

**Jacqueline Patterson** <patterson@tera.org>  
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cc: dourson@tera.org, 'Dan Briggs' <briggs@tera.org>  
Subject: TERA comments on peer review

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***TERA***

October 28, 2003

Dr. Margo Schwab  
Office of Information and Regulatory Affairs  
Office of Management and Budget  
725 17<sup>th</sup> Street, NW  
New Executive Office Building, Room 10201  
Washington, DC 20503

Dear Dr. Schwab:

Toxicology Excellence for Risk Assessment (*TERA*) is pleased to offer comments on the Office of Management and Budget's *Draft Peer Review Standards for Regulatory Science*. *TERA* is a non-profit, 501(c)(3) organization. Our mission is to protect public health through the best use of toxicity data for risk assessment. In addition to evaluating chemicals for hazard and risk, and developing improved methods for human health risk assessment, we organize peer review and peer consultations of risk assessment documentation. *TERA* conducts work for both public and private entities and seeks to build partnerships and greater understanding between the public and private sectors (see <http://www.tera.org>). *TERA* has conducted independent peer reviews of risk assessment documents for both government and the private sector since 1996. We offer the following comments and questions on the proposed peer review guidelines based upon our experience in organizing and conducting peer reviews and consultations.

Our comments focus primarily on the guidance provided for selection of peer reviewers as described in Section 3. We believe use of these guidance factors would present a significant obstacle to securing qualified experts as peer reviewers. For many studies requiring peer review, only a handful of individuals may be available who are qualified to review the material at the level needed. If the definition of conflict of interest is too restrictive, no qualified reviewers may be acceptable. Specifically, we raise some questions regarding several of the factors enumerated on page 10 –

**(i) “has any financial interests in the matter at issue”**

While this seems like an obvious conflict to avoid, unless the term is defined more precisely, it can be difficult to determine what constitutes a meaningful “financial interest” or what the “matter at issue” is. At one end of the spectrum, exclusion of an expert who has large financial investments in a company that

would be clearly and directly impacted by the regulatory action at hand seems reasonable. But what is “large?” What if an individual inherited a small number of shares of stock in that company? Is it reasonable to assume that a few shares would compromise that person’s independence? What if the matter at hand is not directly linked to a particular company but might encompass a large segment of many industries? Would stock ownership in any particular company in an industry constitute a conflict of interest?

**(iii) “is currently receiving or seeking substantial funding from the agency through a contract or research grant”**

This criterion for exclusion is problematic. It may be reasonable to exclude an individual based upon his or her direct receipt of grants or funding from the agency on the specific matter at hand, especially if the funding comes from the same part of the agency. However, a blanket exclusion of serving as a peer reviewer for any agency study based upon receipt of any funding from that agency seems unduly restrictive. The proposal mentions receipt of funding through another entity, such as a university. Would other entities also include private companies or non-profit organizations that conduct work for the agency under contract or grants? Would the restriction cover all employees of an organization that has agency contracts or grants? In our experience, restricting all those who work for entities with agency grants and contracts would eliminate too many highly qualified individuals, including almost all individuals working for universities and many consulting firms. As these are the entities that conduct research and analyses similar to that which must be peer reviewed; they are generally the sources for the most qualified peer reviewers. In our peer review panels, we routinely include individuals whose employers receive funding from agencies, and have not detected bias or partiality. In the *TERA* program, we focus on whether the individual has conducted work on the subject matter for the agency or sponsor of the review. If so, we believe that the appearance of potential for bias justifies not selecting the individual. We generally do not exclude from consideration those individuals whose companies work on other subjects for the agency or sponsor; although we insist that all such situations are disclosed publicly at the meeting.

**(iv) “has conducted multiple peer reviews for the same agency...”**

Multiple means anything more than one. It would not be reasonable to exclude all candidates who have served only once as a peer reviewer for an agency. Individuals who are highly knowledgeable and skilled in providing expert review and analysis should be permitted to serve more than one time. Familiarity with an agency’s goals and program can help make a reviewer more efficient and productive. A reviewer who has an incomplete understanding of the agency program and objectives may provide comments that are less valuable. For example, in the area of human health risk assessment, an expert on the metabolism of a chemical may have little appreciation for the scientific judgments

and the rationales used to derive a reference dose. There needs to be flexibility to allow panels to include experienced members. This can be accomplished while still avoiding the appearance that the agency selects only a few reviewers with whom it is most comfortable. Barring those who have participated in recent peer review on same specific matter might be appropriate, unless the peer review is a follow up to the previous, in which case one might want to reconvene the same or most of the same panel.

We found the guidance somewhat confusing as Section 3 spells out factors for conflict of interest, but Section 4b notes that agencies “should have specific guidelines as to what entanglements with agencies or affected businesses are so significant as to preclude an individual’s participation as a peer reviewer, irrespective of other factors” (page 12). The criteria in Section 3 do not seem to provide for judging significance. Rather they can be interpreted that as if any financial interest or advocacy concerning the matter at hand, or current and future research funding from the agency, are factors that preclude consideration.

In the section on peer review procedures and the Federal Advisory Committee Act, the last sentence notes that “the agency shall ensure that the firm itself possesses independence (and the appearance of independence) from the agency” (page 12). This should be clarified – does it refer to the firm’s independence from the agency in selecting peer reviewers and setting up the peer review? Or does it refer to the firm’s financial independence, similar to that specified for peer reviewers in item *iii* in the section on selection of peer reviewers (page 10)? The first is essential to an independent peer review. If the second is intended, then finding firms who have the knowledge of the field and contacts with potential reviewers, but who do not do other work for the agency, will be problematic. The ideal peer review firm is one that is knowledgeable about the subject matter and has contacts with a large number of potential reviewers. To be knowledgeable and current, the firm also has to be doing work in the field, and likely would be doing other work for the agency.

The proposal specifically asked for comments in a number of areas (pages 7-8).

**Conflict of interest requirements.** As we mentioned earlier, it is not clear that the factors for peer reviewer selection, enumerated in Section 3, do not specifically preclude individuals with those factors. We do not believe Section 3 strikes an appropriate balance or would be workable in practice. The goal of an independent peer review is to obtain honest and unbiased opinions from experts in the field. Many will say that no person can be totally “unbiased” and that every scientist has biases formed from their training and experience. Nevertheless, by forming a panel of scientists with varied backgrounds and affiliations one can seek to make sure that various opinions and “biases” are heard. However, circumstances that may appear to be a conflict of interest or source of bias should be publicly disclosed.

**Limitations to disclosures.** Disclosure requirements for peer reviewers should be limited to a certain number of years and not go back indefinitely. If the purpose of the disclosure is to alert others to the possibility for bias, 5 years seems a reasonable amount of time, and no more than 10 years. Depending on the type and amount of information expected from the reviewers, it is unreasonable to expect individuals always will be able to accurately remember all that is asked. It is the individual's current activities that provide the most significant potential for bias. Experts frequently serve as peer reviewers for limited or no compensation from a sense of scientific responsibility and duty. If the paperwork is too onerous, peer reviewers may not be interested in serving

**Agencies selecting peer reviewers.** We believe that peer reviewers should be selected by independent outside parties who do not have a stake in the result of the peer review. However, the agency could recommend the types of expertise they think are needed and the issues that should be included in the charge. The agency knows best the scientific issues that need review.

This proposed guidance is for peer reviews; it would not be appropriate to apply it in total to peer consultation efforts. Peer consultation is a concept that is being developed as an approach different from formal peer review. While the conduct of a peer review and peer consultation may look similar, we see a number of key differences, including:

- Independence. For peer review, the expert reviewers should not be affiliated or aligned with the authors or sponsors of the product being reviewed. Peer consultation however, may seek out experts who are not independent (e.g. stakeholders) to gain their input.
- Level of involvement. A peer review is generally a limited interaction between the peer reviewers and authors and sponsors. Peer consultation could involve repeated interaction at various stages of a work product's development.
- Stage of development. A peer review is generally conducted when a work product is nearly final to insure that the product is technically sound. Peer consultation could occur at earlier stages and contribute to scoping and focus of a work product, as well as evaluate technical soundness.
- Final output. A peer review generally reaches group conclusions on the technical accuracy and adequacy of a work product. A peer consultation could seek areas of agreement or disagreement among the peer consultants, but may seek input on issues and approaches for further consideration.

Some of the conflict of interest considerations of a peer review should not apply to a peer consultation effort. Building upon peer review experience, *TERA* is developing a peer consultation program to explore additional ways to gain expert review and input for risk assessment efforts, particularly those evaluating risks to children.

We at *TERA* would be happy to share further our experiences with conducting independent peer reviews. Thank you for this opportunity to provide comments.

Sincerely,

Jacqueline Patterson, M.En.  
Peer Consultation and Peer Review Program Manager

Toxicology Excellence for Risk Assessment (*TERA*)  
1757 Chase Ave.  
Cincinnati, OH 45223  
513-521-7426  
[patterson@tera.org](mailto:patterson@tera.org)