers' investments, employer and business affiliations, grants, contracts and consulting income. For scientific assessments relevant to specific regulations, a reviewer's financial ties to both regulated entities (e.g., businesses) and the agency should be examined.

5. Transparency: A detailed summary or copy of the reviewers' comments, as a group or individually, shall be made available to the public and, where appropriate, be made part of the administrative record for related agency actions. Agencies shall consider the comments of the reviewers.

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

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

(i) could have a clear and substantial impact on important public policies (including regulatory actions) or private sector decisions with a potential effect of more than \$500 million in any year, or

(ii) involves precedent setting, novel, and complex approaches, or significant interagency interest.

2. Selection of Reviewers:

a. Expertise and Balance: Peer reviewers shall be selected to provide the necessary 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 perspectives and fields of knowledge.

b. Conflicts: In order to properly handle participation by scientists with a conflict of interest, 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) apply or adapt the federal ethics requirements for reviewers who are not federal employees; and (iii) consider the conflict of interest policy used by the National Academy of Sciences, including principles regarding potential financial conflicts arising from factors such as a reviewers' investments, employer and business affiliations, grants, contracts and consulting income. For scientific assessments relevant to specific regulations, a reviewer's financial ties to both regulated entities (e.g., businesses) and the agency should be examined.

c. Independence: In order to ensure participation by scientists who are independent of the agency sponsoring the review, the agency – or entity selecting the reviewers – shall (i) bar participation by scientists employed by the agency sponsoring the review unless the reviewer's service as a peer reviewer defines the government employment (i.e., special government employees); (ii) consider requesting the nomination of potential reviewers based on expertise and objectivity from the public, including scientific and professional societies; and (iii) consider the prevailing selection practices of the National Academy of Sciences concerning ties of a potential committee members to the sponsoring agency. Agencies should avoid repeated use of the same reviewer on multiple assessments unless his or her participation is essential. Agencies

are encouraged to rotate membership on 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.

3. 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. Reviewers shall be informed of applicable access, objectivity, reproducibility and other quality standards under the federal laws governing information access and quality.

4. Opportunity for Public Participation: If the agency decides to make a draft assessment publicly available at the same time it is submitted for peer review (or during the peer review process), the agency shall, whenever practical, provide to peer reviewers a compilation or summary of relevant public comments on the draft assessment that address significant scientific or technical issues. When there is sufficient public interest, the agency -- or entity managing the peer review -- shall consider establishing a public comment period for a draft report and sponsoring a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public. Time limits for public participation shall be specified.

5. Peer Review Reports: 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 should either summarize the views of individual reviewers (either with or without specific attributions, as long as the reviewers are informed in advance of the agency's plans for disclosure) or represent the views of the group as a whole (including any dissenting views). The peer review report shall also disclose the names, organizational affiliations, and a short paragraph on the credentials and relevant experiences of each peer reviewer. The agency is required to prepare a written response to the peer review report explaining: the agency's agreement or disagreement; any 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. The agency shall disseminate the final peer review report and the agency's written statement of response on the agency's web site, and all the materials related to the peer review (charge statement, peer review report, and agency response) shall be included in the administrative record for any related agency action.

6. Selection and Management of Peer Review Panel: The agency may commission entities independent of the agency to select peer reviewers and/or manage the peer review process in accordance with this section.

IV. Alternative Procedures.

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

V. Peer Review Planning.

1. Peer Review Agenda: Each agency shall post on its Internet website, and update at least every six months, an agenda designating all planned and ongoing influential scientific information subject to Section II and highly influential scientific assessments subject to Section III of this Bulletin.

2. Peer Review Plans:

- a. General Requirements: For each entry on the agenda that is subject to this Bulletin, 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 review will be conducted by a panel or individual letters; (iii) the anticipated number of reviewers (3 or less; 4-10; or more than 10); and (iv) a succinct description of the primary disciplines or types of expertise needed in the review.
- b. Designations: Each peer review plan shall designate the following: (i) whether reviewers will be selected by the agency or by a designated outside organization; (ii) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers; (iii) 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; and (iv) whether the agency will provide peer reviewers copies of significant and relevant public comments prior to doing their work.
- c. Agenda Updates: Agencies are encouraged to offer a listserve to alert interested members of the public when new entries are added or updated.
- d. Public Comment: Agencies shall establish a mechanism for allowing the public to comment on the adequacy of the peer review plans and designations. Agencies must consider public comments on peer review plans.

VI. 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, it shall include in the administrative record for that action a certification explaining how the

agency has complied with the requirements of this Bulletin and the Information Quality Act.

VII. Safeguards and Waivers.

1. Privacy and Confidentiality: Peer review shall be conducted in a manner that respects (i) privacy interests; (ii) confidential business information; and (iii) intellectual property.
2. Waiver: The agency head may waive or defer some or all of the peer review requirements of Section II and III of this Bulletin where warranted by a compelling rationale. If the agency head waives the peer review requirements prior to dissemination, peer review should be conducted as soon as practicable thereafter.

VIII. Exemptions.

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

1. related to 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. 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 those information products are not represented as the views of a Department or agency. To qualify for this exemption, scientists are advised to include in their information product a clear disclaimer that “the views in this report are those of the author(s) and do not necessarily represent the views of the funding agency”;
3. 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 the influential dissemination is scientifically or technically novel and likely to have precedent-setting influence on future adjudications and/or permit proceedings;
4. a medical, health, or safety dissemination where the agency determines that the dissemination is time-sensitive or is based primarily on data from a recent clinical trial that was adequately peer reviewed before the trial began.
5. an agency regulatory impact analysis or regulatory flexibility analysis subject to interagency review under Executive Order 12866;
6. routine statistical information released by federal statistical agencies (e.g., periodic information about unemployment and poverty rates);
7. accounting, budget, 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
8. information disseminated in connection with rules that materially alter entitlements, grants, user fees, or loan programs, or the rights and obligations of recipients thereof, except that influential scientific information disseminated in connection with non-routine rules is not exempt.

IX. Responsibilities of OIRA and OSTP.

OIRA, in consultation with OSTP, shall be responsible for overseeing implementation of the requirements 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 the implementation of this Bulletin.

X. 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 four months after publication, except that they do not apply to information for which an agency has already commenced a peer-review process. Any existing peer review mechanisms mandated by law should 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 four months of publication. The requirements in Section V apply to documents subject to Section II of this Bulletin one year after publication.

XI. Judicial Review

This Bulletin is intended to improve the internal management of the executive branch, and is not intended to create any new right or benefit, substantive or procedural, enforceable at law or in equity, against the United States, its departments, agencies, or other entities, its officers or employees, or any other person. Nor does this Bulletin abridge any existing rights of action. Consistent with current law, materials generated during the peer review process may be considered by courts adjudicating existing rights of action.