

EPA WORLD TRADE CENTER EXPERT TECHNICAL REVIEW PANEL

comments of

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regarding

PROPOSED PEER REVIEW PROCESS OF WTC SIGNATURE

in:

**Draft Final Sampling Program to Determine Extent
of World Trade Center Impacts to the Indoor Environment (May 2005)²**

June 7, 2005

The Draft Final Sampling Program states on page 19 that “The WTC signature dust screening method validation study report will be subjected to an independent external peer review by experts in this field.”

I wrote in my comments of May 27, 2005 on EPA’s Draft Final Sampling Program that “The proposed peer review process will address only laboratory methods. It will not evaluate EPA’s signature hypothesis or signature criteria. Unlike prior WTC-related peer review processes, there appears to be no provision for public transparency or participation.” I would like to comment further on these two key aspects of the proposed peer review process - scope and public participation.

SCOPE OF PEER REVIEW PROCESS

Jacky Rosati’s presentation to the panel on May 24, 2005 indicated that peer review of the WTC signature validation process will be limited to evaluation of laboratory analytical protocols.³ Given that the WTC signature is a pillar of the proposed sampling plan and that, absent scientific validation of the signature, the plan essentially collapses or must be significantly altered, it is not adequate to limit the peer review process to evaluation of laboratory protocols. Rather, a scientifically appropriate peer review process would consider

¹ New York Committee for Occupational Safety and Health (NYCOSH).

² www.epa.gov/wtc/panel/pdfs/May2005samplingplan.pdf.

³ EPA Office of Research and Development and EPA Region 2. Update: Development of a WTC Dust Screening Method. Slides 16 - 19.

hypotheses, objective criteria for evaluating the validity of candidate signature substances, key assumptions⁴, basis for each key assumption and possible alternatives, sample collection methodologies, and datasets, as well as analytical laboratory methods.

This position finds support in the December 15, 2004 document Final Information Quality Bulletin for Peer Review⁵ issued by the federal Office of Management and Budget, which provides guidelines and requirements for the peer review process.

On the issue of the scope of the peer review process, OMB states:

Peer review typically evaluates the clarity of hypotheses, the validity of the research design, the quality of data collection procedures, the robustness of the methods employed, the appropriateness of the methods for the hypotheses being tested, the extent to which the conclusions follow from the analysis, and the strengths and limitations of the overall product.⁶

Comparison of the scope of EPA's proposed peer review process with OMB guidelines indicates that EPA's current proposal for peer review is inappropriately narrow.

PUBLIC PARTICIPATION IN PEER REVIEW PROCESS

It is my understanding from conversations with fellow panelists and with EPA representatives that the proposed peer review process will have no public participation component. Additionally, neither the Draft Final Sampling Program nor Ms. Rosati's presentation to the panel on May 24 contains any indication of a role for the public in the proposed peer review process.

This EPA position is in stark contrast to two prior peer review processes on WTC issues initiated by EPA and conducted by Versar and TERA, respectively. Each of these peer reviews occurred in public meetings with opportunities for members of the public to submit written comments, present oral comments, and interact with peer reviewers.

TERA (Toxicology Excellence for Risk Assessment) provides extensive guidelines for public participation in peer review processes:

Members of the public are generally invited to attend the independent peer reviews and consultations organized by TERA. It is important that the entire process be transparent so that interested parties can judge the independence and scientific credibility of the review or consultation. The public may be given the opportunity to provide brief oral and written

⁴ For assumptions implicit in the signature validation process, see Comments of David M. Newman with regard to: Draft Final Sampling Program to Determine Extent of World Trade Center Impacts to the Indoor Environment (May 2005), May 27, 2005.

⁵ www.whitehouse.gov/omb/infoereg/peer2004/peer_bulletin.pdf

⁶ Pages 2 - 3.

technical comments on the work product for the panel's consideration.⁷

TERA conducts peer reviews and consultations under the TERA Peer Consultation and Review Program. These meetings are open to the public to observe the proceedings...

The public may be invited to provide written and/or oral technical comments. TERA offers the sponsoring organizations the option of including time on the agenda to hear comments from the public...

Panel members may ... initiate discussion with sponsors, authors, or observers in order to obtain further information. They will be asked to report on these conversations...

If public comments are requested ... (c)omments should be brief ... and should address scientific and technical matters. The purpose of public comments is for stakeholders and others to share scientific data and analyses with the panel, authors, and sponsors...

In addition to written comments, there will be some time set aside at the meeting for observers to make brief technical comments to the panel ... (T)he chair may allow additional oral technical comments. Comments should be limited to technical issues ... Since the purpose of the public comments is to share scientific data and analyses, panel members, authors, and sponsors will be provided the opportunity to ask clarifying questions of those observers making comments.

TERA will prepare a meeting report for each peer review or consultation. Written public comments will be included in the meeting report and oral public comments will be briefly summarized.⁸

OMB provides additional guidance on public participation in peer review processes:

Public comments can be important in shaping expert deliberations... There are situations in which public participation in peer review is an important aspect of obtaining a high-quality product through a credible process... Public participation can take a variety of forms, including opportunities to provide oral comments before a peer review panel or requests to provide written comments to the peer reviewers.⁹

The public should be provided with sufficient time to comment on the agency's peer review plan for that report or product. Agencies shall consider public comments on the peer review plan...¹⁰

⁷ www.tera.org/peer/PeerProcess.html

⁸ www.tera.org/peer/PublicParticipation.html

⁹ Page 20.

¹⁰ Page 29.

Whenever feasible and appropriate, the agency shall make the draft scientific assessment available to the public for comment at the same time it is submitted for peer review (or during the peer review process) and sponsor a public meeting where oral presentations on scientific issues can be made to the peer reviewers by interested members of the public. When employing a public comment process as part of the peer review, the agency shall, whenever practical, provide peer reviewers with access to public comments that address significant scientific or technical issues.¹¹

Each peer review plan shall include: ... (v) whether there will be opportunities for the public to comment on the work product to be peer reviewed, and if so, how and when these opportunities will be provided; (vi) whether the agency will provide significant and relevant public comments to the peer reviewers before they conduct their review; ...and (x) whether the public, including scientific or professional societies, will be asked to nominate potential peer reviewers...¹²

EPA guidelines acknowledge that public participation may include nomination of potential peer reviewers:

Recommendations for potential peer reviewers can be identified from a number of organizations. These include external groups such as the affected party(ies), special interest groups, public interest groups, environmental groups, professional societies, trade or business associations...¹³

CONCLUSIONS

The peer review process should evaluate the WTC signature validation process in its entirety, not omitting any component of the validation process from scrutiny.

The peer review process should provide ample opportunity for public participation, including oral and written comments.

NEED FOR DISCUSSION

Fellow panelists have thus far been silent on the peer review issue. I encourage fellow panelists to weigh in on this issue and I look forward to your comments.

¹¹ Page 38.

¹² Page 28.

¹³ United States Environmental Protection Agency. Science Policy Council Handbook - Peer Review. EPA 100-B-00-001, December 2002, page 73, <http://www.epa.gov/OSA/spc/htm/prhandbk.pdf>.