

based on unnecessarily stringent conflict-of-interest requirements, on the other. OMB is especially concerned about the government's need to recruit the best qualified scientists to serve as peer reviewers.

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

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

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

Part II—Proposed OMB Bulletin and Supplemental Information Quality Guidelines

Section 1. Definitions

For purposes of this Bulletin and guidance:

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

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

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

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

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

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

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

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

Section 2. Peer Review of Significant Regulatory Information

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

During the planning of a peer review for significant regulatory information, the agency should select an appropriate peer review mechanism based on the novelty and complexity of the science to be reviewed, the benefit and cost implications, and any controversy regarding the science. Depending on these factors, appropriate peer review mechanisms for significant regulatory

information can range from review by qualified specialists within an agency (if they reside in a separate agency program) to formal review by an independent body of experts outside the agency. The experts may be selected by the agency or an outside group.

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

If significant regulatory information is subject to the peer review requirements of Section 2 of this Bulletin and (i) the agency intends to disseminate the information in support of a major regulatory action, (ii) the dissemination of the information could otherwise have a clear and substantial impact on important public policies or important private sector decisions with a possible impact of more than \$100 million in any year, or (iii) the Administrator determines that the information is of significant interagency interest or is relevant to an Administration policy priority, then, to the extent permitted by law, the agency shall have a formal, independent, external peer review conducted on the information. The peer review shall proceed in accordance with the following guidance:

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