

another reviewer with a contrary bias is appointed to balance the panel.

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

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

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

Peer Review Reports: The agency shall direct peer reviewers of the regulatory information—individually or often as a group—to issue a final report detailing the nature of their review and their findings and conclusions. The peer

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

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

Certification in Administrative Record: If an agency relies on significant regulatory information subject to the requirements of this section in support of a major regulatory action, it shall include in the administrative record for that action a certification explaining how the agency has complied with the requirements of this Bulletin and the Information Quality Act with respect to the significant regulatory information at issue.

Section 4. Peer Review Procedures

a. Federal Advisory Committee Act

When considering selection of an outside panel of peer reviewers for regulatory information subject to the requirements of this Bulletin, an agency should assess the treatment of such a panel under the Federal Advisory Committee Act, and may retain a firm to oversee the peer review process with instructions to comply with principles

consistent with those set forth in this Bulletin. See *Byrd v. EPA*, 174 F.3d 239 (D.C. Cir. 1999) (holding that peer review panels selected and supervised by outside consultants are not governed by the Federal Advisory Committee Act, 5 U.S.C.S. App. II §§ 1–15). Although such a firm can be engaged to oversee multiple peer review processes for an agency, the agency shall ensure that the firm itself possesses independence (and the appearance of independence) from the agency.

b. Agency Guidelines

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

c. Waiver

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