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Comments on OMB Proposed Guidelines for Peer Review

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Comments on OMB Proposed Guidelines for Peer Review

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I am submitting these comments as an individual, rather than on behalf of NorthWorks, Inc., any
client of NorthWorks, Inc., or Stanford University.

1. **Summary:** The OMB Statement of Proposed Guidelines for Federal Agency Peer Review is a welcome addition and clarification to existing federal policy and federal agency practice. There are a number of federal agencies that do not make sufficient use of outside scientific peer review. Further, even agencies such as the US Environmental Protection Agency (USEPA) with a good tradition of outside peer review have not used it for regulatory impact analysis (RIA). Both the scientific basis for regulatory decision making and the credibility of federal agencies will be enhanced by the new OMB guidelines on scientific peer review. **I therefore urge that, with appropriate enhancements and refinements, these guidelines for peer review be promulgated in final form.** The comments below are intended to help OMB in making appropriate enhancements and refinements for the final version of these guidelines.
2. **OMB might wish to add to its bulleted list on page 2 of important references the National Research Council Report, "Risk Assessment in the Federal Government: Managing the Process," National Academy Press, 1983.** This report recommended peer review of agency risk assessments by an independent science advisory panel. Such peer review should be in the form of "written evaluations," "available for public inspection." (Recommendation #3, page 156.) Risk assessments support regulatory decisions on toxic substances in the environment.
3. Over the past 25 years I have served on a large number of committees of the Science Advisory Board (SAB) of the USEPA and the National Research Council of the National Academies (NaRC). I have also served from 1989 to 1994 as a Presidentially appointed member of the Nuclear Waste Technical Review Board (NWTRB), which was established by Congress through the 1987 Nuclear Waste Policy Amendments Act to provide ongoing peer review of the complex and controversial program by the US Department of Energy to deal with high-level radioactive waste and spent nuclear fuel. Based on my experience, I believe these three organizations have done an exemplary job of meeting the need for federal agency peer review called for in OMB's draft guidelines. I believe OMB should pay careful attention to the experience of the USEPA SAB, NaRC, and NWTRB in developing the final version of its guidelines for federal agency peer review. In particular, **all three organizations carry out peer review through a committee or board of scientists, rather than in the fashion of individual reviews used by scientific journals.**

4. I have also served for many years as a member of the editorial boards of several journals in the fields of risk analysis and management science, so I am well qualified to make a comparison between peer review, as carried out for scientific journals, and peer review for federal agencies. It has been my experience that peer reviews submitted by individuals are often not that well informed and carefully prepared. High quality in scientific journals often comes from the result of evaluations of peer reviews by editors rather than consistent excellence in the peer reviews submitted to the editors. Moreover, progress in science often comes from a small percentage of papers whose value is established subsequent to publication through the judgment of scientists active in the field. Each year the peer-reviewed journals provide a very large number of new scientific publications. Instances of poor peer review are often compensated for by submission and acceptance of a paper by another journal, where it receives an evaluation from different reviewers a different editor, and by readers' judgment that a published paper is not well written done or not interesting. In extreme cases, articles in the scientific literature are retracted or corrections published in subsequent issues of the same scientific journal. **So, from the perspective of a working scientist, the peer review process for scientific journals is far from perfect.** It is not a panacea for determining what is "good science" and what is not. But over many years and many publications, peer review has provided an excellent means for assuring integrity and accuracy in science.
5. I conclude from my experience summarized in points 2, 3 and 4 above that **a committee or board of scientists that meets together and prepares a jointly authored peer review document generally produces a much higher quality of peer review than a small set of individual reviews.** USEPA's SAB, the NaRC, and NWTRB often conduct meetings open to the public in which interested parties provide comments and listen to the discussion among the peer review group. Such open public meetings are highly informative, both to the members of the peer review group and to the interested parties. Such meetings can provide an excellent forum for a federal agency to present the scientific basis for a program or proposed regulation. Such meetings allow criticisms to be evaluated, to determine what is the appropriate "good science" for the federal agency to be using. Such open public discussion of the underlying science, prior to regulatory decision making, can be extremely helpful in avoiding or reducing public perceptions that the science underlying a federal regulatory decision is flawed by selective use of scientific information to justify agency actions, or that agency use of information claimed to be "good science" is not adequately supported by available scientific data.
6. **In the context of a committee peer review process rather than individual peer reviews, issues of bias or conflict of interest can be worked out better easily by constructing a "balanced" committee, rather than by having sharp demarcations for whether an individual can serve as a peer reviewer.** I question whether those responsible for selecting peer reviewers can select someone with a "contrary bias" to offset peer reviewers likely to have useful knowledge but a biased viewpoint on important issues (Section 3, Selection of Peer Reviewers, page 10 of draft guidelines). I think the need is to set up a balanced committee that has the outstanding scientific knowledge and experience in the applicable areas of scientific and technical specialty. It is often the case that people who have worked in a specialized technical area in business or government have excellent information, but also potential for real or perceived bias. It has been my experience that such potential for bias can be evaluated by colleagues on a peer review committee, so that such bias does not unduly influence the committee's written report. As one example, several decades ago I served on a NaRC committee

evaluating alternative methods for disposing of the US inventory of nerve gas and other chemical weapons. One member of the committee was a retired Army general officer, who had worked on the nation's chemical weapons program. By many tests for potential bias he might have been disqualified, but he was not disqualified under the NaRC requirement for balance of the committee as a whole. In my judgment, the general was one of the most valuable members of this NaRC committee. While not strong on the detailed technical issues, he knew the procedures, the language, and the traditions of agency practice, and this knowledge enabled us collectively to do a much better job of evaluating the information we were given and asking the "hard questions" needed for an effective review.

7. This and similar experiences lead me to believe that current and former agency personnel should not be automatically disqualified from serving as peer reviewers. **Rather, the peer review should be carefully set up so that agency personnel, especially agency senior management, do not control the output of the peer review process.** Organizational separation is important. The USEPA SAB reports to the USEPA Administrator's Office, and the mission of SAB is that of peer review. So even though career USEPA personnel serve as staff officers, the peer review process is insulated from pressure from EPA program management. SAB peer reviews go through an Executive Committee of outside scientists, and in some cases, USEPA SAB reports undergo peer review from outside scientists other than those who drafted the report. NaRC reports always go through a peer review process from scientists other than those who draft the report. The NWTRB was set up by Congress as a separate federal agency from DOE to provide an ongoing review of a DOE program.
8. **Requirements for detailed disclosure of current or previous involvement in an issue by peer reviewers (Section 3, "Peer Review Reports," page 11) could easily become excessive and discourage qualified peer reviewers from serving.** I recommend that such details be left to the discretion of the managers of the agency peer review process. I recommend against any set time limit, such as five or ten years, as mentioned on page 8 of the draft guidelines. Peer review managers may wish to have individual peer reviewers go through a careful process of disclosure **that remains confidential**, rather than appearing in a public document. Such disclosure should go back in time as far as needed to determine important relationships. A short paragraph with the background and relevant present/past affiliations for each peer reviewer should be sufficient for the public document. A more detailed listing of previous employment, sources of research funding, clients for peer reviewers who have worked for a consulting firm, past public speeches and publications on the issue, etc. might be solicited but remain in a confidential file for reference by the peer review managers and possibly, by OIRA in a process review (see point 9 below). In this point I am describing the NaRC process, which seems to me a well-tested and excellent model for OMB to follow.
9. **OIRA should reserve the right to audit how agencies set up peer review, and to be able to step in if necessary to require improvements in the agency peer review process.** Both OIRA and the agency should be very careful to avoid possible perceptions that they are influencing the selection process so as to determine how a peer review will come out. Both should work to assure that the peer review is of highest possible technical quality, and both should accept that the peer review could be highly critical of the agency's work products. One possible useful model is the selection process for the NWTRB: Members of the Board are appointed by the President from a list of qualified candidates developed by the staff of the National Research Council. Professional

societies can serve as sources for recommending qualified peer reviewers. OIRA's oversight should focus on the scientific qualifications of the peer reviewers and the management of the peer review process, particularly the potential for real or perceived bias by the peer review group as a whole, as opposed to individual peer reviewers.

10. Peer review takes time, especially when the peer review is carried out by a group that meets together in a process that involves solicitation of public comment and public meetings with mandated prior notification. The openness provisions required by the Federal Advisory Committee Act (FACA) impose an administrative burden as well as requiring a time-consuming process. So a waiver (Section 4, "Waiver," page 12) to allow a speeded up peer review process, or no peer review, is needed to deal with emergency situations. The need for such emergency exceptions was also recognized in the 1983 NaRC report referred to in point 2 above (page 159). This report urged that consideration be given to modifying FACA requirements for peer review committees (p. 160). **I encourage OIRA to write its guidelines to allow flexibility in the details of implementation, so that appropriate tradeoffs can be made on the timeliness and the depth of peer review, so as to avoid inappropriate delay in regulatory decisions – "paralysis by analysis,"** to cite the phrase used in the reports of the Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997.

11. Uncertainties in scientific information are important, and reviewers will often be asked to identify or otherwise comment on scientific uncertainties (Section 3, "Charge to Peer Reviewers," page 10). Whereas I think it is useful that reviewers be asked to "suggest ways to reduce or eliminate those uncertainties," the resulting list of suggestions for additional research and scientific investigation may be too large and costly for the agency to be able to follow. **I suggest OMB revise its wording to encourage peer reviewers to focus on scientific uncertainties that are clearly critical to regulatory decision making.** If it is not clear which uncertainties are critical, OMB may wish to encourage agencies to use value-of-information analysis. Value-of-information analysis was suggested for this purpose in the reports of the Presidential/Congressional Commission on Risk Assessment and Risk Management, 1997: Vol. I, p. 39; Vol. II, p. 91.