

Record Type: Record

To: Mabel E. Echols OMB\_Peer\_Review/OMB/EOP@EOP

CC:

Subject: Comments of American Chemistry Council on revised peer review bulletin

(See attached file: ACC comments on revised OMB PRB.pdf)

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ACC comments on revised OMB PR...

- ACC comments on revised OMB PRB.pdf



June 1, 2004

Dr. Margo Schwab Office of Information & Regulatory Affairs Office of Management & Budget 725 17th Street, NW New Executive Office Bldg., Room 10201 Washington, D.C. 20503

Re: Revised Information Quality Bulletin on Peer Review

Dear Ms. Schwab:

The American Chemistry Council (ACC or the Council) is pleased to submit these comments on the Office of Management and Budget's "Revised Information Quality Bulletin on Peer Review." The Council represents the leading companies engaged in the business of chemistry.<sup>2</sup>

Because chemistry is a science-based industry, and because of ACC and its members' substantial, ongoing investments in research to support regulatory policy, ACC has long had an interest in improving the quality of government science generally and peer review in particular. For example, ACC was the only business group to comment on the panel formation process now being used by EPA's Science Advisory Board.

<sup>&</sup>lt;sup>1</sup> 69 Fed. Reg. 23230 (April 28, 2004).

<sup>&</sup>lt;sup>2</sup> Council members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. The Council is committed to improved environmental, health and safety performance through Responsible Care<sup>®</sup>, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$460 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for ten cents out of every dollar in U.S. exports. Chemistry companies invest more in research and development than any other business sector.

ACC filed extensive comments on the proposed bulletin, which we believed was long-needed and an important addition to OMB's Information Quality Act Guidelines. The Council commends OMB for its work in responding to the broad range of views reflected in the comments it received on the proposed bulletin. In some respects, the revised bulletin improves on the proposed version. At the same time, the revised bulletin represents a significant retreat, in substance and tone, from the proposed version in terms of its requirements for conducting individual peer reviews and the degree of discretion agencies would have. As a result, we fundamentally question whether the revised bulletin would accomplish OMB's stated purpose: to ensure that predissemination review enhances and maximizes the quality of agency science.

We understand that many of the issues associated with the OMB peer review bulletin will only become clear as the bulletin is implemented, and we look forward to a continuing dialogue with OMB on the subject of peer review once that implementation process begins. Nonetheless, we believe OMB can and should make important changes to the bulletin before it goes final, as discussed below.

# **Executive Summary**

The revised peer review bulletin positively addresses several concerns raised by ACC and others over the draft bulletin:

- It does an excellent job of describing what peer review is, the purposes it serves, how it differs from notice and comment and similar stakeholder processes and, most important, why it is necessary in the federal government.
- ACC supports the better-targeted scope of the bulletin on scientific assessments and, in particular, those that are novel, controversial or (not "and") precedential. Assessments used in permitting or adjudicative proceedings that could have precedential effects in any context should be subject to peer review. OMB should reinstate the \$100 million cutoff for assessments uniformly subject to Section 3.
- The peer review planning provisions, if properly implemented, will improve public awareness and promote dialogue between agencies, the public and OMB.
- The federal ethics rules and the NAS policy are appropriate references for peer reviewer selection. OMB should correct inconsistencies in the discussion of peer reviewer selection and require agencies to consider the NAS policy, not its practices, in this regard. OMB should also recognize when persons with conflicts may still serve as reviewers.
- The disclaimer for assessments being peer-reviewed is an excellent idea. OMB must watch carefully to ensure that agencies do not nonetheless rely on assessments still under review.

On the other hand, ACC is extremely concerned that the revised bulletin defers so completely to the NAS and agency discretion that it likely will not produce better agency science, and indeed may lead to backsliding from current agency peer review practices.

- The bulletin should not contain a generic authorization for agencies not to comply with it.
- In light of the differences between the bulletin's procedures and those of the NAS regarding transparency and public participation, agencies should be required to pay particular attention, in subsequent proceedings relying on NAS-reviewed documents, to comments raising scientific issues.
- OMB should reinstate mandatory public participation for Section 3 reviews.
- Reviewer identities and backgrounds must be disclosed for Section 2 reviews.
- Section 3 peer reviews should be conducted by panels that meet face-to-face at least once.
- Agency staff responsible for an assessment should not be involved in management of its peer review.
- ACC is pleased to see that waivers are really only deferrals. Nonetheless, OMB should reinstate the list of examples of a compelling rationale.

#### **Discussion**

# I. The Revised Peer Review Bulletin Positively Addresses Several Concerns Raised by ACC and Others Over the Draft Bulletin

Our earlier comments commended OMB for issuing the proposed bulletin, both because it promised such a significant step forward in improving federal regulation and information quality, and because overall it proposed a workable process. Nonetheless, ACC and many others in and outside government expressed concern over numerous aspects of the proposed bulletin. To its credit, OMB has listened carefully to those comments and has resolved many of those concerns. The final bulletin should preserve those resolutions.

## A. Purpose and Benefits of Peer Review

Many critics of the proposed bulletin raised fundamental questions about whether it was even necessary, whether it would slow down or impair agencies' ability to regulate or disseminate information, and whether its purpose could be served by notice and comment rulemaking or other existing processes.

The revised bulletin does an excellent job of describing succinctly what peer review is, the purposes it serves, and how it differs from notice and comment and similar stakeholder processes.<sup>3</sup> Even more important, the revised bulletin explains why it is necessary: despite the importance of peer review and the inconsistent ways it was implemented across the federal government, there simply were no government-wide

<sup>&</sup>lt;sup>3</sup> OMB insightfully notes one major reason processes that invite interested parties to comment do not serve the purpose of peer review: because "disinterested experts – especially those most knowledgeable in a field – often do not file public comments with agencies." 69 Fed. Reg. 23231.

standards regarding when it was required or how it was to be conducted. The bulletin also cites ample authority for OMB to issue it, addressing another objection leveled aimed at the proposed version.

## B. More Targeted Scope

ACC and many other commenters were concerned that the proposed bulletin might not apply in cases where it was really warranted. We also recognized, however, that lowering the \$100 million annual impact threshold might cause Section 3 to sweep more broadly than was necessary. OMB has resolved the first concern by its concept of a "scientific assessment" and its targeted focus on assessments that involve novel, controversial or precedential issues. OMB should not have raised the \$100 million threshold, however.

1. Scientific assessments involving novel, controversial or precedential issues

ACC commends OMB for formulating the concept of a "scientific assessment." We believe that such synthetic analyses most trigger the need for review by scientific experts. We also commend OMB for providing that the Section 3 requirements apply not only above a dollar impact threshold, but below that threshold where an assessment involves precedent-setting, novel or complex approaches. This alternative criterion for applicability was suggested by both ACC and the American Bar Association's administrative law section, and ties rigorous peer review to the cases where it is most likely to produce benefit. ACC urges OMB to clarify that these three adjectives apply in the disjunctive (*i.e.*, "or," not "and") so that only one – not all three – needs to be triggered. That is the approach followed by EPA's Peer Review Handbook.<sup>4</sup>

#### 2. Exemption for adjudicative and permitting proceedings

Related to the previous point, ACC is pleased that OMB created an exclusion to the bulletin's exception to the adjudication/permitting exclusion in cases where an issue is novel and may be precedential for future adjudication/permitting decisions. However, ACC recommends that OMB expand that exclusion to apply whenever a scientific assessment used in a permitting or adjudicative proceeding could have precedential effects, period -- whether in other permitting or adjudicative proceedings or more broadly. We believe such circumstances will frequently arise, and the exclusion is unclear about what should happen in these cases.

We also ask OMB to clarify that agencies are required to list, in their peer review agendas, permitting or adjudicative proceedings that could have precedential effects, so

<sup>&</sup>lt;sup>4</sup> See EPA Science Policy Council, *Peer Review Handbook* (EPA-100-B-00-001) (Dec. 2000) at 26 ("one or more of the following criteria").

that interested parties could contact the agencies or OMB in cases where they believed a scientific assessment associated with such a proceeding (i) was novel and precedential and yet (ii) was not proposed to be peer reviewed pursuant to the bulletin.

# 3. The revised \$500 million/year cutoff is too high

OMB originally proposed that the more rigorous Section 3 procedures would apply to assessments that could have a clear and substantial impact on public policies or private sector decisions with a potential effect of more than \$100 million in any one year. OMB has now proposed to raise that threshold to \$500 million. ACC strongly believes that this figure is too high. By OMB's own report, there were only two such agency actions in FY03. The \$100 million cutoff is a better proxy for agency actions warranting the more demanding procedures of Section 3. It is also consistent with Executive Order 12866. ACC calls on OMB to reinstate the lower figure.

## C. Peer Review Planning

ACC believes OMB has done a particularly good job with this section of the revised bulletin. The requirement that agencies post on their web sites for comment, updated at least every six months at least, a list of *all* documents that they plan to peer review in the foreseeable future, will go a long way toward forcing agencies to grapple with bulletin's applicability. It will also give interested parties as much advance notice as possible to develop comments and otherwise will promote maximally useful dialogue between agencies and interested parties regarding what will be peer reviewed and how.

### D. Selection of Peer Reviewers

This set of issues was probably the most controversial raised by the proposed bulletin, although ACC believes much of that controversy was based on misunderstandings of OMB's intent. ACC generally supports the approach described in the revised bulletin, although as explained below a number of adjustments need to be made for internal consistency and to make the bulletin more effective. Also, the bulletin should provide greater clarity regarding the significance of conflicts.

## 1. The role of federal ethics rules and the NAS policy

The preamble's section on "Selection of Reviewers" does a good job of explaining the issues of expertise, balance, independence and conflicts. The preamble also correctly references the applicable federal ethics rules. Clearly, agencies must apply the federal conflict of interest rules where those rules apply. The rules are also a good model for agencies to use where they are not strictly applicable.

ACC also believes that the National Academies' current "Policy on Committee Composition and Balance and Conflicts of Interest," cited in the revised bulletin, is a useful and appropriate statement of these issues, as it:

- Emphasizes that knowledge, training and experience are the foremost considerations, and that no one should be appointed to a panel to represent a particular point of view or special interest;
- Helpfully clarifies that, "[f]or some studies . . . it may be important to have an 'industrial' perspective or an 'environmental' perspective," not because these "sides" need to be represented, but 'because such individuals, through their particular knowledge and experience, are often vital to achieving an informed, comprehensive, and authoritative understanding and analysis of the specific problems and potential solutions to be considered by the committee."
- Explains that biases should not be disqualifying -- even where a person works for a company with "a general business interest in" the subject of the panel -- unless the person "is totally committed to a particular point of view and unwilling, or reasonably perceived to be unwilling, to consider other perspectives or relevant evidence to the contrary."
- Notes that "conflict of interest" ordinarily refers to "financial interests," and that these can arise from any quarter, including regulated entities, the government and nonprofit entities (e.g., NGOs). 10
- Recognizes an exception to this rule: a "significant, directly related interest or duty of [an] individual -- e.g., where the individual is currently president of a professional society that espouses the same fixed position on the issue" -- could become a conflict of interest.<sup>11</sup>

On the other hand, our experience with the NAS is that it does not always follow its own policy. In our experience, it has sometimes barred participation by individuals associated with business groups and ignored much greater financial ties to sponsoring agencies. Moreover, its practice has been not to disclose sufficient information about panelists to enable independent evaluation of its conformity to its own policy. Thus, it is crucial that OMB refer consistently to the NAS policy and not NAS practices. This concern is

<sup>6</sup> 69 Fed. Reg. 23235 n. 24.

<sup>&</sup>lt;sup>5</sup> (May 12, 2003).

<sup>&</sup>lt;sup>7</sup> NAS policy at 2-3.

<sup>&</sup>lt;sup>8</sup> *Id*. at 3.

<sup>&</sup>lt;sup>9</sup> *Id*. at 3-4.

<sup>&</sup>lt;sup>10</sup> *Id*. at 4-5.

<sup>&</sup>lt;sup>11</sup> *Id.* at 5-6.

heightened by the bulletin's deference to NAS in terms of peer review adequacy, discussed below.

The bulletin is also internally inconsistent in several respects having to do with reviewer selection:

- Section 2 only discusses "conflicts," not expertise, balance or independence.
- While Section 3 discusses all four of those issues, it only references the NAS policy in connection with independence and conflicts.
- Sections 2 and 3 instruct agencies to "consider" the NAS policy, while the preamble tells them "to adopt or adapt the prevailing practices of the NAS." The NAS's current practices are a concern, as just noted. Moreover, while the policy is easily ascertainable, "current practices" are less so.
- Section 2 only instructs agencies to examine potential reviewers' ties to regulated entities and the sponsoring agency, not other interested organizations.

ACC strongly recommends that OMB redraft the preamble and the text of the bulletin itself so that:

- Both Sections 2 and 3 discuss the four issues of expertise, balance, independence and conflict of interest.
- In both cases, the bulletin states that, in addition to following federal ethics rules in the cases of federal and special government employees, agencies "shall" adopt or adapt those rules for other reviewers and shall "consider" the NAS policy -- as a whole -- with respect to all four issues.
- Section 2.4 states that "a reviewer's financial ties to regulated entities (e.g., businesses), other interested organizations or the agency should be examined."

As discussed below, ACC believes agencies should supplement or amend their own IQA guidelines to implement this bulletin, as OMB initially proposed. If the final bulletin does not reinstate this requirement, it should at least require agencies to publish on their websites their adoption or adaptation of the federal ethics requirements for persons not technically subject to them. Agencies should also be required to document their adherence to the federal ethics rules and the NAS policy.

#### 2. Conflicts

As noted above, the federal ethics rules and the NAS policy both define "conflicts of interest" ordinarily to refer to financial interests, and the NAS policy notes that it is not a conflict for a panel member's employer to have a "general business interest" in the subject of the panel. The federal ethics rules provide a clear exclusion, moreover, in cases of conflicts involving special government employees (like federal agency peer

review panelists). Under this exclusion, the government official responsible for the appointment may, after disclosure by the prospective panelist, issue a waiver certifying that "the need for the individual's services outweighs the potential for a conflict of interest created by the financial interest involved." As participants in the September 4, 2003 NAS workshop on the proposed bulletin explained, there may be issues where many if not all the leading experts have conflicts. OMB should clarify that agencies should not be unwilling to issue such a waiver where the result will be to provide the best possible scientific input.

# E. IQA Disclaimer

ACC and other commenters had been seriously concerned that, while peer review is part of "predissemination review" under the IQA, as a practical matter documents being peer reviewed would be publicly disseminated and could remain under review, or at least not finalized, for an indefinite period of time. ACC is therefore extremely pleased by OMB's requirement that agencies may avoid application of the IQA correction mechanism to documents undergoing peer review only if they use the disclaimer set out in the definition of "dissemination." ACC also support's OMB's recommendation that agencies discourage state, local, international and private organizations from using documents undergoing peer review.

ACC does recommend that the disclaimer language be revised by adding at the end "-- in final or any other form." This addition is needed to ensure that agencies to do not rely on to assessments being peer reviewed by calling them "draft" or "proposed" or "interim" positions of the agency.

ACC also urges OMB to carefully police agencies' compliance with the disclaimer language – i.e., to ensure that agencies do not, in fact, begin to rely on such documents or represent them as agency policy until the peer review process is concluded (including the agency's issuance of its response to the peer review report and its conduct of any actions promised in that response).

To avert these kinds of problems, the final bulletin should also caution against openended peer reviews and make general recommendations about what are appropriate lengths of time for a peer review to be conducted and concluded.

<sup>&</sup>lt;sup>12</sup> See 5 C.F.R. Part 2635, Subpart D, esp. § 2635.402.

<sup>&</sup>lt;sup>13</sup> See transcript (available at http://www7.nationalacademies.org/stl/Peer\_Review\_Transcript.pdf) at 201 ("[E]very single beryllium disease expert in this country works either full time or as a consultant for DOE, the beryllium industry or, in many cases, both.") (statement of David Michaels). See also id. at 183 (James Mahoney), 188-89 (James Schaub).

# II. Remaining and New Concerns with the Revised Bulletin

# A. Escape Clause and Deference to the NAS

# 1. Escape clause

The first sentence of Section II.2 simply states that, "[t]o be considered 'adequate' . . . a peer review need not comply with all of the requirements of this bulletin." ACC is gravely concerned about this sentence, which is essentially a green light to agencies to ignore the requirements of the bulletin. ACC can see no justification for this escape clause standing alone. In conjunction with the all the other places in which the bulletin gives agencies discretion, the cumulative effect is likely to be agencies continuing current practices without change -- or worse, backsliding from current practices.

It may be that OMB intended this sentence only to be an introduction to the succeeding two sentences, regarding prior peer reviews and NAS peer reviews. If so, OMB should delete or revise it to make that clear.

#### 2. Deference to NAS reviews

The third sentence of Section II.2 states that, for purposes of both Section 2 and 3 peer reviews, principal findings, conclusions and recommendations of official reports of the NAS are generally presumed to be adequately peer reviewed. ACC highly esteems the work of this organization, on whose boards and committees several of our most distinguished staff and member personnel have served.

ACC is also aware that Congress in 1997 exempted committees formed by the NAS from the Federal Advisory Committee Act, instead requiring the NAS to follow less demanding requirements spelled out in a special section of that statute. This enactment overruled a federal court decision applying FACA to NAS committees, and was enacted without significant debate.

In light of that history, ACC understands that OMB may be reluctant to require agencies to conduct additional peer reviews, meeting the bulletin's requirements, of NAS-reviewed assessments. However, since the NAS procedures do not track those required by the bulletin, ACC urges OMB to require agencies relying on NAS-reviewed assessments in subsequent proceedings to be particularly attentive to public comments raising scientific issues.

<sup>15</sup> 5 U.S.C. App. 2, §§ 3(2)(C)(ii), 15.

<sup>&</sup>lt;sup>14</sup> 69 Fed. Reg. 23240.

<sup>&</sup>lt;sup>16</sup> American Bar Association Section of Administrative Law & Regulatory Practice, *Federal Administrative Procedure Sourcebook* 412 (3d. ed. 2000).

#### 3. Regulatory Impact/Flexibility Analyses

ACC does not support the new -- and unexplained -- exclusion of RIAs and RFAs from the bulletin. In ACC's experience, such documents typically do not contain influential scientific assessments. To the extent one did, however, it should be subject to the bulletin.

#### B. Excessive Authorization of Agency Discretion

ACC's is extremely concerned by the many other ways the revised bulletin has rolled back many of the proposed "shalls" affecting peer review management to "shoulds." In other cases that the proposal did not explicitly address, the revised bulletin has resolved the uncertainty in ways that leave such discretion with agencies that the resulting peer reviews very likely will fail to produce the benefits OMB is seeking.

#### 1. Reduced public participation for Section 3 reviews.

The proposed bulletin required that agencies in all cases provide the public and other agencies with the opportunity to comment, presumably on the charge and the document being reviewed, early enough that these comments could be provided to panelists with ample time for consideration before the reviewers prepared their report. <sup>17</sup> The revised bulletin drops this requirement without explanation. Indeed, it seems to recognize that agencies normally will not involve the public in the conduct of peer reviews, stating in the preamble that "[a]gencies may decide that peer review should precede an opportunity for public comment," and in the bulletin itself that, "[i]f an agency decides to make a draft assessment available publicly available at the same time it is submitted for peer review (or during the peer review process) . . . . "19 And a public comment period would only be held "[w]hen there is sufficient public interest." 20

ACC strongly believes that OMB's proposed approach was the right one. The public and other agencies should always receive the charge and the assessment in advance of the review panel's meeting, so that they can provide comments that the reviewers can factor into their deliberations. This sort of transparency is entirely feasible – it is the rule with EPA's Science Advisory Board, for example. It will maximize the quality of the reviewers' work in the same way that notice and comment improves the quality of agency rulemakings. Conversely, the approach of the revised bulletin would authorize agencies to roll back current public participation practices. It is difficult to imagine how expanded peer review with diminished public participation will be procedurally credible.

<sup>&</sup>lt;sup>17</sup> 68 Fed. Reg. 54028 (Sept. 15, 2003).

<sup>&</sup>lt;sup>18</sup> 69 Fed. Reg. 23236.

<sup>&</sup>lt;sup>19</sup> *Id.* at 23241 (emphasis added).

<sup>&</sup>lt;sup>20</sup> *Id*.

The preamble says that peer reviews that take place before an opportunity for public comment will "ensure that the public receives the most scientifically strong product (rather than one that may change substantially as a result of peer reviewer suggestions)." ACC believes this notion is illusory. First, such "secret" peer reviews will only raise suspicions that the agency is trying to whitewash its work product, to wrap it in the protective coating of a peer review to deflect subsequent criticisms. The doubts that would be sowed by such an approach will more than cancel out whatever improvement in quality the document gains by having been peer reviewed before release. Second, ACC believes the document would be even more improved it the peer reviewers had the benefit of public comment on the document before they met and prepared their report. Agencies should be less concerned with the quality of the document when it is first provided to the public and more concerned about the ultimate quality of the finished product. Indeed, agency concern with quality at initial release may mask an actual intent to "resolve" all scientific issues prior to peer review.

Agencies could use their peer review agendas to test the hypothesis that there will be no public interest in commenting on a document, but ACC believes that these occasions will be few.

# 2. Disclosure of reviewer identities and backgrounds

The revised bulletin indicates that, in Section 2 peer reviews, the agency need not ever disclose the names and backgrounds of the peer reviewers. Indeed, it begins its discussion of this issue by noting that journal reviews "most common[ly]" do not disclose the identity of reviewers, adding that in the case of agency reviews "such confidentiality may not always add to the credibility of the review process.<sup>23</sup>

ACC submits that, in the case of governmental peer review, concealing the names of the reviewers is certain to undermine the credibility of the review.<sup>24</sup> Agency peer reviews serve a public function that renders them fundamentally different than journal reviews.

<sup>24</sup> See BEN model discussion in footnote 22.

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<sup>&</sup>lt;sup>21</sup> *Id.* at 23236. The bulletin also says that letter reviews may be better "where premature disclosure of a sensitive report to a public panel could cause harm to government or private interests." *Id.* at 23234. ACC doubts that such reports exist, except perhaps in the national security area.

<sup>&</sup>lt;sup>22</sup> A cautionary example in this connection is EPA's difficult experience in those cases where it attempted to conduct secret peer reviews. For example, in 1988 and 1991 EPA conducted closed peer reviews of the "BEN" model that it uses to estimate the economic benefit of noncompliance. Interested parties representing virtually the entire spectrum of regulated entities sought repeatedly to obtain the peer reviewers' reports and associated documents, culminating in a FOIA lawsuit that EPA litigated for years before ultimately settling by disclosing the relevant materials. *Washington Legal Foundation v. EPA*, No. 93-1202 (filed Aug. 13, 1993). In the meantime, however, the agency was repeatedly charged with concealing potentially critical documents. *See* Comments of Bob Fuhrman at EPA Public Hearing on Recovery of Economic Benefit, Washington, D.C. (Nov. 6, 1996) ("EPA has not been willing to disclose the expert advice it received. . . . [I]t is our understanding that these experts were highly critical of BEN. . . . . Why has the Agency not committed itself to an open process . . . ?").

<sup>&</sup>lt;sup>23</sup> 69 Fed. Reg. 23236 (emphasis added).

This may make it comparatively more difficult to recruit reviewers, but that is an inevitable consequence of the difference.

ACC is less concerned about whether statements by particular reviewers are attributed to them in the reviewers' report; this kind of anonymity could substantially alleviate the concerns of potential reviewers.

# 3. Use of panels and face-to-face meetings

The revised bulletin has helpful language about panels of reviewers being "preferable" when time and resources warrant, and talks about more complex processes being appropriate for more complicated and important documents. ACC is concerned, however, that such fuzzy preamble language will not necessarily assure that any agency will conduct a panel review, much less a more complex process, in any given case — especially when the bulletin itself says nothing on the topic. ACC believes it would not be very burdensome on agencies to require that all Section 3 peer reviews be conducted by panels, and that such panels include at least one face-to-face meeting. Again, EPA's Science Advisory Board has successfully operated in this fashion.

# 4. Role of agency staff

In our comments on the proposed bulletin, ACC emphasized that the agency staff person(s) in charge of developing the document being reviewed should not be able to choose the reviewers, make other important decisions regarding the peer review, or write the peer reviewers' report. The revised bulletin does not address any of these topics. We urge OMB to address them in the final bulletin.

# C. The Revised Bulletin's Waiver/Deferral Concept Is too Open-Ended

ACC commented that the proposed bulletin was too generous regarding the opportunity of agencies to waive or defer its requirements. Unfortunately, the revised bulletin is even more generous, allowing an agency to at least defer those requirements for any "compelling rationale." This is loophole is entirely too vague. The proposed bulletin at least provided a list of example rationales: "an emergency, imminent health hazard, homeland security threat." OMB should reinstate the list.

ACC does appreciate OMB's proviso that, where an agency waives peer review before disseminating a document, that review should be conducted as soon as practicable thereafter. OMB should clarify that, in effect, what this means is that agencies can only defer the bulletin's requirements – it can never waive them altogether.

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<sup>&</sup>lt;sup>25</sup> *Id.* at 23234.

# D. Agency Peer Review Guidelines

The proposed bulletin explained that, since it was being issued in primary reliance on OMB's IQA authority, and the IQA requires agencies to publish their own versions of OMB's guidelines, OMB was therefore requiring agencies to supplement or amend their IQA guidelines to implement the bulletin.<sup>26</sup> Curiously, the revised bulletin drops this requirement without explanation. ACC thinks the proposed approach makes sense as a matter of law. We also think it makes practical sense as a practical matter, as it would result in agencies clearly articulating, as only a few agencies (like EPA) have done, exactly what their peer review policies and procedures are. As noted earlier, the revised bulletin requires agencies to adopt or adapt the federal ethics rules where they do not literally apply and to consider the NAS policy on peer reviewer selection. It would seem wise for agencies to do so as part of their own peer review guidelines.

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Once again, ACC appreciates the opportunity to submit these comments. If you have any questions, please contact the undersigned at 703-741-5166.

Sincerely,

James W. Conrad, Jr. Assistant General Counsel

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<sup>&</sup>lt;sup>26</sup> 68 Fed. Reg. 54028.