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Subject: General Electric's comments on revised Bulletin on peer review

Please see below for the text of the General Electric Company's comments on OMB's Revised Information Quality Bulletin For Peer Review, which was released to the public on April 15, 2004. GE's comments also are attached to this message as a separate document.

<<General Electric Company's comments 04.05.14.DOC>>



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**The General Electric Company's Comments on
OMB Revised Information Quality
Bulletin For Peer Review (April 15, 2004)**

May 14, 2004

The General Electric Company (GE) welcomes this opportunity to comment on OMB's Revised Information Quality Bulletin for Peer Review. GE is pleased that OMB retained the core concepts contained in OMB's first draft bulletin, and has in important respects built upon them in this revision.

The revised Bulletin addresses directly the core concerns addressed in the first draft, i.e., the need for more careful, independent peer review of documents containing influential scientific information (I.4), scientific assessments (I.6), and scientific information (I.7). The new Preamble clearly explains what peer review is, and the useful purposes that independent peer review serves. The several provisions for peer review of documents involving precedent-setting, technically novel, and complex documents, regardless of cost or categorized thresholds, are especially welcome (II.2, III.1.(ii), and VIII.3). The definitions of scientific assessments and information further stress this key aspect of federal science policy, especially the importance of peer review of documents analyzing scientific uncertainty (I.6, 7).

Our main concern with the revised Bulletin is that by simplifying the Bulletin and according the agencies more flexibility in its implementation, OMB may have unintentionally created opportunities for agencies to dilute the Bulletin's requirements or evade them entirely. As discussed more fully below, OMB should monitor the agencies' implementation of the Bulletin to ensure that that does not occur.

The new draft (I.3) excludes from the term "dissemination" documents that are distributed for peer review, "provided that the distributing agency includes a clear disclaimer" on a document to the effect that it is not final, and should not be construed to represent an agency decision or policy. This is a useful addition, but appears to leave it to the agencies to decide whether to include the disclaimer, and does not go far enough. Since documents undergoing

peer review are drafts, OMB should *require* agencies to include the disclaimer referenced above on all documents that are distributed for peer review. For the same reason, OMB should require agencies to note on all draft science documents that they should not be cited, quoted, or relied on in any way in federal regulations, individual determinations, or policy making. Any document short of final – especially documents that are subject to change as a result of peer review -- should not be used in whole or part to support federal decisionmaking.

Peer Review Planning: the heart of a workable peer review process. In our view, the more detailed and welcome requirements of Peer Review Planning (V) will go a long way toward ensuring that the Bulletin succeeds in ensuring more uniform, independent, and government-wide scientific and technical peer review in the federal agencies. Stakeholders can monitor the Peer Review Agenda (V.1) that agencies will be required to post at least twice yearly, comment on the agencies proposed peer review plans (V.2. a through d), and participate in the various opportunities for stakeholder input contemplated throughout the Bulletin.

The planning process gives agencies the opportunity to tailor peer review to the unique features of the particular document entered in an agency’s semi-annual agenda. The planning requirements are a reasonable response to some commenters’ criticism that the first draft Bulletin took a “one-size-fits-all” approach. The specificity of the planning requirements is welcome. Stakeholders will be put on notice and will be able to suggest more (or less) peer review, to request to be allowed to nominate reviewers, to request an opportunity to comment on the document under review, to seek an oral public presentation to the peer reviewers in open meetings, to urge agencies to provide “evergreen” list-serve-based updates of peer review information, and to seek agency responses to stakeholder suggestions and inputs.

The Bulletin's transparency requirements go hand-in-hand with the planning process of Section V. To stress: we believe it is important that both stakeholders and OMB ensure that all transparency requirements are fully met. Specifically, the revised Bulletin requires that:

- A detailed summary or copy of the peer reviewers' comments be made available to the public and included in the administrative record for all related agency actions;
- A public comment period for the document under review be considered, and reviewers be provided with any public comments on the document to be peer reviewed (III.3);
- The names, organizational affiliations, and credentials of peer reviewers be disclosed;
- Individual reviewers' views and identities be disclosed if provided for in advance;
- Agencies provide detailed responses to the peer review, and post those responses on the agency's website, together with the peer review(s); and
- All relevant peer review materials (charge, report, agency response, background material) be included in the administrative record for any related agency action.

OMB and OSTP oversight role. Perhaps the most striking aspect of the revised Bulletin is (i) its increased reliance on agencies to implement its less-prescriptive requirements and (ii) the reduced oversight role of the OMB and OSTP. Perhaps the greatly expanded specificity and public comment mechanism for Peer Review Planning will help ensure fuller agency compliance in the absence of an explicit OMB and OSTP oversight role. At present, however, the only two explicit OMB roles are (1) to organize an inter-agency group to meet “periodically” and “foster better understanding” about peer review practices and “assess progress” under the Bulletin (IX), and (2) for the Administrator to approve alternative peer review mechanisms in the event National Academies review does not occur (IV (iii)).

To ensure that agencies fully implement the Bulletin, OMB should (1) actively monitor the agencies' agendas and (2) establish consultative mechanisms under which OMB would

comment on the desirability of inclusion of additional agency documents by applicable category into the Bulletin process. These steps would best be accomplished by including in the Bulletin (1) a specific new provision for annual review by OMB of each agency's implementation of the Bulletin; (2) a requirement that each agency disseminate after OMB approval new or, as appropriate, revised peer review guidance, tailoring the Bulletin's requirements to the specific document categories relevant to each agency; and (3) a requirement that each relevant agency designate a peer review coordinator and liaison to guide these functions and serve as the agency's representative to the inter-agency peer review group called for in Part IX. Finally, to mesh the new Bulletin process with the Information Quality Act's requirement for an annual report on progress implementing the Law, OMB should add to that report a section on progress and problems in implementing the Bulletin.

The revised Bulletin allows agencies to determine when prior peer review can be deemed "adequate," without need for review under the Bulletin (II.1). Here, clearly some OMB and OSTP supervision is warranted. Partial peer reviews, i.e., reviews of some but not all of the issues that are susceptible of review under the thoroughgoing requirements of the revised Bulletin, should not be allowed to pass muster. The OMB should clarify that any peer reviews that an agency proposes as "adequate" should be described in detail in compliance with part V of the revised Bulletin.

The Bulletin should acknowledge more explicitly the role the public can play in ensuring that peer review, once set in motion through advance notice in the agency's peer review agenda (V.1), is carried forward to a strong, useful conclusion. While OMB acknowledges the public's role in the Bulletin's peer review process, the Bulletin's specific requirements for public involvement are not as strong as they could be. For example, the Bulletin does not require

agencies to provide the full text of public comments to the peer reviewers, but instead allows the agencies to provide only summaries of public comments to peer reviewers, thereby allowing agencies to filter the public comments. Peer review cannot be truly independent if the peer reviewers are provided only the agencies' view of the science to be reviewed. Thus, the Bulletin should mandate that the full text of any public comments be provided to peer reviewers. Similarly, the Bulletin does not require agencies to publish the actual charge to the peer reviewers, but instead allows agencies to publish only a statement of the proposed scope of the review. To ensure that the charge is not slanted in favor of any particular outcome, the complete charge should be added to the agenda as soon as available. These enhancements to the public participation provisions of the Bulletin can only serve to bolster stakeholder confidence that the peer review will be objective and thorough.

As a final comment on implementation and oversight, we note that the Bulletin requires that all documentation for peer review and agency response be placed in the administrative record of any agency regulation, decision, or policy. That requirement will ensure that any court reviewing the agency action will have the full benefit of the critical views of independent extramural scientists and engineers, and the agency's rationale for accepting or rejecting them. The peer review record thus provided might prove to be the single most valuable component of a court's decision when it reviews agency decisionmaking.

Clarifying and narrowing exemptions. We believe that the exemption for "information that is...disseminated in the course of an individual agency adjudication or permit proceeding..." is overly broad, and may open a wide path for agencies to avoid applying the Bulletin to several types of science documents that historically are among the federal documents most in need of independent peer review. The draft Bulletin lists "adjudication," "permit proceeding,"

“registration,” “approval,” “licensing,” and “site-specific determination” as types of “individual” proceedings excluded from the reach of the Bulletin (VIII.3). Perhaps realizing that its list is overbroad, OMB states that in any such “individual” proceeding, the Bulletin will apply if the agency determines “that the influential dissemination is scientifically or technically novel and likely to have precedent-setting influence on future...[such] proceedings” (*Id.*).

A useful distinction exists between federal documents, the basic purpose of which is to apply law or regulation to a named party (permits, licenses, orders, entitlements, registrations), and the influential scientific information and assessments that lay the analytic foundation for such documents. To the maximum extent possible, *antecedent* scientific information and assessments should be subjected to peer review under the Bulletin. Otherwise, OMB’s proposed language might be read to exempt from peer review a significant amount of scientific information of the type that would benefit the most from peer review. We do not believe that this was OMB’s intent. We believe that OMB’s core concern was to exempt agency documents that define the rights, duties, and entitlements of “individual” persons or entities. OMB explicitly acknowledges that the Bulletin covers “original data and analytic models used by agencies” in RIAs (Preamble, p. 27). Similarly, the risk assessments used by EPA in the remedial investigations/feasibility studies (RI/FS) that are used to prepare Records of Decisions (RODs) and cleanup orders, and the environmental impact statements (EISes) used in authorizing major federal actions, should all be subject to the Bulletin, as the following discussion develops for each.

Superfund RI/FSes should not be exempted. RI/FSes prepared by EPA or private parties under EPA supervision pursuant to the National Contingency Plan (NCP) under the Comprehensive Emergency Response Compensation and Liability Act (CERCLA) should not be

exempted from the Bulletin. RI/FSes are science and technology-based documents that the EPA uses to support actions the EPA specifies that individual parties must take to remediate NPL sites. The RI/FS is also an excellent example of the type of document that may involve issues that are “scientifically or technically novel” and may very well “have precedent-setting influence on future...proceedings” that would benefit from early, independent external peer review.

Nevertheless, the Preamble to the Bulletin indicates that “site-specific” disseminations made under Superfund are not covered by the Bulletin (p. 26). We urge in the strongest possible terms that such Superfund disseminations not be construed to cover RI/FSes. Rather, we believe that what OMB had in mind were the Records of Decisions (RODs) and entity-specific “individual” orders which EPA prepares subsequent to completion of RI/FSes for specific waste sites. EPA uses the scientific and technical RI/FSes in such quasi-regulatory and enforcement documents directed to particular named parties.

Here, the critical difference is between the “individual” named parties whose obligations are defined in RODs and enforcement documents (consent decrees, administrative orders) and the “site-specific” RI/FS which defines no party’s specific obligations but does apply a welter of scientific and technical models, techniques, and default assumptions to a collection of data, all of which have long been identified as needing close, independent scientific scrutiny, i.e., peer review.

NEPA EISes and EAs should not be exempted. The Environmental Impact Statements (EISes) and Environmental Analyses (EAs) prepared by federal agencies under the National Environmental Policy Act (NEPA) are technical and scientific documents used by federal agencies to support decisions they make pursuant to federal authority. Specifically, most agencies use records of decisions (RODs), as EPA does with Superfund, to select their preferred

alternative course of action after an EIS is prepared, and RODs or findings of no significant impact (FONSI) after an EA is prepared. As science documents, agency EISes and EAs leave a great deal to be desired. Yet the Preamble indicates they are not covered by the proposed Bulletin. Interestingly, not all NEPA documents are “site-specific”; they may analyze the environmental impacts of entire federal programs, impacts on entire geographic regions, or other broad categories of environmental impacts as determined by the agencies preparing them. Certainly, they are not directed at specific “individual” authorizations, as apparently contemplated by the draft Bulletin, but rather at broad federal actions, some of which involve multiple agencies.

Requiring agencies to identify scientific information destined for use in “individual” proceedings. The Bulletin accords flexibility to agencies to tailor the Bulletin to their unique needs. With regards to categorical exemptions, OMB must be careful not to create broad loopholes through which agencies may evade the Bulletin’s requirements by packing important and influential scientific and technical methods and analyses into a vague and accommodating exemption for “individual” information. Consequently, OMB should require the agencies to develop more specific peer review policies under the Bulletin for scientific and technical information destined for use in individual proceedings, lest the agencies be tempted to bypass the Bulletin’s requirements. OMB’s exemption proceeds on the premise that agencies’ case-by-case individual determinations are numerous (workload) and of little policy consequence (fact-specific, limited to the affected party(ies)); however, in a country whose common law was built case-by-case, and whose federal agencies may still make administrative law in the same way, science-rich precedents deserve close scrutiny. Federal health risk assessment was created in no small part through “individual” food additive decisions by the FDA, and “individual” pesticide

registrations and cancellation proceedings in the late 1960s and early 1970s by EPA and its predecessor agency.

The \$500 million threshold. In the earlier draft Bulletin, the threshold for heightened peer review of highly significant regulatory information was \$100 million. The revised Bulletin proposes to raise the threshold for peer review of “highly influential scientific assessments” to \$500 million. OMB estimates “about one or two dozen” highly influential assessments would be peer reviewed in a given year (OMB response to public comments, pp. 13-14). It would be interesting to know how many are likely to be added were the threshold re-set at \$100 million. Our sense is that the marginal increase would be more than repaid by the marginal utility of lowering the threshold to its original level. Although \$100 million might not be a significant sum for the federal government, it is for the regulated community, and documents that are likely to have such an impact warrant careful peer review. If, as the Bulletin is implemented, OMB finds that the \$100 million threshold is resulting in more peer reviews than agencies can reasonably be expected to handle, OMB can increase the threshold.

National Academies and inter-agency peer review. Deferral to the National Academies’ studies as adequate peer review is appropriate (IV.(i), (ii)). Presumably, any other alternative arrangement approved by OIRA and OSTP (IV.(iii)) can include inter-agency peer reviews as specifically contemplated in the first draft Bulletin. Highly influential scientific assessments of “significant inter-agency interest” (III.1.(ii)) may warrant formation of such an interagency peer review working group.

Vigorous stakeholder involvement in the Bulletin’s planning process is all the more important in view of the circumscribed oversight role the OMB and OSTP contemplate under the

briefed, more flexible revised Bulletin. It appears that the revised Bulletin, if finalized, will be largely “self-executing,” i.e., stakeholders will play the leading role, not the OMB.

Scientific and technical information. This may at first appear to be a minor editing suggestion, but we believe that OMB’s intent would be more clearly and accurately conveyed if the key definitions in the Bulletin were changed to read “influential scientific and technical information,” “scientific and technical assessment,” and “scientific and technical information.” Corresponding changes should then be made throughout the Bulletin.

Earth sciences, engineering, and the physical sciences come within the Bulletin’s scope. Even risk assessments are more technical than scientific, e.g., if dam safety, public works projects, or structural strength is involved. Elsewhere, OMB refers to disseminations that are “scientifically or technically novel,” which better captures OMB’s intent (VIII.3).

Respectfully submitted,

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