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

cc:
Subject: Comments on proposed OMB peer review IQA guidance from the Center for Regulatory Effectiveness

The CRE comments are attached.

I will also send them via fax to (202) 395-7245.

I will not attempt to send them via regular mail unless requested.

Bill Kelly
CRE Western Representative

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Dr. Margo Schwab
Office of Information and Regulatory Affairs
Office of Management and Budget
Executive Office of the President
725 17th Street, NW – Rm. 10201
Washington, DC 20503

Subject: CRE Comments on Proposed OMB Bulletin on Peer Review and Information Quality (68 FR 54023, Sept. 15, 2003)

Dear Dr. Schwab:

OMB/OIRA and OSTP are to be complimented for recognizing the critical importance of peer review of agency scientific and technical information and proposing concrete action to address the details of this difficult subject. As noted in the proposal, Congress has given OMB affirmative responsibility to both maximize and ensure the quality, objectivity, utility, and integrity of all information disseminated to the public by federal agencies. In the case of scientific and technical information, it is clearly established that peer review must be considered a necessary part of the process of ensuring and maximizing quality. In fact, there is no other way to ensure and maximize the objectivity of a scientific or technical document prior to dissemination other than by having it peer reviewed. The very definition of objectivity is that findings and conclusions will be viewed similarly by other persons with a similar vantage point (*i.e.*, expertise in the same subject matter). OMB guidelines on peer review are therefore necessary in order for OMB to meets its legal responsibilities under the Information Quality Act and the information dissemination provisions of the Paperwork Reduction Act of 1995[1], and those guidelines have the potential to resolve a number of

[1] In addition to citing the Congressional directives in 44 U.S.C. § 3504 and 3506, the proposal should also cite as authority 44 U.S.C. § 3516, since that section, along with section 3504, is specifically referenced in the Information Quality Act (sec. 515) as the basis for its implementing directives to OMB. Section 515 directed OMB to issue guidelines "under sections 3504(d)(1) and

important and perennial issues concerning federal agency peer review and greatly improve the credibility of government scientific and technical information.

As noted in the proposal, many federal agencies have peer review guidance; however, there is a lack of consistency, and the guidance of some agencies does not address important elements of the process. More importantly, some agencies have retained broad discretion in their internal guidance as to when and how to conduct peer reviews, and there have clearly been instances in which agencies have been extremely lax in deciding whether to conduct or respond to peer reviews under their existing internal guidance. For example, the EPA draft risk assessment for dioxin and related comments never incorporated or responded to the criticisms from its Science Advisory Board, and the SAB was asked to review a document that was infused with agency policy positions. This has led to intense controversy and long delays. And in the case of the di-isononyl phthalates (a widely-used plasticizer), EPA's preliminary hazard assessment for TRI purposes apparently has never been subjected to any peer review, although the assessment is clearly influential information; and this lack of adequate peer review has apparently contributed to a high degree of controversy, inconsistency with peer reviews overseen by other federal agencies and scientific organizations, and long delays. In our view, the potential for peer review guidance to enhance agency credibility and minimize controversy and long delays far outweighs any inconvenience that might be associated with agencies having to adjust their current guidance and institutional procedures. Some federal agencies have already implemented all or most of the essential elements of the OMB proposal; thus, it is clear that it is practicable for other agencies to do the same.

While the need for OMB peer review guidance is clear, the proposal raises issues

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3516 of title 44, United States Code". Section 3516, which is titled "Rules and regulations", states that "The Director [of OMB] shall promulgate rules, regulations, or procedures necessary to exercise the authority provided by this chapter."

It has been suggested by another commenter that the failure of H.R. 9 to be enacted in the 104th Congress indicates that Congress has rejected the idea that agency peer review should be required. H.R. 9 contained many provisions addressing subjects other than peer review. It passed the House easily, but failed to come to a vote in the Senate when it was filibustered. The courts frequently warn about assigning any significance to Congressional inaction.

concerning certain aspects of what constitutes a satisfactory peer review that should be resolved. We will attempt to address what we regard as the most important of these issues, recognizing, however, that the OMB guidance on information quality, as it has noted previously, must be viewed overall as a work in progress.

I. Nature of the Guidance

The proposal's title and text refer to the guidance as a "Bulletin" which would "supplement" OMB's current information quality guidelines. At 54026 1st col. Such terminology could be confusing, especially as to whether the guidance contains requirements equivalent to earlier OMB information quality guidance. When the original OMB guidelines were first supplemented by the January 2002 guidance (later republished in Februrary 2002), the supplemental guidelines were not referred to as a "Bulletin", and the *Federal Register* notice stated that the supplement was an "amendment" to the original guidance. OMB "Bulletins" are not ordinarily published in the *Federal Register*, nor issued for public comment. Nor is the term "Bulletin" used in the statutory directives[1] or the previous OMB guidance. Moreover, the proposal also states that it would "supplement" current agency internal guidance on peer review, implying that agencies would not necessarily have to conform their existing guidance to the OMB guidance. At 54026 1st col. 1. It would avoid any confusion and maintain consistency with existing guidance and the statutory directives to simply state that this is peer review guidance which amends the current OMB guidance of September 2001 and January 2002, and that agencies must amend their information quality guidance, and, if necessary, their peer review guidance, to conform to the new OMB guidance.

II. The Essentials of Agency Peer Review

The proposal contains a definition of peer review; but that definition does not encompass the proposal's views on the essential elements of peer review.

The definition given is that peer review is "a scientifically rigorous review and critique of a study's methods, results, and findings by others in the field with requisite training and expertise." At 54024. In the discussion following this definition, however, it is clear that the definition does not contain two essential elements: independence and transparency. The guidelines should be clear that any satisfactory peer review must be not only rigorous and conducted by expert peers, but also independent, transparent, and objective.

Although the Background section of the proposal discusses all of these elements as important, the actual proposed guidance does not contain a definition or description of what constitutes a satisfactory peer review; instead, it refers to an "appropriate" or "adequate" peer review (for "significant regulatory information"), and "formal", "external"

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[1] See note 1, *supra*.

peer review (for "especially significant regulatory information"). The guidance should clearly define agency peer review as including these essential elements, and then use consistent terminology in referring to such peer review.

In the section of the proposed guidance for "significant regulatory information", it appears that peer review of agency information ("studies") is equated with the type of peer review customarily utilized by scientific and technical journals. As discussed below, peer reviews conducted by scientific journals should not be viewed as "adequate" or equivalent to the type of peer review required of agency information, since such reviews lack essential elements such as transparency, and serve a different purpose entirely – acting as more of a minimal and non-transparent "screening" of information intended for dissemination to an expert audience rather than a transparent and rigorous critiquing mechanism for information intended for dissemination to the general public and possibly supporting regulatory decisions.

III. Types of Information ("Studies") Requiring Peer Review

The proposal creates two new categories of agency information for purposes of establishing peer review requirements: "significant regulatory information" and "especially significant regulatory information." There is no rationale given for creating these new categories; they are not consistent with the existing guidance and statutory directives; and they appear to be largely incapable of application in any objective manner. The statutory directives require OMB to maximize and ensure the quality of all types of information disseminated to the public by federal agencies; the statutory directives are not limited to information which has potential regulatory application. Beyond this, there is simply no reason to require a regulatory connection. Information has impacts on the public regardless of whether it is, or might be, used for regulatory purposes. On the other hand, any agency information "might", by its nature, be used for regulatory purposes, and thus the definition of the category is completely subjective. In summary, introducing the concept and requirement of a regulatory connection in order to trigger peer review requirements is confusing and not reasonable and supportable.

In addition, the proposed category of "especially significant regulatory information" is very restrictive, and it is likely that very few information products would be found to fall within this category, thus defeating obvious Congressional intent. The requirement for assessment of monetary impacts ($100 million in a year) would be extremely problematic. How does one monetize the likely impacts of information, much less information that "might" be used for regulatory purposes? It appears to be impossible to do objectively. And if a regulatory connection is unnecessary and inconsistent with Congressional intent, it seem clearly impossible to monetize non-regulatory impacts.

It is reasonable, however, to distinguish information based on the likely magnitude of its private sector impact apart from any regulatory impact. The existing guidelines already

do this in distinguishing between "influential" scientific, technical, and financial information and other information, and require that a higher standard of quality, including reproducibility, be applied to "influential" information. "Influential", as defined, means that "the agency can reasonably determine that dissemination of the information will have or does have a clear and substantial impact on important public policies or important private sector decisions." We see no reason why the peer review guidance should not build upon this existing basic definition.[1]

[1] In our view, this definition is already unreasonably restrictive and impractical. It calls for an agency determination that there "clearly" are or will be substantial private sector impacts. Such impacts are seldom "clear". We urge OMB to consider using this proposal as an opportunity to consider modifying the definition of "influential" to state that an agency can reasonably determine that information does or is likely to have substantial impact.

Peer review of such information should incorporate all of the essential elements identified by OMB – namely, independence, objectivity, rigor, and transparency.[2] Beginning with this consistent concept of requiring certain basic elements for peer review of all "influential" scientific and technical information could then allow for an additional category which could be designated "influential regulatory information", and be defined along the lines of the current proposal's definition of "especially significant regulatory information". Peer review requirements for such information could then be even more rigorous and detailed, such as requiring agencies to solicit nominations for peer reviewers and providing for at least two peer reviewers on specific significant science issues where rigorous review of the government "study" involves multiple issues requiring different areas of scientific expertise. Regardless of whether there is such an additional category, however, peer review which includes the essential elements of independence, objectivity, rigor, and transparency should at least be required for all "influential" scientific and technical information.

IV. The Presumption that Journal Peer Review is "Adequate".

The existing guidance incorporates the view that peer review prior to publication in a journal is entitled to a rebuttable presumption of "objectivity", and entitles the information reviewed to a similar presumption. The current proposal goes beyond that and proposes the view that journal peer review "may generally be presumed to be adequate" and independent. Such a presumption is not supportable; and the existing rebuttable presumption should be discarded.

Journal peer review is very unlike the peer review envisioned by the OMB proposal. Its basic purpose is to screen out material which has clear defects or is not significant. Journal peer review often does not attempt to address the supportability of a manuscript's conclusions, and focuses more on whether the material is worthy of dissemination to the scientific community where it can then be subjected to further scrutiny and attempts to replicate and validate its findings and conclusions.[1] Thus, journals often publish material

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[2] Peer review would allow for a good review of whether influential information is capable of being substantially reproduced.

[1] A 1992 review of the peer review practices of the top 67 U.S.-based scientific journals found that only half asked peer reviewers for an assessment of the reasonableness of a manuscript's conclusions. Frank E. 1996. Editors' requests of peer reviewers: a study and a proposal. *Prev Med* 25:102-04. A 2002 study found that it was not possible to assess the

because it is believed to contain significant observations, suggest a new hypothesis for further examination, or describe potentially useful new test methods or materials. Journal peer review is not, for example, designed to vouch for the "reliability" of published material, in contrast with the apparent purpose of federal agency peer review. On the other hand, reliability is recognized by the current information quality guidelines as an essential aspect of "objectivity" for government information.

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effectiveness of journal peer review. Jefferson T, Wager E, Davidoff F. 2002. Measuring the quality of editorial peer review. *JAMA* 287(21):2786-89.

Journal peer review is also not transparent. Journals will ordinarily not disclose peer review materials, nor will they identify the peer reviewers.[2] The consequence is that it is not possible to discover whether, in fact, the peer reviewers were independent and unbiased, whether their review was rigorous and objective, and whether the journal editor, or the author(s), adopted the reviewers recommendations, and if not, why not. In other words, there will ordinarily not be material available for an "affected person" to attempt to rebut a presumption of journal peer review objectivity or "adequacy". The presumption is therefore unwarranted and should be discarded, unless a journal is willing to be transparent about its peer review process, the identity of peer reviewers, and peer review materials for a particular published study. Peer reviewers of agency information products which are published in journals, or which rely to some extent on journal publications, as well as "affected persons", should be free to question such publications without any such presumption.

This view is buttressed by the obvious fact that some journals cannot meet the essential requirement of independence. An example is *Environmental Health Perspectives* ("EHP"). EHP is published by a federal agency, the National Institute of Environment Health Sciences ("NIEHS"), and contains peer-reviewed scientific materials. The head of the EHS staff is the Director of NIEHS, who reports directly to the Secretary of Health and Human Services, a political appointee. Some of the editors of EHP are either employees of NIEHS or have affiliations with activist organizations. Since the editors choose the peer reviewers, and are not bound to accept the peer reviewers recommendations or respond to their comments, and the whole process is not transparent, whether the peer review process for such a journal results in an independent and rigorous review that ultimately results in a objective and valid study is clearly an open question rather than something to be presumed.

V. Transparency

The OMB proposal does not require transparency for peer reviews of "significant regulatory information." This is a deficiency which must be remedied. Transparency should be a requirement for peer reviews of all "influential" scientific and technical information. Without transparency there is no way for OMB and others to verify that the

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[2] Parrish DM, Bruns DE. 2002. US legal principles and confidentiality of the peer review process. *JAMA* 287(21):2839-41. For an article arguing in favor of more transparency in the journal peer review process, see Godlee F. 2002. Making reviewers visible. JAMA 287(21):2762-64. Even in the case of FOIA requests to agencies such as CDC for information on the identities of peer reviewers of an agency scientific assessment, CRE has been confronted with refusals to disclose the names, or even the affiliations and areas of expertise, of the peer reviewers.

peer review is, or was, indeed independent, rigorous, and objective. Agencies should be required to post notice of all pending and completed peer reviews on their websites, along with the identity of peer reviewers, the charge, review comments, and any agency responses to the peer review comments. Without transparency, peer review requirements are unlikely to have any real impact.

Transparency is also a requirement that should apply to the study being reviewed. Reviewers, and third parties, should have access to all underlying data, methods, and models or software (and data used to build or run models, and model runs) supporting all significant aspects of the study, including any used in studies published in journals. If such data cannot be provided, or to the extent it cannot be provided, the record of the peer review should clearly inform the public that it was not provided and therefore the study, or that particular aspect of the study, cannot be considered to have been adequately peer reviewed.

VI. Independence

Transparency in making public the identities of peer reviewers (and, if necessary, their qualifications) will go a long ways towards ensuring that independent and unbiased reviewers are selected, or that, if it is not possible to select completely unbiased reviewers, the panel is balanced.

In discussing the issue of independence, the proposal focuses almost exclusively on possible bias due to financial relationships. The guidance should also require that agencies consider pertinent organizational affiliations as a possible source of bias. Such affiliations, particularly in the case of non-profits, might not involve any financial relationship, but might nevertheless involve an even stronger likelihood of personal bias.

Agency affiliation, a type of organizational affiliation, poses a difficult issue. There is a high likelihood of some bias for many agency personnel, but this will not always be the case. Agency personnel from a program with a regulatory mission, or a program related to the program from which the information will primarily emanate, are more likely to be biased than personnel who serve in a scientific research program that is not part of a regulatory program.

Agency programs that do not involve direct regulation can also pose obvious bias issues. An example is the Report on Carcinogens ("RoC") program administered by NIEHS and the inter-agency National Toxicology Program ("NTP"). On the one hand, the RoC program gives the appearance of going to extremes to guard against bias by incorporating four distinct levels of review and three opportunities for public comment. On the other hand, the multiple levels of review could be considered to reinforce inherent biases due to several layers of review being agency-controlled and having little transparency.[1]

[1] NIEHS recently announced that it is considering certain changes to the RoC review

process and will hold a public meeting in late January 2004 to receive public comments on the proposed changes and recommendations for any other changes.

The current RoC review process currently involves three agency review panels and one review by a panel of external experts. The process begins when NIEHS announces that a substance/exposure has been nominated for listing in the RoC, and invites public comment. At approximately the same time, a scientific hazard assessment document is prepared by agency contractors (usually the same contractor for most substances), with input from several outside consultants.[2] The first review is conducted by a standing NIEHS staff involved with the RoC program, and involves consideration of any public comments on the nomination. This panel then votes on whether to recommend listing the reviewed substance as a "known" or "reasonably anticipated" to be a carcinogen in the RoC. The second review is conducted by a standing inter-agency NTP panel, and some NIEHS personnel from the first panel participate. At this point the scientific assessment is released to the public and comments are invited. The third panel is the only one comprised of independent experts, and they also consider public comments and vote on a listing recommendation. Finally, a third inter-agency panel comprised of senior scientific and policy officials (the NTP Executive Committee), some of who also served on the second agency review panel or whose agency was represented on that panel, conducts a review (apparently quite cursory) and votes on a recommendation. The Director of NIEHS and the NTP considers the four recommendations and makes a listing recommendation to the Secretary, who then approves a final decision.

The problem with this process is that three of the four levels of peer review are conducted by panels of agency personnel, most of whom have are assigned to the NTP and who are therefore likely to have some allegiance to the NIEHS personnel who helped prepare the original assessment and who administer the NTP programs, and to the other agency panels which voted on the assessment and a listing recommendation. Not surprisingly, the voting of the three agency panels historically is remarkably consistent from substance to substance, and sometimes the three agency panels will vote consistently for a recommendation that is contrary to the recommendation of the external expert panel.[1]

The apparent independence problems in the RoC process which arise from likely agency allegiances are reinforced by a lack of transparency. The deliberations of the agency panels are not open to the public, and only a very brief summary of their conclusions and voting are made public. Thus, there is no way to evaluate whether their review was conducted with scientific rigor and objectivity. It is likely that policy

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[2] Apparently NTP does not consider these expert consultants to be independent external peer reviewers.

[1] One example is the review of dioxin. The three agency review panels voted for listing as a known human carcinogen, while the external expert panel voted against such a listing. The Director and Secretary sided with the agency panels. A somewhat different example is the review of non-asbestiform talc, where the first two agency panels voted for listing, and the external panel voted against listing, and the Director (and apparently the third agency panel) decided to defer a decision pending further review of the science.

considerations sometimes play a role in the agency panel deliberations, since even the external expert panel is sometimes advised by agency staff that they must adhere to certain agency policy positions.[2]

The proposed guidance would apparently not require any changes to this review process, since it seems to allow agencies to keep their existing peer review guidance in

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[2] One such policy position is that level of exposure to a substance nominated for listing does not matter – any level of exposure, no matter how slight, is to be considered equivalent to a high level. (This position is contrary to the legislative history.) For example, when alcoholic beverages were being considered for listing as a known human carcinogen, agency staff advised the external expert panel that they could not recommend revising the listing to inform the public that alcoholic beverages are only "known" to cause cancer when they are consumed excessively as part of an alcoholic lifestyle and have not been shown to be carcinogenic when consumed in moderation (much less that many studies have even shown that moderate consumption has health benefits). The dioxin review (for upgrading to the "known" category) was also tainted by policy intrusions in the form of NIEHS staff advice to the external review panel that the agency had decided to interpret its listing criteria for the "known human carcinogen" category to allow animal and *in vitro* data to compensate for lack of human data sufficient to indicate a causal relationship.

place, and "supplement" it with any new requirements. The guidance should require independent review. Perhaps the role of the agency panels could be that of providing input into the preliminary assessment, followed by as single independent review of the assessment with public comment. It would be helpful for facilitating such a modification of the process if OMB were to draw a distinction between peer input and peer review, with the agency panels providing input into the assessment document to be reviewed, but not making listing recommendations (except to the extent they are incorporated in the assessment document).

VII. Selection of Reviewers

It might be accurate that who selects the reviews does not matter much if the guidelines require that peer review panels be unbiased or balanced and there is complete transparency regarding the selections. However, there is at least one condition to such an observation. As the NAS report referenced in the proposal recommended, reviewer selection should be conducted by a group independent of the one being reviewed or not connected with the project for which the study being reviewed was undertaken, unless they are personnel with no regulatory responsibilities and are solely scientific researchers.[1]

If the guidance is to allow selection of reviewers by agency personnel, it should require that the agency provide public notice (not in the *Federal Register*, but simply on its website) of proposed selections, and solicit any public comments. This should not result in any significant resource burdens or delays, and would serve the important function of possibly providing the agency with information concerning reviewer bias or qualifications that was overlooked by the agency or unknown. Commenters should also be allowed to suggest additional or alternative reviewers. This is important because in many cases – particularly in the case of exposure from industrial processes – it is likely that industry stakeholders will be the ones most knowledgeable about the nature of the exposures and also the ones most knowledgeable about scientists who are most expert on that particular exposure.

VIII. Scientific Rigor of the Review

To support the scientific rigor of the review, it should be considered essential to allow an opportunity for public comment on the study under review, with the comments then provided to the reviewers. The transparency discussed above in section V (making all data, methods, and models or software available to the peer reviewers and third parties) is also necessary for scientific rigor. Although there is always the possibility that this

[1] National Academy of Sciences, The National Academy Press. 1999. *Peer Review in Environmental Technology Development Programs*, Ch. 2, "Elements of a Credible Peer Review Program", p. 33.

comment opportunity will result in submission of some (perhaps many) comments that are not objective comments on the science but rather are advocacy and policy-oriented, this might be mitigated by informing the public that only objective comments on the science will be provided to the reviewers after screening by the agency.

IX. Objectivity of the Review

It is important that, as the proposal currently requires, reviewers be asked only to review scientific or technical materials, findings, and conclusions. Science should not be mixed with policy in the same document and then presented for review. The result is likely to be confusion on the part of the reviewers and inability to perform an objective review. This has been a perennial problem with some agency peer reviews. This aspect of the proposal is very sound and important and should be retained. At the same time, however, as we have observed previously, the OMB guidance should require that existing agency guidance be revised as necessary in order to comply with the peer review guidance. At present this is not clear from the proposal, which could be interpreted as allowing agencies to retain whatever guidance they have previously adopted.

Summary and Recommendations

1. Congress directed OMB to issue guidelines ("rules, regulations, and procedures") for "ensuring and maximizing" the "quality, objectivity, utility, and integrity" of government information disseminated to the public. In the case of scientific and technical information, independent peer review is widely recognized as the principal means for ensuring and maximizing quality and objectivity. Therefore, in order to carry out its responsibilities under the legislation, OMB must issue guidance on agency peer review of scientific and technical information.

2. Issuance of such guidance is also necessary to ensure consistency among agencies and to ensure that peer review guidance is followed.

3. The OMB peer review guidance should state clearly that it is information quality "guidance" which "amends" and supplements its previous guidance. It should also clarify that agencies must, if necessary, modify any pre-existing guidance to conform to the new OMB guidance.

4. The OMB guidance should require a basic level of peer review of all "influential" scientific and technical information, consistent with its previous guidance requiring a higher level of quality for all such "influential" information. Creation of entirely new categories of information to supplant "influential"information for purposes of peer review – *e.g.*, requiring a regulatory connection – is unnecessary, confusing, and impracticable. If a more intensive peer review process is considered desirable for influential "regulatory" information, the definition should build upon the definition, and requirements, for

"influential" information.

5. The OMB guidance should establish that all peer reviews of influential scientific and technical information must incorporate the essential elements of independence, objectivity, rigor, and transparency.

6. Peer review of government information disseminated to the general public should not be compared with journal peer review, which is intended for dissemination to the scientific community for further post-publication review and which has undergone a non-transparent peer review process which does not allow for public scrutiny. Creating a rebuttable presumption that studies published in a peer-reviewed journal are "objective" and have undergone an "adequate" peer review (within the meaning of the OMB guidance) is not justified.

7. Peer review by agency personnel does pose "independence" issues. This includes review by personnel in other federal agencies. If agency personnel are to be considered "independent" peer reviewers, they must not, at a minimum, have any programmatic connection to the agency program which has produced, or sponsored production of, the information being reviewed. Transparency in the selection process will help to ensure independence. Agencies should be required to post notice of proposed selections of individual peer reviewers and allow public comment on the proposed selections.

8. In considering potential bias of peer reviewers, any current or recent organizational affiliations should be considered in addition to financial involvements.

9. To ensure scientific and technical rigor in the peer review, the reviewers should have the benefit of public comments on the scientific and technical aspects of the information. To enable this, the reviewers and the public should have access to all supporting data, methods, and models or software.

10. To ensure that the peer review addresses objectively only the scientific and technical aspects of the information being reviewed, the information provided to the reviewers must not be commingled with policy views.

Respectfully submitted,

/S/

William G. Kelly, Jr.
CRE Western Representative