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Record Type: Record

To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP
cc: George Gray <ggray@hsph.harvard.edu>
Subject: Peer Review Comments

Please accept the attached as comments on the Proposed Peer Review and Information Quality Guidelines.

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- G Gray Peer Review Comments.pdf

Harvard Center for Risk Analysis



December 15, 2003

Office of Information and Regulatory Affairs
Office of Management and Budget
NEOB, Room 10202
725 17th Street, NW.
Washington, DC 20503.

I am writing to offer comments on the Office of Management and Budget's proposed Peer Review and Information Quality guidelines. These comments are mine alone and do not necessarily reflect opinions of the Harvard Center for Risk Analysis or the Harvard School of Public Health.

I support the effort to increase the level of peer review of agency analyses, improve transparency in analysis details and encourage disclosure of real or perceived reviewer conflicts of interest. It is important to note that the point of peer review is not delay, not trying to enforce some unattainable agreement on "truth", not making things difficult for the agencies, but rather making sure analysis is done well.

My comments focus on the importance of peer review of analyses by Federal agencies. The science done and used by most agencies is routinely peer-reviewed and of high quality. It is the interpretation and use of this science that is the focus of my comments. I begin with a short discussion of the need for careful review of agency analyses and then focus on some specific issues raised in the proposed guidelines.

I have concerns about both the perception and the reality of the quality of analyses conducted by federal agencies. I believe this is a widely held concern in the field of risk analysis. A very telling example of this concern is an address by Professor M. Granger Morgan* to the Society of Risk Analysis on the occasion of his receiving the Society's Distinguished Contribution Award in 1995. Although these comments were made several years ago, I believe they are still relevant. Dr. Morgan decided to grade the field of risk analysis for the quality and rigor of its practice. However, he decided he needed two categories, best practice and typical practice, which he defined as "my assessment of how things typically get done by federal risk management agencies and their contractors." The need for this distinction immediately points out an obvious shortcoming – the analyses conducted by federal risk management agencies do not reflect the best practice of the field.

Dr. Morgan evaluated eight specific attributes of analysis (for a more detail on his address see: <http://www.riskworld.com/Profsoci/sra/newsltrs/96Q2/ps6ae201.htm>). His overall grade for best practice in the field of risk analysis was a B. More disturbing, when evaluating typical agency practice he gave four of the eight areas a D or D- and an overall grade of D+. I believe that serious peer review is necessary to ensure that agencies are using state of the art methods and procedures in their analyses. This

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will improve information available for decision-making and will increase the quality and credibility of agency analyses.

Some specific comments on peer review and the proposed guidelines:

- Peer review by outside experts will help ensure that analyses use appropriate methods, are transparent and reproducible, and are scientifically objective in key assumptions and choices.
- The guidelines do a very good job in recognizing the importance of the charge to peer reviewers. It should be recognized that the “science” being evaluated must include the analytic sciences too. Reviewers must be asked to judge broadly the appropriateness of approaches, assumptions, choices and transparency of an analysis. An excellent guideline for reviewers would be the OMB Circular A-4 and the guidance it provides for characterizing the purpose of an analysis, describing the uncertainty in the analysis and the influence of alternative choices and assumptions, and ensuring transparency and reproducibility of the analysis.
- I strongly support the idea of requiring the contents of peer-reviews to be publicly available and to obliging agencies to publicly post responses to all peer-review comments. I believe that it may be necessary to have a judge, like the editor for a peer-reviewed journal, to determine whether the agency responses to peer review comments are adequate. This responsibility could rest within the Office of Science and Technology Policy or some other independent organization (see final comment below).
- Choosing peer reviewers is a critical component of a credible process. Expertise should be the primary consideration in these choices but it must be recognized that other factors must be considered. I welcome the recognition that direct financial gain might not be the only source of conflict of interest. Reviewers with a professional stake in an issue, illustrated by advocacy for a particular view of an issue or agency funding on the topic subject to peer review, should be very carefully evaluated. I do believe that criterion (iii) under “Selection of Peer Reviewers” is rather broad and might encompass a large group of experts. Perhaps public disclosure of funding sources, including from the relevant agency, would help address this concern.
- I prefer the notion of disclosure of potential conflicts of interest, including work as an expert witness and institutional funding, to strict rules of disqualification in the required agency guidelines (Section 4(b)). Complete and widespread disclosure will allow interested parties to make judgments about the appropriateness of reviewers. Although I recognize that it will sometime be necessary and appropriate, disqualification has the potential to raise questions of agency bias in the choice of experts.
- The simplest solution to many of these problems is vesting responsibility for these peer-reviews in an entity outside of the agency. I would support the establishment of a centralized body, perhaps in the Office of Science and Technology Policy, to choose experts and to “referee” the process to ensure that peer review comments are addressed appropriately to ensure the best analysis to support important decisions.

Sincerely,



George M. Gray, Ph.D.

Paul Beddoe <pbeddoe@naco.org>
12/15/2003 03:30:23 PM

Record Type: Record

To: Mabel E. Echols OMB_Peer_Review/OMB/EOP@EOP

cc:

Subject: Bulletin on Peer Review and Information Quality

The National Association of Counties (NACo) is the only national organization that represents county governments in the United States. NACo ensures that the nation's 3066 counties are heard and understood in the White House and the halls of Congress. NACo's membership totals more than 2,000 counties, representing over 80 percent of the nation's population. We are pleased to submit our comments in strong support of the proposed Bulletin on Peer Review and Information Quality.

NACo has long advocated that sound science must be a cornerstone of federal regulatory policy. Federal departments and agencies must be required to provide fair, peer-reviewed scientifically-sound and consistent assessments of purported health, safety or environmental risks prior to the imposition of new mandates on states or local governments. Local governments need additional information to identify the various environmental mandates, and to evaluate the success of programs formed to comply with them.

NACo supports a fully-coordinated and expanded research effort with should be open to input from state and local governments and private industry. Congress and the Administration should authorize and adequately fund efforts to assess scientifically verifiable risks prior to requiring any actions by local governments.

Scientific peer review is an accepted tool. Peer review of the science used in regulations helps to ensure that the scientific analysis used in regulatory actions and decisions is reliable. With regulations becoming more costly and more complex, peer review of the science used in reaching decisions is especially important.

Peer review at the pre-decisional stage of a study or report, as set forth in the proposed bulletin, is especially important. It is much easier to fix a rule before it is proposed or at the proposal stage than to undo a regulatory decision that has already occurred. The information quality guidelines provide a data correction mechanism to address situations where information has already been disseminated. The peer review requirement provides a complement to this requirement at the pre-dissemination stage.

In addition to rules becoming more costly and more complex, they are also becoming more controversial. More regulatory decisions are being challenged now than ever before. The U.S. Fish & Wildlife had to stop making decisions relating to critical habitat designations in July of this year because it ran out of funding, due to court challenges to its decisions. The Service's work plan on listing and critical habitat decisions is dictated by the courts instead of the agency's priorities.

Peer review of the science used in agency decision-making would hopefully provide greater public confidence in agency rulemakings. Peer-reviewed science is less likely to be appealed or challenged in court. Controversial or cutting-edge science proposed in rulemaking would receive greater credibility if it receives a "second opinion" in the peer review process.

Agency rulemaking is also more likely to be upheld if the science behind it has been peer reviewed. Courts are more likely to respect rulemaking science if it has undergone independent scrutiny. Peer review will better ensure that agency rules are predicated on sound science rather than on court decisions.

Many federal agencies already have their own peer review programs for various types of rulemaking. There is, however, no consistency between agencies on the standards or procedures for the various peer review programs, and possibly no consistency between different programs within the same agency. The Bulletin would provide minimum standard criteria for all agencies to incorporate in peer review programs. These minimum criteria are necessary to improve the quality of rulemaking for all agencies. Agency peer review programs that already meet or exceed the criteria in the Bulletin should not change.

Agency peer review programs prove the point that peer review of agency science does not have to unduly delay the regulatory process. An efficient peer review process can occur in a timely manner without causing regulatory gridlock. We believe that as agencies implement and refine their peer review processes, they will become more efficient so that delay can no longer be considered

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