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12/17/2003 05:51:28 PM

Record Type: Record

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

cc:

Subject: Comments On Proposed Bulletin from OMB on Per Review Guidelines

Dr. Schwab: We apologize for our tardiness in getting these to you (see attachment), but we sincerely appreciate your willingness to accept them after the deadline. You obviously are into the holiday giving spirit! Happy holidays to you.

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Jim Sharpe <jsharpe@nssga.org>  
12/17/2003 06:10:36 PM

Record Type: Record

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

cc:

Subject: NSSGA Comments on OMB's Proposed Bulletin on Peer Review Guidelines - Revised

Dr. Schwab: After sending the first document to you, I discovered - to my horror -that the pages were not numbered and some of the headers were not underlined and were in a different font style. How this happened I do not know, since I had previously numbered the pages and standardized the headers. So I am sending you a cleaned-up version, and ask your indulgence to discard the original e-mail and faxed versions. I apologize for this.

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- OMBPeerReview.doc



*Natural building blocks for quality of life*

December 17, 2003

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**Via e-mail:** [OMB\\_peer\\_review@omb.eop.gov](mailto:OMB_peer_review@omb.eop.gov)

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**Re: *Proposed Bulletin on Peer Review and Information Quality***  
**68 Fed. Reg. 54023 (Sept. 15, 2003)**

Dear Dr. Schwab:

The National Stone Sand & Gravel Association (NSSGA) is pleased to submit the following comments concerning the Office of Management and Budget's *Proposed Bulletin on Peer Review and Information Quality*, 68 Fed. Reg. 54023 (Sept. 15, 2003).

### **National Stone, Sand & Gravel Association**

NSSGA represents more than 850 member companies and approximately 120,000 working men and women in the aggregates industry. Our members are engaged in the mining and production of stone, sand and gravel, industrial and specialty minerals, and include companies that manufacture equipment and provide services to the mining industry. Our primary regulatory and/or governmental focus involves the activities of the Mine Safety and Health Administration (MSHA), the Occupational Safety and Health Administration (OSHA), the Environmental Protection Agency (EPA) and the National Institute for Occupational Safety and Health (NIOSH). Our members also have additional involvement with a wide range of governmental entities including, but not limited to, the U.S. Departments of Transportation, Interior, Agriculture, Commerce, Health and Human Services (HHS), and the U.S. Army Corps of Engineers.

### **Summary**

NSSGA urges the Office of Management and Budget (OMB) and the Office of Information and Regulatory Affairs (OIRA) to make a uniform peer review process mandatory for all scientific and technical information used by agencies in influential rulemaking and related activities, such as rules involving occupational

safety and health and protection of the environment, and economic information relied upon by agencies in making feasibility assessments for such rules.

Independent and objective peer review, as defined in the Proposed Bulletin,<sup>1</sup> is crucial in ensuring the reliability of scientific and technical analyses that ultimately play a role in development of regulations and governmental policy. Therefore, NSSGA believes that OMB should follow the recommendations of the National Academies' National Research Council, which stated that "...[B]enefit-cost analysis should be subject to systematic, consistent, formal peer review."<sup>2</sup> Peer review of the science upon which regulators rely not only encourages improvement of the process, but also it is absolutely critical to the advancement of science.

### **Include Regulatory Impact Analyses and OMB's Peer Reviewer Criteria**

In September 2001, OMB recommended that, for economically significant and major rulemakings, agencies subject Regulatory Impact Analyses (RIAs) and supporting technical documents to "independent, external peer review by qualified specialists." OMB further recommended that:

- (a) peer reviewers be selected primarily on the basis of necessary technical expertise,
- (b) peer reviewers be expected to disclose to agencies prior technical/policy positions they may have taken on the issues at hand,
- (c) peer reviewers be expected to disclose to agencies their sources of personal and institutional funding (private or public sector), and
- (d) peer reviews be conducted in an open and rigorous manner. OIRA will be giving a measure of deference to agency analysis that has been developed in conjunction with such peer review procedures.<sup>3</sup>

In the subsequent data quality guidelines that took effect in October 2002, agencies were required to develop information quality procedures to be applied prior to dissemination of information. The practice of scientific peer review is intended to play a pivotal role in implementation of the data quality guidelines, particularly in establishing a presumption that peer-reviewed information is "objective."

NSSGA agrees RIAs should be included within the scope of this bulletin, and the OMB peer reviewer criteria set forth above be used to benchmark all new agency guidelines for peer review.

### **Include Influential Non-Regulatory Documents**

NSSGA urges OMB/OIRA to include non-regulatory documents that may be influential now or in the future in terms of policy or standard setting. Examples include, but are not limited to,

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<sup>1</sup> 68 Fed. Reg. at 54024.

<sup>2</sup> 68 Fed. Reg. at 54024.

<sup>3</sup> See [http://www.whitehouse.gov/omb/inforg/oira\\_review-process.html](http://www.whitehouse.gov/omb/inforg/oira_review-process.html).

studies conducted by NIOSH, the National Academy of Sciences, the National Toxicology Program, and the National Institute for Environmental Health Sciences.

Modeling activities should also be subject to peer review. Existing EPA guidance on this matter should be considered.<sup>4</sup> New models, or significant modifications and/or new applications of established models, should be considered for publication in refereed journals. However, this step should be supplemental to and not a substitute for the peer review mechanisms presented above.

OMB's peer review guidance should also reflect an open door policy with respect to information on which agencies rely in developing policy and regulatory requirements. An example of such a policy is HHS' National Toxicology Program ("NTP"), which uses a Board of Scientific Counselors to provide peer review for a number of agency activities, including oversight of research conducted in NTP centers and review of nominations for substances to be included in the congressionally-mandated *Report on Carcinogens (ROC)*. Decisions to list or de-list a substance in the *ROC* must be from the publicly available, peer reviewed literature.

### **Require Peer Review During Planning Stages**

Peer review should not be restricted to the penultimate version of work products; in fact, peer review at the planning stage can often be extremely beneficial and should be encouraged through these guidelines. As the EPA notes in its external peer review policy: "Peer review can be an important tool in assisting the Agency to document the quality and credibility of the science upon which its regulatory and policy decisions are made."

NSSGA believes that while external peer review of major technical issues may be a somewhat lengthy process, initiating peer review at early stages may, in fact, save time by redirecting misguided initiatives, identifying alternative approaches, or providing strong technical support for a potentially controversial position.<sup>5</sup>

The final bulletin should encourage agencies to embark on early external peer review of technical documents, especially those involving highly technical subjects - such as human health risk assessments - that will form the basis for significant regulatory action. There

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<sup>4</sup> See, Environmental Protection Agency, Science Policy, *Agency Guidance For Conducting External Peer Review Of Environmental Regulatory Modeling* (July 5, 1994), <http://www.epa.gov/osp/spc/modelpr.htm>. The EPA also issued a comprehensive peer review handbook in December 2000, which includes these same principles. We note, however, our disagreement with EPA's view that holding a technical workshop is an appropriate mechanism for accomplishing external peer review. Nonetheless, agencies should be encouraged to hold such workshops, where the results of external peer reviews could be presented in a public forum; this would enhance the transparency of the rulemaking process.

<sup>5</sup> Early identification of feasible alternatives to a governmental proposal is particularly important for those rules with a significant impact on small business entities, such as set forth by OSHA and EPA. Such rules are subject to the small business panel process under the SBREFA amendments to the Regulatory Flexibility Act, and the agency must apprise the panel of all alternatives that it has considered. If the peer review process is delayed until a proposed rule is written, it subverts the SBREFA process and denies small businesses the opportunity to have credible alternatives presented at the critical early stages of the rulemaking process.

should be an incentive for agencies to conduct peer review in an open and serious manner, perhaps through provision of more deferential review from OMB/OIRA.

### **Insist on Full Disclosure by Peer Reviewers**

Full disclosure should be made whether or not the peer review board includes employees of the governmental agency at issue or other private-sector individuals who are heavily reliant on funding from the subject agency for their own research or employment projects.

In addition, additional review may be warranted where the prior peer review was not subject to the same standards of disclosure set forth for prospective peer review processes; e.g., where significant conflicts of interest exist among the peer reviewers. In such cases, where conflicts of interest were present among the original peer reviewers, an additional review using the bulletin's criteria is warranted.

Further, NSSGA stresses that where critical scientific and technical issues are at stake in a rulemaking, "scientific journal" peer review will not suffice. In these situations, the standard of journal peer review must be exceeded and OIRA must require that such data be reproducible, or at least highly transparent with respect to research design, data sources, and analytic methods. This is particularly true of intra-governmental studies (e.g., those conducted by agencies such as OSHA, MSHA and NIOSH), which are used by those same agencies for their policy and regulatory decisions.<sup>6</sup>

Documentation must emphasize the independence of the peer reviewers, as even the perception of dependency can otherwise subvert the entire process. In particular, NSSGA urges OIRA to specify that review by an agency's "advisory committee" or "board of scientific counselors" –often comprised of agency alumni who have entered the private sector or academia, or whose members are named through the political appointment process – will not satisfy the external peer review criteria. Such pseudo-peer review is more akin to in-house analysis, which can be inadequate, imbalanced, or reflective of the inherent bias of the government employees who peer-review research designed to support their own pet projects. Cronyism must be avoided, and can be eliminated through strong peer review guidelines that eliminate the potential for such abuse of the process.<sup>7</sup>

NSSGA advocates mandating disclosure of the names of peer reviewers as part of the transparency requirements, so that it can be apparent to the regulated community whether an

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<sup>6</sup> Key examples are the "31-Mine Study" and the "baseline sampling" results referenced favorably by MSHA in the preamble to the August 14, 2003, proposed rule for diesel particulate matter exposure. None of these documents were peer reviewed at the time of dissemination, yet they constitute influential scientific, environmental, health and/or safety data that is likely to impact public policy and have significant economic impact on the mining industry. Such internal agency studies must be subject to the OMB/DOL guidelines for peer review, reproducibility, and transparency.

<sup>7</sup> Congress has at times included this mandate in legislation; e.g., the Superfund statute, which bars peer reviewers from having institutional ties with any person involved in the conduct of the study or research under review. 42 U.S.C. § 9604(i)(13). Other governmental entities such as the Agency for Toxic Substances & Disease Registry also bar the practice of having their own employees perform peer review. See 68 Fed. Reg. 54025.

agency is recycling the same peer reviewers to ensure fast-track approval of certain research projects.

### **Enforce Reproducibility Requirements**

Further, the scientific/technical data used in studies that influence significant rulemaking proposals should also be scrutinized through the “reproducibility” standards set forth elsewhere in the OMB guidelines and the peer review bulletin.<sup>8</sup>

Given the unfortunate propensity of some researchers to manipulate data until it fits a preconceived conclusion, the reproducibility provisions of these guidelines are absolutely critical in order to ensure the integrity of the rulemaking process. The final guidelines should ensure governmental agencies make their data available for independent analysis and confirmation if the data are to be used in any way for regulatory purposes or disseminated as authoritative outside of the intra-governmental communications circuit. Such reproducibility requirements are in addition to the previously discussed external peer review mandates. All such requirements must be consistent, applied government-wide, and capable of assuring competent and credible peer review of agency materials.

### **Require Peer Review for Significant Impacts on an Industry Sector**

Peer review should be extended to encompass regulations that have a substantial impact on a particular industry sector, such as the coal, metal or aggregates sectors of the mining industry, even if that economic impact is less than \$100 million. We note that many mining regulations would fall under this ceiling. It is rare for MSHA to admit that any of its rules have a \$100 million impact, yet a rule with far less monetary impact could still threaten the viability of certain mining sectors.

### **Require Documentation of the Peer Review Process**

Requirements for documenting the peer review process should be included in these guidelines. Peer review information must be made publicly available by the agencies under the Freedom of Information Act, and included in relevant rulemaking dockets for standards and regulations which reference or rely upon the data. Agencies that disseminated scientific or technical information during proposed rulemaking activities which occurred prior to the effective date of the peer review guidelines should be required to apply the new peer review

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<sup>8</sup> Such reproduction may help avoid the pitfall of what Nobel Prize recipient Irving Langmuir called “pathological science” or “the science of things that aren’t so.” The hallmarks of such “pathological science” are as follows:

1. The maximum effect that is observed is produced by a causative agent of barely detectable intensity, and the magnitude of the effect is substantially independent of the intensity of the cause.
2. The effect is of a magnitude that remains close to the limit of detectability or, many measurements are necessary because of the very low statistical significance of the results.
3. There are claims of great accuracy.
4. Fantastic theories contrary to experience are suggested.
5. Criticisms are met by *ad hoc* excuses thought up on the spur of the moment.
6. The ratio of supporters to critics rises up somewhere near 50% and then falls gradually to oblivion.

Wilson, J.R., Responsible Authorship and Peer Review, *Science and Engineering Ethics* (2002) 8, 155-174 at 156-157.

procedures, if they intend to use this information in subsequent rulemaking activities or otherwise disseminate it.

Suggested steps for peer review documentation are:

- Identifying the peer reviewers, their expertise, affiliations, and disclosure of any conflicts of interest<sup>9</sup>;
- Disclosing the questions and issues presented to the peer reviewers;
- Disclosing reviewer comments, both collectively and individually (and including such comments in the rulemaking docket for public examination and rebuttal); and
- Revealing the agency's response to the peer reviewer comments, and their rationale for adopting or disregarding the findings and recommendations of the peer reviewers or the peer review consensus.

NSSGA agrees that agencies relying on significant regulatory information subject to the peer review requirements in this bulletin must acknowledge this in a certification, which appears in the administrative record.<sup>10</sup> We suggest the certification and explanation of how the agency complied with the peer review and transparency/reproducibility requirements be set forth in the *Federal Register* preamble accompanying the final rule. This will increase public awareness of those rules affected by the bulletin.

Finally, with respect to the Report to Congress (Section 6) and the Corrections Requests under the Information Quality Act (Section 7), NSSGA supports these disclosures, and suggests the bulletin mandate that agencies publish these reports, correction requests and responses on their websites to further enhance public access to this information.

### **Comments in the Proposed Bulletin NSSGA Does Not Support**

To avoid bias in fact or appearance,<sup>11</sup> we must oppose the suggestion that agency employees could serve on peer review panels for studies being used by the agency where those individuals work.<sup>12</sup> This is especially important in light of the bulletin's suggestion that

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<sup>9</sup> For example, the Agricultural Research Service's peer review manual sets forth the following disqualification factors with respect to peer reviewers: Individuals are barred from participating in peer review of a report if they:

- have an institutional or consulting affiliation with the submitting institution, investigators, or collaborators, or
- will gain some benefit from the project, financial or otherwise, or
- during the preceding four years had any of the following relationships with the submitting applicants and collaborators – (a) collaboration on research projects; (b) co-authorship; (c) thesis or postdoctoral advisorship; (d) work as graduate students or postdoctoral associate.

Agricultural Research Service, *Peer Review of ARS Research Project Plans*, Nov. 22, 2000, (Exhibit 9) at p. 64. NSSGA suggests that similar criteria be included in OIRA's Peer Review Guidelines.

<sup>10</sup> Section 3, 68 Fed. Reg. 54028.

<sup>11</sup> NSSGA questions a statement in the proposed bulletin, which notes: "If it is necessary to select a reviewer who is or appears to be biased in order to obtain a panel with appropriate expertise, the agency shall ensure that another reviewer with a contrary bias is appointed to balance the panel." 68 Fed. Reg. at 54027-28. It is preferable that the centralized body appointing reviewers try to exclude any individuals with clear biases. Otherwise, the process will surely be undermined.

<sup>12</sup> 68 Fed. Reg. 54026.



the reviewers' work be limited to scientific and technical matters, leaving policy determinations to the agency.<sup>13</sup> If the reviewers and the agency decision makers are one and the same, the lines will be impermissibly blurred and the "independent review" may be destined to support a predetermined regulatory decision.

NSSGA also opposes in part the suggestion in Section 4, paragraph C of the proposed bulletin, which permits some or all of the peer review requirements to be waived "if an agency makes a compelling case that waiver is necessitated for specific information by an emergency, imminent health hazard, homeland security threat, or some other compelling rationale."<sup>14</sup> Although we support the waiver in times of national emergency, defense or security reasons, the loophole set forth in the phrase "imminent health hazard" could easily be used by an agency to seek waiver of peer review of regulations, if the rulemaking was prompted by a petition for an emergency temporary standard or through litigation by an entity seeking fast-track standard-setting.<sup>15</sup>

Too often, studies conducted, and then reviewed, by agency personnel or agency alumni have served as authoritative references for influential rules, and private sector entities have been thwarted in their attempts to obtain the data upon which findings are based in order to verify the validity of the analyses and conclusions.<sup>16</sup> When this occurs, independent experts make regulatory decisions without significant analysis. This results in promulgation of regulations based on poor science.

As the EPA's Inspector General noted in 2002, despite efforts to institute peer review policies and requirements, "[t]he critical science supporting the [agency's] rules was often not independently peer reviewed . . . [and a] regulation itself is not subject to EPA's peer review policy, even though the major scientific work products, which support it, are subject to peer

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<sup>13</sup> 68 Fed. Reg. 54028.

<sup>14</sup> 68 Fed Reg. 54028.

<sup>15</sup> Just recently, such actions occurred when the U.S. Court of Appeals, Third Circuit, ordered OSHA to expedite a rulemaking governing occupational exposure to hexavalent chromium. A similar lawsuit, pertaining to occupational exposure to metalworking fluids, was filed on October 21, 2003, in the Third Circuit by the United Automobile Workers and the United Steelworkers of America. Under the waiver provision, OSHA could claim that there was no time to peer review the research upon which it relies in setting these health standards, which could easily result in unwarranted exposure limits being set because of the inability of the public to examine the science upon which the rulemaking relies.

<sup>16</sup> A refreshing exception to this is the National Institutes of Health, which voluntarily adopted *Guidelines for the Conduct of Research in the Intramural Research Programs at NIH* (Jan. 1998). The NIH research guidelines declare the expectation that "results of research will be carefully recorded" and "...data, including the primary experimental results, should be retained...to allow analysis and repetition by others of published material from those data." The Food and Drug Administration also has a long-standing policy promoting transparency in its research process. That policy states: "'The results of all testing or research conducted by or with funds provided by the Food and Drug Administration...are available for public disclosure when the final report is complete and accepted by the responsible Food and Drug Administration official.... Access to all raw data, slides, worksheets, and other similar working materials shall be provided at the same time that the final report is disclosed." Similar policies government-wide, as applied through the OIRA guidelines, would be most welcome and beneficial, although if the agencies will not disclose data prior to finalization of a report, then interim reports should not be disseminated or relied upon in rulemaking activities.

review.<sup>17</sup> Consequently, the quality of some science that forms the basis for some of the most extensive and expensive regulations currently in effect remains unknown.

### **NSSGA Favors Provisions for Public Comment**

NSSGA supports the proposal which would permit members of the regulated community to question the scientific basis of significant regulations, and urges OIRA to require, in such instances, that an independent, centralized panel (rather than one selected by the regulatory agency being questioned) be convened to examine the research upon which the agency relies.<sup>18</sup>

### **Conclusion**

Data quality is of premier importance in the federal government's regulatory process. Therefore, NSSGA urges the OMB/OIRA to make a uniform peer review process mandatory for all scientific and technical information used by agencies in influential rulemaking and related activities. Without assurances that the research relied upon is valid, serious questions will be raised about the efficacy and legitimacy of agencies' actions.

Peer review is effective when monitored but it has its limitations: it cannot detect fraud;<sup>19</sup> only those verifying the peer review process can accomplish that mission, perhaps through reproducing the underlying study to see if the same results occur. With millions of dollars, if not more, resting on the scientific "findings" of regulatory agencies, our government cannot afford to get it wrong.

NSSGA commends OIRA and OMB for embarking on this project that will ultimately improve the quality, objectivity, utility, and integrity of information disseminated by the Federal Government to the public. We agree with the statement made by OIRA's John Graham, upon release of these proposed standards:

Peer review is an effective way to further engage the scientific community in the regulatory process. A more uniform peer review policy promises to make regulatory science more competent and credible, thereby advancing the Administration's 'smart-regulation' agenda. The

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<sup>17</sup> See *Science to Support Rulemaking* (November 15, 2002), at 18. The IG report is published at <http://www.epa.gov/oig/reports/2002/SSRulemaking.pdf>.

<sup>18</sup> See 68 Fed. Reg. 54027.

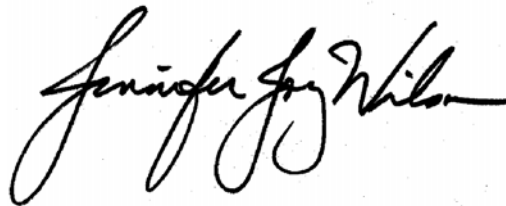
<sup>19</sup> As A.S. Relman wrote on this subject: "Even at its best the system can guarantee the truth of a manuscript no more than it can the honesty of an author. Rather, its function is to hold a scientific report to the best current standards, to ensure that the design and method are acceptable by those standards, and to ensure that the data are properly analyzed and interpreted. As knowledge in the field develops, new developments will improve methods and modify older concepts. Even the best current research will probably be superseded by more sophisticated and insightful work, which might reveal unsuspected limitations or flaws in previous reports." See, *The value of peer review*, in: CBE Editorial Policy Committee, eds., *Ethics and Policy in Scientific Publication*, Council of Biology Editors (1990), Bethesda, Md., pp. 272-277, at p. 276.

goal is fewer lawsuits and a more consistent regulatory environment, which is good for consumers and businesses.<sup>20</sup>

The guidelines adopted by each of the individual departments are a good first step, but implementation of adequate peer-review, transparency, and reproducibility procedures are additional steps necessary to ensure regulatory integrity and effectiveness. NSSGA supports the actions of OMB/OIRA in this regard, and asks these comments be included in the public record for this proposal.

Please let us know if we can provide any assistance in further work to improve this process.

Respectfully submitted,

A handwritten signature in black ink, reading "Jennifer Joy Wilson". The signature is written in a cursive, flowing style with a long horizontal stroke at the end.

Jennifer Joy Wilson  
President and CEO

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<sup>20</sup> OIRA Press Release, August 29, 2003, <http://www.whitehouse.gov/omb/pubpress/2003-34.pdf>.