

Agency Comments on OMB's Peer Review Bulletin

Introduction

The Environmental Protection Agency (EPA) strongly supports and has long been an experienced practitioner of peer review for regulatory science documents, methods, and models; EPA's first Agency-wide peer review policy was established in 1993. As reflected in our Peer Review Policy, the Agency supports the goal of enhancing the quality and credibility of decisions by ensuring that the scientific and technical work products underlying these decisions receive appropriate levels of peer review by independent scientific and technical experts. We support OMB's goal of providing cogent advice for Federal regulatory agencies on how to structure peer review processes so as to obtain effective independent scientific advice on key science issues encountered in implementing regulatory programs. However, the proposed Bulletin contains some elements that, if interpreted too stringently, would impose additional burdens without benefits to peer review processes. EPA recommends that OMB revisit the proposed guidance to address those elements and to clearly stress the flexibility that individual agencies need to efficiently and effectively manage their peer reviews.

Objective, transparent peer review of the science and technical studies behind agency policy supports the development of better information for decision-making. EPA already adheres to many of the standards proposed in this Bulletin. For example,

- EPA has a peer review policy that in many ways is substantially the same as, and in some cases more rigorous than, these provisions. Agency guidance is provided in the Science Policy Council's Peer Review Handbook (EPA 100-B-00-001, December 2000), as well as laws and regulations that govern peer review processes (e.g., the Federal Insecticide, Fungicide, and Rodenticide Act [FIFRA], and the Federal Advisory Committee Act [FACA]);
- Over 750 work products of the EPA were peer reviewed in 2002 (of which 91% were reviewed by external peers);
- Many EPA products are published in peer-reviewed scientific, refereed journals;
- EPA already has independent bodies established under the Federal Advisory Committee Act that conduct peer reviews (e.g., the Science Advisory Board [SAB] and the FIFRA Scientific Advisory Panel [SAP], and the Office of Research and Development's [ORD] similar body for scientific research, the Board of Scientific Counselors [BOSC]);
- EPA has established Information Quality Guidelines (IQGs) (EPA 260R-02-008, October 2002) that contain EPA's policy and procedural guidance for ensuring and maximizing the quality of information the Agency disseminates.

In addition to supporting the spirit and objectives of the OMB Bulletin, we find the following specific provisions to be excellent and recommend that they remain in the final Bulletin (with noted revision):

- “For purposes of this Bulletin, peer review undertaken by a scientific [and refereed]

- journal may generally be presumed to be adequate.” (p. 9)
- “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. These experts may be selected by the agency or an outside group.” (p. 9)
- “Peer reviewers shall be selected primarily on the basis of necessary scientific and technical expertise.” (p. 10)
- “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.” (p. 10)

Despite our general agreement with the goal of OMB’s proposal, we believe a number of specific provisions warrant reconsideration or refinement. The proposed Bulletin does not appear to substantively improve upon EPA’s existing peer review processes as described in the Agency’s Peer Review Handbook. The EPA’s peer review policies and procedures have undergone an extensive period of review and development and some important elements of EPA’s processes are reflected in the proposed Bulletin. However, without revision to clarify certain provisions, the Bulletin could increase the burden upon the Agency substantially, without improving the peer review process.

Given the breadth of Federal programs, the diversity of information products they produce, and the various approaches to obtaining peer review, we appreciate the complexity of the task before OMB to develop government-wide guidance on peer reviews and some specific elements of the peer review process. In light of these complexities, EPA believes that any guidance issued on this matter should stress flexibility with regard to individual agencies developing their own guidance for peer review processes. As discussed below, the broadly applicable standards proposed in the draft Bulletin are too restrictive and may lead to lost time and resources with minimal value added, impediments to recruiting the best qualified experts to serve as peer reviewers, diminished quality of peer review advice, and inconsistencies with existing laws and regulations that agencies must follow. For example, the Bulletin appears to reduce Federal agencies’ discretion and flexibility in several areas, including (1) developing their own guidance regarding which work products are subjected to various approaches for peer review; (2) the timing of public comment processes and provision of written responses to peer review recommendations; and (3) the provision of information to peer reviewers regarding their charge. Further, the Bulletin requires additional reporting and consultation processes that will increase the burden on agencies with regard to time and resources. EPA recommends that revisions to the proposed guidance clearly stress the flexibility that individual agencies need in these areas to efficiently and effectively manage their peer reviews. Individual agencies should be accorded considerable discretion in developing the guidance needed to achieve the objectives put forward in OMB’s Bulletin.

Below we articulate the Agency’s key concerns with the Bulletin in three areas: lost time and resources with minimal value added; impediments to recruiting the best qualified experts; and areas for clarification. That discussion is followed by a section on other issues that we believe should be addressed in the revised document. Finally, we offer a few editorial suggestions.

Key Concerns:

5. OMB's proposed requirements may result in lost time and resources with minimal value added beyond requirements of EPA's peer review policy.

There are several provisions in the Bulletin that would contribute to lost time and resources at the Agency while adding minimal value beyond EPA's current policy on peer review. These include the following provisions:

- (1) New peer review of analyses underlying every economically significant rule even when no new or innovative methodology is used;
- (2) Public comment period with every peer review conducted for Especially Significant Regulatory Information (ESRI);
- (3) Consultation and reporting requirements with OIRA and OSTP;
- (4) Requirement to brief reviewers on IQGs and OMB's guidelines for regulatory analysis;
- (5) Potential for selection of peer reviewers to be taken away from agencies.

These are discussed in detail, below.

- (1) The proposed Bulletin appears to call for a new peer review for analyses underlying every economically significant rule when no new or innovative methodology is used.

Requiring a peer review when no new or innovative methodology is used may add minimal value to the information product, consume limited resources at the Agency, overtax the limited pool of qualified reviewers, and unnecessarily slow down the decision process. Agencies need discretion in developing their internal peer review guidance so that resources may be used in the most efficient manner.

Provide reasonable agency discretion in determining scope: OMB has excluded some categories of information from the scope of the Bulletin (e.g., national security information, and information that is disseminated in the course of an individual adjudication or permit proceeding). The Bulletin also states that information that has already been adequately peer reviewed is exempted from the peer review requirements. In addition, the Bulletin should clearly state that agencies have some discretion in determining what categories of information are exempt from the requirements (e.g., analyses representing a routine application of generally accepted methodologies or methodologies that have been adequately peer reviewed previously).

Proposed Changes to Section 2:

We recommend the following language be added to the second sentence at the beginning of Section 2, page 9:

".... Agencies need not, however, have further peer review conducted on studies that have already been subjected to adequate independent peer review, including those based on routine application of accepted, previously peer-reviewed

methodologies.”

Provide agency discretion for reviews under Section 2: The final Bulletin should clarify the discretion that agencies have regarding how to approach peer reviews for various types of “significant regulatory information.” Currently, EPA employs a variety of specifically-tailored review processes for different types of assessments of scientific or economic data prepared to assist the Agency in reaching “licensing” decisions for specific chemicals or products. It is EPA’s understanding that the Bulletin would not apply to adjudications, such as pesticide registration or reregistration decisions, review of State emergency exemption submissions under FIFRA, and premanufacture review decisions under the Toxic Substances Control Act (TSCA). EPA believes that the review approaches it has established over the years for various types of routine licensing decisions serve to ensure the accuracy, objectivity, and transparency of its decisions better than a “one size fits all” approach.

Base peer review decisions on science: Section 3 indicates that external peer review is required if the “[OIRA] Administrator determines that the information is of significant interagency interest or is relevant to an Administration policy priority.” It is unclear that interagency interest warrants a higher level of scientific peer review. The level of peer review would more appropriately be based on the novelty and complexity of the science rather than on the interest level of other agencies or the Administration’s policy priorities. If retained, we recommend that this provision be amended to state that OMB would “consult with relevant agencies” to identify any such additional information for external peer review.

(2) Requirement for a public comment period with every peer review conducted for Especially Significant Regulatory Information. (Section 3)

The proposed Bulletin states the following: “the agency shall provide an opportunity for other interested agencies and persons to submit comments . . . for consideration before the peer reviewers conclude their review and prepare their report” (page 11).

It is important to note that an appropriate peer review is not intended to be a jury on public comments; rather, it is intended to provide an independent technical review.

Provide flexibility in selection of vehicle for soliciting public comments: Agencies should be allowed flexibility on selecting the appropriate vehicle for soliciting public comments based on the type of document to undergo peer review. The public comment process sometimes provides an opportunity for outside experts to address peer reviewers, providing them with scientific information of which they may not have otherwise been aware (e.g., the public comment process associated with advisory committees such as the FIFRA Scientific Advisory Panel or SAP). More frequently, public comments addressing pending government decisions and regulatory policy matters focus upon issues not directly related to the quality of science and technical information. Consequently, a blanket requirement for a formal public comment period to be associated with every peer review conducted for especially significant regulatory information may not provide benefits to justify the costs of doing so in some instances. If the Bulletin requires a formal public comment period for every peer review rather than recognizing the range of approaches to

commenting on peer reviews, the burden placed on peer review panels (time, effort), funding agencies (extramural costs, full-time equivalents [FTE], delay of action) and the public (delay of receiving information, agencies meeting statutory obligations) would be significant.

Currently, EPA and other agencies utilize a variety of peer review mechanisms, some of which provide opportunities for public comment. For example, all peer reviews conducted by Federal advisory committees are required by FACA to allow opportunities for public comments. Peer reviews conducted through other means (e.g., panels selected and supervised by outside consultants) provide options for obtaining public comments when they will add the most value to the specific information product under review. The peer review of a narrowly focused scientific issue that requires highly specialized expertise is an example that may benefit minimally from a public comment period. Later in the process, when this scientific information is incorporated into a broader regulatory decision, the resources expended for public comment may result in greater benefits. The Bulletin should allow agencies flexibility to develop their own guidance on providing opportunities for public comments when they will result in the greatest return on the invested resources, and clarify that the FACA requirement of inviting public comment on documents that are sent to peer reviewers and made available to the public should be considered adequate under this provision.

Provide flexibility in timing of public comment solicitation: The timing of the required public comment provision is unclear in the current draft of the Bulletin. The addition of a public comment period prior to the peer review (rather than a public comment or viewing period concurrent with peer review) would often lengthen the process and increase costs, potentially resulting in substantial delays. Agencies should be allowed flexibility on the timing of the public comments based on the type of document to undergo peer review. For guidance documents, seeking public input before or during peer review may be appropriate. For technical documents supporting rulemaking, we often seek peer review prior to the rule's proposal. The public is given time to comment on the proposal and supporting documentation during the Notice of Proposed Rulemaking, so an additional provision allowing public comment before or during the course of the peer review is unnecessary and redundant and would negatively impact the regulatory schedule. There are cases where it would be most appropriate to first conduct a peer review and then solicit public input afterwards on that document and policy considerations not examined by the peer review panel. Flexibility in seeking public comments is key.

- (3) Requirement to report to and consult with OIRA and OSTP has important resource implications and also raises concern over the public's perception of the independence of the peer review process. (Section 3)

This provision may, depending on how it is implemented, give OIRA considerable control over the peer review process, with control possibly extending to the selection of peer reviewers. EPA strives to maintain a separation between those who make policy decisions related to what is peer reviewed and how reviewers' input is considered, and the actual management of a peer review. EPA's Peer Review Handbook calls for strictly separating the management of scientific and technical work products from the actual conduct of peer review of those work products (section 1.4.3). This means that the EPA decision maker and the peer review leader should never be the

same person. The decision maker is accountable for the decisions regarding the identification of products to be peer reviewed and the mechanism(s) of peer review used for each product; the decision maker will also decide how EPA will address the reviewers' comments. The peer review leader organizes and coordinates the conduct of the peer review and any follow-up activities, such as establishing and maintaining the peer review record. Uncertainty regarding which specific peer review activities may require consultation also raises important resource implications. It would be more appropriate for OMB to issue a broad set of guidelines that allow a sufficient amount of latitude for each agency in the conduct of its peer review program. Any consultation with OIRA should be transparent and part of the public record.

Ensure independent selection for peer reviews: EPA guidance on performing external peer reviews prohibits the individuals authoring the work being reviewed from selecting reviewers. Neither should OIRA nor OSTP, as policy-makers, be involved in the process of selecting peer reviewers for scientific and technical work products. In addition, when a peer review is conducted through an outside contractor, such involvement would raise serious issues under contract law and create vulnerabilities under FACA.

Allow agency latitude in assessing adequacy of peer review plans: The Bulletin indicates that the consultation with OIRA/OSTP is to serve as one of the pre-dissemination quality procedures envisioned by the Information Quality Act. Consequently, it should suffice that EPA's Peer Review Policy is reviewed by OIRA/OSTP rather than specific scientific and technical documents. The Agency should retain the authority to determine whether its peer review plan for specific documents is sufficient to ensure the principles of the Information Quality Guidelines and the Peer Review Policy.

- (4) Requirement to brief peer reviewers on Information Quality Guidelines (OMB's and agency's) and OMB's guidelines for regulatory analysis would provide minimal benefits compared to time and resources required. (Section 3)

The Bulletin states that the charge to peer reviewers "should ask reviewers to apply the standards of OMB's Information Quality Guidelines and the agency's own information quality guidelines." Further, they state that "[r]eviewers 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."

Emphasize developing peer review charge that addresses applicable standards: It is unclear what benefits are to be expected from briefing peer reviewers on this information and asking them, generally, to apply the standards. It should be incumbent on each agency to develop clear peer review charges that address the standards contained in the Information Quality Guidelines, as appropriate. Developing an educational process for each new group of experts to learn about OMB's guidelines and the Data Quality Act would appear to provide minimal benefits from the time and resources involved. These sections of the Bulletin should be revised to place the emphasis back onto the peer review charge developed by the agencies.

- (5) Taking selection of peer reviewers away from agencies would be inefficient and raise other concerns. (Part I - Background and Request for Comment)

The Bulletin states the following: “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.”

The Bulletin does not offer any specific arguments supporting a centralized system for peer review management but provides the following general statement, “. . . the latter approach might lend the appearance of greater integrity to the peer review process . . .”

Maintain agency management of peer reviews: The integrity of peer review is best served through the openness and transparency of the processes used by agencies in managing their own peer reviews. The objective should be to obtain an impartial panel, external or in-house, with the appropriate expertise. Taking peer reviewer selection away from the agencies would be inefficient and may engender an atmosphere of mistrust. A centralized organization for peer review management would be subject to the same appearance problems as individual agencies if the processes are unclear to the public. Further, a centralized organization may be subject to additional “perception problems” if the public views the organization as being too closely tied to policy-makers of the Executive Office of the President or Congress. Such perception could lead to speculation regarding whether administration policy matters are unduly influencing the management of scientific peer reviews. In such cases where an agency (or OIRA) believes that public perception of a potential lack of independence or objectivity outweighs the benefits of an agency-managed peer review, other options are currently available such as a review by the National Academy of Sciences.

B. Selection criteria and disclosure and transparency requirements may create impediments to recruiting the best qualified experts to serve as peer reviewers.

There are several provisions on selection criteria and disclosure and transparency requirements in the Bulletin that may create impediments to recruiting the best qualified peer reviewers if they are not clarified. These include the following provisions:

- (1) Need for more precision in Bulletin language concerning ethical standards of conduct;
- (2) Inflexible and stringent selection criteria;
- (3) Financial disclosure requirements;
- (4) Public disclosure of otherwise confidential information;
- (5) Need for more explicit language addressing peer reviewers who might benefit financially from the regulatory decision at stake;
- (6) Need to clarify that the Bulletin does not discourage peer reviews conducted under FACA.

These are discussed in detail, below.

- (1) Bulletin needs to be more precise in its use of language concerning ethical standards of

conduct.

The document states that peer reviews should be conducted with “genuine independence and objectivity” as well as an avoidance of an “appearance of a conflict-of-interest” (pg. 2). Later on (pg. 4), there is language concerning “real or perceived conflicts of interest.” The guidance itself (pg. 10) contains language concerning “real or perceived conflicts of interest” or the advocacy of positions on “specific matter at issue.”

Rely on ethical standards developed by the Office of Government Ethics: The entire body of existing regulations and statutes created by the Office of Government Ethics (OGE) as well as supplemental regulations and advisories published by individual agencies concerning ethical conduct would be informative here. The Bulletin would be strengthened considerably and ambiguity greatly decreased by making appropriate language changes and references to existing regulations that have served as the basis for ethical conduct in the Executive Branch for decades. EPA (as well as other Federal agencies) has been using these ethical standards for decades during the process of selecting advisory committee panelists. Similarly, appropriate language changes and references should be considered with respect to the Federal Acquisitions Regulations and implementing agency regulations and practice.

Proposed Changes to Section 3 and Throughout the Document:

- With respect to Federal employees and Special Government Employees who are asked to serve on peer review panels, replace “real or perceived conflicts of interest” with “financial conflicts of interest as defined by existing regulation under 18 U.S.C. 208.”
- With respect to Federal employees and Special Government Employees replace the term “specific matter” with “particular matter as defined by existing regulation under 5 CFR 2635.402.”
- With respect to Federal employees and Special Government Employees, replace the term “perceived conflict of interest” with “appearance of a lack of impartiality as defined by existing regulation under 5 CFR 2635.502.”

It should be noted that the above changes do not constitute an exhaustive list, but merely present examples of where the Bulletin should be rewritten to make it consistent with existing Federal regulations concerning ethical standards of conduct. For example, using the term “particular matter” under existing regulations would mean that disqualifying financial interests would depend upon these interests having a direct and predictable effect if there is a real, as opposed to a speculative, possibility that the matter will affect a given financial interest.

We commend your attention to EPA’s Peer Review Handbook (2nd ed., 2000) that also provides useful guidance with respect to terminology, especially in Section 3.4.

Clarify reference to Superfund legislation: The draft Bulletin further notes that, in Superfund, Congress provided that “reviewers should not have ‘institutional ties with any person involved in

the conduct of the study or research under review.’ 42 U.S.C. § 9604(i)(13)” (pg. 4). The lack of “institutional ties with any person involved in the conduct of the study or research under review” is one of the bases by which EPA selects peer reviewers under 42 U.S.C. § 9604(i)(13). We understand, however, that the existence of an institutional tie does not disqualify an expert from selection in all cases; rather, the institutional tie is one of the factors that EPA is to consider. We are concerned that the draft may be erroneously interpreted to indicate that an institutional tie alone would disqualify an otherwise appropriate expert from selection, and therefore request that the draft’s reference to § 9604(i)(13) be revised by adding a footnote clarifying the Congressional intent.

- (2) If selection criteria are inflexible and stringent, they could jeopardize the existence of a pool of acceptable experts and, consequently, diminish the quality and breadth of advice received through peer review. (Section 3)

In Section 3 of the Bulletin, the following factors are identified as considerations that may be used in selecting peer reviewers without “real or perceived conflicts of interest” who can approach “the subject matter in an open-minded and unbiased manner”:

“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)”;

“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.”

Provide agency discretion in assessing and interpreting these factors: EPA agrees that an expert whose livelihood appears to be primarily dependent on agency grants and contracts may not make an appropriate candidate for a peer reviewer. However, there are many experts who receive agency grants and contracts as part of their broader research activities and, by virtue of these activities, could provide important, independent advice to the agency through peer reviews. Agencies should be allowed discretion in developing guidance on the definition of “substantial funding.” Inadvertently setting a broad standard that is inflexible and too stringent could jeopardize the existence of a pool of acceptable experts with the possible consequence of diminishing the quality and breadth of advice received by agencies through the peer review process.

Similarly, agencies should be allowed discretion in developing guidance regarding what is meant by “multiple peer reviews . . . in recent years.” For some scientific topics, the pool of experts is very limited and certain experts are widely recognized as being the leaders. These experts will be in demand for agency reviews addressing a variety of programs and topics related to their areas of expertise. Limiting access to these experts could adversely impact the quality of advice obtained through peer reviews.

As for reviewers who have prior involvement with the same specific matter, EPA agrees that repeatedly reconvening the same group of core experts to address a specific topic may diminish the independence of the review. However, there often are benefits to including several experts

who have been involved with prior agency peer reviews on a topic on a larger panel of reviewers. These reviewers may impart historical perspectives that could lead to greater depth in the review process. For example, their knowledge may assist the panel in exploring the agency's progress at various stages in the development of the information and in understanding how previous peer review recommendations have been addressed. Agencies should be allowed flexibility to provide guidance that could allow for such situations.

Proposed Changes to Sections 3 and 4b:

To address these issues, the factors presented in Section 3 of the Bulletin should acknowledge (as does the EPA's Peer Review Handbook, p. 55) that "the very need to have experienced individuals on a peer review, along with the desire to have appropriate technical balance and representation, can mean that the selection of potential reviewers often comes from those who are considered as having a potential bias."

Section 4b of the Bulletin (p. 12) should be revised as follows - ". . . agencies should have specific guidelines as to what entanglements with agencies, affected businesses, or other stakeholders are so significant as to preclude an individual's participation as a peer reviewer, irrespective of other factors. *These guidelines should address factors relevant to this determination such as i through iv, listed in Section 3 under Selection of Peer Reviewers. In particular, the guidelines should address how to apply these factors in a manner that is consistent with the variety of peer review mechanisms that may be used within the agency (e.g., Federal advisory committees versus peer review panels selected and supervised by outside contractors).*"

- (3) The collection of complete and comprehensive disclosure of pertinent financial and professional information is essential.

Complete and comprehensive disclosure of pertinent financial and professional information is essential in order to determine whether a panel member has a conflict of interest or appearance of a lack of impartiality. Current Federal law allows the Federal Government to collect, for Federal employees and Special Government Employees, confidential financial disclosure information pursuant to Title I of the Ethics in Government Act of 1978 (5 U.S.C. App.), Executive Order 12674, and 5 CFR 2634.

The primary use of the information is for review by Government officials to determine compliance with Federal conflict of interest laws and regulations. Generally speaking, this information is covered under the Privacy Act and may not be disclosed to other parties except under limited circumstances (e.g., when an Agency becomes aware of a violation or potential violation of law or regulation). This confidentiality acts as a catalyst for full and complete financial disclosure of potential panel members.

Consider relying on Office of Government Ethics guidelines on financial disclosure: OMB should give further consideration to existing Office of Government Ethics guidelines and regulations in addressing the financial disclosure requirements and reporting period for Federal employees and

Special Government Employees.

The OMB guidance, or implementing agency guidance, needs to be explicit on the need, scope, format and review procedures for financial disclosure from potential peer reviewers who are Federal employees or Special Government Employees, as well as the confidentiality of any information collected for the purpose of determining conflicts of interest. Most Federal Agencies use the OGE-450 form (available from the Office of Government Ethics at <http://www.usoge.gov>) for financial disclosure. Additionally, the EPA, in partnership with the Office of Government Ethics, developed a form (“EPA Form 3110-48 Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency”) specifically designed to collect a greater level and scope of information than would have been obtained using the OGE-450 form.

Furthermore, financial disclosure forms (such as the OGE-450 or EPA Form 3110-48) obtained pursuant to the selection of panel members undergo careful scrutiny by Federal employees. The procedures for review may be found in the OGE document “OGE Form 450: A Review Guide (1996)” available from OGE.

Length of reporting period: EPA’s current tool for financial disclosure by advisory committee members who serve as Special Government Employees (EPA Form 3110-48) asks candidates to disclose activities and sources of income occurring during the previous two years from the date of filing (with the exception of liabilities which are reportable for the preceding 12 months). This two-year reporting period exceeds the current Office of Government Ethics regulations requiring information to be reported for the preceding twelve months from the date of filing (see 5 CFR 2634.908, Reporting Periods). Extending the reporting period to five or ten years (and especially indefinitely) would add substantially to the burden and would discourage the participation of some candidates.

In some cases, candidate peer reviewers may have involvements extending back indefinitely that need to be considered when determining whether the reviewer is independent and does not appear biased (e.g., a scientist who, 10 years ago, developed a competing theory or model to one that will be undergoing peer review). Even in this case, inclusion of that scientist as a peer reviewer may be appropriate to provide a balanced review of the agency’s proposed approach. Such significant past involvements generally can be determined through review of the candidate’s resume and the interview process and should not be confused with the financial disclosure reporting requirements.

Proposed Changes to Section 3 “Selection of Peer Reviewers”:

“Complete and comprehensive disclosure of pertinent financial and professional information is essential in order to determine whether a peer reviewer has a conflict of interest or an appearance of a lack of impartiality. Therefore, experts who are Federal employees or Special Government Employees who are appointed for the purpose of peer review by Agencies are required to submit financial disclosure information sufficient to ensure that there are no unresolved issues of conflict of interest or an appearance of a lack of impartiality. The OGE-450 form (Confidential Financial Disclosure Form), EPA 3110-

48 Form (Confidential Financial Disclosure Form for Special Government Employees Serving on Federal Advisory Committees at the U.S. Environmental Protection Agency) or other financial disclosure forms approved by the U.S. Office of Government Ethics are considered appropriate levels of financial disclosure.”

“Furthermore, comparable financial disclosure information should be obtained by contractors for the purpose of selecting experts and such information should receive a similar level of review as is usual for reviews done by Federal employees and as described in such documents as “OGE Form 450: A Review Guide (1996)” available from the U. S. Office of Government Ethics. Such information should also be afforded confidentiality.”

- (4) Public disclosure of otherwise confidential financial information on peer reviewers may also discourage participation. (Section 4)

Section 4b of the proposed Bulletin states: “Agency guidance should also address the following additional aspects of the peer review process . . . any types of information regarding the peer reviewers that should be publicly disclosed [*emphasis added*] 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).”

While we understand this was not the intention, this statement could be interpreted to suggest that the following information regarding peer reviewers should potentially be publicly disclosed.

From Section 3 of the Bulletin - 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);
- (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.

From Section 4 of the Bulletin -

- (v) prior service as an expert witness;
- (vi) sources of personal or institutional funding; and/or
- (vii) other matters that might suggest a possible conflict of interest or appearance of a conflict of interest.

Clarify that public disclosure of such information is not required: Such information is currently collected by EPA through confidential financial disclosure forms (EPA Form 3110-48) and is protected by the Privacy Act (5CFR 2634.604). The Bulletin seems to require agencies to develop guidelines that potentially provide for public disclosure of such information. The

language in the Bulletin should be tightened to make clear that this is not the intention. The public disclosure of such information (notwithstanding the legal questions it raises) could greatly discourage the participation of many peer reviewers.

Further, the information provided through a public disclosure process may not be meaningful to members of the public and may raise more questions than it answers. It may be more beneficial to provide the public with information regarding the process the agency follows to determine whether peer review candidates qualify for participation. For example, the FIFRA SAP has posted on its web site the panel formation process, telephone interview checklist, and confidential financial disclosure form used by its Designated Federal Officials to screen candidates. Filings by individual peer reviewer candidates are reviewed by FIFRA SAP staff and a Designated Agency Ethics Official but are not made available to the public.

In addition, a statement directing that agency guidelines address conflict of interest information that should be publicly disclosed seems inconsistent with the direction in Section 4b of the Bulletin which states that the agency-specific guidelines address “any other needs for confidentiality in the peer review process (including any privacy interests of peer reviewers).”

Proposed Changes to Section 4b:

The Bulletin should be revised to remove from Section 4b the statement regarding public disclosure. The preceding direction could be revised to read: “. . . any other needs for confidentiality in the peer review process, *including any privacy interests of the peer reviewers and what, if any, information may be appropriate for public disclosure.*”

- (5) Bulletin needs to more explicitly address potential peer reviewers who might benefit financially from the regulatory decision at stake.

Need to more explicitly address peer reviewers’ financial relationships with the regulated community: On page 4, the document emphasizes the importance of understanding the relationship of reviewers to the Agency, and the specific concerns raised are funding history (i.e., grants) and financial ties. However, the Bulletin is relatively silent with regard to any financial relationships that reviewers might have with the regulated community. We understand that the Bulletin was intended to also address those reviewers who might benefit financially from the regulatory decision at stake (or whose employer might benefit financially from the regulatory decision). These (in)direct financial interests need to be taken into consideration more explicitly to provide balance in the proposal. Declaration of financial interests in the case of regulatory science must include disclosure of financial ties to the agency and to the regulated community (i.e., potential financial gain by the individual or his/her employer from any forthcoming regulatory decision).

Seek overall balanced panel rather than calling for reviewers with contrary bias: In addition, the Bulletin’s articulation of balance - - e.g., bias complemented by “contrary bias” – seems to distort the appropriate objective of seeking a balanced panel. It is unclear how “biases” and “contrary biases” are to be defined so that an Agency can meet this objective. It would be better for the Bulletin to set an overall requirement for a balanced panel rather than explicitly calling for a

reviewer with a contrary bias. An alternative approach for promoting panel balance would be the disclosure of interests and relationships of panelists to the rest of the panel and the public. In addition, the EPA Peer Review Handbook has specific policy procedures that help ensure that biased reviewers are not selected.

Proposed Changes to page 4 and Section 3:

We recommend revising the paragraph on page 4 to reflect the above issues. Additionally, we recommend the following changes to Section 3, subpart “Selection of Peer Reviewers”:

“Factors relevant to whether an individual satisfies these criteria include whether the individual: (i) has any financial interests in the matter at issue; (ii) *stands to gain financially (either directly or through another entity, such as a regulated industry, or from an institution that receives significant financial support from one or more regulated industries) from the regulatory issue at hand*, (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); (iv) *is currently receiving or seeking substantial funding from an entity with interest in the matter at issue, such as the regulated community or other stakeholders in the regulatory process, or from an institution that receives significant financial support from one or more regulated industries*; or (v) has conducted multiple peer reviews for the same agency *or other entity, such as the regulated community or other stakeholders in the regulatory process, or from an institution that receives significant financial support from one or more regulated industries* in recent years, or has conducted a peer review for the same agency *or other entity, such as the regulated community or other stakeholders in the regulatory process, or from an institution that receives significant financial support from one or more regulated industries* on the same specific matter in recent years. If it is necessary to select a reviewer who, *by virtue of these interests or relationships could be considered biased in order to obtain a panel with appropriate expertise, the agency shall disclose the interests or relationships that present the potential for bias to the other members of the peer review panel and to the public.*”

- (6) Bulletin should not discourage use of peer reviews conducted under the Federal Advisory Committee Act (FACA) as long as committee procedures are well-documented, transparent, and establish diverse viewpoints.

Section 4(a), as it currently reads in the Bulletin, seems to favor the use of outside consultants over a FACA panel. FACA panels have many advantages over a contracted firm. They generally provide administrative efficiency and cost containment. Further, FACAs are transparent (i.e., open to the public with documentation available for public inspection). We recommend the following wording change.

Proposed Changes to Section 4(a):

“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~~. Alternatively, it may retain a firm to oversee the peer review process with instructions to comply with principles consistent with those set forth in this Bulletin.”

Compensation of peer reviewers: Although not explicitly addressed, several statements in the draft Bulletin could be interpreted as calling into question the practice of agencies compensating their peer reviewers for their participation in reviews.¹ Being paid by EPA to serve as a "special government employee" to serve on a peer panel should not be construed as "substantial funding" since it is merely compensating the reviewer for the time involved in the review.

Given that peer reviews of major programs or actions often require significant blocks of time from experts, lack of compensation would discourage the participation of some experts and may place agencies in the position of relying on outside organizations which could pay peer reviewers to manage their peer review processes. OMB should consider that some financial relationships between agencies and their peer reviewers actually lead to greater disclosure requirements, increasing the agency's ability to detect possible conflicts of interest and potential independence problems (e.g., Federal advisory committees that hire experts as Special Government Employees).

3. Important Clarifications Needed:

There are three important areas that would benefit from clarification in the Bulletin:

- (1) Need to clarify that the Bulletin does not create rights to judicial review;
- (2) Need to clarify relationship between Bulletin and IQGs;
- (3) Need to redefine effective date.

These are discussed in detail, below.

- (1) Need to clarify that the Bulletin does not create rights to judicial review by adding language similar to that in E.O. 12866.

Although the draft Bulletin is labeled “guidance,” it uses mandatory language and applies to information used in actions such as rulemakings that are subject to judicial review. As such, it

¹For example, in the Background and Request for Comment section, OMB states “it might be thought that scientists employed or funded by an agency could feel pressured to support what they perceive to be the agency’s regulatory position, first in developing the science, and then in peer reviewing it.” The Bulletin similarly raises questions regarding agencies paying outside consultants to manage the peer review process. For example, under Section 4a the Bulletin states “Although such a firm [outside consultant] 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.” Section 3 of the Bulletin discusses financial relationships between reviewers and agencies.

could be viewed as creating new rights for parties to challenge agency actions. To avoid these types of challenges, we recommend adding language similar to the language in E.O. 12866 regarding rights and judicial review.

Proposed Changes (New Section):

Nothing in this Bulletin displaces the agencies' authority or responsibilities, as authorized by law. Nothing in this Bulletin affects any otherwise available judicial review of agency action. This Bulletin is intended only to improve the internal management of the Federal Government and does not create any right or benefit, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, its officers or employees, or any other person.

History of use of similar language: Please note that such language has been effective in limiting judicial review of agency actions when challenged as being inconsistent with the provisions of applicable Executive Orders. See, for example, *Hecht v. Barnhart*, 217 F. Supp. 2d 356, 360-361 (E.D. N.Y. 2002) and *Idaho Mining Ass'n, Inc. v. Browner*, 90 F. Supp. 2d 1078, 1102 (D. Idaho 2000). Please also note that the incorporation of such language is not limited to Presidential Executive Orders; it also appears in OMB Circular A-119, "Federal Participation in the development and Use of Voluntary Consensus Standards and in Conformity Assessment Activities" (63 FR 8546, Feb. 19, 1998) at Section 17: "This Circular is intended to implement Section 12(d) of Public Law 104-113 and to establish policies that will improve the internal management of the Executive Branch. This Circular is not intended to create delay in the administrative process, provide new grounds for judicial review, or create new rights or benefits, substantive or procedural, enforceable at law or equity by a party against the United States, its agencies or instrumentalities, or its officers or employees."

(2) Relationship between the applicability of the proposed Bulletin and existing Information Quality Guidelines issued by agencies is not clear or consistent.

The Bulletin should clarify the relationship between the proposed peer review requirements and the existing IQGs issued by agencies. As written, the proposed requirements could be read as expanding the scope of the IQGs to apply to information generated by third parties (peer review panels) and, in general, information not "disseminated" by EPA (products of peer review panels that are not used by EPA to support a decision, position or viewpoint). Because peer reviews are typically pre-dissemination, they should not be subject to Requests for Correction. The Bulletin also may foster misinterpretations of the original EPA IQGs and, therefore, could require extensive revisions to the IQGs and the existing corrections process. This would impose additional burden on the Agency. We have three areas of concern.

Relationship between the applicability of the Bulletin as proposed and existing Information Quality Guidelines issued by Federal agencies. The scope of the draft Bulletin is too broad and needs clarification with regards to "disseminated" information (defined on pages 15-16 of EPA's IQGs). Since "regulatory information" could include information that has not been "disseminated," this provision may expand the applicability of the IQGs. This issue also arises in

the Bulletin provision regarding charges to peer reviewers. While we understand this was not the intention, that provision can be read to expand the applicability of the IQGs to external peer review panels (i.e., third parties) if these panels are to apply the IQGs to their products.

The next to final sentence under “Peer Review Report” in Section 3, p. 11, of the draft Bulletin, states that agencies “shall disseminate the final peer review report(s).” This, however, should not be read as subjecting such peer review reports to the requirements of the IQGs, and, in particular, the Request for Correction process. By definition, peer reviews are independent work products that cannot be modified by the requesting agency. Please clarify.

Relationship between the IQGs and provision in proposed Bulletin in Section 3 “Charge to Peer Reviewers”: As written, the proposed Bulletin states that peer review panels would need to apply the IQGs to their review (“Charge to Peer Reviewers”). This is inconsistent with the applicability of the EPA and OMB IQGs. Both guidelines apply to “disseminated” information (i.e., information distributed by EPA to represent a view or position of the Agency). Information generated by peer review panels is not by default an Agency product and is not “disseminated” by EPA. Therefore, the EPA IQGs, and other policies for that matter, would not apply to such peer review panels. Should the panel consist of Agency staff and should that panel “disseminate” a report that represents EPA’s view point or position, then the IQGs would apply. It would then be the agency’s responsibility to ensure IQG compliance in the Agency’s use and presentation of that information “disseminated” by EPA.

Provision in Bulletin regarding the rebuttable nature of peer review conducted by a peer review journal: In the EPA IQGs, we state that “objectivity” will be presumed for information that undergoes an external, independent peer review but that the presumption of objectivity is rebuttable through the corrections process. It is unclear what process OMB envisions for those who wish to refute the presumption of “objectivity” for information subject to the Bulletin (broader than information subject to the IQGs)? The current EPA IQG corrections process only applies to “disseminated” information (applicability of IQGs) and would not be the method for refuting the “objectivity” of “regulatory information” which may not have been “disseminated” by the agency. EPA recommends that the rebuttable presumption be expressed through the existing IQGs corrections process or the peer review process for that information, rather than creating a new, separate process. To this effect, the Bulletin should clearly state its applicability only to “disseminated” information by Federal agencies.

- (3) Effective date should be redefined to state the Bulletin applies to peer reviews commenced after a certain date (rather than referring to information dissemination).

Because of the long lead time between peer review of technical support documents and actual dissemination (typically when a regulation is issued) it will be very difficult to meet the effective date requirement currently in the Bulletin.

Agencies should be given two years after the Bulletin is issued in final form to issue supplemental guidance on peer review as required in the current proposed Bulletin. Consequently, a reasonable effective date would be two years after OMB finalizes the Bulletin. At that point, all new peer

reviews that begin after the effective date would need to conform to Agency-specific guidance as well as the final Bulletin on peer review and information quality.

As a separate comment, the effective date provision, as currently written, does not distinguish between information *first* disseminated after January 1 and information continuously disseminated, such as information on a website. At minimum, the term “first” should be added in the first sentence.

Other Issues:

- **Scientific Journal** (Section 2, p. 9)

“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.”

The use of the term “scientific journal” is imprecise and open to a wide interpretation. The definition should be clarified to avoid the implication that an advocacy magazine could be considered an objective scientific journal for peer review purposes. We recommend that this term be changed to “publication in a scientific *and refereed* journal.”

- **Scientific Uncertainties** (Section 3 - Charge to Peer Reviewers, p. 10)

“Where reviewers are expected to identify scientific uncertainties, they should generally be asked to suggest ways to reduce or eliminate those uncertainties.”

This opens the door to delay - there are a large number of inherently uncertain parameters in most technical assessments and there will always be ways to reduce them. Such choices are sometimes policy decisions. The charge should focus on whether the Agency has adequately identified and characterized these uncertainties. Also, imposing this requirement may represent an inappropriate crossing of the line between peer review and involving the peer review panel in the co-authorship of the agency’s work product.

- **Background Information on Controversial Issues** (Section 3 - Information Access, p. 11)

“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.”

OMB should clarify that this refers to credible controversies within the scientific community rather than broad policy debates unrelated to the science. It would often be appropriate to provide such background information through the agency’s charge questions that may seek to resolve sometimes contradictory opinions in the scientific literature.

- **Agency Response to Peer Review Report** (Section 3 – Peer Review Reports, p. 11)

“The agency shall also provide a written response to the peer review report explaining: the agency’s agreement or disagreement with the report, 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; and (if applicable) the reasons the agency believes those actions satisfy any concerns or recommendations expressed by the report.”

We agree that written responses to peer review comments should be part of the overall peer review process, and this is addressed in EPA’s Peer Review Handbook. However, the OMB requirement could carry a more stringent interpretation and constrain agencies’ needs for flexibility in making efficient use of their resources. In some instances it may be more appropriate for the agency to respond jointly to peer review comments for several related documents or methods rather than to each one individually as it is completed. Agencies should be allowed to develop guidance regarding the need for and timing of written responses to peer review recommendations so that they will result in the greatest benefit to the overall peer review process.

- **Add language explicitly incorporating Standards of Conduct for Employees of the Executive Branch on contractors performing peer review** (Section 4(a) – FACA, p. 12)

The OMB guidance explicitly states that the peer review process may be contracted out. Therefore, in order to protect the interests of the public and to ensure ethical standards are of the highest standard, it should be made clear that similar ethical standards will apply to contractors conducting the peer review process as would have applied had the peer review been managed by Federal employees. In accomplishing this, however, modifications to the draft Bulletin should be made consistent with legal and practical limits of Federal procurement law, principles of proper contract management, and the Federal Advisory Committee Act. The Bulletin should make agencies responsible for developing guidance to reconcile these various authorities.

Proposed Changes to Section 4a:

“It is expected that the highest ethical standards will be upheld by any firm hired to oversee the peer review process. Therefore, in order to protect the public’s interest and to prevent issues of conflict of interest or appearance of a lack of impartiality, peer review conducted by an outside firm must be governed by standards that are similar to existing Agency standards for Federal employees and Special Government Employees. However, agency guidance should be consistent with legal and practical limits of Federal procurement law, principles of proper contract management, and the Federal Advisory Committee Act.”

- **Waivers** (Section 4(c), p.12)

The Bulletin describes a process of waivers requiring a compelling case to be presented before the Administrator of OIRA. Such waivers would be necessary even when court-ordered deadlines are a factor affecting the peer review process (68FR178, p. 54026). The impact of the waiver process with regard to time and resources could be considerable.

Proposed Change to Section 4c:

“Within a period commensurate with the stated urgency of the agency’s need, 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, imminent court-ordered deadlines that an agency has taken reasonable time to anticipate, or some other compelling rationale. . . .”

- **Exemptions**

It is unfortunate that the standards in the Bulletin are not intended for application to all government regulatory information, including national defense and foreign affairs. It is understandable that technical information related to national security would be treated differently from other forms of scientific information, but peer review of the merit of technical information or scientific analyses used for regulatory decisions, no matter its source, should not be precluded. If there are other peer review standards or guidelines that do apply to these waived categories, it would be in the Federal Government’s interest to incorporate or reference them in this document.

- **Reports on Agency Peer Reviews** (Section 6, p. 13)

The Bulletin states that agencies shall provide, at least once a year, a list of anticipated peer reviews for existing, ongoing, or contemplated studies and a plan for conducting peer reviews of these studies. EPA’s Science Inventory Database, which contains information on our planned and ongoing peer reviews, is available on the internet at www.epa.gov/si. We will work with OMB to ensure that this satisfies OMB reporting requirements.

The Bulletin should acknowledge that it is often not possible for agencies to predict all the peer review activities that are planned within the next year. Some peer reviews are convened on short notice in response to court orders or other unforeseen circumstances. The Bulletin should clarify that in such cases, the peer review activity would not be delayed because it is not part of the annual report. In addition, planned peer reviews reported in annual reports may be canceled or postponed until the following year due to unforeseen circumstances. The Bulletin should acknowledge such contingencies.

- **References to “administrative record.”**

The Bulletin directs agencies to place various information in the “administrative record.” If the intent is to make this information available to the public, we recommend replacing the term “administrative record” with language referring to “public docket” or making material “available to the public.” This would be similar to the approach in E.O. 12866. “Administrative record” generally refers to the record agencies prepare to support a particular decision in an administrative or judicial action. Although materials related to peer review may often be part of

the administrative record, the materials specified in the draft Bulletin may not be relevant in all cases. Additionally, because the administrative record is not always required to be publicly available, the draft Bulletin would not necessarily result in making the materials available to the public in all cases.

Proposed Changes to Section 3:

Section 3, *Peer Review Reports*: “All of these written materials should be included in the ~~administrative record~~ *public docket* for any related rulemakings.”

Section 3, *Certification*: “...it shall ~~include in the administrative record for that action~~ *make available to the public* a certification explaining how the agency has complied . . .”

Section 8, *Interagency comment*: “OIRA may make such comment public, or direct ~~that it be included in the administrative record~~ *the agency to include it in the public docket* for any related rulemakings.”

- **Correction Requests under the Information Quality Act** (Section 7, p. 13)

“Upon request by OIRA, each agency shall provide a copy of its draft response to any such information quality correction request or appeal at least seven days prior to its intended issuance, and consult with OIRA to ensure the response is consistent with the Information Quality Act, OMB’s government-wide Information Quality Guidelines, and the agency’s own information quality guidelines. The agency shall not issue its response until OIRA has concluded consultation with the agency.”

This open ended review period will make it difficult for the Agency to meet its obligation for timely decisions on information correction requests.

The Bulletin further states: “OIRA may consult with OSTP as appropriate if a request alleges deficiencies in the peer review process.”

This has the potential to result in time consuming procedural challenges over “alleged deficiencies in the peer review process” rather than addressing legitimate challenges to EPA science.

At a minimum, we recommend the following sentence be added to the end of the above paragraph: “*OIRA shall conclude its review and consultation in a period commensurate with the urgency of the topic.*”

- **Interagency Comment** (Section 8, p. 14)

Requests for interagency comments should be limited to reviews involving especially significant regulatory information and applied narrowly. The ability for OIRA to seek interagency comment has the potential to delay actions and place schedules out of the control of the responsible Agency. Including one or two experts from other agencies as members of balanced peer review panels can

be appropriate. Of course, any interagency review process should require agencies that are potentially responsible parties or agencies potentially covered by the regulations under review to make their comments in a public process.

Editorial Remarks:

p. 2, first full paragraph

Omit the word “genuine” (and later, “genuinely”) in this paragraph. Including these words implies that agencies are currently disingenuous in their peer review practices, and it adds nothing to the meaning of the sentence(s). Also, delete the two sentences beginning with “For example, . . .” and ending with “. . . face a similar issue.” They are unnecessary, and they are decidedly vague: “it might be thought” and “could feel pressured” are both suggestive wording. This is one of several places in the document where it is implied that the agency is not always aboveboard when conducting reviews.

p. 3, second paragraph

The evidence supplied in this paragraph regarding the findings of an agency Inspector General (EPA OIG reference) is misleading. It sets EPA up as an example of an agency with insufficient peer review mechanisms. Extensive agency peer review policies and mandates had not been issued at the time of the OIG’s case studies. We suggest editing this sentence to read: “Indeed, for one agency (studied before extensive agency peer review policies and mandates went into effect), the Inspector General found that “[t]he critical science supporting the [agency’s] rules was often not independently peer reviewed. Consequently the quality of some science remains unknown.” Otherwise, this misrepresents current peer review practices and policies at EPA.

p. 3, third paragraph

A statement in this paragraph seems to contradict the proposed guidelines. On page 3, the document reads “Nonetheless, some agencies sometimes use their own employees to do peer reviews . . .” Both the placement of this sentence and use of the word “nonetheless” imply that this is not good practice and that it is misdirected. However, on page 7 and again in Section 2 on p. 9 the guidelines support peer review by qualified specialists within an agency. We recommend editing this paragraph on page 3 to change the negative connotations and make it more consistent with OMB’s own guidelines.

p. 5, second paragraph

Revise: “...the results **of the peer review** are not always available for public scrutiny or comment.”

p. 12, last paragraph

Suggest: “. . . imminent health **or ecological** hazard”